BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version

DETAILS

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BIOWATCH AND PUBLIC HEALTH SURVEILLANCE

Evaluating Systems for the Early Detection of Biological Threats

Abbreviated Version

Committee on Effectiveness of National Biosurveillance Systems:
BioWatch and the Public Health System

Board on Health Sciences Policy
Board on Chemical Sciences and Technology
Board on Life Sciences

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This report has been reviewed in draft form by individuals 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 institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Georges C. Benjamin,** American Public Health Association, and **Chris G. Whipple,** ENVIRON. Appointed by the National Research Council and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

Biological warfare is not a new phenomenon. In North America, the first historically documented use was by Lord Jeffery Amherst, the British commander in North America during the French and Indian War, who proposed spreading smallpox among vulnerable American Indians. Population vulnerability to infectious agents wielded by enemies who wish to destroy and terrorize is of increasing concern to our nation. We also have come to recognize the threats to our health and to our social well-being caused by the natural emergence of infectious diseases, such as HIV and SARS, that can be rapidly spread in our interconnected globe. In response to these concerns, the United States of America, as well as many other countries, has been actively seeking means to improve capabilities to detect and respond to biological threats. Our nation has done so through a mixture of enhancing existing time-honored public health approaches to disease and by developing new approaches to prevention, early detection, and treatment. These new approaches need to be integrated into the overall prevention and response system, and their cost-effectiveness needs to be evaluated in comparison to other investments that could be made to attain the same goals.

As described in the body of this report, the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System has prepared a review and assessment of the effectiveness and costs of surveillance for and detection of disease threats through the Department of Homeland Security's (DHS's) BioWatch program and through the public health and health care systems. The report presents the committee's findings and conclusions concerning the comparative merits of these approaches,

examines costs, and describes promising enhancements to strengthen the nation's capacity to conduct surveillance for major natural and man-made disease threats. As a result of its review, the committee identified various opportunities to further these enhancements, and it recommends actions that DHS, the Department of Health and Human Services, and others should undertake to help realize them.

The members of the committee have welcomed being participants in the ongoing recalibration of the nation's response to the threat of major natural and man-made disease outbreaks. Review and recalibration is a continuous process. Changes in technology related both to the threat and to the response will necessitate repeated revisiting of the many issues related to how best to protect the public. We hope that our specific recommendations about technical aspects of detection of disease threats will soon be out of date—replaced by newer methodologies that provide enhanced security to our nation. We also hope that our recommendations related to process will persist, particularly those that call for improved coordination among the disparate governmental bodies: local, state, and national.

The fragmentation of powers related to protecting the health of the public, which is built into our Constitution and in many ways has served us so well, inherently necessitates coordination among governmental organizations to effectively address national issues that require local or regional responses. This is particularly true for the BioWatch program for which the organizations involved in assessing the threat and in determining the technology, configuration, and reporting pathways of this key surveillance approach extend well beyond those traditionally involved in disease surveillance and response. In view of its formation at a time of recognized need for rapid response, and the decision to place the BioWatch program within DHS where it can most effectively coordinate with others involved in the national response to terrorism, as well as the inherent fragmentation of our public health system, it is not surprising that the committee has found that coordination of BioWatch with the public health community is still a work in progress. Fortunately, it is clear that the BioWatch program has recognized this need and is moving toward meeting it.

The breadth of the topic, and the involvement of so many different governmental programs at the federal, state, and local levels which contribute to the overall mission of protecting the public against biothreats, inevitably has limited our ability to probe as deeply as we would like in all of the relevant areas. Not surprisingly, it has been challenging to compare BioWatch, a reasonably well-defined system with a specific budget and hosted in a single federal agency that began just a few years ago, with a diverse public health system that has roots dating back to the middle ages, diverse responsibilities, and a structure that does not readily lend itself to comparative cost accounting of essential cross-cutting activities, such as

surveillance for infectious diseases. Meeting this challenge has been helped by the committee's recognition that BioWatch should best be considered as part of the nation's overall surveillance activities. We also recognize that in response to concern about the nation's public health infrastructure, the National Academy of Sciences (NAS) and other major national organizations in recent years have reviewed and made recommendations about the U.S. public health system that are pertinent to our charge. This recognition has led us to focus on the BioWatch system and how it could be integrated into an enhanced public health surveillance system.

It is also clear that the nation's public health system is a funnel that collects and sees all types of health situations, natural and otherwise, and in many ways is the ideal place to detect all biological outbreaks, regardless of the disease or the exposure mechanism (air, food, water). It is also a place where small improvements may pay significant dividends to improve its effectiveness.

We have also faced the challenges of needing a relatively large committee (25 members) so as to adequately address the broad range of scientific and technical issues, and of having a relatively short time period (6 months between the first and last of our five meetings) to do so. As leaders of the committee, we want to particularly acknowledge the hard work and collegiality of the committee members. Without their willingness to listen and to learn, and the deep respect they have shown to each other and to the committee staff, this report could not have been completed.

We deeply appreciate the cooperation received from the leadership and staff of the BioWatch program, especially Robert Hooks, Diane Berry, Malcolm Johns, Constantin Langa, and Brian Smith. Also providing especially notable assistance to the committee are Daniel Sosin and many unnamed colleagues at the Centers for Disease Control and Prevention and three consultants to the committee: Jennifer Baxter and Henry Roman of Industrial Economics, Incorporated, and David Buckeridge at McGill University. The committee is also very grateful to numerous other contributors to the committee's information gathering during meetings held in Washington, DC. These contributors are listed in Appendix A.

We also note that the staffing for this committee cut across three different NAS organizational components: the Board on Health Sciences Policy in the Institute of Medicine (IOM) and the Board on Chemical Sciences and Technology and the Board on Life Sciences in the Division on Earth and Life Studies (DELS). The challenge of coordinating all of these components was ably met by all of the contributing staff: Lois Joellenbeck, IOM (study director); Jane Durch, IOM; Kathryn Hughes, DELS; Susan McCutchen, IOM; Michael McGeary, IOM; Ericka McGowan, DELS; Andrew Pope, IOM; Jessica Pullen, DELS; Donna Randall, IOM; Jon Sanders, IOM; Frances Sharples, DELS; and Dorothy Zolandz, DELS. We

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Before its public release, and as required under the terms of the contract for this study, the full report was sent to DHS for security classification review. DHS has determined that the full report contains information exempt from public disclosure pursuant to the Freedom of Information Act (FOIA), 5 USC Sections 552(b)(2), 552(b)(7)(E), and 552(b)(7)(F). Therefore, dissemination of the full report is limited to those federal, state, and local governments and their officials, employees, and contractors, as well as non-governmental entities, who have a need to know the information exempt from public disclosure pursuant to the cited FOIA exemptions. Requests for the full report may be directed to the NAS Program Security Office. Requests for the full report may also be directed to DHS. Requests for the full report will be considered on a case-by-case basis.

The NAS reached agreement with DHS that this abbreviated version of the report could be released without restriction. Although certain operational details have been omitted in the public version of the report, the committee's recommendations remain unchanged from the full report provided to DHS.

Bernard D. Goldstein
Chair
Joseph M. DeSimone
Vice Chair
Committee on Effectiveness of National Biosurveillance Systems:
BioWatch and the Public Health System

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Acronyms and Abbreviations

AAR	after-action report
AHIC	American Health Information Community
AIDS	acquired immune deficiency syndrome
AOAC	Association of Analytical Communities
APDS	Automated Pathogen Detection System
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
BAC	BioWatch Advisory Committee
BAND	Bioagent Autonomous Networked Detector
BAR	BioWatch Actionable Result
BASIS	Biological Aerosol Sentry and Information System
BDS	Biohazard Detection System
BERT	Bioagent Event Reconstruction Tool
BRRAT	Bioterrorism Rapid Response and Advanced Technology Laboratory
BTAC	BioWatch Technical Advisory Committee
BTRA	Bioterrorism Risk Assessment
BWIC	Biological Warning and Incident Characterization
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
CIDRAP	Center for Infectious Disease Research and Policy
CRS	Congressional Research Service
CSTE	Council of State and Territorial Epidemiologists

DFU	Dry Filter Unit
DHS	Department of Homeland Security
DNA	deoxyribonucleic acid
DoD	Department of Defense
DOE	Department of Energy
DSBCC	Detection Systems for Biological and Chemical Countermeasures
DT&E	developmental testing and evaluation
ED	emergency department
EHR	electronic health record
ELR	electronic laboratory reporting
EMR	electronic medical record
EPA	Environmental Protection Agency
ESP	Electronic Support for Public Health
ESSENCE	Electronic Surveillance System for the Early Notification of Community-based Epidemics
FBI	Federal Bureau of Investigation
FEMA	Federal Emergency Management Agency
FOUO	For Official Use Only
FTE	full-time equivalent positions
FY	fiscal year
GAO	Government Accountability Office
GI	gastrointestinal
HAN	Health Alert Network
HEPA	high-efficiency particulate air
HHS	Department of Health and Human Services
HIE	health information exchange
HITSP	Healthcare Information Technology Standards Panel
HPP	Hospital Preparedness Program
HSARPA	Homeland Security Advanced Research Projects Agency
HSEEP	Homeland Security Exercise and Evaluation Program
HSPD	Homeland Security Presidential Directive
HVAC	heating, ventilation, and air conditioning
ICD-9	International Classification of Diseases, Ninth Revision
ICD-10	International Classification of Diseases, Tenth Revision
IEc	Industrial Economics, Incorporated
IMAAC	Interagency Modeling and Atmospheric Assessment Center

IOM	Institute of Medicine
IT	information technology
LACDPH	Los Angeles County Department of Public Health
LANL	Los Alamos National Laboratory
lidar	light detection and ranging
LIMS	Laboratory Information Management System
LLNL	Lawrence Livermore National Laboratory
LOINC	Logical Observation Identifiers Names and Codes
LRN	Laboratory Response Network
MDHSS	Missouri Department of Health and Senior Services
NACCHO	National Association of County and City Health Officials
NAS	National Academy of Sciences
NBAS	National Biosurveillance Advisory Subcommittee
NBIC	National Biosurveillance Integration Center
NBIS	National Biosurveillance Integration System
NEDSS	National Electronic Disease Surveillance System
NETSS	National Electronic Telecommunications System for Surveillance
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NNDSS	National Notifiable Diseases Surveillance System
NPHPSP	National Public Health Performance Standards Program
NRC	National Research Council
NSF	National Science Foundation
O&M	operation and maintenance
ODIN	Outbreak Detection Information Network
OHA	Office of Health Affairs
OMB	Office of Management and Budget
ORD	operational requirements document
OT&E	operational testing and evaluation
PA-OH	Pennsylvania-Ohio
PCR	polymerase chain reaction
PHEP	Public Health Emergency Preparedness
PHRED	Public Health Reporting of Electronic Data
PSU	Portable Sampling Unit
RHIO	regional health information organization
RODS	Real-time Outbreak and Disease Surveillance

RT-PCR	real-time polymerase chain reaction
S&T	Science and Technology Directorate
SARS	severe acute respiratory syndrome
SNOMED	Systematized Nomenclature of Medicine–Clinical Terms
SPADA	Stakeholder Panel on Agents for Detection Assays
STD	sexually transmitted disease
T&E	testing and evaluation
TCL	Target Capabilities List
TEMP	Test and Evaluation Master Plan
TFAH	Trust for America's Health
TOPOFF	Top Officials
TRL	technology readiness level
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USPS	U.S. Postal Service
UTL	Universal Task List
VSL	value of a statistical life
WADOH	Washington State Department of Health
WHO	World Health Organization
WMD	weapons of mass destruction

Summary[1]

ABSTRACT *Concern about bioterrorism and potential infectious disease epidemics has spurred interest in developing ways to detect biological threats as quickly as possible. The Department of Homeland Security's (DHS's) BioWatch program has air samplers deployed in more than 30 major U.S. cities intended to swiftly detect the presence of certain aerosolized biological agents to help local and state health officials respond promptly. In response to congressional questions about BioWatch's technological capabilities and plans for a new generation of devices, DHS asked the National Academies to examine the BioWatch program and its costs and merits in relation to methods for disease surveillance through the public health and health care systems.*

The current BioWatch system needs better technical and operational testing to establish its effectiveness. It also needs better collaboration with public health systems to improve its usefulness. The proposed enhancements of the BioWatch system will be possible only if significant scientific and technical hurdles are overcome. In principle, however, BioWatch and surveillance through the public health and health care systems are complementary. BioWatch has the potential to provide a more timely alert than the public health and health care systems under certain specific conditions:

[1]This report is a public version of the document provided to the Department of Homeland Security on October 2, 2009. It has been modified slightly to omit operational details about the BioWatch system that the Department of Homeland Security considers sensitive information. The modifications have not resulted in any changes to the wording of the committee's recommendations.

if a large-scale aerosol attack occurs where BioWatch is deployed, if an air sampler lies in the path of the release, and if the pathogen used is one of those included in the BioWatch laboratory assays. To date, the BioWatch system has generated dozens of BioWatch Actionable Results, none of which has been associated with bioterrorism or human illness. The annualized direct cost of continuing the current program (Generation 2) over the next 10 years is estimated to be $80 million; if the planned transition to the timelier and more widely deployed Generation 3 is successful, the estimated annualized direct cost for acquisition and operation over 10 years is $200 million.

Given the BioWatch system's serious technical and operational challenges and its costs, DHS should assess its effectiveness and frame program goals from a risk-management perspective; conduct systematic operational testing of current and proposed BioWatch technologies; establish an external advisory panel with technical and operational expertise; and strengthen collaboration and coordination with public health officials in BioWatch jurisdictions.

Infectious disease surveillance through the public health and health care systems is broader and more flexible than BioWatch, having the potential to detect infectious diseases resulting from various exposures. Surveillance is an essential activity for health departments at local, state, and federal levels and relies on information from health care providers and laboratories in the public and private sectors. But insufficient data are available to measure the overall costs and effectiveness of infectious disease surveillance.

To enhance disease surveillance capabilities, the Department of Health and Human Services (HHS) should lead efforts to develop, test, and evaluate new disease surveillance methods and technologies to improve clinical recognition and reporting of infectious diseases of concern. DHS and HHS should aim to integrate BioWatch's health protection role more effectively into a stronger, nationally coordinated public health surveillance system and should further the development of mechanisms for improving situational awareness of biological threats, including secure sharing of relevant intelligence information with state and local health officials. DHS and HHS should also collaborate to build and sustain essential state and local workforce and operational capacities for detecting and responding to disease outbreaks and biological attacks.

Concern about the possibility of bioterrorism and epidemics of emerging infectious diseases has spurred interest among the national security, public health, and health care communities in developing new and better ways to detect biological threats as quickly as possible so that preventive measures or treatment can be started in time to reduce illnesses and deaths.

In 2003, the Department of Homeland Security (DHS) rapidly introduced BioWatch—a federal environmental monitoring system intended to speed detection of specific biological agents that might be released in aerosolized form in a biological attack. BioWatch air sampling devices are currently deployed, primarily in outdoor locations, in more than 30 major urban areas. Samples are typically collected and analyzed in designated laboratories once every 24 hours to test for genetic material from specified pathogens. DHS plans to replace the current "Generation 2" BioWatch system with an expanded deployment of a new biodetection system capable of more frequent, more rapid, and more comprehensive automated analysis and reporting of results ("Generation 3").

In response to congressional direction, DHS asked the National Academies to evaluate the current and potential capabilities of BioWatch in detecting biological threats; examine the capabilities of the current and an enhanced surveillance system that relies on hospitals and public health agencies to detect biological threats; examine the costs of BioWatch and surveillance based in public health and health care; and consider whether BioWatch and traditional surveillance are redundant or complementary.

The committee concluded that the current BioWatch system requires better testing and validation and better collaboration with the public health system. The proposed enhancements to the BioWatch system are appropriate but very ambitious; they will be possible only if significant advances can be made against long-standing scientific and technical challenges. But in principle, BioWatch and surveillance through the public health and health care systems are complementary. BioWatch has the potential to provide a more timely alert than the public health and health care systems if a large-scale aerosol attack using certain pathogens were to occur in the localities where BioWatch is deployed, and if BioWatch successfully detects the pathogen. In addition, the proposed Generation 3 technology, if it can be successfully tested and deployed, should be able to provide timelier detection than Generation 2. However, surveillance through the public health and health care systems is broader and more flexible than BioWatch, permitting detection of infectious diseases arising from a broader range of exposures. Moreover, it is already an essential element of daily public health activities at local, state, and federal levels.

Furthermore, DHS needs to conduct systematic technical and operational testing and evaluation of current as well as future BioWatch technologies, and to evaluate the effectiveness of the BioWatch system from a risk-management perspective. Similarly, the Department of Health and Human Services (HHS) should lead efforts to evaluate and improve infectious disease surveillance and detection resources for the public health and health care systems. To achieve its health protection goals, the BioWatch system should be better linked to a broader and more effective national

BOX S-1
Statement of Task

The Institute of Medicine (IOM) and National Research Council (NRC) will evaluate the effectiveness of BioWatch, including a comparison of benefits and costs for Generations 2 and 3; the costs and benefits of an enhanced national surveillance system that relies on U.S. hospitals and the U.S. public health system will also be assessed, and its effectiveness compared to that of the current BioWatch approach. The evaluation will include examination of the reliability of BioWatch monitoring data and the ability of hospitals and public health officials to respond based on information received from that system. Services under this contract will encompass the evaluation of the effectiveness of both current and enhanced biosurveillance systems to detect biological terrorism or other biothreats to human health, including (1) differing technological generations of BioWatch, (2) current human health-related surveillance systems, including those for zoonotic disease, and (3) describing necessary enhancements to hospital and public health systems based on measures of effectiveness in detecting attacks of bioterrorism or other biothreats. Measures of effectiveness will include the ability of surveillance systems to warn sufficiently to provide effective post-exposure prophylaxis and effective post-infection treatment to affected populations following a bioterrorist attack or other biothreat event. . . .

The IOM/NRC will:

1. Evaluate the relative merits, and current and potential capabilities of the BioWatch monitoring system (Generation 2 and Generation 3) to detect bioterrorist attacks and other biothreats via environmental monitoring, with the aim of early warning and pre-infection prophylaxis and expedited response and recovery. The evaluation will consider

biosurveillance framework that will help provide state and local public health authorities, in collaboration with the health care system, with the information they need to determine the appropriate response to a possible or confirmed attack or disease outbreak.

SCOPE OF THE STUDY

The study committee was asked to evaluate the effectiveness of BioWatch and compare it to an enhanced national surveillance system that relies on the health care and public health systems (see Box S-1). The charge

both BioWatch Generation 2 and Generation 3 equipment, and the relative advantages and disadvantages of each, including their costs and benefits.

2. Describe the characteristics of an "enhanced national surveillance system" that relies on U.S. hospitals and the U.S. public health system.

3. Examine the costs, merits, and capabilities of the current and a potential "enhanced national surveillance system" to provide a basis for a rapid response to bioterrorist attacks or other biothreats, including initiation of pre-infection prophylaxis and expedited response and recovery.

4. Reach a conclusion as to whether the two systems are redundant or complementary, both in current configuration and potential "enhanced" configuration. The analysis shall include a comparison of the effectiveness of the potential "enhanced" national surveillance system with the current and planned BioWatch approach.

5. Prepare an interim report to outline the progress to date on addressing the major issues under consideration by the committee including the types of information that have been collected for assessment and any obstacles to addressing items in the task. The interim report will also provide any conclusions reached by that date.

6. Utilize the results obtained in items 1 through 4 to compile a comprehensive final report of the study. The final report shall include all findings and results concerning the effectiveness of BioWatch. The contractor shall present and brief the final report to OHA senior management prior to its public release in prepublication form and dissemination according to the regular practices of the National Academies. The publication process for the final report will be completed following its public release.

focuses specifically on surveillance and detection of infectious diseases or biological agents that pose a serious threat to human health. Bioterrorism, as the primary context for the BioWatch program, was the principal focus of attention.[2]

[2]This study focused on the detection of biological threats to the civilian population in the United States. While recognizing the need to monitor and potentially respond to international disease activity, the committee did not examine disease surveillance systems in other countries or ones operated by international organizations. Disease threats to animals and plants per se are also excluded, although surveillance tools to monitor animal health and the presence of animal pathogens that can infect humans are an important component of public health surveillance systems.

Three issues are beyond the scope of the study but are, nevertheless, fundamental to the committee's assessment and recommendations.

1. Systems for surveillance and detection of disease threats need to be accompanied by the capability to respond with appropriate public health or medical measures that will minimize illness and death.
2. The BioWatch program is designed to detect certain biological agents that could be intentionally released in aerosolized form. Detecting a bioterrorism event involving other pathogens or routes of exposure requires other approaches.
3. There is considerable uncertainty about the likelihood and magnitude of a biological attack, and how the risk of a release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural diseases.

EVALUATING BIOWATCH

BioWatch is a federal program led by DHS that operates in collaboration with federal partners and with the states and localities where BioWatch air samplers are deployed. The federal partners include the Centers for Disease Control and Prevention (CDC) in HHS, the Environmental Protection Agency (EPA), the Federal Bureau of Investigation (FBI) in the Department of Justice, and the Department of Defense (DoD). The review of BioWatch identified several concerns about program management and priorities, and about the system's technical performance. Recommendations regarding enhancing the response to BioWatch alerts are made with the assumption that the current BioWatch system can be shown through operational testing to provide useful information.

Strengthen the BioWatch Interface with State and Local Jurisdictions

The BioWatch system needs to establish a more effective relationship with public health systems where it is deployed. Public health officials particularly need greater assistance in developing the necessary capabilities to interpret and respond to BioWatch Actionable Results (BARs). A BAR signals detection of segments of the DNA of a target organism, but the committee finds the term to be misleading because it sees a BAR alone as unlikely to be a sufficient basis for public health action. Detection of DNA consistent with that of a bioterrorism agent does not automatically mean that an attack has occurred, that an infectious agent has been released, or that people have been exposed. The committee concluded that local officials

will generally need to gather and assess additional information to determine the proper response to a BAR.

The apparent lack of systematic assessment of dozens of BARs that have occurred—none of which has been associated with bioterrorism or human illness—is a missed opportunity to capture and share lessons learned among the BioWatch jurisdictions and to inform program planning and development by DHS, CDC, and other federal partners. A formal mechanism is needed for the creation and sharing of BAR after-action reports. Local jurisdictions would also benefit from improved decision support tools to help in the synthesis and analysis of information relevant to decisions after a BAR is declared. DHS should continue its efforts to develop such tools.

RECOMMENDATION 1: DHS and its federal BioWatch partners should provide coordinated and collaborative support to local jurisdictions to improve their ability to respond to a BAR. This support should include

- **strengthening relationships with state and local health officials and other key responder agencies (law enforcement, emergency management, environmental protection) through additional and improved training, exercises, and information exchange;**
- **developing, validating, and implementing rapid environmental sampling and testing methodologies to characterize the scale and scope of the incident immediately post-BAR. As validated methodologies are developed, situational awareness and decision support systems with analytical tools to facilitate analysis of critical information needed to inform decisions in response to a BAR should be developed;**
- **preparing detailed guidance for local and state public health officials with specific recommendations on public health measures and decisions following a BAR;**
- **ensuring that a team, with specific training in reacting to BARs and relevant subject matter expertise (e.g., infectious disease epidemiology, laboratory science, environmental assessment, risk communication), would be available to provide around-the-clock expert federal assistance following a BAR; and**
- **developing a formal mechanism for reviewing and sharing the "lessons learned" from the operation of BioWatch, including all BARs and interagency exercises.**

The states and local jurisdictions where BioWatch is deployed have been incurring unreimbursed financial and in-kind costs to support its operation. These costs, even if limited, are an added burden, especially with the current significant fiscal constraints for state and local government.

RECOMMENDATION 2: DHS should provide funding to cover local costs incurred in support of BioWatch resulting from space utilization, laboratory management oversight of BioWatch staff, training and exercises, and other support functions.

Conduct Systematic Testing and Evaluation of Current and Planned Technology

The rapid initial deployment of BioWatch did not allow for sufficient testing, validation, and evaluation of the system and its components. The suspension of plans for the deployment of an interim technology and a delay in the acquisition and deployment of a Generation 3 system provide DHS with a needed opportunity to establish a more systematic, scientifically sound, and stakeholder-approved approach to technology acquisition, development, testing, and deployment than was possible when the BioWatch program began.

DHS has developed plans for testing and evaluation for Generation 3. However, these plans reveal that technology goals for Generation 3 will be very difficult to achieve, and the planned test and evaluation time line may be too short. There is little allowance for delays to respond to problems that often emerge during testing, and there is limited provision for operational testing under diverse environmental conditions. Moreover, the operational test results must be evaluated against measures of effectiveness that should be developed through a genuine collaboration between the BioWatch program office and the public health community. The results of this and other BioWatch testing should be made available to public health stakeholders, with appropriate provisions for security requirements.

With the delay in the planned deployment of Generation 3, a clearer understanding of the capabilities of Generation 2 is critical, and operational testing of Generation 2 should be undertaken now. Improvements are needed in the laboratory assays as well. The committee endorses DHS collaboration with CDC, EPA, and the FBI to develop validated and consistent assays and assay platforms that will be used in continued operation of Generation 2.

RECOMMENDATION 3: DHS should conduct operational testing of BioWatch Generation 2 at sites where it is currently deployed to provide agent-specific performance specifications (based on use of appropriate surrogates as necessary) that are needed to refine Generation 3 requirements and to make effective use of BioWatch results (e.g., risk-management decisions). Generation 3 should undergo thorough operational testing before deployment. Results should be formally and thoroughly documented and made available to public health stakeholders in BioWatch jurisdictions.

Within DHS, operational responsibility for the BioWatch program moved in 2007 from the Science and Technology Directorate to the Office of Health Affairs. These two organizations must have an effective collaboration plan to ensure that BioWatch's operational needs are reflected in the research and technology development activities.

RECOMMENDATION 4: DHS should improve the level of cooperation and collaboration between its Office of Health Affairs and its Science and Technology Directorate to promote effective research and technology development in support of the BioWatch program.

Opportunities to Advance Future Biodetection Systems

A continuing research and development effort is needed to provide the technology and knowledge for effective and sustainable outdoor and indoor environmental monitoring in urban environments. This program should focus on lowering the cost of biodetection, improving the knowledge base for interpreting surveillance results, providing flexibility for addressing unknown threats, and allowing for multiple applications (e.g., surveillance for both bioterrorism and natural disease agents) to make resource-intensive systems more cost effective.

RECOMMENDATION 5: As part of its response to the technical and operational challenges posed by the development and launch of Generation 3 BioWatch, DHS should collaborate with HHS, DoD, EPA, the National Science Foundation, and other agencies doing relevant work to develop and execute an aggressive research and development plan focused on (1) shorter-term goals to improve the capabilities and cost-effectiveness of the environmental monitoring for airborne biological threats performed by the BioWatch system, and (2) longer-term goals to improve the knowledge base needed to support transformational innovations in environmental biosurveillance. Work in support of shorter-term goals should focus on

- **Advancement of the state of science needed for the development of an autonomous field-deployable detector with capabilities to meet Generation 3 BioWatch operational requirements and beyond.**

Work supporting longer-term goals should include

- **Temporal and spatial characterization of pathogen and near-neighbor populations in air and natural reservoirs in urban areas, including those near BioWatch sites, and**

- **Participation in the work by others on host–pathogen interactions, surveillance, and epidemiologic research investigations and establishment of shared databases.**

Make BioWatch Planning Risk-Based and Responsive to User Needs

To be successful, BioWatch requires well-functioning, sophisticated detection technology. But to contribute to saving lives, it also requires effective coordination and communication with the public health decision makers and responders who must be able to determine with confidence whether BioWatch signals call for initiation of prophylaxis or other actions before clinical evidence of illness is evident.

DHS has tended to assess BioWatch in terms of its technology. But the program should operate from the perspective of a more complete system that includes not only its detector technology and equipment and associated assays, but also the responsibilities that fall to state and local public health officials for additional information gathering to confirm and characterize a BAR; for communication with varied federal, state, and local authorities and with the public; and for response planning and training. DHS should emphasize its stated goal of timely response to mitigate illness and deaths from a biological attack, not just successful detection of genetic material that may indicate a terrorist event, and should collaborate with federal, state, and local stakeholders to develop BioWatch program objectives.

Most importantly, DHS should ensure that the BioWatch program evaluates its planning within the framework of both a careful analysis of the risks of an airborne biological attack and the most effective ways to manage these risks. DHS's existing Bioterrorism Risk Assessment (BTRA) program was developed for the specific purpose of providing input for this kind of decision making. A close link between BioWatch and the BTRA, modified as recommended in a 2008 National Research Council (NRC) report,[3] would allow for careful evaluation and analysis of BioWatch's potential contributions to improving health outcomes under realistic scenarios for public health decision making and response.

This evaluation should include all risk scenarios, each pathogen that BioWatch monitors, and outdoor and indoor monitoring. The BioWatch program should not expand its coverage of biological agents or jurisdictions without a clear understanding of the change's contribution to reducing mortality or morbidity in conjunction with clinical case finding and public

[3]NRC (National Research Council). 2008. *Department of Homeland Security Bioterrorism Risk Assessment: A call for change*. Washington, DC: The National Academies Press.

health surveillance. Furthermore, changes to the BioWatch program, including those recommended by this committee, should be subjected to rigorous analysis of their costs and benefits.

RECOMMENDATION 6: DHS should use its existing and periodically conducted bioterrorism risk assessment and other analyses to evaluate the overall effectiveness of the BioWatch system, examine the costs and benefits of the system's current configuration and of significant proposed changes, and articulate its program goals and associated performance metrics, using risk-assessment and risk-management principles. To accomplish this, DHS should

- **Actively solicit input from and collaborate closely on all aspects of the program with key partners and stakeholders at the federal, state, and local levels; and**
- **Conduct comprehensive modeling and analysis to evaluate the potential contributions of the BioWatch system to public health decision making and outcomes using, where appropriate, a Bioterrorism Risk Assessment (BTRA) that has been modified according to the recommendations in a 2008 NRC report. Such analyses should be performed for *all* pathogens for which BioWatch will test and for both outdoor and indoor monitoring programs.**

In the continued development of the BioWatch system, DHS and HHS should work collaboratively, and their joint effort should be guided by advice from an independent panel of external stakeholders and subject matter experts having operational, decision-making, and technical expertise. This panel should advise on setting program goals and objectives, evaluating progress toward them, and decision making and planning for the BioWatch system. Advisors should include state and local public health officials with decision-making roles in response to a BAR. Areas of expertise should include epidemiology, environmental health, public health laboratory systems, infectious diseases, biochemistry, genetics, law enforcement, emergency management, detection technology, meteorology, systems engineering, decision and information science, and operations research.

RECOMMENDATION 7: DHS and HHS should jointly establish a formal mechanism for receiving ongoing *external* advice on all technical and operational issues related to the BioWatch system. The advisory panel should include both technical experts and state and local officials who have experience working with the BioWatch system and would have decision-making roles in the event of a BAR.

ENHANCING NATIONAL SURVEILLANCE CAPACITY AND RESOURCES

The public health and health care systems face many challenges in meeting preparedness goals, including achieving more effective infectious disease surveillance and capabilities for analysis and exchange of information. Capabilities vary across local and state health departments, contributing to inefficiencies and the potential for surveillance gaps. Investments, especially increases in federal funding since 2001, have brought improvements; but further improvements are needed and federal funding covering all aspects of preparedness has declined since the initial post-2001 increases.

Develop and Evaluate New Opportunities in Infectious Disease Surveillance and Detection

Detecting and responding to infectious disease threats is a core function for the public health and health care systems. Efforts are being made at the local, state, and federal levels, spurred in part by funding for bioterrorism and public health emergency preparedness, to strengthen existing resources and develop improved surveillance techniques. For example, enhancement of public health laboratory capability and capacity to conduct molecular subtyping to detect clusters of genetically similar pathogens isolated from patients has the potential to detect and characterize bioterrorism or outbreaks more quickly. "Syndromic" surveillance programs have been developed to aggregate and analyze various types of data to identify unusual statistical patterns that may signal a disease outbreak. But their value for early detection of disease outbreaks, especially for detection of bioterrorism, is still uncertain and requires additional evaluation. Approaches to improving automated aggregation and analysis of surveillance data and interoperability of data systems are still evolving.

HHS, in partnership with state and local public health agencies, should coordinate a strategic, goal-oriented program of intra- and extramural research and development, pilot-testing, and operational evaluation of improved public health surveillance methods. The program should identify and address evidence gaps, unevenness in the geographic deployment and quality of public health surveillance, evaluation of promising methods and technologies, costs and effectiveness, and integration and harmonization of approaches across the many surveillance programs used by CDC and the public health community. Cost-effective methods resulting from this effort should be deployed across state and local jurisdictions through a combination of federal funding and local investments.

RECOMMENDATION 8: HHS should support the development, testing, and evaluation of improved methods for surveillance for infectious disease outbreaks. HHS, through CDC, should take a stronger leadership role in evaluating and enhancing efforts for automating both traditional provider and laboratory reporting and syndromic and other approaches to surveillance, including the development of standards, coordination of state and local initiatives, and integration of federal programs with state and local activities. HHS should assign this leadership role to those responsible for the prevention and control programs these surveillance systems are intended to serve, and it should rigorously evaluate these surveillance efforts.

Achieve Better Information Sharing and Situational Awareness

Much of the information that enables detection, characterization, and ongoing management and mitigation of natural and bioterrorism-related infectious disease outbreaks is generated by health care providers and laboratories, collected at the local or regional level, assembled at a statewide level, and then reported to CDC at the federal level. However, geographic and programmatic compartmentalization of this information can impede identification of regional, national, and international health events. Appropriate and timely exchange of health information also depends on the willingness of local and state authorities to provide it, which, in turn, is related to the value and costs of the process for those providing the information.

Better information sharing can contribute to quicker and more effective outbreak detection, improved communication between public health officials and clinical providers, and improved situational awareness and response capabilities. The scope of information access should include information on animal health, vector control, water and air quality, meteorology, and other information to aid in monitoring or assessing potential threats to human health. Efforts are also being made to increase information sharing between public health agencies and law enforcement and the intelligence community in ways that respect the privacy of individuals and the confidentiality of personal health information that public health agencies are entrusted to collect.

Federal efforts to improve situational awareness are still evolving. For example, DHS's National Biosurveillance Integration Center is intended to bring together national and international information that could enhance advance warning of potential biological threats. In HHS, the BioSense program is emphasizing aggregation of data from hospitals and other health care sources, and the BioPHusion program is focusing on providing analysis of public health data such as that collected by BioSense. Ensuring that information from BioWatch is effectively integrated into such systems will help maximize its value.

RECOMMENDATION 9: DHS and HHS should enhance the efforts to develop a mechanism for providing a national situational awareness of biological threats and significant disease outbreaks, to better inform rapid decision making and response through cross-jurisdictional data sharing and analysis of data. To this end, DHS and HHS should facilitate the development of an interoperable, secure, bidirectional, nationwide information-sharing infrastructure and ensure that local and state health officials have ready access to the system.

Develop and Evaluate Decision Support for Clinical Case Recognition and Reporting by Health Care Providers

Early detection of a bioterrorism event or the emergence of a naturally occurring disease threat may depend on the ability of astute clinicians to diagnose the first few cases, or recognize suspicious clinical presentations that require special scrutiny by experts in infectious diseases. However, this requires busy clinicians to recognize a rare disease they may well be seeing for the first time—a challenging prospect in the best of circumstances. Index case recognition is particularly difficult in the early stages of disease, when symptoms may be vague or consistent with other, much more common (and less dangerous) diseases.

Clinically useful, bidirectional, and modifiable decision support tools for use by emergency departments and other acute care settings should be developed and evaluated as means to improve the speed and consistency of the clinical recognition, reporting, and management of index cases of diseases of greatest public health concern, as well as other reportable public health conditions. Providing effective tools of this sort to emergency departments and other acute care settings, many of which already face challenges in adequately serving patients under routine circumstances, is a high priority. Other technologies under development, such as rapid point-of-care diagnostic testing, may also enhance timely case recognition.

RECOMMENDATION 10: HHS should promote the development, testing, and evaluation of technologies that strengthen the accuracy, timeliness, consistency, and completeness of clinical diagnosis of infectious diseases of public health importance, and that facilitate timely reporting of these diagnoses to public health authorities.

COMPLEMENTARY SURVEILLANCE ROLES FOR BIOWATCH AND PUBLIC HEALTH AND HEALTH CARE

While recognizing the need for more and better testing of the BioWatch system's ability to meet its technical and operational requirements, the com-

mittee concluded that BioWatch in its current form (Generation 2), or with planned enhancements (Generation 3), has the potential to fill a unique and complementary functional niche in the nation's biosurveillance resources. However, this potential can be realized only if a large-scale aerosol attack occurs in a locality where BioWatch is deployed, if an air sampler lies in the path of the release, and if the pathogen used is one of those included in the BioWatch laboratory assays. In particular, some modeling analyses show that under these conditions, BioWatch has the potential to provide a more timely alert than the public health and health care systems. The potential benefit appears likely to be greater for the detection of anthrax spores than other monitored threat agents, given the potential for aerosolized distribution of anthrax spores, the rapid progression and high case fatality rate of inhalation anthrax, and the opportunity to limit infections with timely post-exposure prophylaxis and to lower morbidity and mortality with early treatment.

But BioWatch is specialized, and it does not eliminate the need for the broader and more flexible surveillance activities of the public health and health care systems, either in their current forms or with various enhancements. Infectious disease surveillance is an essential part of daily activities at local, state, and federal levels to protect the public's health from various threats, including bioterrorism or naturally occurring infectious disease. With or without BioWatch, the public health system needs to be capable of monitoring disease trends and accessing information from multiple sources (e.g., animal health, environmental monitoring, and law enforcement) to identify or characterize situations that may signal a public health emergency. At best, BioWatch is only one source of such information.

Table S-1 provides a broad-brush summary of key features of BioWatch and traditional disease surveillance systems. This kind of summary comparison is challenging because of the differences in the purpose and scope of the BioWatch system and infectious disease surveillance activities through the public health and health care systems.

A cost comparison of the BioWatch system and enhanced surveillance by the public health and health care systems is especially problematic. BioWatch is supported by a relatively well-defined federal program, albeit imposing some poorly identified costs on states and localities in supporting daily operations and responding to periodic BARs. Projections suggest that the average annual direct federal costs over the next 10 years will be approximately $80 million for continuing the BioWatch program in its current form (Generation 2). If the transition is made to the planned Generation 3 system, the annualized direct costs will be about $200 million for acquisition, deployment, and operation.

The costs of the broader infectious disease surveillance activities in the public health and health care systems are difficult to determine. Current

TABLE S-1 Capabilities and Costs of the BioWatch System and Surveillance Through the Public Health and Health Care Systems

System	Detection Capability	Coverage	Sensitivity and Specificity
BioWatch System			
Generation 2	Certain biological agents; environmental presence of airborne genetic material	> 30 major metropolitan areas (i.e., BioWatch jurisdictions)	Not publicly available Dozens of BARs to date; none linked to bioterrorism
Generation 3 *(proposed)*	Biological agents covered by Generation 2, with goal of including additional agents; environmental presence of airborne pathogens	Expanded coverage	System not yet selected
Public Health and Health Care Systems			
Disease recognition and reporting by health care providers and laboratories to health departments	All human health hazards (e.g., biologic, chemical, environmental) that result in clinically recognized disease or injury	Entire country, reports of uneven quality submitted to nearly 3,000 local and state health departments	Not readily quantified; varies by disease, provider, location, reporting system, epidemiologic expertise, and other resources

Timeliness	Benefits	Annual Costs	Other Considerations
Typical 24-hour sample collection cycle; 10- to 36-hour window from release to confirmation of screening test	If aerosolized pathogen is detected, potential reduction in casualties if distribution of prophylaxis and treatment can be started sooner; potential interruption of contagion or environmental spread*	$80 million (10-year average) Costs of recommended program changes not included	Need for testing and evaluation of technology, holistic evaluation of goals, better tools to aid public health response, and assessment of environmental risk after a BAR
Proposed 4- to 6-hour time to detect; automated sample processing and testing and reporting of results	Potential for reduction in casualties may be greater than with Generation 2 because of plans for more frequent testing*	$200 million (10-year average) for acquisition, deployment, and operation Costs of recommended program changes not included	System not yet selected; actual performance may differ from proposed specifications; significant technological hurdles must be overcome to achieve desired system capabilities
May depend on disease, skill of health care provider, availability of appropriate analysis tools, scale of pathogen exposure, reporting system; depends on evidence of infection, so not likely to detect before environmental surveillance	Provide ongoing detection of intentional and naturally occurring outbreaks for prevention or treatment	Unknown; data necessary to estimate costs of disease surveillance systems or marginal cost of surveillance for significant infectious disease threats not available	Need for additional integration and information sharing across federal, state, and local levels; need for evaluation and incorporation of new techniques

continued

TABLE S-1 Continued

System	Detection Capability	Coverage	Sensitivity and Specificity
Syndromic surveillance	Varies by system design and application	Currently > 80% of state, tribal, large local jurisdictions have some form	Varies by system design and application, scale of outbreak

NOTE: BAR, BioWatch Actionable Result.

*Achieving a reduction in mortality with the BioWatch system depends on the BioWatch technology and communication of a BioWatch Actionable Result, expeditious information gathering to confirm a bioterrorist event, and having the capability to distribute mass prophylaxis or treatment to prevent or reduce illness and mortality.

budgeting and accounting systems at the local, state, and federal levels do not usually provide this information, and the surveillance costs incurred by the private-sector components of the health care system are even less readily captured. Furthermore, surveillance for significant biological threats, or specifically for bioterrorism threats, cannot be readily separated from other health surveillance programs. Annual governmental expenditures on all public health activities are estimated at approximately $64 billion. But the committee was unable to obtain information that would allow a determination of the portion of these costs attributable to infectious disease surveillance. Better data are needed to assess the costs of surveillance systems, and innovative strategies will be needed to assess the cost-effectiveness of any surveillance system enhancements.

A NATIONAL BIOSURVEILLANCE SYSTEM

A national biosurveillance system should aid in protecting the nation's population from significant, time-critical biological threats of all types. "National" in this context means encompassing the information needs of potential users across the country and facilitating access to data that can help in the recognition of and response to either localized health emergencies or geographically dispersed events that may arise from circumstances such as contamination of widely distributed foodstuffs or a bioterrorism event that targets a transportation hub.

Timeliness	Benefits	Annual Costs	Other Considerations
May depend on scale of pathogen exposure, but not likely to detect before environmental surveillance	May help detect and track sporadic and recurring infectious disease outbreaks	Would be included in costs of disease surveillance; cost of developing and operating individual systems expected to vary widely	Requires further testing and evaluation to assess strengths and limitations as tool to aid detection of infectious disease outbreaks

This system would employ a layered approach that includes

1. judicious use of environmental surveillance tools, such as BioWatch, to detect a small number of current and potential future airborne threats that could harm a large number of people;
2. an enhanced capacity to recognize, isolate, and report index cases from clinical settings;
3. refined approaches to analyzing epidemiologic data to detect aberrant signals that may indicate a disease outbreak and track its spread;
4. improved and more rapid methods for use in the laboratory or at the point of care to detect, verify, and characterize a biological threat;
5. improved tools for data management and for communication of information among all appropriate stakeholders;
6. streamlined approaches at the federal, state, and local levels to intelligence and information sharing and to decision making to minimize delay between the emergence of a threat and appropriate action to minimize its consequences, and timely after-action analysis to identify strengths and weaknesses in policies and procedures; and
7. sustainable funding that encourages integration of data across programs.

At present, the nation lacks a clear, overarching architecture of interlocking interagency goals, metrics, and accountability to assure a seamless process from detection of biological threats through response and recovery.

BUILDING AND SUSTAINING CAPACITY TO DETECT AND RESPOND TO HEALTH EMERGENCIES

Despite substantially increased federal funding since 2001 to improve emergency preparedness in state and local health departments and in the health care system, long-standing concerns about the nation's capacity to respond to health emergencies remain. The infusion of federal funds for public health and medical preparedness has improved the general level of preparedness, but the categorical nature of the funding and some uncertainty about its continuation has generally discouraged public health agencies from integrating new capacities with traditional programs.

At the same time, investment in the basic public health infrastructure, such as staffing and electronic information management and analysis systems, has been more limited. The unevenness of organizational and technical capacity at state and local levels across the public health system weakens the nation's preparedness to detect and, especially, to respond to and manage the consequences of a major health emergency. With reductions in federal funds and financial challenges facing state and local governments in 2009, these weaknesses may worsen.

Federal assistance is needed to achieve the desired minimum state and local capacities for surveillance for bioterrorism and infectious disease threats, but the task will be challenging, requiring effective coordination and collaboration in state and local public health systems and in the complexities of both state and federal relationships and federal interagency action.

RECOMMENDATION 11: HHS and DHS should give high priority to building and sustaining sufficient public health workforce strength and competencies, along with associated laboratory and information management capacities, needed by all states and communities to detect a bioterrorism attack or other public health emergency. They should pursue a nationally consistent minimum level of disease surveillance and communication sufficient to provide early warning and tracking of bioagent attacks and outbreaks of natural disease. Key state and local capacities should include the following:

- **Adequate amounts and types of staff expertise, including infectious diseases, veterinary health, laboratory science, environmental health, applied epidemiology and biostatistics, and health informatics;**
- **Adequate public health reference laboratory capacity;**
- **Electronic laboratory reporting systems to ensure timely and complete transmission of notifiable disease reports from commercial and hospital-based laboratories to public health;**

- **Universal access to public health reference laboratory services for detecting and confirming biothreats and other emerging infectious diseases and performing molecular typing to link cases in outbreaks;**
- **Robust surveillance and outbreak management information systems;**
- **Electronic death registration systems;**
- **Health alert networks that connect public health departments with all health care facilities and providers in their jurisdictions; and**
- **Integration of public health needs and systems into emerging health information exchanges.**

CONCLUDING OBSERVATIONS

The federal BioWatch program faces the challenge of supporting both a national security mission and the health care and public health systems, at state and local levels, in monitoring threats to human health. The BioWatch system has the potential to contribute to its health protection goal by providing early warning of a biological attack, but only if the attack uses certain aerosolized pathogens and if BioWatch air samplers lie in the path of the release.

BioWatch's potential contribution to minimizing illness and death relies upon an awkward and organizationally challenging arrangement for responding to BARs and depends heavily on the ability of health departments and the health care system to analyze the nature of a detected threat and to take quick and decisive action. It is therefore essential that the operation and management of the BioWatch system be well integrated with the jurisdictions where it operates. State and local authorities, whose legal responsibilities as well as knowledge of endemic health risks and available resources cannot be replicated at the federal level, must be recognized as essential and valuable partners not only in the BioWatch program but also in broader national biosurveillance and emergency preparedness efforts.

It is essential that policy makers recognize that the benefits of any form of infectious disease surveillance will not be realized if states and communities do not also have the capability to respond effectively to a public health emergency. Despite the substantial progress that many localities have made in advancing mass dispensing capacity, having the ability to administer antibiotic prophylaxis to hundreds of thousands, if not several million, urban area residents within a few days following detection of a bioterrorist attack remains challenging.

1

Introduction and Background

Surveillance for, detection of, and response to natural or unintentional disease outbreaks are traditional responsibilities of public health authorities, who rely heavily on health care providers and laboratories to provide timely reports on diagnoses and test results. The national security community also has a long history of biosurveillance and response for defense against threats from biological weapons used as agents of warfare or terrorism. Since the 1990s, growing concerns about bioterrorism and potential epidemics of emerging infectious diseases have spurred interest in developing new and better ways to detect biological threats as quickly as possible so that preventive measures or treatment can be started in time to reduce illnesses and deaths.

After the 9/11 attacks and the anthrax letters in 2001, one response to the threat of bioterrorism was the initiation in 2003 of an environmental air monitoring program called BioWatch. Under this program, the Department of Homeland Security (DHS) has deployed hundreds of air samplers in more than 30 major cities, primarily in outdoor locations, to detect the presence of certain pathogens of concern, should any of them be released in aerosolized form. The aim of the BioWatch program is to speed the detection of aerosolized pathogens to help local health officials respond swiftly to a potential bioterrorism emergency.

Implementing the BioWatch program within a few weeks after it was announced in January 2003 required identifying an air sampling device that could be quickly adapted for field use and deployed. It also required determining how many devices would be used, where they would be placed, where and how the samples would be analyzed, and what the daily operat-

ing procedures would be. Since 2003, DHS has modified several aspects of the BioWatch system by enhancing the air samplers; deploying additional monitoring devices; relocating devices; and revising protocols for routine operations, analyses, and actions following a positive laboratory result. DHS has also been pursuing alternative approaches to sample collection and analysis to respond to a recognized need to produce results more quickly, more frequently, and from more varied locations than is possible with the current system.

The BioWatch system is a civilian environmental monitoring component of a much broader domestic biodefense effort that encompasses a variety of activities. These include information gathering and analysis to identify potential threats and the risk they pose, various monitoring and detection activities, public health and law enforcement responses, and programs leading to restoration and recovery (The White House, 2004; FEMA, 2008).

Among these activities are efforts being made to strengthen the ability at the local, state, and national levels to detect and respond to infectious disease emergencies of all types.[1] The Department of Health and Human Services (HHS) is leading the federal activities with funding and other resources to support the development of a more robust capacity within the public health and the health care sectors to recognize unfamiliar illnesses or unusual clusters of cases, effectively assemble essential information to guide decision making, and speed deployment of an appropriate response.

Despite improvements since 2001 in the nation's preparedness to detect and respond to bioterrorism or emerging infectious disease threats, some concerns remain. For example, the Government Accountability Office (GAO, 2009) highlighted continuing needs to clarify federal leadership roles and close known gaps in pandemic influenza preparedness plans. Particular concerns about BioWatch include the timeliness, probability, and accuracy of detection using the current system and the maturity of plans for the introduction of a new generation of devices for automated collection, preparation, and analysis of air samples (e.g., O'Toole, 2007a,b; Price, 2008). Another concern is whether the BioWatch system is appropriately integrated with other health-related surveillance and response efforts that must be available to act on a BioWatch alert (e.g., O'Toole, 2007b; Downes, 2008; Price, 2008; Lindley, 2009).

Because of such concerns, Congress, through the Subcommittee on Homeland Security of the House Appropriations Committee, directed the Office of Health Affairs (OHA) in DHS to engage the National Academies to evaluate the effectiveness of BioWatch, to compare the benefits and costs of the current version of BioWatch with a planned modification, and to

[1]Throughout this report, the phrase "federal, state, and local" encompasses territorial and tribal entities.

compare BioWatch with an enhanced national surveillance system that relies on the health care and public health systems.

STUDY CHARGE AND COMMITTEE MEMBERSHIP

To carry out this congressionally mandated study, the National Academies convened the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System. The charge from DHS calls for the committee (1) to evaluate the effectiveness of BioWatch, including a comparison of benefits and costs for the existing program (referred to here as Generation 2) and for a planned "next generation" program that uses new, automated field devices deployed in greater numbers (Generation 3); (2) to assess the costs and benefits of enhanced national surveillance that relies on U.S. hospitals and the U.S. public health sector; and (3) to compare the effectiveness of surveillance activities and tools used by the public health and health care systems to that of the current BioWatch approach. The complete statement of task appears in Box 1-1.

Committee members were selected to contribute expertise in areas that include biological threat assessments, evaluation of biological detection systems, environmental monitoring technologies, biological assays, microbiology, virology, epidemiology, syndromic surveillance, health information technology, the U.S. public health sector, hospital systems, emergency medicine, laboratory operations, statistical methods, systems engineering, operations research, and economic analysis.

The committee met in person five times from July 2008 through January 2009 and conferred by conference call several times during the study. The group gathered information from presentations by invited participants at its first three meetings, responses to written requests for information submitted to DHS and the Centers for Disease Control and Prevention (CDC) in HHS, commissioned analyses, and examination of published literature. An interim report, which described the state of the committee's review but contained no findings or recommendations, was released in February 2009.[2] Additional information about the committee's activities appears in Appendix A.

Invited participants at the committee's meetings included Congressman David Price; representatives of DHS, HHS, and other federal agencies; representatives of state and local health departments; physicians in clinical practice; and researchers from academia and commercial firms who are developing laboratory testing tools. At the committee's request, the firm Industrial Economics, Incorporated, prepared information on the costs of

[2]The interim report is available from the National Academies Press at http://www.nap.edu/catalog.php?record_id=12599.

the BioWatch program and of biosurveillance activities in the public health and health care systems. The committee also commissioned Dr. David Buckeridge of McGill University to perform a simulation analysis to compare the effect of detection methods on the time from release of aerosolized anthrax spores to initiation of treatment.

SCOPE OF THE STUDY

The committee interpreted its task as assessing current and proposed approaches for detecting serious human disease threats, especially those resulting from bioterrorism. These approaches include (1) aerosol monitoring by the BioWatch system, (2) public health case reporting from clinical and laboratory settings, and (3) "syndromic" surveillance programs that aggregate and analyze various types of data that might be available before the diagnosis of the first case (e.g., chief complaints at emergency department visits, pharmacy sales, absenteeism) to identify unusual patterns that may signal a disease outbreak.

National policy emphasizes the importance of surveillance for detection, as quickly as possible, of potentially catastrophic biological threats to the civilian population of the United States in order to have an opportunity to maximize the decisiveness, timeliness, and effectiveness of public health actions to control disease. The *National Response Framework* (FEMA, 2008, p. 42) defines a catastrophic incident as "any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions."

The study considered detection of both deliberately introduced and naturally occurring infectious diseases—that is, agents of bioterrorism and significant emerging infectious diseases such as pandemic influenza and SARS. Detection of bioterrorism received greater attention because it is the purpose of the BioWatch program. The committee recognized that the national security community maintains an active information acquisition and analysis system that focuses on a subset of the infectious disease threat that is related to bioterrorism and biowarfare. The committee also recognized, and emphasizes in this report, that the health care and public health systems together are intrinsically a funnel through which information about all forms of disease flow, whether related to bioterrorism or not.

Tasks the committee considered to be beyond the scope of the study include an evaluation of underlying assumptions about and estimates of the magnitude of (1) the risk of bioterrorism; (2) the risk of bioterrorism relative to other terrorism threats; (3) the risk posed by any one potential bioterrorism agent compared with another; and (4) relative risks from natural versus bioterrorist threats. Also beyond the study's scope is an examination of the capability at

BOX 1-1
Statement of Task

The Institute of Medicine (IOM) and National Research Council (NRC) will evaluate the effectiveness of BioWatch, including a comparison of benefits and costs for Generations 2 and 3; the costs and benefits of an enhanced national surveillance system that relies on U.S. hospitals and the U.S. public health system will also be assessed, and its effectiveness compared to that of the current BioWatch approach. The evaluation will include examination of the reliability of BioWatch monitoring data and the ability of hospitals and public health officials to respond based on information received from that system. Services under this contract will encompass the evaluation of the effectiveness of both current and enhanced biosurveillance systems to detect biological terrorism or other biothreats to human health, including (1) differing technological generations of BioWatch, (2) current human health-related surveillance systems, including those for zoonotic disease, and (3) describing necessary enhancements to hospital and public health systems based on measures of effectiveness in detecting attacks of bioterrorism or other biothreats. Measures of effectiveness will include the ability of surveillance systems to warn sufficiently to provide effective post-exposure prophylaxis and effective post-infection treatment to affected populations following a bioterrorist attack or other biothreat event.

The IOM and the NRC shall provide expert advisors that reflect expertise in relevant fields, such as biological threat assessments, biological detection systems evaluation, environmental monitoring technologies, biological assays, microbiology, virology, epidemiology, health information technology, the U.S. public health system, hospital operations, local emergency management, public health response, statistical methods, infectious disease modeling, syndromic surveillance, systems engineering, operations research, complex database management and analysis; and economic analysis. The following are specific requirements under this requirement. The IOM/NRC shall provide sufficient staff support to organize meetings, generate reports and manage the contract. The IOM/NRC will:

the federal, state, and local levels to mount a timely and effective response to the detection of a serious disease threat. Even so, the committee understands that these matters of risk and response capability are critically important to assessing the value of BioWatch and returns to them later in this chapter.

The study's focus on the civilian population in the United States means that the committee, while recognizing the need to monitor and poten-

1. Evaluate the relative merits, and current and potential capabilities of the BioWatch monitoring system (Generation 2 and Generation 3) to detect bioterrorist attacks and other biothreats via environmental monitoring, with the aim of early warning and pre-infection prophylaxis and expedited response and recovery. The evaluation will consider both BioWatch Generation 2 and Generation 3 equipment, and the relative advantages and disadvantages of each, including their costs and benefits.

2. Describe the characteristics of an "enhanced national surveillance system" that relies on U.S. hospitals and the U.S. public health system.

3. Examine the costs, merits, and capabilities of the current and a potential "enhanced national surveillance system" to provide a basis for a rapid response to bioterrorist attacks or other biothreats, including initiation of pre-infection prophylaxis and expedited response and recovery.

4. Reach a conclusion as to whether the two systems are redundant or complementary, both in current configuration and potential "enhanced" configuration. The analysis shall include a comparison of the effectiveness of the potential "enhanced" national surveillance system with the current and planned BioWatch approach.

5. Prepare an interim report to outline the progress to date on addressing the major issues under consideration by the committee including the types of information that have been collected for assessment and any obstacles to addressing items in the task. The interim report will also provide any conclusions reached by that date.

6. Utilize the results obtained in items 1 through 4 to compile a comprehensive final report of the study. The final report shall include all findings and results concerning the effectiveness of BioWatch. The contractor shall present and brief the final report to OHA senior management prior to its public release in prepublication form and dissemination according to the regular practices of the National Academies. The publication process for the final report will be completed following its public release.

tially respond to international disease activity, did not examine disease surveillance systems in other countries or ones operated by international organizations. Disease threats to animals and plants per se are also excluded, although these disease threats are very much a part of the broader perspective on bioterrorism (e.g., NRC, 2002; GAO, 2004; The White House, 2004, 2007). Many known infectious disease agents and potential

bioterrorism agents are zoonotic; that is, they are animal diseases that can be transmitted to humans. New zoonotic disease threats may also arise as changes occur in the ability of animal diseases to adversely affect human health. As a result, surveillance tools that monitor animal health and the presence of zoonotic pathogens are an important component of surveillance systems that focus on human health.

CURRENT FEDERAL FUNDING FOR CIVILIAN ACTIVITIES FOR DEFENSE AGAINST BIOLOGICAL THREATS

No consolidated summary of federal funding for civilian activities to defend against bioterrorism and other significant biological threats is directly available from federal budget documents. Past estimates have been compiled from an examination of programs distributed across several departments, including DHS, HHS, the Department of Defense (DoD), the Department of Agriculture, and the Environmental Protection Agency (e.g., Franco, 2008). Although the President's budget for fiscal year (FY) 2010 became available as this report was being completed, aggregated estimates were available only through FY 2009. The estimated FY 2009 total for federal funding for civilian activities to defend against bioterrorism and other significant biological threats was approximately $8.0 billion (Franco, 2008). Of this, $4.2 billion was for activities in HHS and $2.5 billion for DHS. Approximately $2.2 billion of the FY 2009 budget proposal for DHS was for a multiyear allocation for Project BioShield.[3] The remaining $1.3 billion of the $8 billion total was to support activities in other agencies.

The HHS funding supports activities that range from basic research to operational support for states and communities in national emergencies. This includes the federal funding through CDC for public health surveillance activities, the cooperative agreement program to build state and local emergency preparedness capacity, and the Strategic National Stockpile.[4] Excluding Project BioShield, the DHS funding includes the BioWatch program in OHA, the National Biosurveillance Integration Center, and research and development activities in the Science and Technology Directorate. Table 1-1 shows appropriated or proposed federal funding from FY 2007 through FY 2010 for specific activities in HHS and DHS.

[3]Project BioShield was created in 2004 to foster the research, development, and acquisition of medical countermeasures to chemical, biological, radiological, and nuclear (CBRN) threats (HHS, 2008). The program gives the secretary of HHS authority and flexibility to facilitate the research and development for these countermeasures and has a reserve fund for the procurement of countermeasures.

[4]The Strategic National Stockpile holds vaccines, medications, and medical supplies that can be rapidly deployed to supplement state and local resources in the event of a significant medical emergency.

TABLE 1-1 Federal Funding for Selected Civilian Activities to Defend Against Bioterrorism and Other Significant Biological Threats, Fiscal Years 2007–2010 (in millions $)

	FY 2007	FY 2008	FY 2009	FY 2010 *(proposed)*
Department of Health and Human Services				
Upgrading state and local emergency preparedness capacity	$ 767	$ 746	$ 746	$ 761
BioSense	57	34	34	34
Enhancing the Laboratory Response Network	10	9	8	8
Strategic National Stockpile	496	552	570	596
Department of Homeland Security				
BioWatch	85	77	112	95
National Biosurveillance Integration Center		10	8	8

NOTE: FY, fiscal year.
SOURCES: Franco (2008); CDC (2009a); DHS (2009b).

State and local funds also support related activities. The amount of state and local support for disease surveillance and other activities related to bioterrorism is difficult to estimate because these activities are generally carried out as part of a system aimed at detecting and responding to naturally occurring diseases.

BIOLOGICAL THREATS TO HUMAN HEALTH

Potential Bioterrorism Agents

Biological agents that might be deliberately introduced in an act of war or bioterrorism include a variety of bacteria, viruses, protozoa, multicellular parasites, and biological toxins. These may be naturally occurring pathogens or pathogens enhanced to increase their usefulness as bioterrorism agents. Biological agents that are publicly recognized as potentially useful for bioterrorism have been categorized by CDC on the basis of characteristics such as their lethality and potential for dissemination (see Box 1-2). The "Category A" agents are a high priority. The agents included in categories B and C are ones that appear to pose serious but more limited risks.

Further analysis and delineation of current and future potential bioterrorism and biowarfare threats is an ongoing activity performed by the

BOX 1-2
CDC Categories of Potential Bioterrorism Agents and Their Related Diseases

Category A
Agents that include organisms that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.

- *Bacillus anthracis* (anthrax)
- *Clostridium botulinum* toxin (botulism)
- *Yersinia pestis* (plague)
- Variola major (smallpox)
- *Francisella tularensis* (tularemia)
- Viruses causing hemorrhagic fevers, including
  - Filoviruses (e.g., Ebola, Marburg)
  - Arenaviruses (e.g., Lassa, Machupo)

Category B
Agents that are moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

- *Brucella* species (brucellosis)
- Epsilon toxin of *Clostridium perfringens*
- Food safety threats, including

national security community. In its work, the committee focused on surveillance for currently acknowledged bioterrorism threats, especially those addressed by the BioWatch program, but it recognizes the potential for other bioterrorism agents that may pose new surveillance challenges.

Because biological agents vary in their physical characteristics and impact on human health, no single strategy to defend against bioterrorism is likely to suffice. Inhalation anthrax and botulism, for example, are highly lethal if untreated, but these are not contagious illnesses (i.e., not transmissible from person to person). Smallpox, caused by the variola major virus, is contagious, but the mortality rate for untreated illness is likely to be much lower than that for inhalation anthrax. Medical options for prevention and treatment also vary. Vaccines are available to protect against anthrax and smallpox. Infections with some of these agents are susceptible to antibacterial or antiviral medications, and an antitoxin is available to treat some forms of botulism. However, other illnesses can only be treated

Salmonella species
Escherichia coli O157:H7
Shigella species
Burkholderia mallei (glanders)
Burkholderia pseudomallei (melioidosis)
Chlamydia psittaci (psittacosis)
Coxiella burnetii (Q fever)
Ricin toxin from *Ricinus communis* (castor beans)
Staphylococcal enterotoxin B
Rickettsia prowazekii (typhus fever)
Viruses causing encephalitis, including
Alphaviruses (e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis)
Water safety threats, including
Vibrio cholerae (cholera)
Cryptosporidium parvum (cryptosporidiosis)

Category C
Agents that include emerging pathogens that could be engineered for mass dissemination in the future because of availability, ease of production and dissemination, and potential for high morbidity and mortality rates and major health impact.
Emerging infectious agents such as Nipah virus and hantavirus

SOURCE: Adapted from CDC (2008a).

with supportive therapies (e.g., mechanical ventilation, hydration) that may reduce mortality.

In their naturally occurring forms, many of the Category A, B, and C agents are probably poorly suited to the aerosol dispersal that the BioWatch system is designed to detect, but some are naturally stable in the environment (e.g., the spores of *Bacillus anthracis*) (Sinclair et al., 2008). It is also possible to stabilize aerosolized agents to enhance retention of their infectivity. However, aerosol dispersal is not the only way biological agents might be used. Detection of an alternative dispersal mode would require a means other than BioWatch. For example, BioWatch is not designed to detect dissemination of biological agents through foodstuffs or deployed to detect them through postal delivery.

Modern medical and public health experience with many of these biological agents is limited, as is experience with bioterrorism. In 1984, there were 751 known cases of salmonellosis from deliberate contamination of a

salad bar but no deaths (Török et al., 1997). The 2001 anthrax letters produced infections in 22 patients, and 5 of these patients died (Jernigan et al., 2002). About 32,000 people who may have been exposed to the anthrax spores received antimicrobial prophylaxis (CDC, 2001a). The committee also noted that the impacts of bioterrorist activities can go far beyond morbidity and mortality statistics, as witnessed by the impacts of the anthrax letter attacks. The potential for impacts similar to other national security threats provides the basis for the classification of bioterrorism agents as weapons of mass destruction.

Naturally Occurring Infectious Disease Threats

Among the potential emerging disease threats, a highly virulent, pandemic influenza is a leading concern. The appearance of the novel influenza A (H1N1) virus in spring 2009 (as this report was being completed) gave an indication of the serious challenges that are anticipated, not only in managing the delivery of medications and medical care but also in implementing quarantines or other disease containment measures and minimizing the disruption of essential public and private services. The past decade has also seen the emergence of diseases caused by previously unrecognized threats (e.g., the SARS coronavirus) or the sudden appearance in a new environment of unfamiliar pathogens (e.g., West Nile virus or the monkeypox virus). These experiences point to several challenges for timely public health science and practice: distinguishing novel outbreaks from endemic disease, defining diagnostic criteria, identifying the causal agent and its route of transmission, tracking the spread of the disease, and identifying and deploying methods for prevention and treatment. Unusual disease outbreaks may also involve both the national security and public health communities until the origin of the outbreak is determined.

While the United States is preparing against the possibility of major infectious disease outbreaks from natural or intentional causes, infectious diseases are routinely responsible for tens of thousands of deaths each year. CDC estimated the infectious disease toll in 2000 at 75,000 deaths, plus approximately 15,000 additional deaths related to HIV/AIDS (Mokdad et al., 2004). In a typical year in the 1990s, as many as 36,000 deaths were related to influenza (Thompson et al., 2003). However, the influenza pandemic of 1918–1919 resulted in an estimated 675,000 deaths in the United States and perhaps as many as 50 million deaths worldwide (HHS, no date). The 2003 SARS epidemic was responsible for 774 reported deaths and 8,098 cases worldwide (WHO, 2004). The United States had 29 reported cases, 8 of which were confirmed by laboratory testing, but no deaths (CDC, 2003). The 2009 novel influenza A (H1N1) epidemic is still under way at the time this report is being finished. As of July 1, 2009, the World Health

Organization (WHO, 2009) had received reports of 77,201 cases and 332 deaths. CDC (2009b) was reporting 27,717 confirmed or probable cases and 127 deaths in the United States as of June 25, 2009.

DETECTING BIOLOGICAL THREATS

Routinely, health care providers, laboratories, and health departments work together to diagnose disease and recognize outbreaks that require a broader response than standard treatment provided for individual, unrelated cases. The BioWatch system is intended to provide an earlier warning to health departments of the aerosolized release of certain bioterrorism agents so that a rapid response can limit morbidity and mortality. While the use of this sort of "environmental monitoring" is intuitively appealing (assuming detection is likely and likely to be accurate), many questions arise from the premise that earlier awareness of the presence of a pathogen will result in a faster and more effective response and fewer deaths or illnesses. Recognizing the complexities around detection of and response to biological threats can help policy makers evaluate the scope, capability, and effectiveness of various biosurveillance approaches.

What Does "Early" Detection Mean?

One set of questions concerns the definition of "early" and the amount of time (hours? days?) that using BioWatch might save over clinical case finding or other surveillance approaches in delivering an appropriate response. As BioWatch currently operates, the air samplers typically have a 24-hour collection cycle, and their dry filters are manually collected and transported to laboratories for processing and analysis. The analysis of these samples can provide evidence that segments of the DNA of certain organisms were present some time during the 24-hour period before the filter was collected. Although the presence in the environment of segments of DNA associated with a pathogenic organism is a signal of possible danger, the committee saw that this information alone is not necessarily sufficient to determine the appropriate next steps and that it may be necessary to assess other important information to determine if an effective bioterrorism attack has occurred. Such information may include whether infectious organisms are present, whether these organisms are naturally occurring in the local environment, or perhaps whether hospitals are seeing patients with symptoms consistent with infection by the detected agent.

Alternatively, an epidemic arising from a bioterrorist attack or other source may be recognized by health care providers who notice an unusual pattern of disease among their patients or who diagnose an unusual infection that is recognized as a potential "index case" for an epidemic that is

yet to become fully manifest. Syndromic surveillance systems seek to automate and expand the recognition of unusual disease trends by capturing data related to the onset of illness, such as visits to emergency departments, clusters of patients with certain symptoms, increases in absenteeism, or purchase of over-the-counter medications. The resulting time line, which may run to days or weeks after an attack, will depend on multiple factors, such as the number of people exposed, the amount of the pathogen exposed people take in (i.e., the dose received), the incubation period of the disease, when and where infected people decide to seek care, and, for clinical case reporting, the astuteness of clinicians seeing those patients.

Figure 1-1 illustrates the general temporal relationship among different means of detecting the presence of a pathogen or illness or death resulting from exposure to the pathogen in jurisdictions where BioWatch operates. Depending on the nature of specific events, the relative sequence or overlap of events may vary from what is depicted here. For example, clinicians may recognize and report an increase in nonspecific manifestations of disease before syndromic surveillance systems yield statistical alarms. If laboratory testing of BioWatch samples were delayed, unusual trends in illness may be recognized before BioWatch yields an alert. Similarly if there is significant time between collection of clinical specimens and the availability of pre-

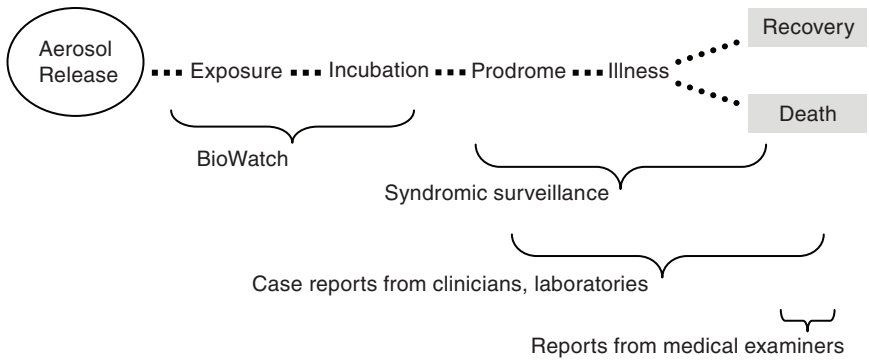


FIGURE 1-1 Schematic illustration of the temporal relation among potential mechanisms for detecting an aerosolized biological threat. The brackets span the interval over which a particular mechanism would have the potential to detect the presence of a pathogen (e.g., via BioWatch) or illness or death caused by the pathogen. This illustration represents the initial detection of a bioterrorism event. The time line for detection of subsequent events that are part of the same attack may be compressed because an initial detection is likely to increase attention to the potential threat.
SOURCE: Adapted from Sosin (2008).

liminary or definitive laboratory assessments, a signal from the BioWatch system may speed awareness of the attack.

For inhalation anthrax, considered by many to be the bioterrorism threat of greatest concern, the incubation period may be as little as 24 to 48 hours for susceptible individuals who receive a large dose, but cases may also occur as long as 1 to 2 months after exposure. The prodrome (a period of nonspecific signs and symptoms) may last 1 to 5 days before the onset of severe illness. Death may follow severe illness within 24 to 36 hours (CDC, 2002; Inglesby et al., 2002). Vaccination or antibiotics given soon after exposure may prevent many infections, and aggressive treatment before the onset of severe illness may prevent some deaths.

Does Early Detection Help?

A second set of questions concerns whether earlier detection by itself will make a difference. It is not a foregone conclusion that the systems of decision making and response in any particular location are able to use the advantage of earlier detection to prevent or limit exposure to a detected pathogen or effectively distribute medical countermeasures. As noted, effective medical countermeasures (e.g., antibacterials, antivirals, and vaccines) are available for some pathogens but not all. Even if such countermeasures exist, they will be most effective if they can be distributed and administered before most of the people who have been exposed develop illness. In the event of a massive airborne bioterrorist attack in an urban area, this may require delivering medications to hundreds of thousands, if not several million, people. For inhalation anthrax, the window between exposure and effective prophylaxis may be as short as 48 hours. However, the value of early detection may be less important or of unknown value for exposure to other agents, depending on the incubation period or the potential effectiveness of post-exposure prophylaxis. Furthermore, while failure to respond quickly in the face of a significant biological threat may have dire consequences, initiating an unnecessary response on the basis of misleading or erroneous information may have its own adverse results. For example, people may become ill from taking unnecessary medications, and mistakenly alarming the public may reduce the credibility and impact of justified warnings in the future.

A follow-on consideration is whether surveillance systems that detect a biological threat in one locality can contribute to improved "situational awareness" during the course of a prolonged or multisite attack or outbreak. With heightened awareness, it may be possible to intensify environmental sampling or disease surveillance activities in ways that will increase the chances of earlier detection of subsequent attacks or related outbreaks. This is similar to what may occur in a natural outbreak, such as the recent H1N1 pandemic.

What Should Be the Focus of Early Detection?

A third set of questions concerns the focus of any environmental monitoring system such as BioWatch. At present, BioWatch is designed to detect a limited number of potential bioterrorism agents, and DHS has proposed increasing this number (DHS, 2009a). Although this expansion may prove feasible, the rationale for selecting additional agents will have to be considered carefully in terms of the bioterrorism risk that any given agent represents, the reduction in poor health outcomes that would be possible with a BioWatch detection, and the potential costs of including additional agents in the monitoring program. An expanded panel of agents may add marginal improvements in bioterrorism detection capacity, but it may also increase the possibility of detecting closely related but nonpathogenic organisms, or even a target agent if it is naturally present in the environment. Unless the technology used to signal the presence of a targeted pathogen is highly selective, an expanded panel may increase the number of questionable alerts that must be investigated by local and state health department personnel and potentially reduce confidence in detection signals. To date, positive test results from BioWatch samples have not been related to bioterrorism. Instead, they have been attributed to the natural presence of microbiologic agents in the environment and have not been associated with recognized increases in human disease.

A somewhat similar set of questions can be asked about where BioWatch should be used. Will it be most valuable in major cities and administrative centers where population or high-risk targets are concentrated? Do national security concerns and intelligence information support its use in a limited number of specific localities or in specific sites in a locality? The plans for wider use of BioWatch in high-throughput indoor facilities are likely to result in risk-management and cost-effectiveness assessments that are distinctly different from those for the current outdoor deployment.

What Are the Trade-Offs Among Detection Approaches?

A fourth set of questions might concern trade-offs related to the costs, workforce requirements, and active attention required by a system like BioWatch. With limited financial and personnel resources in state and local health departments to meet day-to-day responsibilities, it may prove challenging to maintain a specialized monitoring system for a low-probability, albeit potentially catastrophic, event. At the federal level as well, there are trade-offs to be made in allocating available resources for the full range of needed biosurveillance activities.

TERMINOLOGY

Biosurveillance

Homeland Security Presidential Directive (HSPD) 21 (The White House, 2007) defines biosurveillance as "the process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health—whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin—in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity." The full scope of biosurveillance as defined in HSPD-21 was beyond the scope of this report, which focuses on activities intended to detect threats to human health specifically from pathogens and biological toxins that might be used in bioterrorism or that might be associated with infectious diseases of public health significance. Detection may occur via means including environmental monitoring, clinical case finding, laboratory testing, or syndromic surveillance. Many of these activities are consistent with the long-standing use of the term "surveillance" to describe the process that public health and national security agencies use to monitor trends in diseases or other conditions as part of public health and national security programs (CDC, 2001b; Buehler, 2008).

The BioWatch Program and BioWatch System

Throughout this report the term "BioWatch program" describes the programmatic activity managed and funded by DHS. In managing the program, DHS works with other federal agencies and state and local partners. The "BioWatch system" refers to the collection of operational components (which are themselves systems) that produce information from air sampling and feed it into a public health decision-making process to determine the appropriate response to a BioWatch Actionable Result (BAR). Thus, the BioWatch system includes the technology to collect and test air samples, the associated laboratory assays, the additional information gathering needed to confirm and characterize an incident, operational guidance, interagency and risk communication, response planning and exercises, and the personnel to support these operations, whether or not these activities at federal, state, or local levels are directly funded by DHS.

For its goal of minimizing casualties in the event of a bioterrorist attack—the focus of this report—the BioWatch system should be seen as part of a public health approach to identifying disease hazards and making decisions regarding action to limit the impact of these hazards. Other perspectives are appropriate to assess the contributions that the BioWatch

system is intended to make in support of national security, law enforcement, and forensic aspects of detecting and responding to a bioterrorist attack.

In addition to DHS's BioWatch program, the U.S. Postal Service (USPS) and DoD operate their own aerosol monitoring systems. The USPS has deployed the automated Biohazard Detection System (BDS) at more than 200 mail processing centers. The BDS collects air samples from mail sorting equipment and uses genomic testing specifically for the presence of DNA segments associated with *B. anthracis* (National Association of Letter Carriers, 2008). DoD has installed outdoor air samplers similar to those used in the BioWatch system at selected military bases in the United States. DoD also uses other technologies, such as lidar and the Joint Biological Standoff Detection System, for outdoor monitoring and has installed indoor monitoring systems at certain facilities (DoD, 2007; Mayor et al., 2008). DoD also has worked for many years to develop biodetection technologies to protect against biowarfare threats on the battlefield and in military facilities. The committee received briefings on these systems but does not review them in this report.

Other biodetection tools are being developed and offered in the private sector. For example, commercial vendors are offering a variety of handheld biological detection devices intended for use by first responders. Information about these devices has been compiled for DHS (2007), but systematic testing has not yet been done to establish the reliability and effectiveness of the devices (GAO, 2008b).

The Public Health and Health Care "Systems"

It is common to refer to the public health "system" or the health care "system," but in the United States these systems are highly decentralized and only very loosely linked. Neither in public health nor in health care is there an overarching national mechanism for unifying or coordinating the disparate, and often competing, entities involved.

Health care is provided by an amalgam of clinicians in individual practice and group settings such as clinics and hospitals. These activities operate as a mix of public, private nonprofit, and for-profit enterprises and are funded by a variety of public and private payers. "Public health" is largely a governmental responsibility, with primary legal responsibility resting with the states, which sometimes delegate this responsibility to local governments. The federal government's role in public health is extensive, including (but not limited to) leadership in policy development and financial and operational support for research, data collection, and certain services (e.g., vaccine purchase). The organization and operation of public health services is implemented through various configurations of state and local health departments, working with federal agencies, health care providers and organizations, contractors, entities they regulate, and public–private

partnerships. The boundaries between health care and public health services vary and are often vague, with many health departments providing some clinical services and clinicians and health care institutions playing a role in public health functions. In addition, both the health care and public health systems rely on an array of private- and public-sector laboratory services to detect, confirm, and report evidence of infectious disease.

CONSIDERATIONS GUIDING THE COMMITTEE'S WORK

This report focuses on the committee's assessment of BioWatch and its relation to infectious disease surveillance through the public health and health care systems for detection of bioterrorist attacks. The effectiveness of each of these approaches is considered on its own merits, without an attempt to assess the merits of other aspects of the preparedness efforts of which each is a part. Even though the full range of preparedness concerns is beyond the scope of this study, three observations require specific note because they are inextricably linked to the committee's assessments:

1. Systems for surveillance and detection of disease threats need to be accompanied by the capability to respond with appropriate public health or medical measures to minimize illness and death.
2. The BioWatch system is designed to detect certain biological agents that could be intentionally released in aerosolized form, and it operates in a limited number of localities. Detecting a bioterrorism event that relies on other routes of exposure or that involves aerosols released in places where BioWatch detectors are not deployed requires other approaches.
3. There is considerable uncertainty about the likelihood and magnitude of a biological attack and, as a result, uncertainty about the risk of an aerosolized release of a pathogen. There is also uncertainty about how this risk compares with risks from other potential forms of bioterrorism or from natural diseases.

Linking Surveillance and Response

Without an effective response capability, good surveillance and detection alone can contribute very little to limiting morbidity and mortality. Therefore, the committee emphasizes, as a fundamental premise, that the capability to effectively deliver public health and health care services, as well as law enforcement and other public services, in response to detected threats is essential. While early warning of an incipient epidemic may have some inherent value, achieving the full benefits of early detection depends on other factors, such as whether exposed people can be provided counter-

measures in time to prevent severe illness and whether additional exposure can be prevented by evacuation, limiting the movement of people into contaminated areas, or sheltering in place. It also depends upon whether the agent causes a communicable illness. Meeting the challenges posed by bioterrorism attacks or other large-scale disease outbreaks requires attention to a range of needs, of which effective surveillance and detection systems are only a limited portion. Indeed, there are serious questions about the current capabilities of the U.S. preparedness architecture and how to measure the effectiveness of current preparations (e.g., Nelson et al., 2007; TFAH, 2008, 2009; WMD Commission, 2008).

BioWatch Is Not Designed to Be Comprehensive

The BioWatch system, as the committee was informed by DHS officials, is specifically designed to detect the presence of certain aerosolized pathogens that have been released in a quantity that has the potential to infect substantial numbers of people in localities where air samplers have been deployed. Although this capacity addresses some high-priority concerns, the committee also recognizes that these concerns account for a circumscribed set of possible high-consequence terrorist scenarios. Because of the nature of the study charge, the committee has not addressed technologies analogous to BioWatch that would be needed to detect other forms of biological terrorism, such as contamination of food or water or environmental exposure to infectious agents distributed by means that BioWatch is not designed or deployed to detect (e.g., the 2001 anthrax letters). Nor is BioWatch designed to accomplish the necessary epidemiologic characterization of disease outbreaks. The health care and public health systems, however, need the capacity to detect and respond both to the health threats posed by the aerosolized pathogens that BioWatch is designed to detect and to the full range of other infectious disease threats. Regardless of how a significant biological threat is detected, the response is likely to require an array of resources, including not only public health and health care but also emergency response and law enforcement.

Given these fundamental differences in scope among different surveillance systems, the committee sought an approach to make comparative assessments. In some cases, the committee made head-to-head comparisons between BioWatch and other modes of surveillance specifically for an aerosol attack, such as with anthrax spores. In other cases, the committee accepted that no direct comparison was appropriate.

Uncertainty About Risk

Both bioterrorism agents and emerging infectious diseases are considered health threats for the United States; that is, they have the potential to

cause harm (IOM, 2003; Blair, 2009). The existence of the BioWatch program bears witness to a perceived threat to the nation from the intentional release of aerosolized biological agents. However, knowledge of the existence of a threat is different from an understanding of the likelihood that specific threat events will occur and the consequences they will produce.

DHS is charged with conducting biennial risk assessments to "provide the basis for risk-informed investments for national strategic biodefense planning while identifying key knowledge gaps and defining critical vulnerabilities" (DHS, 2009c). It has produced Bioterrorism Risk Assessment (BTRA) reports in 2006 and 2008. However, a National Academies report presented several concerns about the approach and methodology used in the 2006 DHS risk assessment (NRC, 2008).

For this report on BioWatch and biosurveillance through the public health and health care systems, the committee was not tasked to evaluate threat or risk information. For this reason, many of the conclusions of this report are couched in terms of a strongly conditioning assumption, such as, "Given that a particular biological agent, in a given quantity, is released at a specific location, how well would various surveillance systems perform?" The probabilities of such assumptions and the associated consequences are combined in the BTRAs to estimate the "risks." Although risk assessments are not incorporated in the conclusions reached in this report, the committee is very conscious of the importance of understanding risk in evaluating the decisions to actually implement risk-mitigating strategies such as BioWatch and disease surveillance.

RELATED ACTIVITIES

Because of the salience and evolving nature of the nation's civilian efforts to defend against bioterrorism and other biological threats, other related activities were under way during the course of this study. Two in particular—one by GAO and another by CDC—proceeded largely in parallel with the work of this committee. The concurrent nature of these activities limited the opportunity for the committee to benefit from their findings.

GAO, under Public Law 110-53, Implementing Recommendations of the 9/11 Commission Act of 2007, was charged with preparing a report for Congress on "the state of [f]ederal, [s]tate, local, and tribal government biosurveillance efforts" and making recommendations on integration of biosurveillance systems and the effective use of biosurveillance resources (P.L. 110-53, Sec. 1102). As described to the committee at its first meeting, the GAO has interpreted its task as encompassing all aspects of biosurveillance, including activities related to threats to plant and animal health (Jenkins, 2008). In congressional testimony in July 2008, GAO described the DHS plans to introduce new air sampling technology but provided no

evaluation of those plans or the program as a whole (GAO, 2008a). GAO plans to issue four reports from its review of biosurveillance, with the first two reports expected in summer 2009 (Tapia-Videla, 2009).

In mid-2008, CDC was given responsibility for leading the HHS planning and implementation of "an operational national epidemiologic surveillance system for human health . . . ," which was called for under HSPD-21, "Public Health and Medical Preparedness" (The White House, 2007). During much of the time the committee was studying the issues and preparing this report, CDC staff were engaged with numerous contributors from other federal agencies, state and local governments, and the private sector to develop a document laying out a national strategy for biosurveillance, including identifying potential enhancements of current systems and capabilities (Sosin, 2008, 2009a). A working document, distributed for comment in December 2008 (CDC, 2008b), identified six strategic priorities: (1) electronic health information exchange, (2) electronic laboratory information exchange, (3) unstructured data, (4) integrated biosurveillance information, (5) global disease detection and collaboration, and (6) the biosurveillance workforce of the future. Guidance for continuing development of the strategy is being provided by CDC's National Biosurveillance Advisory Subcommittee, which will issue its initial report late in 2009 (Sosin, 2009b).

Also ongoing are local, regional, and national efforts to advance the development and adoption of health information technology, including electronic medical records and health information exchanges. The February 2009 federal economic stimulus package (P.L. 111-5)[5] included $2 billion to promote wide deployment of health information technologies. Two HHS advisory committees are to guide the development of information system standards and information technology policy. A health care perspective appears to predominate in much of the work on health information technology, but the need to establish better information linkages between health care and the public health system has been recognized (AHIC, 2008; HITSP, 2008). These information system activities, although not driven by biosurveillance priorities, are clearly crucial in shaping the environment for improving information systems for biosurveillance.

Within the National Academies, two committees are at work on related topics. The Committee to Review the Department of Homeland Security's Approach to Risk Analysis is to issue a report at the end of 2009 or in early 2010. Its charge is to review how DHS is building capabilities in risk analysis to inform decision making. The study includes an evaluation of the

[5]The American Recovery and Reinvestment Act of 2009 (P.L. 111-5) also includes provisions for approximately $17 billion in incentive payments to Medicare and Medicaid hospitals and providers to promote adoption of health information technology.

quality of the current DHS approach to estimating risk for terrorist threats and for natural disasters and to applying those estimates in its management, planning, and resource-allocation activities.

The Committee on Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin is expected to issue its final report in late 2009. The issues being examined include the causes of and trends in the emergence and spread over the past several decades of agents of zoonotic origin; the risks of animal and human interactions, especially for diseases of international significance such as H5N1 influenza; lessons from previous human and animal health responses to emergent zoonotic diseases; the current state of and gaps in global systems for surveillance of zoonotic infections in human and animal populations; and the appropriate balance between emergency response to threats and sustainable global surveillance capacity.

THE COMMITTEE'S REPORT

This report provides a review and assessment of the effectiveness and costs of surveillance for and detection of disease threats through the BioWatch program and through the U.S. public health and health care systems. The committee presents its findings on the comparative merits of these approaches, examines costs, and describes promising enhancements to strengthen the nation's capacity to conduct surveillance for major natural and man-made disease threats. As a result of its review, the committee identified various opportunities to further these enhancements, and it recommends actions that DHS, HHS, and others should undertake to help realize them.

REFERENCES

AHIC (American Health Information Community Workgroup). 2008. *Population health and clinical care connection: Transition report.* September 23. http://www.hhs.gov/healthit/ahic/materials/09_08/pop/transition_report.html (accessed March 6, 2009).

Blair, D.C. 2009. Annual threat assessment of the Intelligence Community for the Senate Select Committee on Intelligence. Unclassified statement for the record, February. Washington, DC: Office of the Director of National Intelligence. http://intelligence.senate.gov/090212/blair.pdf (accessed February 25, 2009).

Buehler, J.W. 2008. Surveillance. In *Modern Epidemiology*, 3rd ed. Edited by K.J. Rothman, S. Greenland, and T. L. Lash. Philadelphia, PA: Lippincott Williams & Wilkins. Pp. 459–480.

CDC (Centers for Disease Control and Prevention). 2001a. Update: Investigation of bioterrorism-related anthrax and adverse events from antimicrobial prophylaxis. *Morbidity and Mortality Weekly Report* 50(44):973–976.

CDC. 2001b. Updated guidelines for evaluating public health surveillance systems: Recommendations from the guidelines working group. *Morbidity and Mortality Weekly Report* 50(RR-13):1–35.

CDC. 2002. *Factsheet: Anthrax information for health care providers*. http://emergency.cdc.gov/agent/anthrax/anthrax-hcp-factsheet.asp#inhalation (accessed April 7, 2009).

CDC. 2003. Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases—United States and worldwide, December 2003. *Morbidity and Mortality Weekly Report* 52(49):1202–1206.

CDC. 2008a. *Bioterrorism agents and diseases*. http://www.bt.cdc.gov/agent/agentlist-category.asp (accessed December 19, 2008).

CDC. 2008b. *National biosurveillance strategy for human health, 2008–2013*. Version 1.0. Atlanta, GA: CDC. http://sites.google.com/site/nbshh10/Welcome (accessed April 27, 2009).

CDC. 2009a. *Justification of estimates for appropriation committees: FY 2010*. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2010_CDC_CJ_Final.pdf (accessed July 21, 2009).

CDC. 2009b. *Novel H1N1 situation update, June 26, 2009*. http://www.cdc.gov/h1n1flu/update.htm (accessed July 1, 2009)

DHS (Department of Homeland Security). 2007. *Guide for the selection of biological agent detection equipment for emergency first responders, 2nd ed.* Guide 101-06. Washington, DC: DHS. http://www.eeel.nist.gov/oles/Publications/dhs101-06.pdf (accessed August 4, 2009).

DHS. 2009a. *BioWatch Gen-3 request for proposal*: *HSHQDC-09-R-00045*. https://www.fbo.gov/download/54e/54e9ae25a4a9d2d39a9e9e836955001f/HSHQDC-09-R-00045_(5-27-2009).pdf (accessed August 5, 2009).

DHS. 2009b. *Department of Homeland Security FY 2010 congressional justification budget*, http://www.dhs.gov/xlibrary/assets/dhs_congressional_budget_justification_fy2010.pdf (accessed July 28, 2009).

DHS. 2009c. *Selected chemical and biological projects*. http://www.dhs.gov/xres/programs/gc_1228845015753.shtm (accessed March 6, 2009).

DoD (Department of Defense). 2007. *Department of Defense Chemical and Biological Program annual report to Congress*. Washington, DC: DoD. http://www.acq.osd.mil/cp/cbdreports/cbdpreporttocongress2007.pdf (accessed April 13, 2009).

Downes, F.P. 2008. *One year later—Implementing the biosurveillance requirements of the '9/11 Act.'* Testimony before the Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology of the Committee on Homeland Security, U.S. House of Representatives, July 16. Washington, DC. http://homeland.house.gov/SiteDocuments/20080716143630-34598.pdf (accessed August 4, 2009).

FEMA (Federal Emergency Management Agency). 2008. *National response framework*. http://www.fema.gov/NRF (accessed February 12, 2009).

Franco, C. 2008. Billions for biodefense: Federal agency biodefense funding, FY2008–FY2009. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 6(2):131–146.

GAO (Government Accountability Office). 2004. *Emerging infectious diseases: Review of state and federal disease surveillance efforts*. GAO-04-877. Washington, DC: GAO. http://www.gao.gov/new.items/d04877.pdf (accessed July 1, 2009).

GAO. 2008a. *Biosurveillance: Preliminary observations on Department of Homeland Security's biosurveillance initiatives*. GAO-08-960T. Washington, DC: GAO. http://www.gao.gov/new.items/d08960t.pdf (accessed August 3, 2009).

GAO. 2008b. *Homeland security: First responders' ability to detect and model hazardous releases in urban areas is significantly limited*. GAO-08-180. Washington, DC: GAO. http://www.gao.gov/new.items/d08180.pdf (accessed August 3, 2009).

GAO. 2009. *Influenza pandemic: Sustaining focus on the nation's planning and preparedness efforts*. GAO-09-334. Washington, DC: GAO. http://www.gao.gov/new.items/d09334.pdf (accessed April 6, 2009).

HHS (Department of Health and Human Services). No date. *Pandemics and pandemic threats since 1900*. http://www.pandemicflu.gov/general/historicaloverview.html (accessed June 9, 2009).

HHS. 2008. *Project Bioshield: Annual report to Congress, August 2006–July 2007*. Washington, DC: Office of the Assistant Secretary for Preparedness and Response.

HITSP (Healthcare Information Technology Standards Panel). 2008. *HITSP biosurveillance interoperability specification*. HITSP/IS02. Version 3.2. http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=false&PrefixAlpha=1&APrefix=IS&PrefixNumeric=2&ShowISId=452 (accessed April 27, 2009).

Inglesby, T.V., T. O'Toole, D.A. Henderson, J.G. Bartlett, M.S. Ascher, E. Eitzen, A.M. Friedlander, J. Gerberding, J. Hauer, J. Hughes, J. McDade, M.T. Osterholm, G. Parker, T.M. Perl, P.K. Russell, K. Tonat, and the Working Group on Biodefense. 2002. Anthrax as a biological weapon, 2002: Updated recommendations for management. *Journal of the American Medical Association* 287(17):2236–2252.

IOM (Institute of Medicine). 2003. *Microbial threats to health: Emergence, detection, and response*. Washington, DC: The National Academies Press.

Jenkins, W.O. 2008. Public comments to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31, Washington, DC.

Jernigan, D.B., P.L. Raghunathan, B.P. Bell, R. Brechner, E.A. Bresnitz, J.C. Butler, M. Cetron, M. Cohen, T. Doyle, M. Fischer, C. Greene, K.S. Griffith, J. Guarner, J.L. Hadler, J.A. Hayslett, R. Meyer, L.R. Petersen, M. Phillips, R. Pinner, T. Popovic, C.P. Quinn, J. Reefhuis, D. Reissman, N. Rosenstein, A. Schuchat, W.J. Shieh, L. Siegal, D.L. Swerdlow, F.C. Tenover, M. Traeger, J.W. Ward, I. Weisfuse, S. Wiersma, K. Yeskey, S. Zaki, D.A. Ashford, B.A. Perkins, S. Ostroff, J. Hughes, D. Fleming, J.P. Koplan, J.L. Gerberding, and the National Anthrax Epidemiologic Investigation Team. 2002. Investigation of bioterrorism-related anthrax, United States, 2001: Epidemiologic findings. *Emerging Infectious Diseases* 8(10):1019–1028.

Lindley, C. 2009. *BioWatch actionable result response: 2008 Democratic National Convention, August 28, 2008*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, February 19.

Mayor, S.D., P. Benda, C. Murata, and R.J. Danzig. 2008. Lidars: A key component of urban biodefense. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 6(1):45–56.

Mokdad, A.H., J.S. Marks, D.F. Stroup, and J.L. Gerberding. 2004. Actual causes of death in the United States, 2000. *Journal of the American Medical Association* 291(10):1238–1245.

National Association of Letter Carriers, AFL-CIO. 2008. *Safety and Health: USPS Biohazard Detection System (BDS)*. http://www.nalc.org/depart/safety/USPSBDS.html (accessed July 8, 2009).

Nelson C., N. Lurie, and J. Wasserman. 2007. Assessing public health emergency preparedness: Concepts, tools, and challenges. *Annual Review of Public Health* 28:1–18.

NRC (National Research Council). 2002. *Countering agricultural bioterrorism*. Washington, DC: The National Academies Press.

NRC. 2008. *Department of Homeland Security bioterrorism risk assessment: A call for change*. Washington, DC: The National Academies Press.

O'Toole, T. 2007a. Hearing on bioterrorism preparedness and the role of DHS Chief Medical Officer. Testimony before the U.S. House of Representatives Committee on Appropriations, Subcommittee on Homeland Security, March 29. Washington, DC.

O'Toole, T. 2007b. *Six years after anthrax: Are we better prepared to respond to bioterrorism?* Testimony before the U.S. Senate Committee on Homeland Security and Governmental Affairs, October 23. Washington, DC.

Price, D. 2008. Opening statement by David Price, Chairman, Subcommittee on Homeland Security, U.S. House of Representatives Committee on Appropriations, April 1, at the Hearing on the Office of Health Affairs, Department of Homeland Security. Washington, DC. http://appropriations.house.gov/pdf/PriceHealthAffairs04-01-08.pdf (accessed April 7, 2008).

Sinclair, R., S.A. Boone, D. Greenberg, P. Keim, and C.P. Gerba. 2008. Persistence of category A select agents in the environment. *Applied and Environmental Microbiology* 74(3):555–563.

Sosin, D. 2008. *National biosurveillance for human health*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31, Washington, DC.

Sosin, D. 2009a. *Enhancing nationwide biosurveillance for human health: Biosurveillance Coordination Unit*. Presentation at the Integrated Surveillance Seminar, CDC, Atlanta, GA. http://www2.cdc.gov/ncphi/disss/seminars/archive.asp (accessed March 4, 2009).

Sosin, D. 2009b. *RE: two questions for NAS/IOM study.* Email to L. Joellenbeck, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, by D. Sosin, CDC, July 10.

Tapia-Videla, J. 2009. *GAO's Biosurveillance work: Scoping and reporting strategy.* Email to L. Joellenbeck, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, by J. Tapia-Videla, GAO, February 11.

TFAH (Trust for America's Health). 2008. *Ready or not? Protecting the public's health from diseases, disasters, and bioterrorism*. Washington, DC: TFAH. http://healthyamericans.org/assets/files/bioterror-report-2008.pdf (accessed July 17, 2009).

TFAH. 2009. *Pandemic flu preparedness: Lessons from the frontlines*. Washington, DC: TFAH. http://healthyamericans.org/report/64/pandemic-flu-frontlines (accessed June 4, 2009).

Thompson, W.W., D.K. Shay, E. Weintraub, L. Brammer, N. Cox, L.J. Anderson, and K. Fukuda. 2003. Mortality associated with influenza and respiratory syncytial virus in the United States. *Journal of the American Medical Association* 289(2):179–186.

Török, T.J., R.V. Tauxe, R.P. Wise, J.R. Livengood, R. Sokolow, S. Mauvais, K.A. Birkness, M.R. Skeels, J.M. Horan, and L.R. Foster. 1997. A large community outbreak of salmonellosis caused by intentional contamination of restaurant salad bars. *Journal of the American Medical Association* 278(5):389–395.

The White House. 2004. *Homeland Security Presidential Directive 10 (HSPD-10): Biodefense for the 21st Century*. April 28. Washington, DC. http://www.dhs.gov/xabout/laws/gc_1217605824325.shtm (accessed March 6, 2009).

The White House. 2007. *Public health and medical preparedness*. Homeland Security Presidential Directive (HSPD) 21, October 18. Washington, DC. http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm (accessed March 6, 2009).

WHO (World Health Organization). 2004. *WHO SARS risk assessment and preparedness framework*. WHO/CDS/CSR/ARO/2004.2. http://www.who.int/csr/resources/publications/CDS_CSR_ARO_2004_2.pdf (accessed June 8, 2009).

WHO. 2009. *Pandemic H1N1 2009–update 56*. http://www.who.int/csr/don/2009_07_01a/en/index.html (accessed July 1, 2009).

WMD Commission. 2008. *World at risk: The report of the Commission on the Prevention of WMD Proliferation and Terrorism*. New York: Vintage Books. http://www.preventwmd.gov/report/ (accessed December 5, 2008).

2

The BioWatch System

BioWatch is an early warning system for detection of certain pathogens that have been intentionally released into the air. The decision to field a "network of sensors to detect biological attack" was announced in January 2003 in the State of the Union address (The White House, 2003). Implementing this decision required rapid deployment of air sampling equipment and tools for laboratory analysis and development of procedures for operation and management of the system. By the end of 2003, BioWatch air samplers were operating on a continuous basis in more than 30 major metropolitan areas.[1] The BioWatch system currently tests for the presence of airborne DNA from certain pathogens. As of mid-2008, millions of laboratory assays had been carried out on collected samples (Hooks, 2008a). With the current technology and practices, the laboratory results indicating a potential biological aerosol release are available 10 to 34 hours after sample collection. The program is working toward a transition in technology to reduce the interval from sample collection to completion of initial analysis to 4 to 6 hours.

This chapter describes the current features of the BioWatch system, including the technology and deployment of the air samplers, the laboratory analysis, the interpretation of data from BioWatch as a basis for public health action, and the plans for new technology for air sampling and analysis, organized in terms of planning and management, operations, and response. The chapter also presents a discussion of the costs of the BioWatch

[1]The major metropolitan areas where the BioWatch system is operating are referred to as "BioWatch jurisdictions" throughout the report.

program in its current form and with proposed changes in technology and scale of operation. Chapter 3 presents the committee's evaluation of the effectiveness of the BioWatch program and system and provides recommendations for improvements.

BIOWATCH PROGRAM PLANNING AND MANAGEMENT

DHS states that the goal of the BioWatch program "is to establish and operate a bio-aerosol monitoring capability to accurately detect the release of biological threat agents of greatest concern to the [n]ation in locations that are at greatest risk of catastrophic consequences and to enable timely response and mitigation" (DHS, 2008c). The rationale for the BioWatch program is that early detection of an aerosolized bioterrorist attack could allow for mass distribution of prophylactic medications or other medical countermeasures in time to prevent widespread illness or deaths. For example, under a DHS "worst case" planning scenario involving an aerosolized anthrax attack in a large urban area and exposure of a few million people, hundreds of thousands of people would develop life-threatening disease requiring intensive medical care. Under this planning scenario, providing antibiotic prophylaxis to the exposed population within 3 days of the attack is projected to prevent nearly all of the deaths that would otherwise occur (Hooks, 2008a).

The program's scope includes management and operation of the day-to-day air sampling and laboratory testing as well as planning and preparation for a bioterrorist attack and coordination and management tasks when DNA (or nucleic acid evidence) of a targeted pathogen is detected. The BioWatch system generates information that feeds into public health decision making and response, and DHS looks to state and local health agencies and the Department of Health and Human Services (HHS) at the federal level to prepare for and manage the public health response to BioWatch results.

Participants and Responsibilities

BioWatch is a federal program led by DHS and designed to operate in collaboration with other federal partners and with the states and localities where air samplers are deployed. The program is currently managed by the DHS Office of Health Affairs (OHA). Until 2007, the program was the responsibility of the DHS Directorate for Science and Technology (S&T). OHA continues to rely on S&T for technology development. S&T is also responsible for analyses to characterize biological threats and assess the risk they pose, including preparing the biennial Bioterrorism Risk Assessment (BTRA) and an integrated chemical, biological, radiological, and nuclear (CBRN) risk assessment.

Other federal partners in BioWatch include the Centers for Disease Control and Prevention (CDC) in HHS, the Environmental Protection Agency (EPA), the Federal Bureau of Investigation (FBI) in the Department of Justice, and the Department of Defense (DoD). The program also works closely with components of several of the Department of Energy's (DOE's) National Laboratories. These agencies participate in federal interagency activities that contribute to development of program planning and guidance for BioWatch, and some have operational responsibilities. CDC's primary roles are the development of the BioWatch laboratory analyses, oversight of the quality assurance and quality control for those analyses, and consultation with state and local agencies on the public health response to an alert from the BioWatch system. EPA's operational role has transitioned from having major responsibilities for routine field operations to advising on and participating in post-detection environmental sampling upon invitation from local jurisdictions. The FBI contributes intelligence and leads any resulting criminal investigation. DoD has separate biological monitoring systems for military bases and is beginning to coordinate its monitoring activities with the civilian BioWatch system. DOE National Laboratories are involved primarily in the development of technologies and analytic tools, but Lawrence Livermore National Laboratory (LLNL) also provides routine laboratory analysis for some BioWatch jurisdictions.

At the local level, some of the BioWatch jurisdictions have DHS-funded personnel responsible for coordinating the routine operation and maintenance of the air samplers and the collection and transport of the filters. Elsewhere these duties are carried out by local partners. State and local public health laboratories typically provide the facilities to house BioWatch laboratory operations for analysis of the filters, but the BioWatch program currently provides contract personnel to perform the analyses within these laboratories.

Each jurisdiction is expected to have a BioWatch Advisory Committee (BAC), or similar mechanism, that brings together critical decision makers who can establish local plans and procedures for the use of and response to BioWatch results. The BAC also serves as the focal point for coordination with federal officials in evaluating BioWatch data and determining the appropriate actions. Because BioWatch jurisdictions are major metropolitan areas, the planning and decision-making mechanisms may span multiple cities, counties, and states. In the event of a bioterrorist attack, public health officials will play an important role in decision making, but a unified response involving law enforcement, emergency management, environmental protection, and others will take place.[2]

[2]A suspected bioterrorism event is managed within the framework of incident command and the National Incident Management System (FEMA, 2008). In this system, federal assets exist primarily to support local response, and to manage interstate and international issues.

BIOWATCH OPERATIONS

This section describes the operation of the BioWatch system, from the deployment of air samplers to the declaration of a BioWatch Actionable Result (BAR). A BAR occurs when analysis of a filter from a BioWatch air sampler confirms the presence of targeted signature nucleic acid sequences associated with a pathogenic organism.

Performance attributes of the BioWatch detection system can be described (or specified) in terms of two critical parameters:

- *Sensitivity* refers to a system's ability to detect a pathogen when it is present (a true positive event). This is commonly defined as the probability the system will produce a positive result for a particular pathogen, given that this pathogen is in fact present (in some predesignated amount or concentration) in the area being monitored.
- *Specificity* refers to the system's ability to detect a pathogen only when it is present and not to detect other "non-target" biological agents that are present (detection of a non-target is a "false positive" event). Defining the false alarm probability to be the probability that a system will produce a positive result for a particular pathogen given that pathogen is not present, specificity is seen to be equal to [1 – false alarm probability]. A system with a given specificity s and sampling rate r will have a false alarm rate = $s \bullet r$ (events per unit time).

For BioWatch, as in virtually any detection system, there is an inherent trade-off between sensitivity and specificity. Moreover, these parameters must be considered on two levels: (1) detecting the presence of a pathogen the system is intended to detect, and (2) the fraction of these detections that also exhibit evidence of a bioterrorist attack (see Box 2-1). The BioWatch system must exhibit, in testing and in practice, high enough values of sensitivity and specificity that public health decision makers will have confidence in the system's performance and consequently in determining the course of action in response to a positive result from analysis of a BioWatch sample.

DHS has reported that among the millions of BioWatch assays that have been conducted, none have produced "false positives," which reflects the narrow perspective of air sampling and laboratory testing (Hooks, 2008a; DHS, 2009). Indeed, the laboratory assays have never indicated the presence of a biological agent when it was not present, although several BARs have been declared that have been attributed to the detection of ambient DNA that was naturally present in the local environment. From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been

BOX 2-1
Definitions of Key Terms Related to the Performance of BioWatch

Assay sensitivity	The probability that a laboratory test will correctly indicate the presence of a particular pathogen when it is present above a certain concentration.
Assay specificity	The probability that a laboratory test will correctly identify the absence of a target pathogen when it is not present.
False negative	A negative assay reading for the target pathogen when the pathogen is present.
False positive	A positive assay reading for the target pathogen when the pathogen is not present.
BAR false negative	Failure to declare a BAR when a bioterrorist attack has occurred.
BAR false positive	Declaration of a BAR when a bioterrorist attack has not occurred.

SOURCES: Adapted from CRS (2003); NRC (2005).

"BAR false positives," meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.

In addition to the performance of the BioWatch system's technologies for sample collection and analysis, detection also depends on the numbers and distribution of air samplers, weather conditions (e.g., wind speed and direction), and the effects of the natural and man-made physical environments on dispersion. No finite array of even "perfect" collectors can detect all conceivable terrorist releases, even large-volume releases, under all circumstances. Thus the overall sensitivity of the BioWatch system will always be imperfect (less than 1).

BioWatch Air Samplers and Their Deployment

DHS is responsible for selecting the devices that are used for air sampling, and it funds their purchase and deployment. Changes in types of detector technology and deployment within the BioWatch program are described as different BioWatch "Generations." Table 2-1 describes the characteristics of Generations 1 and 2, and the planned Generation 3.

TABLE 2-1 Features of BioWatch Generations 1, 2, and 3

BioWatch Generation	Year Deployed	Deployment Characteristics
Generation 1	2003	Jurisdictions: >30 Multiple air samplers per jurisdiction
Generation 2	2005	Jurisdictions: Same as Generation 1 More air sampling units deployed outdoors in selected jurisdictions; indoor facility monitoring. Multiple units per jurisdiction; a few hundred units deployed in total.
Generation 3 (as proposed)	2012–2013	Jurisdictions: Some increase over Generation 2 Detectors: Some increase over Generation 2

NOTES: BASIS, Biological Aerosol Sentry and Information System; DHS, Department of Homeland Security; LANL, Los Alamos National Laboratory; LRN, Laboratory Response Network; OHA, Office of Health Affairs; PCR, polymerase chain reaction; S&T, Science and Technology Directorate.
SOURCES: DHS (2008a, 2009); Gordon (2008); Hooks (2008b); Johns (2008).

The initial deployment of BioWatch air samplers took place in 2003 (Generation 1), and a revised, expanded deployment using the same sampler technology was carried out in 2005 (Generation 2). A Generation 3 deployment is being planned. It will differ from Generation 2 in its planned use of new, automated devices that will combine sample collection, preparation, and analysis within the device and that will send results electronically to the local public health laboratory director for interpretation. DHS had also planned (and subsequently cancelled) deployment of a Generation 2.5 to provide an interim automated indoor detection capability before the deployment of Generation 3.

BioWatch Air Samplers

The BioWatch air samplers are designed for continuous routine air monitoring in urban environments. Air is mechanically pulled into the instrument and particles are collected onto a dry filter housed within a removable filter unit. The filter units are collected and taken to a laboratory where the filters are removed and the particles on the filters are extracted and characterized by genomic analysis. Under routine conditions, the filter units are collected at 24-hour intervals; filters may be collected more frequently during high-profile events. Up to 10 hours may elapse from the time

Technical Features	Developed by	Managed by
Air sampler: Portable Sampling Unit (PSU) and Dry Filter Unit (DFU) Sample collection: Manual sample collection typically every 24 hours, followed by manual laboratory analysis Analytic Methods: Manual sample analysis using real-time PCR	Adapted from BASIS technology by DHS S&T	DHS S&T
Air sampler: Same as Generation 1 Sample collection: Same as Generation 1 Analytic methods: Similar to Generation 1	Same as Generation 1	2005–2007: DHS S&T 2007–present: DHS OHA
Detector: Unknown Sample collection: Automated sample collection and preparation Analytic methods: Automated systems	Not determined as of this writing	DHS OHA

a filter unit is collected until the results of the initial testing of the sample are available (see Figure 2-1).

The current BioWatch air samplers were adapted from the Biological Aerosol Sentry and Information System (BASIS), which was developed by Los Alamos National Laboratory (LANL) and LLNL (DHS, 2008b). BASIS monitors had been deployed in some locations after the 9/11 attacks and were used at the 2002 Winter Olympics in Salt Lake City, Utah (Heller, 2003). They were designed and developed for short-term biological threat aerosol monitoring at special events (Heller, 2003).

Deployment of Air Samplers

Each BioWatch jurisdiction currently has multiple samplers (DHS, 2009). DHS also provides additional air samplers for special events. Originally, the BioWatch samplers were mounted on existing outdoor EPA air quality monitoring sites (EPA, 2005). The siting of the air samplers has been modified over time.

Plans for Generation 3 Samplers and Deployment

DHS has been pursuing an automated detection capability for the BioWatch system since 2003 (HSARPA, 2003) to reduce the time needed to

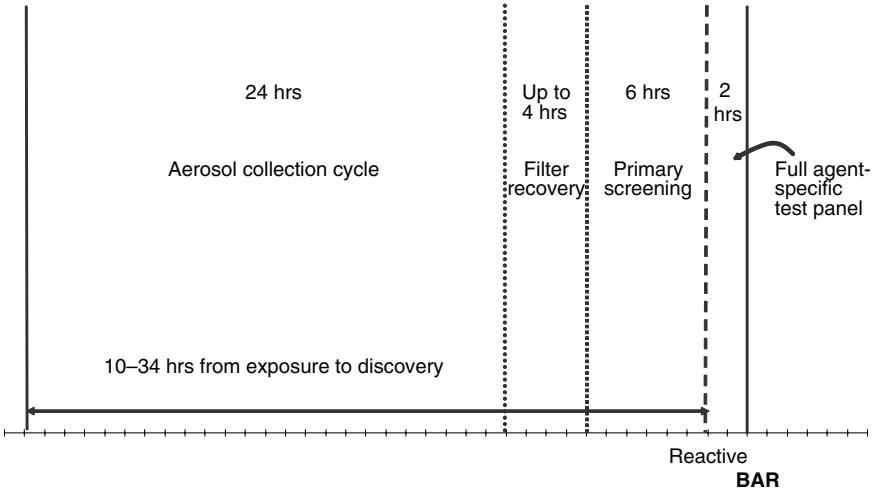


FIGURE 2-1 Event-to-detection time line for BioWatch Generations 1 and 2. Filter recovery and transport can take up to 4 hours, and primary laboratory screening takes about 6 hours. If the primary screening indicates a positive result, confirmatory testing requires an additional 2 hours.
SOURCE: Adapted from Runge (2008).

obtain test results to within 4 to 6 hours of sample collection. The Generation 3 plans include increasing the number of jurisdictions participating in the BioWatch program, the number of monitoring devices in the participating jurisdictions, the number of devices in indoor locations, and potentially the number of biological agents being monitored. Chapter 3 discusses the objectives and planning for Generation 3 in detail.

BioWatch Laboratories

With the current Generation 2 BioWatch system, filters from the air samplers are collected daily for analysis in designated laboratories. In most BioWatch jurisdictions, the laboratory facilities are housed in state public health laboratories that are reference facilities in the national Laboratory Response Network (LRN).[3] In some large jurisdictions, the LRN reference

[3]The Laboratory Response Network (LRN) is an integrated network of state and local public health, federal, military, and international laboratories that can respond to terrorism and other public health emergencies. In the United States, the LRN relies on three tiers of laboratories. The sentinel laboratories perform routine diagnostic and identification testing. Reference laboratories are able to perform more advanced testing and pursue investigation of specimens. A small number of national laboratories are responsible for highly specialized testing and have facilities suitable for handling highly infectious biological agents. The LRN is described further in Chapter 3 and at http://www.bt.cdc.gov/lrn/.

laboratories are located in the local public health department. CDC provides oversight in the development of the laboratory assays for the BioWatch system and approves and validates their use. The personnel who perform the BioWatch analyses currently work under contract with DHS. The state or local host laboratory provides support such as safety training and security but does not have direct authority over the BioWatch personnel.

RESPONSE TO A BIOWATCH ACTIONABLE RESULT

Declaring a BAR

When a positive result from tests of a BioWatch sample is deemed to warrant it, a BAR is declared. Local, state, and federal officials assess relevant information and determine the course of action to pursue.

The committee considers the term "BioWatch Actionable Result," or BAR, misleading because the term implies that action can be taken immediately, but further investigation and deliberation are generally needed. A BAR indicates only that genetic material consistent with a target pathogen was present on a BioWatch filter. A BAR does not confirm that a terrorist attack has occurred, that a viable pathogen was detected, or that people have actually been exposed. Thus, the committee sees a BAR alone as unlikely to be a sufficient basis to automatically trigger a specific response by public health authorities. Instead, the response will be specific to the situation. So far, BARs have been attributed to the detection of ambient DNA that was naturally present in the local environment, and no evidence of increased rates of human disease has been noted.

Critical Information Needed to Respond to a BAR

The declaration of a BAR begins a process of information gathering and assessment to interpret the significance of the BAR and determine what response, if any, is appropriate. A primary goal of the immediate post-BAR steps is to collect, analyze, and interpret available data to decide whether they indicate that a bioterrorist attack has occurred. The decision to interpret a BAR as evidence that a bioterrorist attack has occurred would lead to predictable strategic responses that would be difficult to roll back once started. These actions may have a massive impact on public perception of and confidence in the public health system if they are initiated in response to what proves to be a false alarm.

There is no simple algorithm to guide decision makers on the public health response to a major biological threat from the release of a bioterror agent. The decisions made will hinge on a variety of inputs and depend heavily on whether the information is sufficient to determine that an effective release of a bioterrorism agent is likely to have occurred. Critical

inputs for decision making in response to a BAR are reviewed in the sections that follow.

Biological Agent Detected

The particular biological agent detected has major implications for the interpretation of a BAR and for shaping the potential response if bioterrorism is likely or suspected. The detected agent also has implications for the selection of medical countermeasures and guidance to be given to health care providers and the public. Different agents are mitigated with different drugs or vaccines and are different in their incubation periods, symptoms and effects, and transmissibility. Thus, the pathogen detected will influence the amount of time decision makers may have for additional information gathering and the potential consequences (positive and negative) of the decisions that must be made. Knowledge of the detected agent will help in specifying clinical syndromes warranting heightened surveillance and targeting guidance to emergency and other health care providers regarding the isolation, evaluation, treatment, and disposition of patients with illness that may arise from exposure.

Information from Air Samplers

Information from the network of BioWatch air samplers in a jurisdiction may provide additional context that is important in interpreting the significance of a BAR. The number of filters testing positive, their collection times, the duration of the collection process, and the locations of the air samplers that the filters came from may provide important information regarding the potential scale of population exposure and environmental contamination. Determining whether any other BioWatch jurisdictions have reported BARs or whether there are any suspected bioterrorist attacks reported elsewhere will contribute to situational awareness. Systems to rule out tampering and spoofing, such as closed circuit television or physical surveillance, may also provide valuable information.

Information from Law Enforcement

Local law enforcement agencies, the FBI, and intelligence agencies may have intelligence (e.g., observed behaviors, threats, intent, capabilities; or diversion of microbial stocks) that will help in assessing the likelihood that a BAR is the result of a bioterrorist attack. Other concerns may include whether any high-profile events took place in the area during the time that the filter that tested positive was in place. If a BAR is the result of bio-

terrorism or other deliberate action, law enforcement personnel will lead subsequent criminal and forensic investigations.

Disease Surveillance Data

As described in Chapter 4, data from a variety of public health and health care sources can be used in surveillance for infectious disease outbreaks. To inform the interpretation of a BAR, public health officials can take several steps to heighten surveillance for syndromes or diagnoses of concern. These steps may include implementing enhanced surveillance for both human and animal illness that targets the clinical signs and symptoms characteristic of illness caused by the detected pathogen. This may include heightened scrutiny or modifications of existing surveillance systems that monitor trends in specific diseases or trends in nonspecific manifestations of disease, or it may include outreach to hospitals, laboratories, or other health care sites to actively solicit reports of suspect illness. Local officials' understanding of baseline rates of disease in their jurisdictions is important in interpreting the data that may be collected.

Post-BAR Environmental Testing and Incident Characterization

Environmental sampling may be conducted following declaration of a BAR. The information obtained may be used for various purposes, including aiding in interpretation of the laboratory finding, in an assessment of the nature and extent of the distribution of a detected pathogen, and in guiding the response to the BAR and other subsequent actions that may be needed. However, a lack of data validating the usefulness of environmental sampling and a lack of validated methods for carrying it out are concerns (GAO, 2008) and are discussed further in Chapter 3. In addition, laboratory capacity is a critical consideration following a BAR because of the needs for more frequent testing of BioWatch filters and post-BAR environmental sampling analyses.

Event Reconstruction Models

Event reconstruction models can be used to estimate the location of an aerosol release, bounds on the size of the release, and the time of release. Such models may also be used to suggest sites for additional environmental sampling following a BAR (Brown et al., 2006). Plume models can estimate the downwind zone of potential exposure, but essential information about the location, time, amount, and duration of a release is unlikely to be readily available immediately following a BAR, except in special circumstances.

Chapter 3 further discusses the limitations of event reconstruction models in public health decision making following a BAR.

COSTS OF THE BIOWATCH SYSTEM

To evaluate the costs of BioWatch Generation 2 and Generation 3 and the relevant merits and capabilities of the system, the committee engaged Industrial Economics, Incorporated (IEc), to assist in collecting information and developing a model to forecast the costs of operating the current and future BioWatch monitoring systems. Under the committee's guidance, IEc used data provided by DHS concerning the current costs of the BioWatch system to estimate expenditures necessary to operate the program, without improvement (Generation 2), for the next 10 years. It provided a similar forecast assuming DHS's proposed improvements (Generation 3) are implemented. At the request of the committee, IEc also considered a third scenario in which the current air samplers are replaced with the improved technology (i.e., autonomous detection equipment); however, no new detection sites within existing jurisdictions or new jurisdictions are added to the program (Generation 3 without expansion).

DHS provided cost data in briefings to the committee and in response to a detailed request for cost information on development, maintenance, and other aspects of each BioWatch generation. According to IEc calculations, the majority of costs under each scenario (roughly 95 percent or more) are borne by the federal government. This information is supplemented by limited data obtained from committee members familiar with the funding and in-kind support provided by local jurisdictions. In-kind support consists of labor and laboratory materials contributed to BioWatch procedures by local jurisdictions without reimbursement by DHS.

As shown in Table 2-2, under a scenario in which the existing air samplers are used and replaced with similar technology when their useful life expires, the annualized direct cost of maintaining the current BioWatch system (Generation 2) is estimated to be $80 million. Annualized cost represents the total present value cost (total anticipated costs of the program over the 10-year period applying a discount rate), divided by 10. The specific funding requirements for the program will vary significantly from year to year, depending on when the existing instruments are replaced.

Upgrading the BioWatch system to Generation 3 involves improvements that include replacing the existing air samplers, which require manual retrieval and laboratory analysis of filters, with automated detectors capable of onsite sample analysis and an anticipated expansion of the BioWatch system's coverage. Over the next decade, such upgrades will more than double the direct cost of the program to $200 million on an annualized basis. The higher cost is mainly driven by the expansion of coverage. As shown by comparing

TABLE 2-2 Forecasted Cost of Implementing Alternative BioWatch Scenarios (10-year forecast)

Scenario	Total Present Value Cost[a]	Annualized Cost
Generation 2	$0.6 billion	$ 80 million
Generation 3	$2.0 billion	$200 million
Generation 3 without expansion[b]	$0.8 billion	$100 million

NOTE: The calculations assume a 7 percent real discount rate. If a 3 percent real discount rate is applied, total costs for Generation 2 and Generation 3 without expansion are $0.7 billion and $0.9 billion, respectively, and total costs for Generation 3 are $2 billion. Total annualized costs are unchanged. Because resources invested today are worth more than the same investments in the future, total present value (in 2009 dollars) of the stream of future costs over 10 years is calculated assuming a 7 percent discount rate.

[a]Total present value cost is the total anticipated cost of the program over a 10-year period, after applying a discount rate.

[b]"Generation 3 without expansion" refers to only direct replacement of current Generation 2 air samplers with the automated detectors to be used in the Generation 3 deployment, without other changes proposed for Generation 3.

SOURCE: IEc (2009).

the Generation 2 scenario to a scenario in which the Generation 3 technology is used without expanding the number of jurisdictions or deployed detectors, the cost of acquiring and fielding new technology is largely offset by the cost savings associated with automated analysis of the detector samples.[4]

The estimate of the total cost of each of the scenarios is subject to considerable uncertainty because of limitations in the data available for the analysis. The estimates do not account for the financial and in-kind costs borne by the states and localities in which BioWatch is deployed. These states and localities must currently provide some support for day-to-day BioWatch operations as well as the costs for responding to periodic BARs. The automated testing anticipated with Generation 3 may tend to reduce the day-to-day demands on states and localities, but the implications of the new generation of BioWatch technology for the frequency of BARs are unknown.

REFERENCES

Brown, M.J., M.D. Williams, G.E. Streit, M. Nelson, and S. Linger. 2006. *An operational event reconstruction tool: Source inversion for biological agent detector*s. 86th American Meteorological Society Annual Meeting. Atlanta, GA. http://ams.confex.com/ams/pdfpapers/126686.pdf (accessed July 9, 2009).

[4]The cost estimates for Generation 3 without geographic expansion are sensitive to the length of time required to operate and phase out the Generation 2 air samplers after the new Generation 3 detectors are installed.

CRS (Congressional Research Service). 2003. *The BioWatch program: Detection of bioterrorism*. RL32152. Washington, DC: Library of Congress. http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-8189:1 (accessed April 21, 2009).

DHS (Department of Homeland Security). 2008a. *Annual performance report, fiscal years 2007–2009*. Washington, DC: DHS. http://www.dhs.gov/xlibrary/assets/cfo_apr_fy2007.pdf (accessed August 5, 2009).

DHS. 2008b. *BioWatch outdoor program: Guidance documents for BioWatch jurisdictions*. Washington, DC: DHS.

DHS. 2008c. *NAS information request #2, DHS OHA written responses*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, October 31. Washington, DC.

DHS. 2009. *BioWatch Gen-3 industry day*. https://www.fbo.gov/download/18d/18d10ae7b9c2106327715c7a5dc53c43/BiowatchGen3_Industry-Day_Slides.pdf (accessed March 24, 2009).

EPA (Environmental Protection Agency). 2005. *EPA needs to fulfill its designated responsibilities to ensure effective BioWatch program*. Inspector General Report No. 2005-P-00012, March 23. Washington, DC: EPA. http://www.epa.gov/oigearth/reports/2005/20050323-2005-P-00012.pdf (accessed July 9, 2009).

FEMA (Federal Emergency Management Agency). 2008. *National Incident Management System*. http://www.fema.gov/emergency/nims/ (accessed April 13, 2009).

GAO (Government Accountability Office). 2008. *Homeland security: First responders' ability to detect and model hazardous releases in urban areas is significantly limited*. GAO-08-180. Washington, DC: GAO. http://www.gao.gov/products/GAO-08-180 (accessed July 9, 2009).

Gordon, R. 2008. Application of aerosol plume modeling in BioWatch program. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 3, November 3–5, Washington, DC.

Heller, A. 2003. BASIS counters airborne counterterrorism. *Science & Technology Review* (October):6–7. Lawrence Livermore National Laboratory UCRL-52000-03-10. https://www.llnl.gov/str/October03/pdfs/10_03.pdf (accessed February 10, 2009).

Hooks, R. 2008a. *BioWatch program*. Presentation and public comments to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31, Washington, DC.

Hooks, R. 2008b. *BioWatch generation 3 deployment strategy*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 2, September 22–24, Washington, DC.

HSARPA (Homeland Security Advanced Research Projects Agency). 2003. *Detection systems for biological and chemical countermeasure (DSBCC)*. Research Announcement 03-01, September 23. Washington, DC: Department of Homeland Security.

IEc (Industrial Economics, Incorporated). 2009. *Revised estimated cost of BioWatch generations 2 and 3*. Commissioned paper. Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Washington, DC.

Johns, M. 2008. *BioWatch past and projected costs*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 3, November 3–5, Washington, DC.

NRC (National Research Council). 2005. *Sensor systems for biological agent attacks: Protecting buildings and military bases*. Washington, DC: The National Academies Press.

Runge, J.W. 2008. *Effectiveness of national biosurveillance systems: BioWatch and the public health system*. Presentation and public comments to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31, Washington, DC.

The White House. 2003. *State of the Union Address*. January 28. http://www.gpoaccess.gov/sou/index.html (accessed March 4, 2009).

3

Evaluation of the BioWatch System

The committee was tasked with evaluating the relative merits and current and potential capabilities of the BioWatch monitoring system (Generation 2 and Generation 3) to detect bioterrorist attacks and other biothreats. This chapter provides (1) an evaluation of the current BioWatch system; (2) an assessment of plans for the next generation of environmental monitoring technology; and (3) recommendations for improving the program's operation and processes for further development.

In its evaluation, the committee considered the entire BioWatch "system," as introduced in Chapter 1—the technology to collect and test air samples, the associated laboratory assays, the additional information gathering needed to confirm and characterize an incident, operational guidance, interagency and risk communication, response planning, and the personnel to support these operations. It also looked at the BioWatch program—the programmatic activity managed and funded by the Office of Health Affairs (OHA) in the Department of Homeland Security (DHS) and carried out through work with other federal agencies and state and local partners.

EVALUATION OF THE CURRENT BIOWATCH SYSTEM

For the BioWatch system to effectively detect a terrorist attack and prevent illness and death, a variety of conditions must be met. Some of these conditions are clearly independent of the performance of the BioWatch system (e.g., whether people are exposed to the biological agent, or whether the agent is susceptible to medical countermeasures), but they are necessary conditions for prevention of illness and death:

1. An airborne bioterrorist attack must occur in a place where the BioWatch system is deployed and with a biological agent that BioWatch air samplers and laboratory test methods can detect.
2. Atmospheric conditions must disseminate the material in a way that exposes people to a viable pathogenic biological agent.
3. Atmospheric conditions must disseminate the material in the direction of the BioWatch air samplers, resulting in sufficient quantities reaching their filters to allow detection.
4. The samplers must function as anticipated; samples must be collected, managed, and tested appropriately to allow for detection of the genetic signature of the biological agent; and positive results must be reported to public health authorities in time to allow for any assessment that must be made before a decision regarding mass prophylaxis can be reached.
5. Public health and other authorities must collaborate effectively in conducting an assessment of the likelihood that the positive test indicates a bioterrorist attack and a population health risk, based on the mix of factors that may shape such assessments (see Chapter 2); and, taken together, the correct conclusion must be made that mass dispensing is indicated.
6. Infection with the biological agent can be successfully prevented or treated with the drugs or other medical countermeasures that could be used in the mass prophylaxis program.
7. State or local public health systems must be able to deliver mass prophylaxis in time for its benefits to be realized; depending on the disease-causing agent and the size of the exposed population, this may involve providing prophylaxis within 2–3 days to several million people.

As noted in Chapter 1, evaluation of the likelihood of an airborne biological attack that could be detected by the BioWatch system is beyond the committee's scope, as is an evaluation of the ability of public health officials to deliver mass prophylaxis in a limited time period. Here, the committee evaluates elements of the BioWatch system that are necessary, if not sufficient, for the system to be effective, including the air samplers and their placement, the samplers' capture of targeted organisms, the laboratory assays, information reporting, event characterization, and public health decision making.

PERFORMANCE OF BIOWATCH TECHNOLOGY

The committee considered information provided by DHS regarding the separate components of the BioWatch system, as well as information relevant to the operational capabilities of the components working together.

BioWatch Air Samplers

There are two types of BioWatch air samplers: the Portable Sampling Unit (PSU) and the Dry Filter Unit (DFU). Information about the performance of these devices is critical for a realistic assessment of system performance. The committee examined the available evidence provided by DHS, but some of the information that the committee would have liked to review has not been collected. The committee also considered information about the number and placement of air samplers in BioWatch jurisdictions and the analytic tool that was developed by the Los Alamos National Laboratory and used to guide their placement for the Generation 2 deployment. The committee considered the siting methodology applied in the Generation 2 deployment to be an improvement over the original approach, but it saw areas where better data and modeling approaches for complex urban environments would be valuable.

Analysis of BioWatch Samples

Since 2003, millions of BioWatch samples have been analyzed. Positive laboratory findings have led to BioWatch Actionable Results (BARs) being declared in a few dozen instances, none of which has been shown to be the result of the intentional release of a biological agent. DHS does not consider these BARs to be "false positives" because the target DNA was actually detected by the specified assays.[1] The committee's view is that from an operational perspective these detections can indeed be considered "BAR false positives," because the detections were not the result of a bioterrorist attack.

The laboratory assays used to detect the presence of genetic material from biological agents of interest need to be both specific and sensitive: that is, the assay must have a high probability of detecting the biological agents that BioWatch targets and have a low probability of reporting the presence of genetic material from other organisms as "detections." Several agents of concern, and their close genetic relatives, exist naturally in water or soil (Kuske, 2005; Kuske et al., 2006). Distinguishing natural background levels of endemic agents from a bioterrorism threat and separating genetic "near neighbors" from the target agent present technical challenges. In addition, the potential exists for newly emerging or "engineered" threats to be used in an airborne biological attack. Ideally, BioWatch probes and assays could

[1]The probe for PCR screening confirms the presence of DNA matching the probe; however, a given DNA signature may be shared between species sharing the same branch on a phylogenetic tree.

be rapidly updated as newly emerging or engineered threats are recognized and as risk-management analyses indicate a need.

An assay that is not sufficiently sensitive can give false negative results, if, for example, an airborne threat were present but was undetected during analysis. This "missed detection" probability is a parameter that is essential for evaluating the effectiveness of the system. In addition, the PCR assay panels employed on the existing analysis platforms need to be adequately compared, standardized, and validated in pursuit of optimal performance across the BioWatch system. A close collaboration is needed between DHS and the Department of Health and Human Services (HHS) to do so.

Collection efficiency, efficiency of extraction, and subsequent sample dilution are all important factors in assessing a detection system's sensitivity. Members of the committee had the opportunity to review information about the BioWatch Generation 2 sensitivity levels, but the committee did not have adequate test and validation data to evaluate the ostensible performance of the BioWatch technology. However, as discussed earlier, the experience available from BioWatch Generation 2's deployment to date provides real-world data to consider: numerous BARs for certain agents, and no alarms (and no apparent misses) for other BioWatch target pathogens.

To the extent it is well understood for a particular biological agent, the consideration of infectious dose (i.e., the minimum amount of a biological agent necessary to cause infection in a host) may help in the interpretation of BioWatch results. However, uncertainties about infectious doses for some agents, differences among pathogens in the size of their infectious doses, and uncertainties about the concentrations and dispersion of an aerosolized agent used in an attack mean that the committee does not recommend that consideration of infectious dose be a factor in distinguishing between an attack and natural background. To the extent that the analysis of BioWatch samples can relate the amount of genetic material present in a sample to infectious dose, the information is likely to aid public health officials in planning a response. But BioWatch collectors and assays should be sensitive enough to detect small quantities of genetic material for a targeted pathogen, because the presence of small quantities at one collector may be related to the presence of much larger quantities elsewhere or, perhaps, a failed attack that requires further investigation.

System Testing and Evaluation

Test and evaluation (T&E) processes provide an opportunity to assess a system's actual performance against the stated requirements and specifications, to assess technical maturity, and to provide assurance that the system will effectively perform its mission. Developmental T&E (DT&E) focuses on the technological and engineering aspects of the system, and operational

T&E (OT&E) evaluates a system's ability to perform as intended in its operating environment, including consideration of end users' capabilities and proficiencies. OT&E can identify critical issues in system operations (e.g., failure, inaccuracies, subsystem incompatibility, and cost) that need to be resolved to ensure that the system performs to stated capabilities. OT&E can also provide the opportunity to empirically and realistically compare the costs and benefits of next-generation technology against currently fielded systems. It provides the opportunity to consider otherwise-unforeseen barriers to accurate and reliable detection and to make corresponding system improvements before full-scale deployment.

At Dugway Proving Ground, it is possible for an entire sampling device or its components to be challenged with simulants[2] or live agents in chambers or to undergo whole-system testing with simulants in open-air tunnels. DT&E at Dugway allows a designer to assess the performance of a system in a relatively "pristine" environment, without consideration of confounding factors (e.g., weather, pollution, humidity, buildings or other physical structures, and people and animals and pathogens associated with them) that may affect the performance of a system in an urban environment.[3] The BASIS technology that was adapted for BioWatch underwent DT&E at Dugway, where it was challenged with live agents inside a sealed chamber, but the results from the tests were not provided to the committee.

With only limited information available from test and evaluation studies, the committee could not appropriately evaluate whether the BioWatch system meets user needs.

FINDING: The rapid deployment of BioWatch Generations 1 and 2 allowed limited opportunities for testing, validation, and evaluation of the system. Rigorous technical and operational testing and documentation of system performance are needed as a basis for risk-management decisions.

PUBLIC HEALTH RESPONSE TO A BAR

DHS has direct programmatic responsibility for the BioWatch air samplers, laboratory assays, and the reporting of assay results by its contractor staff to local public health officials. DHS's role after the declaration of a BAR, along with that of HHS/CDC and other federal partners, is to support

[2]Simulants to be used in such tests would be nonpathogenic or nontoxic surrogates for bioterrorism agents. Testing with well-selected simulants would provide useful information for evaluating the performance of a biological detection system (NRC, 2008a,c).

[3]Dugway Proving Ground, located in Utah, has minimal background interferents. It is dry, isolated, and free of urban pollutants.

their state and local partners who are responsible for public health decision making. Having the information tools necessary to make post-BAR decisions as rapidly as possible is likely to be crucial in being able to maximize the possible benefit from the BioWatch system's detection of a bioterrorism attack.

Little or no empirical data were available to help the committee in its evaluation of the response aspect of the BioWatch system. One after-action report was provided to the committee (Lindley, 2009), but the chief source of information was testimony by state and local public health officials during the committee's information-gathering meetings. (See Appendix A for a list of participants at these meetings.)

In its information gathering, the committee explored aspects of the current BioWatch response capability, including the coordination and collaboration between DHS and public health officials as well as the resources needed for response. The committee presents its findings and recommendations for improvements to the BioWatch system in this chapter. These improvements can be implemented immediately to increase the potential effectiveness of the existing system and need not await development and implementation of the next generation of BioWatch technology.

Coordination and Collaboration

The BioWatch program appears to lack necessary coordination, communication, and collaboration among the several contributors at federal, state, and local levels that must be fully engaged for a functional system. The committee heard testimony about significant shortcomings in the earliest days of the BioWatch program in DHS's inclusion of public health officials as partners and collaborators in developing plans and procedures for a response to BARs. At that time, the planning and concept of operations for the response to a BAR had not been well developed and did not appropriately take into account the central role of local officials. A lack of consensus about communication with local officials was illustrated by a 2005 instance in which tests of air samples indicated the presence on the National Mall in Washington, DC, of one of the biological agents monitored by the BioWatch system. The criteria for a BAR were not fully met, but local officials were informed of the detection 4 to 5 days after the event (Dvorak, 2005). Moreover, they learned of it from CDC rather than from DHS (Dvorak, 2005). Public health officials also told the committee that DHS had initially been reluctant to inform local and state officials about the locations of BioWatch air samplers within their own jurisdictions.

Further, DHS has not always provided technical information to public health officials about the sensitivity, specificity, and limits of detection of the laboratory assays that are the basis for declaring a BAR. As a result,

the laboratory directors in some jurisdictions, whose responsibility it is to report a BAR, have not had the means to evaluate the laboratory evidence concerning the presence of a biological agent (Personal communication, Scott Becker, Association of Public Health Laboratories, April 22, 2009). Although procedures for interpreting and responding to positive test results have improved, there remain serious gaps in effective communication and trust between the BioWatch program and public health personnel in BioWatch jurisdictions.

The seeming lack of trust by DHS in public health officials has been mirrored by an apparent lack of confidence in DHS and the BioWatch program by many local public health officials. They are cautious about the interpretation of BARs because of experience with the system to date, and some question the value of BioWatch.

The BioWatch system relies on prompt public health action, such as prophylaxis in response to a BAR, to be most effective in saving lives. Critical to the success of the BioWatch system is the confidence of local and state public health officials and decision makers in the system's detection and assay technology, and in their ability to work as partners with DHS and other federal agencies in preparing for and possibly having to respond to a bioterrorist attack detected through BioWatch. Public health officials emphasized in their discussions with the committee that they are aware that they depend on the public's trust to be able to motivate action and cooperation and avoid panic in life-threatening circumstances. These officials do not want to risk this trust by initiating potentially high-regret actions for a possible bioterrorist attack when a full-blown response is not warranted, as has been the case with the BARs to date. Some stated to the committee that they would be unlikely to administer prophylaxis on the basis of a BAR alone, waiting instead until clinical cases occur before taking that step.

The committee sees the need for DHS to strengthen its relationships with state and local health officials and other key responders through training, exercises, and information exchange. The annual BioWatch meeting provides one forum for information exchange between BioWatch jurisdictions and DHS and among the jurisdictions. However, this annual conference is not sufficient for such information sharing. In the past, DHS has provided limited opportunities for state and local input into the conference agenda or an active role in planning it. Going forward, DHS should use this conference as an opportunity to more actively involve local partners as part of forging a stronger partnership.

DHS has begun taking some important steps to test and validate BioWatch assays that should help build confidence in the assays. DHS can further improve upon this in continuing its efforts to strengthen relationships with its local and state partners. It needs to not only invite input but also respond to it, and it needs to facilitate more information sharing about

matters such as BARs so that the BioWatch jurisdictions can learn from others' experiences. To the extent that such information sharing has been constrained by security concerns, DHS should help ensure that essential public health officials in each jurisdiction have appropriate security clearances. The training and exercises that DHS holds with BioWatch jurisdictions should also continue to be helpful in strengthening necessary skills and the relationships vital to effective action under critical circumstances following a BAR.

Information and Tools for Decision Making

Several critical decisions need to be made in the event of a BAR: (1) Does it indicate a real bioterrorist attack? (2) If so, or if an attack cannot be ruled out, should public health officials begin to mobilize to start prophylaxis, and what population should be targeted initially? (3) Is it safe to allow persons to stay in the area around the site of the BAR, or should recommendations be made to evacuate or shelter in place? and (4) What information should be provided to the public?

Decisions such as these will need to be made very quickly, even though important information is likely to be limited. At the time of a BAR, the available information may include the site(s) of the air sampler(s) that produced positive assay results, weather conditions, and the biological agent detected. It may take 1 to 2 days to obtain additional data from environmental sampling and surveillance inputs. Initial decisions may need to be revised as additional information becomes available.

Information from law enforcement and national security sources is not typically a factor in public health decision making, but it will be critical if bioterrorism is suspected. While it is quite likely that a biological attack could occur without any meaningful intelligence warning, all relevant foreign and domestic intelligence that might possibly reflect on the likelihood of an attack that threatens human health should be immediately delivered to public health decision makers, along with any insights on how to evaluate or interpret such findings. The decision makers will need to know of any information such as thefts or diversions of agent stocks or known efforts by potential terrorists to culture organisms or develop means of dissemination.

Incident Characterization and Event Reconstruction

Environmental Sampling

One critical gap in current tools and technology is a means to determine the extent of contamination. The 2001 anthrax attacks demonstrated seri-

ous weaknesses in the environmental sampling approaches taken by federal agencies to determine the presence or absence of a biological agent. Because validated methods for collection of environmental samples and analysis were not used, there could be little confidence in the results (GAO, 2007). Draft guidance on environmental sampling following a BAR has been developed by DHS (2008c), and other agencies have also offered relevant guidance (CDC, 2002; EPA, 2008). Nevertheless, no validated sampling strategy and collection methods are currently available for use in situations in which contamination from a biothreat agent is suspected. Without such validated methodologies, states and localities lack much-needed means to determine the extent of contaminated areas or identify populations most likely to be exposed.

Dispersion Modeling

Another potential tool for characterizing an event that may be a bioterrorist attack is the use of dispersion modeling to assess where exposures to airborne pathogens may be likely.[4] According to GAO (2008b), field testing and evaluations show that plume models developed by federal agencies specifically for tracking the atmospheric release of CBRN (chemical, biological, radiological, or nuclear) materials in urban areas have severe limitations and require additional field evaluation. Moreover, the deficiencies in environmental sampling, noted above, mean that it is unlikely to be helpful in refining the results produced by dispersion models.

DHS has supported the development of tools intended to help jurisdictions assess a biological event. For example, the Bioagent Event Reconstruction Tool (BERT) employs modeling to simulate what might happen during an airborne biological agent attack (Brown et al., 2006). It uses as inputs measurements from biological agent detectors and data from wind sensors. While BERT can estimate the amount of material released and offer possible locations for a release for certain kinds of scenarios, it is not applicable to other conditions. In addition, its plume models have important limitations (Brown et al., 2006). During TOPOFF exercises led by DHS, contradictory results provided by competing plume models led to confusion by first responders and decision makers.

The DHS Interagency Modeling and Atmospheric Assessment Center (IMAAC) at Lawrence Livermore National Laboratory has been designated as the focal point for coordinating and disseminating plume modeling products. However, GAO (2008b) concluded that IMAAC needs better

[4]For more information on the use of dispersion models for event reconstruction, see Keats et al. (2007); Rao (2007); Chow et al. (2008); Delle Monache et al. (2008); Senocak et al. (2008); and Yee (2008).

procedures for working with federal, state, and local agencies to deal with conflicting modeling results.

The available dispersion models can be used to generate hypotheses for testing and to inform analysis of release sites, but they are not designed to guide public health interventions. On the other hand, as made clear in other parts of this report, the use of epidemiological models, and models of responses to detection, alerts, and positive reports from syndromic surveillance, can and should be used to evaluate the current (and proposed) versions of BioWatch and related systems and technologies.

Decision Support Tools

Beginning in 2005, DHS sponsored development of a decision support tool called the Biological Warning and Incident Characterization (BWIC) system, which was pilot tested in three jurisdictions. The aim of BWIC is to integrate databases and several modeling programs into a common system for an emergency management team. A major component is the application of plume models to indicate where a release is likely to have occurred and what populations and areas are likely to have been exposed. It also includes a situational awareness tool to keep decision makers informed of estimates from analysts using the modeling components (Argonne National Laboratory, 2008). As tested, BWIC also supports monitoring routine operations, such as daily filter collection from BioWatch air samplers and reports from laboratory analysis of filters. It also incorporates scenarios to facilitate exercises and planning. Decision support and situational awareness tools such as BWIC may well aid state and local decision making following a BAR, but further development to address limitations identified during pilot testing is needed.

Developing New and Better Tools to Aid Decision Makers

The committee urges action to improve tools for environmental characterization of the nature and extent of aerosol releases of biological agents in order to inform public health decision makers following a BAR. DHS should work with HHS (CDC), EPA, and the states and localities to ensure that the public health and law enforcement authorities in BioWatch jurisdictions have the capabilities to rapidly confirm and characterize an event that results in a BAR (event reconstruction) via environmental testing and other methodologies (e.g., plume modeling) to rapidly determine the area affected in order to target control measures effectively. Support is needed for work to identify, develop, and validate methodologies for specimen collection, laboratory analyses, and interpretation of environmental data. Examples of potential approaches to improving tools for incident characterization are shown in Box 3-1.

BOX 3-1
Potential Approaches for Improving Incident Characterization

If release of a bioterrorism agent is suspected or confirmed, public health officials will need additional information to understand the scale of the release and the extent of the dispersion of the agent. Various approaches to producing such information could be developed and tested to determine their feasibility and effectiveness. Some examples include

- Developing low-technology strategies for quick-look assessments of the scale of an incident (e.g., test subway train ventilation filters with PCR as a first check on transport through or dispersion out of a subway system or existing ventilation systems);
- Developing national standards for indoor and outdoor environmental sampling strategies and collection methods and federally validated procedures for DNA extraction and analysis from environmental sampling;
- Encouraging academic–public partnerships to design new data analysis strategies and methods that leverage preexisting regional meteorological and engineering expertise and experience to integrate environmental sampling data with meteorological data, and find ways that allow these new partners to assist both routinely and during emergencies;
- Building an interactive database for some or all BioWatch jurisdictions that contains simulations for several thousand releases of bioterror agents and that reflects a comprehensive range of meteorological conditions anticipated through the year and judgments by local FBI or police of higher-risk targets and potential release points. This database could be used for planning and training purposes and also during an actual event, when the database could be queried for releases yielding the precise number and location of positive BioWatch detectors during similar meteorological conditions. This information could help generate new hypotheses that could be tested with additional environmental sampling following an event; and
- Integrating data from sources such as atmospheric aerosol lidars or other monitoring systems to help corroborate positive results from analysis of BioWatch samples and suggest source locations and dispersion trajectories.

As new methodologies for incident characterization and event reconstruction are developed and validated, DHS and its BioWatch partners should also be furthering the development of computer support systems that can capture information as events are unfolding to maximize support for informed decision making. These decision support tools should reflect evidence and experience gained from event characterization. Because experience with BARs is currently limited to the detection of certain naturally occurring organisms, it will be important to understand whether or how this experience can be applied to the decision making that would follow a BAR for other biological agents.

Assistance to Jurisdictions in Responding to a BAR

With the declaration of a BAR, the planned procedure is for local public health officials to immediately notify both DHS and CDC, and for CDC to "provide public health consultation, support, and guidance to BioWatch jurisdictions regarding disease surveillance, laboratory issues, and/or environmental and occupational health" (DHS, 2008c, p. 11). Particularly in light of declining public health budgets (discussed in Chapter 4), BioWatch jurisdictions may find themselves in need of additional expert advice or information-gathering resources in planning for or responding to a BAR. In testimony to the committee, some public health officials noted the shortage of staff to carry out routine public health activities and the challenges posed by the need for additional information gathering following a BAR.

As the nation's lead public health agency, CDC has a broad role in the preparedness and planning activities for biological threats and other hazards and should be working with all BioWatch jurisdictions to prepare for the response to a BAR. Specific areas where additional CDC assistance may be most useful include developing and ensuring the availability of resources such as the following:

- improved environmental sampling methods and laboratory assays for characterizing an incident after a BAR,
- criteria for each bioterror agent to help guide the decisions on if and when to start prophylaxis,
- guidance for decisions regarding initial targeting of prophylaxis if the extent of exposure is not yet clear,
- guidance for decisions regarding evacuation versus sheltering in place for the area(s) surrounding where the BAR was detected,
- additional templates for risk communication messages to the public and health care providers, and
- guidance on environmental risk assessment and remediation.

The lack of such guidance may have a crippling effect on decision making, or even on a jurisdiction's willingness to participate in the BioWatch program. According to its annual performance reports, DHS did not reach its target for deploying additional air samplers in indoor locations in FY2007 and FY2008, in part, because of "some jurisdictions' reluctance to employ bioaerosol collectors in indoor venues" without sufficient guidance on responding to an indoor detection of a biological agent (DHS, 2008a, p. 41, 2009d). The committee suggests as a model the guidance for responding to alerts from an automated system to detect *B. anthracis* in the workplace (CDC, 2004). This general guidance for employers, health departments, emergency responders, health care providers, and hospitals reflects collaboration between CDC, the U.S. Postal Service, and state and local officials to establish specific guidelines to accompany the installation of the Postal Service's Biohazard Detection System.[5]

In addition to guidance documents and related resources, the committee also sees a need for public health departments and other key local responders (e.g., law enforcement, emergency management, and environmental protection agencies) to conduct tabletop or functional exercises in collaboration with CDC and the BioWatch program at least annually to assess and improve their alert response capacities. BioWatch jurisdictions also have a need for on-the-ground assistance from subject-matter experts at the time of a BAR. This assistance could take the form of a team of trained experts, assembled jointly by the BioWatch program and CDC, who could be invited to come to the aid of local officials. This team could provide assistance for planning and conducting periodic exercises designed to evaluate state and local preparedness to respond to BARs, and it could also be available to provide immediate assistance following an actual BAR. Such assistance would include guidance regarding critical issues related to estimating the population potentially exposed, risk communication, the initiation of antimicrobial prophylaxis or other countermeasures, determining the scope of environmental contamination, and the requirements for environmental remediation. This resource should be integrated with the local incident command.

Learning from BioWatch Exercises and BARs

Since the initial deployment of BioWatch in 2003, numerous exercises have been held by BioWatch jurisdictions to plan and prepare for a bioterrorist attack that might be detected by the BioWatch system. There have

[5]The U.S. Postal Service has installed the Biohazard Detection System in more than 200 major mail processing and distribution centers. The devices perform automated analyses to test for the presence of genetic material from *B. anthracis* in air samples from high-speed mail-handling equipment.

also been a few dozen BARs declared to date, giving the jurisdictions where they occurred firsthand experience in contemplating the critical information needed after a BAR. When shared, jurisdictions' experiences with exercises and BARs could be helpful to other communities and to DHS and the other federal BioWatch partners.

The committee sees the creation, sharing, and synthesis of information from after-action reports (AARs) on BARS as important to the continuing improvement of the BioWatch system. They can offer insights into the capabilities of and desired improvements to planning, operation, and response for the BioWatch system. These reports can also help identify opportunities to improve the future architecture and technical specifications of the BioWatch system and ways to improve the efficiency and effectiveness of response.

There is precedent for requiring such reports: the Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417) requires that localities receiving preparedness funding under cooperative agreements with HHS provide reports regarding strengths and weaknesses identified through preparedness exercises or drills (Sec 201). To enhance the generalizability of findings and ensure that lessons learned from each event are maximized, AARs could use Homeland Security Exercise and Evaluation Program (HSEEP) concepts and the federal Target Capabilities List (TCL) and the Universal Task List (UTL) (DHS, 2007a,b).[6] Given both the burden and importance of preparing AARs, the committee urges DHS to provide funding to support their preparation rather than having this cost borne by BioWatch jurisdictions. Examples of the types of information that such BAR AARs could include are shown in Box 3-2.

The BioWatch program and its federal partners, including CDC, should jointly institute a systematic process for capturing, reviewing, and sharing the insights and recommendations of local, state, and federal officials involved in operating the BioWatch system. These reviews should address such issues as experiences in fielding BioWatch equipment, financial and other impacts of BioWatch operations on local jurisdictions, and key findings noted in after-action reports for BioWatch alerts or exercises. The reviews should identify common gaps as well as best practices in planning or conducting responses to BARs. Updates on lessons learned should be a standing agenda topic for an external BioWatch advisory panel (see Recom-

[6]The Homeland Security Exercise and Evaluation Program provides a standardized methodology and terminology for the design, development, conduct, evaluation, and improvement of preparedness and response exercises. The Target Capabilities List offers a guide to capabilities considered necessary to prevent, protect against, respond to, and recover from major events of all types. It includes capabilities for epidemiologic surveillance and investigation and for laboratory testing for biological (and other) hazards. The Universal Task List is the catalog of tasks that may need to be performed by governmental, nongovernmental, and private-sector organizations and the general public.

BOX 3-2
Possible Elements of an After-Action Report Following a BAR

A BAR AAR could include the following elements:

Identification and characterization of the event
- Date, time, location, and duration of detection
- Organism/species detected
- Viable organisms found in the environment
- Number of air samplers in jurisdictions and the specific samplers that tested positive or negative
- Populations at risk or potentially exposed

Interagency communications and timeline
- Who was notified (city, county, state, federal [e.g., DHS, CDC, and FBI])
- Time and date when each agency or jurisdiction was notified; and calculation of time that elapsed between declaration of the BAR and initial notification
- Time interval between notification, BAC meeting, and national interagency conference call, and summary of decisions made

Summary of event response
- Evaluations of delays in notification and response, and corrective actions to be taken on subsequent BARs
- Description of public health and other local response (e.g., press releases, health care provider alerts, enhanced or active surveillance methods and findings, results of environmental sampling, decisions regarding mobilization of the Strategic National Stockpile)
- Evaluations of actions initiated
- Overall lessons learned

mendation 7), which can identify issues requiring program improvement and ensure that its recommendations are incorporated in the program's continuous quality improvement plan. Lessons learned should also inform capacity-building and technical assistance programs for state and local public health departments participating in BioWatch.

Support for BioWatch Operations

The introduction of the BioWatch system into major metropolitan areas across the country has generated a variety of additional responsibili-

ties and obligations for state and local health departments. Although the guidance from the BioWatch program has matured over time, it continues to leave local health officials with limited insight into determining the appropriate public health actions following a BAR. CDC is a source of some assistance to local decision makers, but the coordination between the two federal agencies has not always been optimal. The committee sees a need for both the BioWatch program in DHS and relevant offices in CDC to provide better and more coordinated guidance to BioWatch jurisdictions.

In making the following recommendation and others in this chapter, the committee emphasizes an important caveat: The recommendations are made based on the assumption that the BioWatch technologies can be shown to perform satisfactorily and to produce useful data. Because certain critical testing is still needed for Generation 2, and has not yet been performed for Generation 3, there is uncertainty regarding the performance of the BioWatch system.

RECOMMENDATION 1: DHS and its federal BioWatch partners should provide coordinated and collaborative support to local jurisdictions to improve their ability to respond to a BAR. This support should include:

- **strengthening relationships with state and local health officials and other key responder agencies (law enforcement, emergency management, environmental protection) through additional and improved training, exercises, and information exchange;**
- **developing, validating, and implementing rapid environmental sampling and testing methodologies to characterize the scale and scope of the incident immediately post-BAR. As validated methodologies are developed, situational awareness and decision support systems with analytical tools to facilitate analysis of critical information needed to inform decisions in response to a BAR should be developed;**
- **preparing detailed guidance for local and state public health officials with specific recommendations on public health measures and decisions following a BAR;**
- **ensuring that a team, with specific training in reacting to BARs and relevant subject matter expertise (e.g., infectious disease epidemiology, laboratory science, environmental assessment, risk communication), would be available to provide around-the-clock expert federal assistance following a BAR; and**
- **developing a formal mechanism for reviewing and sharing the "lessons learned" from the operation of BioWatch, including all BARs and interagency exercises.**

While the response to a BAR demands resources and expertise from a BioWatch jurisdiction, the day-to-day operations of BioWatch also impose costs. DHS pays for personnel and equipment for the laboratory assays, but localities provide space and personnel time for planning, training, and exercises. The committee received only limited information to evaluate the scale of these costs (e.g., Downes, 2008), but the data gathered suggest that they are modest relative to annual BioWatch program costs (see additional discussion in Chapter 2). The committee recommends that these day-to-day costs be assumed by DHS as part of the costs of operating the BioWatch program.

RECOMMENDATION 2: DHS should provide funding to cover local costs incurred in support of BioWatch resulting from space utilization, laboratory management oversight of BioWatch staff, training and exercises, and other support functions.

PLANS FOR BIOWATCH GENERATION 3

Using an autonomous detection system for the next generation of BioWatch technology is a potential means to reduce operating costs and improve timeliness of results. Automating the analysis of air samples within the field devices would eliminate the need for manual collection of filters and their transport to a laboratory for analysis, and reduce the time between agent release and detection.

Comparing Generation 2 to Generation 3

Replacement of Generation 2 BioWatch samplers with continuously operated automated air samplers capable of sample collection and preparation, analysis, and data transfer as proposed for Generation 3 could resolve some problems that exist with the current system. Key features of the two systems are shown in Table 3-1.

Under routine operation, the BioWatch system currently produces test results once per day for samples collected 10 to 34 hours earlier. This window accounts for a 24-hour collection period and the time for sample collection, transport to a laboratory, and laboratory analysis. For Generation 3, the program is seeking to acquire devices that will be able to collect and test samples in the field and report results within 4 to 6 hours of sample collection. In principle, faster and more frequent testing provides the opportunity for earlier detection of a biological agent and therefore an earlier decision to begin a public health response, which may result in a significant increase in lives saved over a Generation 2 time line.

TABLE 3-1 Key Features of the BioWatch Generation 2 System and the Proposed Generation 3 System

	Generation 2	Generation 3 (proposed)
Time to detect	10–36 hours	4–6 hours
Automated analysis and reporting	No	Yes
Number of units deployed	A few hundred	> Generation 2
Annualized cost[a] (10-year projection)	$80 million	$200 million[b]

[a]Annualized costs represent the total present value cost (total anticipated costs of the program over a 10-year period applying a discount rate, divided by 10).

[b]The annualized cost for Generation 3 reflects the proposed deployment of Generation 3 as described by DHS in December 2008 (replacement of Generation 2 air samplers and deployment of additional devices).

SOURCES: DHS (2008a,b,d); IEc (2009).

In addition to deployment of the autonomous detectors, the Generation 3 plans include increasing the number of jurisdictions participating in the BioWatch program, the number of monitoring devices in the participating jurisdictions, and the number of devices in indoor locations. Currently, a few hundred air samplers are deployed (DHS, 2008a). Plans for Generation 3 include deploying additional units (DHS, 2008b,d). Anticipated costs for Generation 3 are discussed in Chapter 2.

Development and Acquisition

Since 2003, DHS has been pursuing an automated detection capability for BioWatch, aimed at reducing the time needed to obtain test results to within 4 to 6 hours of sample collection (HSARPA, 2003). When the BioWatch program was run by DHS S&T, development began for a system called the Bioagent Autonomous Networked Detector (BAND), which was anticipated to serve as the Generation 3 technology. After OHA was given operational responsibility for BioWatch, it announced plans to deploy an interim system—Generation 2.5—while final testing and acquisition of BAND units were completed for Generation 3 (Hooks, 2008b). DHS planned the interim system, referred to as the Autonomous Pathogen Detection System (APDS), because completion of work on BAND was progressing more slowly than expected, in part, because OHA issued revised specifications for Generation 3 in January 2008 (GAO, 2008a).

In fall 2008, DHS cancelled plans for Generation 2.5 because of delays in validation and production, and it revised plans for Generation 3. The change in DHS's strategy for Generation 3 development and deployment has resulted in a new acquisition process, reflected in the release of a request for information, a request for proposals, and an operational requirements document (DHS, 2008b, 2009b,c). The specifications for the Generation 3 detection system call for a fully autonomous, networked biosensor that is capable of continuous monitoring (24 hours per day, 365 days per year) in indoor and outdoor environments for at least the pathogens currently included in the BioWatch program. Units are to collect and analyze samples at the sampling site and electronically report data on the results of the analysis of samples and of various self-tests (DHS, 2009c). Operational requirements have been set for the automated sample collection, preparation, analysis, preservation of samples, and waste handling.

Continued development of a program such as BioWatch is a long-term effort that must be approached more systematically than was possible in the program's earliest days. Over many decades, the Department of Defense (DoD) has gained considerable experience in technology development and acquisition. It has developed an acquisition process that includes the generation of goals, measures to assess those goals, and test and evaluation methodologies to validate performance (Chadwick, 2007). Although DoD's application of its system is not always successful (GAO, 2009), the committee sees the benefit of applying a similar systematic and structured approach for BioWatch. A formal acquisition plan for BioWatch would address factors such as costs (e.g., for operations, equipment, reagents, training, and response), technology update cycles, maintenance, and performance standards.

Development of a formal acquisition plan is particularly important because the BioWatch "user" community is almost exclusively external to DHS and composed primarily of state and local governmental entities (whereas DoD has the benefit of a defined set of users within the department). If a detailed plan for Generation 3 is shared with and incorporates input from end users, it may also encourage buy-in from the user community by displaying a level of rigor, detail, and partnership in planning and potential execution of the system that is currently lacking.

Plans for Testing and Evaluation

DHS plans to subject candidates for Generation 3 to T&E according to a Test and Evaluation Master Plan (TEMP) that was being finalized as this report was being written. To meet the proposed time line, potential

candidates must be at a Technology Readiness Level of 6 or higher[7] to be accepted into the competition and must be deployable with 12 months (DHS, 2009a). Testing is scheduled to begin in mid-2009 and procurement in 2012. A number of participants will be involved in the process. A T&E workgroup is involved in developing and finalizing the TEMP. Units within DHS S&T will review the test plan and the test results for OHA. All stakeholders (i.e., CDC, EPA, FBI, state and local public health agencies) will be invited to participate in any or all parts of testing.

This proposed test plan demonstrates a welcome and substantive improvement in the BioWatch management approach, demonstrating an effort to apply more rigorous and systematic procedures to the development of BioWatch technology than were feasible during its initial hurried deployment. However, serious challenges remain in meeting the testing time line, overcoming technical risks, and providing for needed stakeholder involvement.

Time Line

The T&E time line is too short. It does not allow for preproduction qualification tests or likely challenges to, or obstacles in, the development and testing process. The timing, duration, and location of the field test seem too limited to provide a basis for high confidence in intermediate technology decision points. The committee emphasizes that field testing needs to occur in various locations under a range of environmental conditions to which the detector will be subject under routine operation in order to gain representative results.

Technical Risks

The technical risks of the acquisition and test plan for Generation 3 technology are too high. A first principle in technology acquisition is to assess technology maturity. It is unclear if DHS has adequately assessed the maturity of the technology needed for Generation 3 BioWatch. The committee saw no indication that DHS is planning to assess the environmental background levels of monitored pathogens in the BioWatch jurisdictions. This information could reveal whether environmental backgrounds will affect the performance of the biodetector assays. Also, the plan described to

[7]A technology readiness level, or TRL, is a measure used by U.S. government agencies to assess the maturity of an evolving technology before incorporating that technology into a system or subsystem (DoD, 2006). DHS (2009c) defines TRL 6 as follows: A representative model or prototype system, which is well beyond the breadboard tested for level 5, is tested in a relevant environment. Examples include testing a prototype in a high-fidelity laboratory environment or a simulated operational environment.

the committee indicates that the information technology component of the system will be developed separately from the detector. This approach may produce obstacles in testing and challenges in integrating these components. In addition, the system's automation component provides an opportunity for failure that could produce errors in sample analysis and electronic data exchange. Also of concern are the apparent plans to use equipment operators from the technology vendors or the national laboratories. The system should also be tested with representative operators from one or more BioWatch jurisdictions.

A requirement that will hamper development of the Generation 3 detector, but that has little operational relevance, is a false positive "rate" that is stated only as an exponential factor of 10, with no specification of the operational interval to which it applies (DHS, 2009c). In this form, it is difficult to interpret this performance requirement. But however it is interpreted, it represents an enormous T&E hurdle for obtaining statistically valid test data.

The assays that will be a critical feature of Generation 3 pose another technical challenge. New assays that are successful in the test panels are expected to be introduced into field testing for the Generation 3 system in mid-2009. Additionally, it appears that the requirements for sensitivity and selectivity are based on an estimation of capabilities of the existing analytical collection and assay technology, as opposed to being based on consideration of the infectious dose of the pathogens or other criteria that are based on the operational goals for the BioWatch system. The trade-offs between these two approaches for setting requirements are complex, with many uncertainties, but the latter needs to be taken into account in setting specifications for Generation 3.

An objective for Generation 3 is to increase the number of pathogen targets. This reinforces the need for validation of the assay component of the system. Moreover, the committee emphasizes that selection of biological agents for Generation 3 should be based on risk analyses and risk-management considerations to avoid inclusion of pathogens for which BioWatch is not an appropriate detection tool and unnecessary investment in related technology and assay development. Even if autonomous biological detectors are fielded, further laboratory analysis may be necessary to determine pathogen viability and antimicrobial sensitivity and for post-BAR environmental sampling.

The committee believes that the plans that DHS described for testing in an operational environment will not be sufficient to evaluate the efficacy of detector placement in a BioWatch jurisdiction. This experimental design issue is exacerbated by the fact that DHS does not appear to have a protocol for determining effective placement of detectors to ensure a high probability of sensing a bioterrorist attack. The committee urges that DHS make every

effort to arrange for the Generation 3 testing to include an experiment involving the release of simulant in a BioWatch jurisdiction to test and validate both siting models and system operation. Conducting such a test will require careful selection of appropriate simulants and close collaboration with a variety of officials in the jurisdiction. The operational testing may also need to consider the security of detector sites and appropriate tools (e.g., video monitoring) that can help assure local jurisdictions that a BAR is not the result of tampering or other interference with a detector.

DHS should consider whether, other than providing a more timely BAR, Generation 3's automated process for generating a detection signal provides state and local public health officials with a more reliably "actionable" output than Generation 2's manually detected genetic signature. In its development and selection of the Generation 3 system, DHS needs to be establishing with public health officials how the overall utility of Generation 3 outputs can be evaluated.

Stakeholder Involvement

Stakeholder involvement is critical to the T&E process; unfortunately, the extent of stakeholder involvement described by DHS is too narrow. DHS indicates that it is reaching out to EPA, CDC, and FBI for very specific portions of the Generation 3 testing. It has also begun outreach efforts to some public health organizations. It appears, however, that state and local partners will be invited to observe the testing but will have no official role and no support from DHS to facilitate their participation.

To ensure that the goals of the test plan address public health needs, it is important that state and local public health officials be involved in the entire process. The absence of a formal means of involving these stakeholders gives the impression that DHS does not view their perspectives as a necessary and valuable component of the testing process. Failing to formally include (and fund the involvement of) state and local public health agencies risks missing the identification of faults that may be revealed during operational testing, such as problems in detector performance, shortcomings in operator training and operations protocols, or inadequacies in supporting agencies (e.g., public health laboratories or supply systems). The user community must have an active role as early as possible to have confidence in the system.

FINDING: The challenges associated with development of the BioWatch Generation 3 technology are great and include meeting the time line, achieving greater stakeholder involvement, and reducing technical risks. Suspension of the deployment of Generation 2.5 and the delay in the deployment of Generation 3 provide DHS with a needed opportunity to establish a more systematic, scientifically sound approach

to technology acquisition, development, system testing and validation, and deployment, as well as obtaining earlier and ongoing input from users at the local level.

As the selection and deployment of Generation 3 move forward, DHS should conduct operational testing of BioWatch Generations 2 and 3 in representative jurisdictions, against operationally representative, open-air simulant releases using a method that might be employed by a terrorist in a limited number of sites (indoor and outdoor) and using representative operators and decision makers. This testing should be conducted before Generation 3 is widely deployed. Ideally, operational testing of Generation 2 should provide the extensive agent-specific performance characterization needed for development of Generation 3 requirements and to inform risk-management decisions in response to BioWatch results. Thorough operational testing of Generations 2 and 3 should include the development of readiness criteria that address the end user's ability to interpret and use results from the system. The design of this testing should permit an evaluation of the entire system, including the following elements:

- the detector's performance (the probability of a correct detection and identification within an acceptable time, rejection of background noise, and preservation of the sample to test for the viability and antimicrobial sensitivity of the detected pathogen), reliability, and supportability (setup, operation, maintenance, and repair);
- the effectiveness of the BioWatch training program for its operators;
- the ability of the BioWatch logistics system to provide adequate support to the operators and end users; and
- the suitability of BioWatch data to support low- and high-regret response decisions by local public health officials for the full spectrum of agents and bounding scenarios.

Operational test results should be evaluated against measures of effectiveness that are collaboratively developed by the BioWatch program office and the public health community. Possibilities include sensitivity and specificity, pathogens detected, timeliness, and coverage.

RECOMMENDATION 3: DHS should conduct operational testing of BioWatch Generation 2 at sites where it is currently deployed to provide agent-specific performance specifications (based on use of appropriate surrogates as necessary) that are needed to refine Generation 3 requirements and to make effective use of BioWatch results (e.g., risk-management decisions). Generation 3 should undergo thorough operational testing before deployment. Results should be formally and

thoroughly documented and made available to public health stakeholders in BioWatch jurisdictions.

Given the technical risks that exist in the acquisition and test plan for Generation 3, DHS would benefit from an external technical review entity that could assess the technical risks of the candidate technologies and aid in the development of criteria for decision making at critical decision points. A subsequent recommendation (Recommendation 7) proposes such an advisory group.

CHALLENGES TO DEVELOPMENT OF GENERATION 3 TECHNOLOGY

If BioWatch Generation 3 technology can be successfully developed and deployed, it could facilitate greater population coverage, aid in achieving an earlier initiation of a public health response to an attack, and reduce per-unit operating costs by eliminating filter transport and manual analysis. However, it is not apparent that science and technology exist that can be engineered into a functional detector that meets, even marginally, the proposed performance requirements for Generation 3.

Development of a field-deployable autonomous biological aerosol threat detector that can meet appropriate performance requirements has been and continues to be a major challenge of biodefense. Over the past several decades, beginning with the DoD XM19 biodetection system that was pursued in the early 1980s, hundreds of millions of dollars have been spent in efforts to develop a functional biodetector, and the challenge remains. Yet the plans for the Generation 3 BioWatch system depend on the successful development and fielding of an automated biodetector system, both outdoors and indoors, within a relatively short period of time.

Technical Challenges

The technical challenges associated with developing a successful detector for the BioWatch program are great. Several deserve specific note.

- Distinguishing between target pathogens and near neighbors: It is estimated that only a small fraction of the microbial world has been identified, let alone cultured, characterized, and genetically sequenced. While the functional (phenotypic) effects of a human pathogen are dramatically different from a nonpathogenic near neighbor, their molecular signatures can be remarkably similar.
- Impact of the operational environment: The outdoor operational environment (e.g., temperature and humidity extremes) and the need for

a detector to function without being serviced for extended periods of time put a great engineering burden on the device.

- Coverage and cost trade-offs: The BioWatch program is emphasizing coverage of major metropolitan areas and within them, locations and special events that bring large numbers of people together. But within jurisdictions, population densities and distributions vary between workday and evening and workday and weekend. Achieving desired population coverage will require fielding many samplers and thus the costs of a system's capital equipment and operations must be extremely low to be affordable.
- Uncertainty about the characteristics of airborne biological threats: The BioWatch program currently focuses on certain specific pathogens, but the scope of potential aerosol biothreats is great. Future bioterrorism threats may include engineered agents, and recent experience has demonstrated the threat from emerging respiratory pathogens (e.g., Legionnaires' disease). Ideally, a biodetector should be readily upgradable to address novel naturally occurring and engineered biothreats.

These challenges to development of the Generation 3 BioWatch detector underscore the need for significant investments in early applied research leading to transformational innovations. Significant advances in several diverse scientific areas hold promise of converging to achieve development of the required biodetector. For example, developments in engineering research may permit creation of more robust and inexpensive detector platforms, and new communication systems and network architectures will support "smart" networks.

Opportunities also exist to refine the analysis of BioWatch air samples, but an important prerequisite is the characterization of endemic environmental organisms in and near BioWatch jurisdictions to establish background levels of both the pathogens of concern and near relatives that might cross-react in assays. With high-throughput sequencing technology rapidly filling in the genomic microbial tree of life, it is possible to refine the nucleic acid assays used in the BioWatch system to optimize their sensitivity and specificity for detection of the particular pathogens of interest. In addition, studies supported by several federal agencies are rapidly establishing relationships between organisms' molecular information (e.g., genomics, proteomics) and their pathogenicity. With this knowledge, chemical analysis of aerosol samples may provide a better basis for judging the health hazard associated with a BAR.

Operational Challenges

Significant logistical challenges need to be resolved before full fielding of the Generation 3 system. Currently, the BioWatch program has a few

hundred samplers deployed (DHS, 2008a), but intends to deploy a greater number for Generation 3. The BioWatch program, in close coordination with HHS, has to ensure that the entire BioWatch system has sufficient resources. This includes not only the air sampling equipment and laboratory analysis, but resources for all associated maintenance and upgrade capabilities, doctrine and technical procedures, the initial and sustainment training base, laboratory facilities (and their safety systems), courier services, communications and computer systems, trained staff and leadership, and a fully resourced public health response capability. Even though it may be reasonable to assume that the BioWatch Generation 3 system will alleviate some of the current analytical and logistical burdens, it is equally reasonable to assume that its complex, automated detectors will require new, specialized technical and maintenance support and personnel with appropriate training to interpret the results it produces. The total system architecture must account for all of these system components, and program budgeting must be adequate to support all aspects of the system.

Programmatic Challenges

The availability of a Generation 3 autonomous detector has the potential to provide a major advance in capability and logistics of the BioWatch system. But DHS should heed the scale of the challenge, as signaled by the considerable investments by DoD and others—with only limited progress—toward the goal of an automated detector for bioaerosol threats. Further progress in the development and deployment of the Generation 3 system for BioWatch should benefit from a strong and effective collaboration within DHS between OHA and S&T. OHA should ensure that operational needs and concerns from BioWatch jurisdictions and federal BioWatch partners are brought to the development effort, while S&T should ensure that Generation 3 development responds to both technological opportunities and hazards.

RECOMMENDATION 4: DHS should improve the level of cooperation and collaboration between its Office of Health Affairs and its Science and Technology Directorate to promote effective research and technology development in support of the BioWatch program.

Opportunities to Advance Future Biodetection Systems

The instruments and knowledge currently used in the BioWatch system have origins in and are built upon previous research in academic, industrial, and governmental institutions, supported by a wide range of agencies. For example, the APDS system that was originally proposed for use in a Genera-

tion 2.5 deployment contains components and concepts from flow injection and segmented flow analysis introduced originally for high-speed analysis of large sample populations (Bergamin et al., 1978; Ruzicka and Hansen, 1978, 1988; Ruzicka and Guebeli, 1991); microfluidic analysis system concepts introduced for multiplex analysis based on mixtures of functionalized polymer beads, each containing unique capture/receptor chemistry (Manz et al., 1992; Harrison et al., 1993; Jacobson et al., 1994a,b); fluorescence labeling to detect unique hybridization reactions which was a part of the genome sequencing chemistry (Hunkapiller et al., 1991); information technology systems; and nucleic acid amplification chemistry (Saiki et al., 1985). A foundation of support for research and the resulting advances in knowledge and technology are crucial to maintain the essential science base that will support development of next generation biothreat reduction capabilities.

A sustained research and development effort is needed to provide the scientific and technological knowledge required for effective and sustainable outdoor and indoor environmental biosurveillance in urban environments. The committee encourages DHS to work with other research funding agencies (e.g., the National Science Foundation, DoD, EPA, and HHS) to coordinate and leverage investments that will contribute to the development of less expensive and more capable environmental biosurveillance systems, including contributing to the knowledge and innovation required to engineer an autonomous environmental biodetection system.

In particular, DHS should collaborate with DoD and the National Institutes of Health to establish an applied research program to advance the state of science needed for development of an autonomous, field-deployable detector with capabilities to meet operational requirements for BioWatch Generation 3 and beyond. Research is also needed to improve the knowledge base for interpreting surveillance results, developing techniques for addressing unknown threats (i.e., emerging, re-emerging, and engineered biothreats), and applying environmental monitoring systems to surveillance for natural disease (e.g., monitoring for *Legionella*) as well as biodefense to make them more cost-effective.

DHS should also consider participation in the work being done by DoD, the National Institute of Allergy and Infectious Diseases in HHS, and the World Health Organization on host–pathogen interactions, surveillance, and epidemiologic research investigations and, as part of that effort, establish shared databases to consolidate information of value to the work of all the participants. Through research on host–pathogen interactions it may prove possible to identify genetic or molecular markers that signal virulence or antimicrobial resistance in pathogens or increased vulnerability in human hosts. This kind of information may make it possible to devise more informative detection techniques that would help public health officials maximize the effectiveness of their response plans.

A research program could consider including the BioWatch jurisdictions as study sites in a program to characterize the microbial ecology in urban areas. Objectives would include characterization of the geographic and temporal distribution of pathogen and near-neighbor populations in air and natural reservoirs (e.g., soil, lakes, and sanitary waste facilities). The BioWatch air samplers currently in use have capabilities that may be useful for such research. One priority should be full characterization of samples from BARs, but examination of the large number of other BioWatch samples may also be informative.

Results of the ongoing characterization effort and BAR follow-on studies would be included in a central database for use in the design of bioassay signatures and interpretation of BAR results. This central database could be shared with bioforensic databases, thereby bringing together knowledge derived from biosurveillance and bioforensic programs. Seroprevalence studies could help to understand current human exposures to these endemic organisms.[8] To the extent that the currently deployed BioWatch system can contribute to such research efforts, it should be seen as a resource to inform and enlarge the science and technology base from which new generations of BioWatch technologies will be derived.

As with other enhancements to BioWatch proposed by the committee, the costs and benefits of various research and development activities have to be evaluated and prioritized against the range of demands on DHS and BioWatch program resources.

RECOMMENDATION 5: As part of its response to the technical and operational challenges posed by the development and launch of Generation 3 BioWatch, DHS should collaborate with HHS, DoD, EPA, the National Science Foundation, and other agencies doing relevant work to develop and execute an aggressive research and development plan focused on (1) shorter-term goals to improve the capabilities and cost-effectiveness of the environmental monitoring for airborne biological threats performed by the BioWatch system, and (2) longer-term goals to improve the knowledge base needed to support transformational innovations in environmental biosurveillance. Work in support of shorter-term goals should focus on

- **Advancement of the state of science needed for the development of an autonomous field-deployable detector with capabilities to meet Generation 3 BioWatch operational requirements and beyond.**

[8]Seroprevalence is an indication of the proportion or number of people in a given population with antibodies in their blood indicating exposure to a particular organism.

Work supporting longer-term goals should include

- **Temporal and spatial characterization of pathogen and near-neighbor populations in air and natural reservoirs in urban areas, including those near BioWatch sites; and**
- **Participation in the work by others on host–pathogen interactions, surveillance, and epidemiologic research investigations and establishment of shared databases.**

BIOWATCH PROGRAM PLANNING AND MANAGEMENT

The preceding sections have described a series of needs and challenges facing DHS and the BioWatch program as it moves forward. In doing so, the program should be guided by strategic planning based upon program missions, goals, and objectives. The committee was very interested in whether DHS has documented overall programmatic goals, such as the number of cities (or people) the BioWatch program is intended to protect, the number of agents to detect, or the desired probabilities of detection of various kinds of aerosol releases. In response to a committee request, DHS (2008d) stated the goal noted in Chapter 2: "to establish and operate a bioaerosol monitoring capability to accurately detect the release of biological threat agents of greatest concern to the nation in locations that are at greatest risk of catastrophic consequences and to enable timely response and mitigation." Although this goal provides a high-level focus for the program, it does not provide the detail needed, or identify the spectrum of capacities required, for development, operation, and continuous improvement of such a complex activity involving diverse stakeholder groups.

The relatively weak documentation and statement of the program's goals—and associated performance metrics—may well be the result of the short time frame for the initial deployment of the BioWatch system and the infancy of DHS as a federal agency. Now, with several years of operational experience, a more mature program in a more mature agency requires more rigor in program planning and a better understanding of the goals for not only technological performance but overall system performance, including effective engagement of key partners in states and localities where the BioWatch system is deployed.

For a system to meet user needs, the users should participate in determining the goals and performance metrics. The BioWatch program management has apparently placed more emphasis on the "early detection" aspect of a bioaerosol monitoring capability than on "enabling timely response and mitigation." Facilitating response and mitigation requires cooperation among DHS, public health, and other federal partners and the integration and assessment of many different types of information. The concerns of local

decision makers, who will have to act in response to a BAR, must be taken into account to validate performance measures and program scope, enhance confidence in BioWatch results, and achieve buy-in from key partners. State and local government officials, including public health representatives, should be involved in decisions regarding all stages of BioWatch planning, deployment, maintenance, and upgrades within their jurisdictions.

The committee recognizes that DHS does plan a more concerted effort to improve the relationship between the BioWatch program's management and its federal, state, and local partners. DHS should produce a formal acknowledgement of this commitment and follow through with its implementation.

The BioWatch program needs both a stronger information base and better and more systematic input, analysis, and evaluation on an ongoing basis. The committee is encouraged by the more systematic and technically rigorous approach to planning and technical evaluation proposed for Generation 3. DHS should also take this opportunity to incorporate risk-assessment and risk-management approaches into its planning for the BioWatch program. Such an evaluation should include a reexamination of the agents to include in the monitoring program, the selection of jurisdictions, the location of air samplers or detectors within jurisdictions, and even the justification for the existence of the program. In the context of the program's goals, analytical tools should be brought to bear to aid in decision making each time DHS considers a significant change regarding a technology or process.

In particular, DHS should make use of its biennial Bioterrorism Risk Assessment (BTRA) in assessing the BioWatch system. But the concerns about the 2006 BTRA that were noted in a recent NRC report should be resolved (NRC, 2008b). Using an improved BTRA, DHS should model scenarios and assess risks, and apply this information in its decision making about, and continuous evaluation of, the BioWatch program. Indeed, DHS appears to have applied these principles in its initial decision making in planning for the demonstration of the APDS (Hooks, 2008a).

Such an approach might include an examination of the most effective applications of the BioWatch system. DHS might, for example, consider whether special event monitoring would be more effective than constant monitoring, or whether focusing on transportation hubs would be better than attempting comprehensive coverage of localities. Any plans to add biological agents to the set to be monitored by the BioWatch system should include an assessment of whether analytical challenges will be encountered because of natural background levels of these biological agent signatures or the presence of other interferents. The committee did not receive evidence that DHS has factored such analyses into most decision making for the BioWatch program.

Finally, just as the committee advocates rigorous analysis of the costs and benefits of existing plans for BioWatch 2 and 3, it also advocates that any further work based on the recommendations in this report, or through other research and development efforts, be subjected to thorough scrutiny of the associated costs and benefits.

RECOMMENDATION 6: DHS should use its existing and periodically conducted bioterrorism risk assessment and other analyses to evaluate the overall effectiveness of the BioWatch system, examine the costs and benefits of the system's current configuration and significant proposed changes, and articulate its program goals and associated performance metrics, using risk-assessment and risk-management principles. To accomplish this, DHS should

- **Actively solicit input from and collaborate closely on all aspects of the program with key partners and stakeholders at the federal, state, and local levels; and**
- **Conduct comprehensive modeling and analysis to evaluate the potential contributions of the BioWatch system to public health decision making and outcomes using, where appropriate, a Bioterrorism Risk Assessment (BTRA) that has been modified according to the recommendations in a 2008 NRC report. Such analyses should be performed for *all* pathogens for which BioWatch will test and for both outdoor and indoor monitoring programs.**

In the committee's view, the BioWatch program has suffered from too little input from outside experts who can bring broader perspectives to bear. Obtaining advice from an independent panel, consisting of members with a mix of technical and operational expertise, would enhance the BioWatch program. Such an external advisory panel would provide specific analyses and recommendations on the BioWatch program's technology upgrades, planning, and operations. Panel members could also receive, and relay back to their constituencies, information about pertinent research and development activities.

The advisory panel should bring to DHS expertise in epidemiology, environmental health, public health laboratory systems, meteorology, infectious diseases, biochemistry, genetics, law enforcement, emergency management, detection technology, systems engineering, decision and information science, and operations research. Among the members should be state and local officials responsible for responding to a BAR.

To further coordination and communication between DHS and HHS, the advisory panel should report jointly to both secretaries. The committee anticipates that the input from the advisory panel would lead to improved collabo-

ration among the state- or local-level constituents of the lead federal agencies, which would improve working relationships between those responsible for implementing environmental sampling technologies and those responsible for acting on the information that such sampling produces. It could also lead to better communication at all stages in the BioWatch implementation process, including selection of participating cities, identification of monitoring sites, ongoing program operation, and response planning and evaluation.

The BioWatch program is already benefiting from the work of some advisory groups. The BioWatch Technical Advisory Committee (BTAC), for example, consists of federal experts with backgrounds in microbiology and engineering from DHS (OHA and S&T) and CDC who provide DHS with technology input. But this group lacks sufficient breadth of expertise and the external perspectives that the BioWatch program needs. DHS also benefits from the work of the Stakeholder Panel on Agents for Detection Assays (SPADA), which is developing voluntary consensus standards for the collection and analysis of environmental samples of biothreat agents.[9] DHS and HHS need such external expert input for all aspects of the BioWatch system.

RECOMMENDATION 7: DHS and HHS should jointly establish a formal mechanism for receiving ongoing *external* advice on all technical and operational issues related to the BioWatch system. The advisory panel should include both technical experts and state and local officials who have experience working with the BioWatch system and would have decision-making roles in the event of a BAR.

REFERENCES

AOAC (Association of Analytical Communities). 2008. *Much accomplished, much to do: SPADA update*. http://www.aoac.org/ILM/jan_feb_08/spada.htm (accessed April 8, 2009).

Argonne National Laboratory. 2008. *Software package coordinates response to biological threats*. http://www.dis.anl.gov/publications/fact_sheets/BWIC_FactSheet.pdf (accessed June 17, 2009).

Bergamin, H., E.A. Zagatto, F.J. Krug, and B.F. Reis. 1978. Merging zones in flow injection analysis: Part 1. Double proportional injector and reagent consumption. *Analytica Chimica Acta* 101(1):17–23.

Brown, M.J., M.D. Williams, G.E. Streit, M. Nelson, and S. Linger. 2006. *An operational event reconstruction tool: Source inversion for biological agent detectors*. 86th American Meteorological Society Annual Meeting. Atlanta, GA. http://ams.confex.com/ams/pdfpapers/126686.pdf (accessed July 9, 2009).

[9]SPADA is an expert review panel organized by the Association of Analytical Communities at the request of DHS. Its members are drawn from the federal government, state governments, academia, and the private sector (AOAC, 2008).

CDC (Centers for Disease Control and Prevention). 2002. *Comprehensive procedures for collecting environmental samples for culturing* Bacillus anthracis. http://emergency.cdc.gov/agent/anthrax/environmental-sampling-apr2002.asp (accessed July 9, 2009).

CDC. 2004. Responding to detection of aerosolized *Bacillus anthracis* by autonomous detection systems in the workplace. *Morbidity and Mortality Weekly Report* 53(RR-7):1–11.

Chadwick, S.H. 2007. *Defense acquisition: Overview, issues, and options for Congress*. RL34026. Washington, DC: Congressional Research Service. https://www.policyarchive.org/bitstream/handle/10207/18699/RL34026_20070604.pdf?sequence=2 (accessed August 5, 2009).

Chow, F.K., B. Kosovič, and S. Chan. 2008. Source inversion for contaminant plume dispersion in urban environments using building-resolving simulations. *Journal of Applied Meteorology and Climatology* 47:1553–1572.

Delle Monache, L., J.K. Lundquist, B. Kosovič, G. Johannesson, K.M. Dyer, R.D. Aines, F.K. Chow, R.D. Belles, W.G. Hanley, S.C. Larsen, G.A. Loosmore, J.J. Nitao, G.A. Sugiyama, and P.J. Vogt. 2008. Bayesian inference and Markov Chain Monte Carlo sampling to reconstruct a contaminant source on a continental scale. *Journal of Applied Meteorology and Climatology* 47:2600–2613.

DHS (Department of Homeland Security). 2007a. *Homeland security exercise and evaluation program. Vol. III: Exercise evaluation and improvement planning*. Washington, DC: DHS. https://hseep.dhs.gov/support/VolumeIII.pdf (accessed July 1, 2009).

DHS. 2007b. *Target capabilities list: A companion to the National Preparedness Guidelines*. Washington, DC: DHS. https://www.llis.dhs.gov/docdetails/details.do?contentID=26724 (accessed July 1, 2009).

DHS. 2008a. *Annual performance report, fiscal years 2007–2009*. Washington, DC: DHS. http://www.dhs.gov/xlibrary/assets/cfo_apr_fy2007.pdf (accessed August 5, 2009).

DHS. 2008b. *BioWatch Gen-3 autonomous detection system: Operational requirements document*. December 11. Washington, DC.

DHS. 2008c. *BioWatch outdoor program: Guidance documents for BioWatch jurisdictions*. Washington, DC: DHS.

DHS. 2008d. *NAS information request #2, DHS OHA written responses*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, October 31, Washington, DC.

DHS. 2009a. *BioWatch Gen-3 industry day*. https://www.fbo.gov/download/18d/18d10ae7b9c2106327715c7a5dc53c43/BiowatchGen3_Industry-Day_Slides.pdf (accessed March 24, 2009).

DHS. 2009b. *BioWatch Gen-3 request for proposal*: *HSHQDC-09-R-00045*. https://www.fbo.gov/download/54e/54e9ae25a4a9d2d39a9e9e836955001f/HSHQDC-09-R-00045_(5-27-2009).pdf (accessed August 5, 2009).

DHS. 2009c. *BioWatch Gen-3—Request for proposals: HSHQDC-09-R-00045*. Attachments J.1–J.5 and J.7–J.9. Washington, DC: DHS. https://www.fbo.gov/download/c38/c38d6b04219a2594558239806721149 9/HSHQDC-09-R-00045_(Attachments_J_1__J_2__J_3__J_4__J_5__J_7__J_8__J_9).pdf (accessed August 5, 2009).

DHS. 2009d. *Department of Homeland Security annual performance report, fiscal years 2008–2010*. Washington, DC: DHS. http://www.dhs.gov/xlibrary/assets/cfo_apr_fy2008.pdf (accessed June 17, 2009).

DoD (Department of Defense). 2006. *Defense acquisition guidebook*. http://www.acq.osd.mil/sse/pg/guidance.html (accessed July 9, 2009).

Downes, F.P. 2008. *Testimony before the Committee on Homeland Security, U.S. House of Representatives, July 16*. http://homeland.house.gov/SiteDocuments/20080716143630-34598.pdf (accessed June 18, 2009).

Dvorak, P. 2005. Health officials vigilant for illness after sensors detect bacteria on Mall. *The Washington Post*, Sunday, October 2, C13. http://www.washingtonpost.com/wp-dyn/content/article/2005/10/01/AR2005100101209_pf.html (accessed April 21, 2009).

EPA (Environmental Protection Agency). 2008. *Standardized analytical methods for environmental restoration following homeland security events*. Revision 4.0. EPA/600/R-04/126D. Cincinnati, OH: EPA. http://www.epa.gov/nhsrc/pubs/600r04126d.pdf (accessed July 10, 2009).

GAO (Government Accountability Office). 2007. *Anthrax detection: DHS cannot ensure that sampling activities will be validated*. GAO-07-687T. Washington, DC: GAO. http://www.gao.gov/new.items/d07687t.pdf (accessed August 5, 2009).

GAO. 2008a. *Biosurveillance: Preliminary observations on Department of Homeland Security's biosurveillance initiatives*. GAO-08-960T. Washington, DC: GAO. http://www.gao.gov/new.items/d08960t.pdf (accessed August 5, 2009).

GAO. 2008b. *Homeland security: First responders' ability to detect and model hazardous releases in urban areas is significantly limited*. GAO-08-180. Washington, DC: GAO. http://www.gao.gov/products/GAO-08-180 (accessed July 9, 2009).

GAO. 2009. *Defense acquisitions: Assessments of selected weapon programs*. GAO-09-326SP. Washington, DC: GAO. http://www.gao.gov/new.items/d09326sp.pdf (accessed August 5, 2009).

Harrison, D.J., K. Fluri, K. Seiler, Z. Fan, C.S. Effenhauser, and A. Manz. 1993. Micromachining a miniaturized capillary electrophoresis-based chemical analysis system on a chip. *Science* 261(5123):895–897.

Hooks, R. 2008a. *APDS block-1 deployment strategy*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, September 19, Washington, DC.

Hooks, R. 2008b. *BioWatch program*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31. Washington, DC.

HSARPA (Homeland Security Advanced Research Projects Agency). 2003. *Detection systems for biological and chemical countermeasures*. RA 03-01. Washington, DC: Department of Homeland Security. https://baa.st.dhs.gov/Solicitations/HSARPA_RA-03-01_Body.pdf (accessed July 16, 2009).

Hunkapiller, T., R.J. Kaiser, B.F. Koop, and L. Hood. 1991. Large-scale and automated DNA sequence determination. *Science* 254(5028):59–67.

IEc (Industrial Economics, Incorporated). 2009. *Revised estimated cost of BioWatch generations 2 and 3*. Commissioned paper. Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Washington, DC.

Jacobson, S.C., R. Hergenrider, L.B. Koutny, R.J. Warmack, and J.M. Ramsey. 1994a. Effects of injection schemes and column geometry on the performance of microchip electrophoresis devices. *Analytical Chemistry* 66(7):1107–1113.

Jacobson, S.C., L.B. Koutny, R. Hergenroeder, A.W. Moore, and J.M. Ramsey. 1994b. Microchip capillary electrophoresis with an integrated postcolumn reactor. *Analytical Chemistry* 66(20):3472–3476.

Keats, A., E. Yee, and F.-S. Lien. 2007. Bayesian inference for source determination with applications to a complex urban environment. *Atmospheric Environment* 41(3):465–479.

Kuske, C. 2005. Analysis of pathogen backgrounds in soils and EPA aerosol samples. Report No. LA-UR-04-3191. Los Alamos, NM: Los Alamos National Laboratory.

Kuske, C.R., S.M. Barnes, C.C. Grow, L. Merrill, and J. Dunbar. 2006. Environmental survey for four pathogenic bacteria and closely related species using phylogenetic and functional genes. *Journal of Forensic Science* 51(3):548–558.

Lindley, C. 2009. *BioWatch actionable result response: 2008 Democratic National Convention, August 28, 2008*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, February 19, Washington, DC.

Manz, A., D.J. Harrison, E.M. Verpoorte, J.C. Fettinger, A. Paulus, H. Ludi, and H.M. Widmer. 1992. Capillary electrophoresis and sample injection systems integrated on a planar glass chip. *Journal of Chromatography* 593(1–2):253–258.

NRC (National Research Council). 2008a. *A framework for assessing the health hazard posed by bioaerosols*. Washington, DC: The National Academies Press.

NRC. 2008b. *Department of Homeland Security Bioterrorism Risk Assessment: A call for change*. Washington, DC: The National Academies Press.

NRC. 2008c. *Test and evaluation of biological standoff detection systems*. Washington, DC: The National Academies Press.

Rao, K.S. 2007. Source estimation methods for atmospheric dispersion. *Atmospheric Environment* 41:6964–6973.

Ruzicka, J., and T. Guebeli. 1991. Principles of stopped-flow sequential injection analysis and its application to the kinetic determination of traces of a proteolytic enzyme. *Analytical Chemistry* 63(17):1680–1685.

Ruzicka, J., and E.H. Hansen. 1978. Flow injection analysis: Part X. Theory, techniques and trends. *Analytica Chimica Acta* 99(1):37–76.

Ruzicka, J., and E.H. Hansen. 1988. *Flow injection analysis,* 2nd ed. New York: Wiley & Sons.

Saiki, R.K, S. Scharf, F. Faloona, K.B. Mullis, G.T. Horn, H.A. Erlich, and N. Arnheim. 1985. Enzymatic amplification of beta-globin genomic sequences and restriction site analysis for diagnosis of sickle cell anemia. *Science* 230(4732):1350–1354.

Senocak, I., N.W. Hengartner, M.B. Short, and W.B. Daniel. 2008. Stochastic event reconstruction of atmospheric contaminant dispersion using Bayesian inference. *Atmospheric Environment* 42:7718–7727.

Yee, E. 2008. Theory for reconstruction of an unknown number of contaminant sources using probabilistic inference. *Boundary-Layer Meteorology* 127:359–394.

4

Detecting Biological Threats Through the Public Health and Health Care Systems: Current Status

Part of the charge to the committee was to "[d]escribe the characteristics of an 'enhanced national surveillance system' that relies on U.S. hospitals and the U.S. public health system." To provide a snapshot of the nation's current capability to detect outbreaks of infectious disease, this chapter focuses on local, state, and federal public health agencies, which have the lead responsibility for disease surveillance, investigation, and response. This chapter also describes the role of health care providers, hospitals, and other health care organizations in disease surveillance. Chapter 5 examines areas where surveillance for bioterrorism and infectious diseases might be enhanced.

In practice, the same surveillance capacities would support detection and monitoring of epidemics, regardless of whether they arise from an act of bioterrorism, from natural factors, or from the consequences of actions such as a failure to observe safe food handling or processing procedures. The committee did not review all of public health surveillance, which includes monitoring a wide spectrum of infectious and noninfectious diseases, injuries, behavioral risk factors, and other conditions; nor did it review all of biosurveillance, which includes monitoring for human diseases and animal or plant diseases and other biosphere conditions that may affect human health.

FRAMEWORK FOR INFECTIOUS DISEASE SURVEILLANCE

In the United States, state and local public health agencies have the authority and responsibility for carrying out most public health actions. Their responsibilities include disease surveillance, and they are the lead re-

sponders to public health emergencies in their jurisdictions. This allocation of responsibility reflects the fact that protection of public health was not established as a federal function in the Constitution and is therefore reserved to the states. However, the federal government has acquired public health responsibilities over the years, including acting in support of state and local public health agencies. A bioterrorism event, or other significant health emergency, will likely be met with a multiagency and multilevel response that includes participation by law enforcement and emergency management in addition to public health agencies. Federal roles and responsibilities in working with states and localities in the event of a major disaster or public health emergency are outlined annexes to the National Response Framework (FEMA, 2008a,b).

To ensure the broadest surveillance capabilities, health departments depend on receiving information from health care, occupational settings, environmental monitoring, and other sources, with the health care sector being the most critical source. Accordingly, a major determinant of the effectiveness of disease surveillance is the capacity of health care providers in various settings—hospitals, outpatient practices, and laboratories—to collect and report relevant information to public health authorities. Equally important is the capacity of public health agencies to receive and compile the data, conduct analyses, interpret the results, report the findings to constituents, and mount a timely and appropriate response when the data indicate a need for further investigation or public health intervention. Figure 4-1 illustrates in a generic fashion the basic flow of information for surveillance for significant infectious disease threats.

Especially in the event of an outbreak associated with a highly pathogenic organism or a bioterrorist attack, the capacity to act promptly in response to surveillance alerts is crucial to mitigate morbidity and mortality. But surveillance systems aimed at detecting outbreaks quickly must be calibrated in a way that effectively balances the inherently competing demands for timely recognition of outbreaks that merit public health intervention and for avoidance of excessive false alarms that may consume public health and health care resources for investigations, or even lead to an inappropriate and potentially dangerous response.

SURVEILLANCE OF INFECTIOUS DISEASES

Surveillance refers to an ongoing process of systematic collection, analysis, interpretation, and dissemination of health data that can be used to plan, implement, and evaluate appropriate medical and public health interventions (Thacker and Berkelman, 1988). Surveillance for the health effects of bioterrorism is generally integrated with other public health surveillance systems aimed at detecting the full range of infectious disease threats.

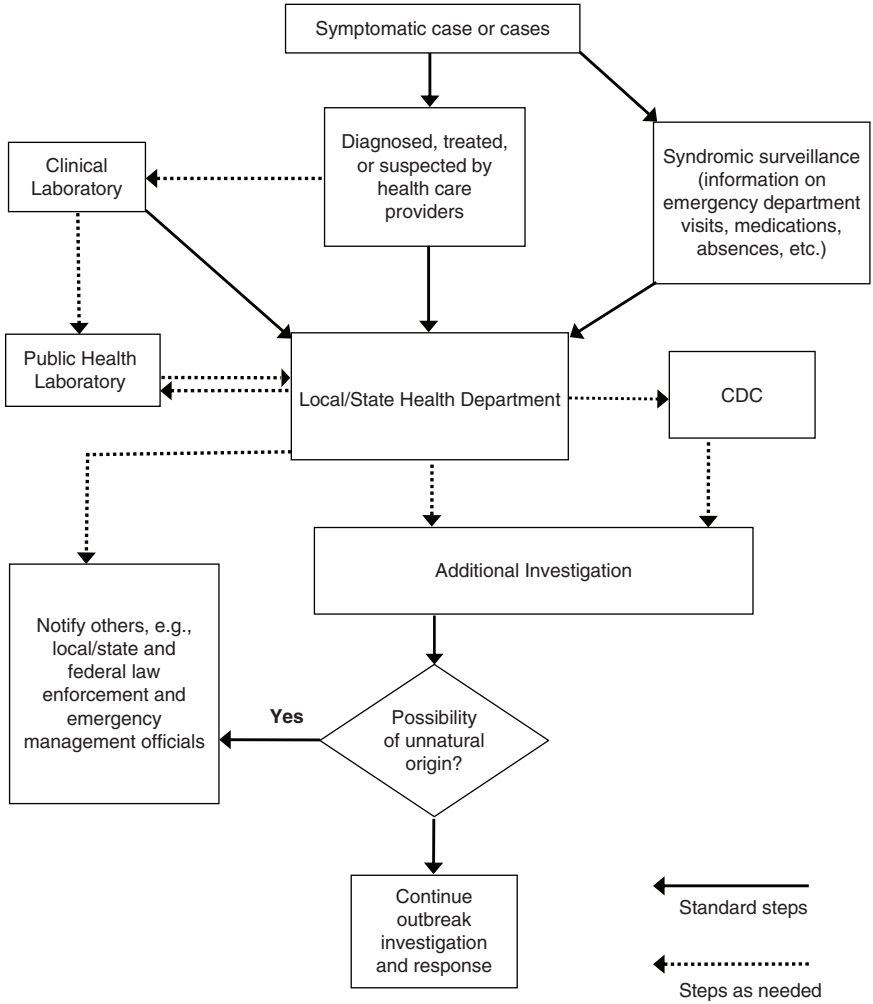


FIGURE 4-1 Simplified depiction of information flow in outbreak detection and reporting through the public health and health care systems. As a generic diagram, this figure shows core elements of the generation, capture, and analysis of and response to information on human health and tests of human specimens that are used to detect disease outbreaks. It does not attempt to convey all aspects of the information capture, analysis, and reporting or possible variations in the depicted pathways that may be used in this process or that are described in the text. This figure represents information flow stemming from human cases only; Figure 6-1 illustrates other important sources of surveillance information (e.g., monitoring environmental hazards or animal health) that may be used to detect bioterrorism or infectious disease outbreaks.

Traditionally, *case reporting by health care professionals* has been the mainstay of public health surveillance for the infectious diseases that states designate as reportable and other indications of disease outbreaks of concern. Because the criteria for confirming cases of reportable diseases typically include evidence of illness combined with laboratory-based documentation of specific infections, *timely laboratory reporting* of positive test results or cultures is also important and required by state health departments. Clinical and laboratory information may be combined with additional epidemiologic data, such as demographic data or information on possible exposures, to complete the case reporting process.

In the past decade, a number of local, state, and federal efforts to detect outbreaks through the collection and analysis of data on relatively nonspecific disease-related indicators, often called *syndromic surveillance*, have been launched (Buehler et al., 2008). Syndromic surveillance looks toward statistical signals of increases in the incidence of symptom complexes (e.g., diarrhea), use of health care services, or sales of over-the-counter medications (e.g., antidiarrheals) as indicators of potential disease epidemics. Another area of recent effort is combining and comparing data streams from different sectors to detect or interpret indications of a potential health emergency, or what is called biosurveillance *data integration* or *information fusion*.

Disease Reporting Requirements

Every state and territory has laws or regulations, or both, requiring the reporting of suspect or confirmed cases of specific diseases and other conditions to public health authorities. In addition, these laws typically mandate reporting of recognized disease outbreaks, regardless of whether they are the result of conditions listed as notifiable. Once disease reports are received by local health officials, actions may include verifying the diagnosis, investigating the sources of infection, ensuring appropriate treatment and infection control, identifying and providing appropriate care to contacts, and sometimes additional active case finding to assess the presence of additional cases in the community.

The states' lists of reportable diseases vary, reflecting differences in the geographic distribution and importance of some conditions (e.g., certain insect-borne diseases). The combined total includes approximately 90 diseases.[1] In terms of detecting cases of potential bioterrorism, all states require reporting of any cases of anthrax, botulism, tularemia, and brucel-

[1]The composite list of diseases reportable to state health departments is available at http://www.cdc.gov/ncphi/disss/nndss/phs/files/NNDSS_event_code_list_January_2009_CLEARED.pdf.

losis. All but one requires reporting of any cases of plague, and all but five any cases of smallpox.[2]

The authority for mandating disease reporting resides at the state and local level, but the state-based systems are harmonized at the national level by a voluntary set of reporting criteria and case definitions established by the Council of State and Territorial Epidemiologists (CSTE) and the federal Centers for Disease Control and Prevention (CDC). These arrangements allow CDC to collect reports of cases of specified diseases (without identifying information for individual patients) via the National Notifiable Diseases Surveillance System (NNDSS) for use in tracking and investigating regional- and national-level trends. The NNDSS encompasses the listing of nationally notifiable diseases, case definitions, and a system for transmitting case reports from local to state public health agencies to CDC. Currently, approximately 70 infectious diseases are designated as nationally notifiable.[3] The list of these diseases is maintained and updated annually by CSTE in collaboration with CDC.

The National Electronic Telecommunications System for Surveillance (NETSS) is the current CDC mechanism that the 50 state health departments, New York City, the District of Columbia, and five U.S. Territories use to submit weekly reports of cases of nationally notifiable diseases.[4] Since 1999, CDC has been developing and deploying the National Electronic Disease Surveillance System (NEDSS), an Internet-based system for automatically capturing and analyzing surveillance data that are already in electronic form, such as reports from many clinical laboratories (CDC, 2008b, 2009e). NEDSS is expected to replace NETSS and several other CDC surveillance systems.[5] NEDSS seeks to facilitate the collection and interoperable use of case information from providers through vocabulary and transmission standards. A 2007 survey found that states are using a mix of software systems, with 13 states having established some interoperability across at least two surveillance modules (CSTE, 2008). At the time of the survey, 27 states were still acquiring necessary hardware and software. Funding was cited as an important obstacle to progress in implementing NEDSS (CSTE, 2008).

Case Reporting from the Health Care System

Physicians, nurses, and other health care workers see individuals seeking care for a health problem. The clinician provides a diagnosis based on

[2]The list of notifiable diseases reported by state is at http://www.cdc.gov/ncphi/disss/nndss/phs/files/SRCA_FINAL_REPORT_2007.xls.

[3]The list of nationally notifiable infectious diseases is available at http://www.cdc.gov/ncphi/disss/nndss/phs/infdis2009.htm.

[4] See http://www.cdc.gov/ncphi/disss/nndss/netss.htm.

[5] See http://www.cdc.gov/NEDSS/.

history, physical examination, general observations, laboratory and radiologic tests, and other information. If the suspected or confirmed diagnosis is of a legally reportable disease, the health care provider is required to report it to the local or state health department. Similarly, if a laboratory performs a test diagnostic of a reportable condition, it is required to make a report. (The role of the laboratory is discussed below.)

Diagnosis and Reporting by Health Care Providers

Reporting by health care providers is one of the essential sources of information used to recognize or determine that a disease outbreak is occurring. An analysis of 43 disease outbreaks reported in *Morbidity and Mortality Weekly Report* in 1999 and 2000 found that information generated by the clinical health care system (defined in the study as nongovernment hospitals, physicians, pharmacists, and laboratories) was used in detecting 72 percent of the outbreaks, while detection of several others resulted from reports from other settings, including schools, prisons, and STD clinics (Dato et al., 2004).[6] The same researchers drew from other sources to examine the initial detection of outbreaks of Lyme disease, Legionnaires' disease, AIDS, hantavirus pulmonary syndrome, and SARS. The recognition of each of these newly emerging diseases involved reports from "astute" clinicians or other individuals who noted an unusual manifestation or clustering of disease (Dato et al., 2004).

Reporting of certain diseases is relatively prompt and complete, but it is well established that clinicians do not always remember to report the required diseases or to report them in a timely fashion (Doyle et al., 2002; Jajosky and Groseclose, 2004). They may simply be too busy to stop what they are doing, not know that the condition they have just diagnosed is reportable, or assume that a laboratory or infection control professional will report the case. In hospitals, infection control professionals usually report notifiable diseases, and with their targeted responsibility, their reporting tends to be more complete. However, most outpatient and ancillary health settings lack these focused professionals.

Several factors limit the effectiveness of provider reporting for early detection of bioterrorism. Reporting cannot occur until an infected patient becomes ill and seeks medical attention, and some individuals may not seek care. For those who do, arriving at a clinical facility involves a period of examination, testing, and diagnosis. If a patient is one of the first cases in a community, an atypical disease may be more difficult to diagnose,

[6]Another study found that health care providers reported 25 percent of 1,099 outbreaks worldwide between 1988 and 1999, infection control practitioners reported 12 percent, and health departments reported 31 percent (Ashford et al., 2003).

and assessment and testing may take longer than usual. Clinicians may misdiagnose the patient, especially when the disease in question is rare, the clinical setting is extremely busy, the treating clinician typically manages a wide range of clinical problems, or the clinical staff are subject to frequent interruptions. These characteristics are commonly encountered in hospital emergency departments (EDs), which are increasingly used by the public for same-day or after-hours acute care. A diagnosis may also be missed or delayed if diagnostic laboratory tests are not done.

CDC and many state and local health departments have produced pocket cards and posters about case reporting for distribution to clinicians, and several professional organizations have developed short courses and other educational programs to maintain awareness of the clinical signs and symptoms of diseases caused by potential bioterrorism agents. Although such offerings may transiently increase practitioner knowledge, it is not clear that they have a sustained impact on the knowledge or behavior of health care providers.

In many jurisdictions, case reporting is still done with paper forms that are mailed or faxed. But reporting by telephone may be specified for diseases requiring the most rapid investigation or response. Regardless of how it is reported, a single report of a disease of special concern, such as inhalation anthrax or other infection associated with bioterrorism, is likely to trigger an immediate investigation. The advances in information technology are making it possible for health departments to provide Internet-based reporting systems to replace paper forms, often making it easier and faster to file a report.

Generally, however, scant resources are being directed towards strengthening the completeness, sensitivity, timeliness, and accuracy of provider reporting. Because traditional public health surveillance is heavily dependent on timely diagnosis and reporting by front-line health care providers and laboratory personnel, additional efforts are required to facilitate the performance of this essential task. For example, the future availability of well-tested clinical decision support systems may improve timeliness and accuracy of diagnoses, especially in busy EDs and other inpatient services, which are likely to first encounter the seriously ill. Increased educational outreach by health departments may make clinicians more aware of reporting requirements and reportable diseases.

In addition to improving health care providers' awareness and compliance with reporting requirements, it is equally important that every health department have trained public health professionals designated to receive reports by telephone at all times. These individuals should be capable of handling queries about disease recognition, confirmatory diagnosis, infection control, and public health management, and they should also be able to quickly identify a subject matter expert if necessary. In a 2006 study,

however, less than a third of a sample of local health departments were able to connect a caller with an urgent case report to an appropriate public health professional within 30 minutes (Dausey et al., 2008).

Automated Surveillance Using Electronic Medical Records

As electronic medical records and electronic health information exchange become more common and more robust, these resources are also being used to support identification of reportable conditions. For example, Klompas and colleagues have piloted a system for automated detection and reporting of notifiable diseases using electronic medical records (EMRs) (Klompas et al., 2008; Lazarus et al., 2009). They report that EMR-based detection and notification of the four notifiable diseases they examined is more timely, complete, and clinically detailed than traditional reporting. The program scans the EMR for combinations of diagnoses, symptoms, physical signs, and laboratory results to detect likely cases of reportable conditions and alerts and assists clinical staff to report these if warranted.

CSTE, under contract with CDC, is now identifying standardized codes from ICD-9 and ICD-10, SNOMED, and LOINC that correspond to each of the required elements of a case report.[7] Although many challenges remain in operationalizing automated record and reporting systems, this work should facilitate faster and more complete detection and transmission of case reports based on information from EMRs, laboratory information systems, and regional health information exchanges.

Laboratory Reporting

In the process of establishing diagnoses, clinicians often have laboratory tests performed. These tests are performed by a mix of clinical, commercial, and public health laboratories. Most states mandate that definitive test results that are diagnostic of a reportable disease be reported directly from laboratories to public health authorities. In fact, laboratories are responsible for a much larger share of mandated case reporting than clinicians.

The generation of complete, accurate, reliable, and timely laboratory data is very important in surveillance. With laboratories required to report certain results directly to state (and some local) health departments, public health decision makers may have access to the information before the

[7]ICD-9 and ICD-10 refer to versions of the International Classification of Diseases, which provide a set of codes used to classify mortality data. Morbidity data are coded according to a separate clinical modification if the ICD code sets. SNOMED (Systematized Nomenclature of Medicine) and LOINC (Logical Observation Identifiers Names and Codes) are sets of standardized codes and terminology used to aid in exchanging and pooling clinical information.

clinician is able to use it to make a diagnosis and report it. However, since some the most common conditions, such as acute diarrhea, are often treated symptomatically, laboratory diagnosis is not always pursued, particularly as rising health care costs have resulted in efforts to limit unneeded tests.

Many laboratories use electronic laboratory information systems (LISs), which create the potential for electronic laboratory reporting (ELR) automatically between LISs and public health disease surveillance systems. ELR systems have improved both the timeliness and completeness of reporting for some diseases (e.g., Nguyen et al., 2007; CDC, 2008d; Moore et al., 2008; Overhage et al., 2008). Currently, at least 44 states have the capability for electronic laboratory reporting to the health department (TFAH, 2008).

ELR typically involves the creation of a unique interface between each laboratory and each public health surveillance program, which is often a costly and time-consuming barrier. As laboratory results are increasingly delivered to multiple users through community-wide electronic health information exchanges, the need for multiple interfaces is reduced and new opportunities are created to facilitate the speed and completeness of ELR transactions. For example, the Indiana Health Information Exchange has documented that the exchange could produce a major increase in the volume of laboratory reporting over that performed spontaneously by laboratory personnel (Overhage et al., 2008).

ELR has been found to be more timely and complete than paper reporting (Effler et al., 1999; Overhage et al., 2008), but this may not necessarily hold true for all conditions (Nguyen et al., 2007; CDC, 2008d). Electronic laboratory reports generally increase the ascertainment of conditions (and thus number of reports) at health departments, but these reports often lack demographic and clinical information. The end result can be a greater burden on public health agency personnel for case follow-up. Some intentional reductions in system sensitivity have been made to reduce false alarms (CDC, 2008a,d). In addition, ELR may not simplify reporting for diseases for which multiple tests must be evaluated, and it may generate misleading reports because of coding problems and inconsistencies (Nguyen et al., 2007).

Public Health Reference Laboratories and Molecular Epidemiology

State public health laboratories, and some local public health laboratories, often serve as reference laboratories for definitive characterization of microbial pathogens. Increasingly clinical specimens also now undergo phenotypic analysis or genetic "fingerprinting" using tools such as pulsed-field gel electrophoresis, insertion segment analysis, and nucleotide sequencing, the results of which can be compared to databases of other isolates around

the nation or world. This has allowed cases of illness to be linked to common sources that would otherwise have gone unnoticed (e.g., Malakmadze et al., 2005), and it underlies the detection and characterizations of several recent national and international outbreaks of food-related disease (e.g., CDC, 2008c, 2009d). Similar tools were used to trace the October 2001 anthrax attack strains to a strain of anthrax stored in one particular federal facility.

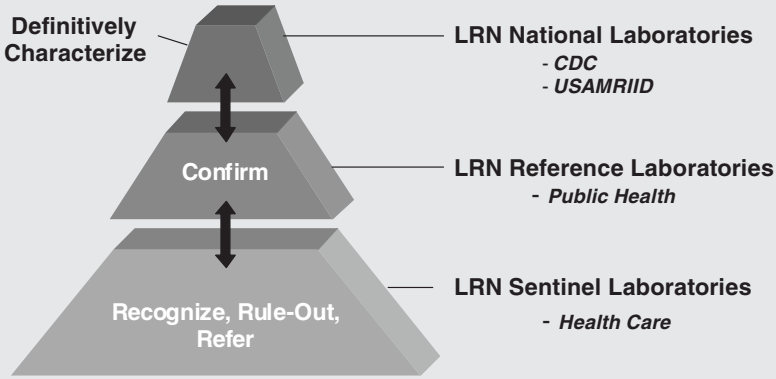
Given the importance of prompt and capable laboratory diagnostics for conditions of public health and bioterrorism concern, the Laboratory Response Network (LRN) was established in 1999 to improve and sustain diagnostically and biosafety-proficient reference laboratories across the nation. The LRN resulted from the collaborative effort of the CDC, the Association of Public Health Laboratories, and the Federal Bureau of Investigation. More than 160 laboratories, at least one in each state, are part of the LRN, and they include hospital- and community-based "sentinel" laboratories, state and local public health reference laboratories, and national laboratories for highly specialized reference needs (see Box 4-1).

Syndromic Surveillance

Syndromic surveillance refers to surveillance methods that monitor disease syndromes, such as influenza-like or diarrheal symptom complexes, or other illness-associated behavior using data from ED or clinic visits, medication purchases, 9-1-1 calls, and work or school absenteeism (Mandl et al., 2004; Buehler et al., 2008). Another approach described recently involves assessing the frequency and nature of Internet searches for health-related information (Polgreen et al., 2008; Ginsberg et al., 2009). The rationale for syndromic surveillance is that it may provide warning of intentional or natural disease outbreaks earlier than traditional methods of surveillance that rely on disease diagnosis. Syndromic surveillance has been established rapidly and across large geographies for detection and tracking of rapidly moving emerging diseases (Foldy et al., 2004). Such systems can also be used to monitor a spectrum of infectious diseases, including seasonal respiratory and gastrointestinal viral illnesses, and health concerns other than infectious diseases (e.g., to examine changes in smoking cessation [Henning, 2004], falls [Dey et al., 2008], or respiratory illness associated with smoke exposure from wildfires). Thus, syndromic surveillance offers agility and multifunctionality often lacking in other surveillance methods (Olson et al., 2007; Buehler et al., 2009).

Since the 2001 anthrax attacks, syndromic surveillance has become widespread, with use reported by more than 80 percent of the respondents to a survey of the health departments in the states, territories, the District of Columbia, and three large metropolitan jurisdictions (Buehler et al., 2008).

BOX 4-1
National Biosurveillance System:
Laboratory Response Network



Local health care laboratories in hospitals and clinics and large commercial laboratories serve as LRN Sentinel Laboratories. All state public health laboratories and several large local public health laboratories serve as LRN Reference Laboratories. Both sentinel laboratories and reference laboratories work closely with CDC laboratories and programs to conduct standardized testing for the detection and confirmation of pathogens that threaten public health, including bioterrorism agents.

Sentinel laboratories are at the front line for detecting infectious disease threats. They are trained by LRN Reference Laboratories to use standardized rule-out tests. If a sentinel laboratory suspects that a biological isolate from a patient may be an agent of bioterrorism (because the possibility cannot be ruled out), the laboratory immediately contacts the nearest LRN Reference Laboratory and transfers the agent to the reference facility for identification. If the LRN Reference Laboratory is unable to identify the isolate, it or the original specimen is sent to the CDC for definitive testing. Currently, more than 150 LRN laboratories are capable of submitting messages to CDC for all LRN assays using the LRN Results Messenger (CDC, 2009c). As described in Chapter 2, certain LRN Reference Laboratories are part of the BioWatch system.

NOTE: USAMRIID, U.S. Army Medical Research Institute of Infectious Diseases.

Syndromic surveillance is typically built on existing electronic streams of health information, including ED registration, medical record, pharmacy, and billing data. Once mechanisms are established for identifying data of interest and transmitting it to a health department or other designated recipient, the costs of collecting such electronic data are modest and decreasing per unit of information.

A number of states and local jurisdictions use such systems as Real-time Outbreak and Disease Surveillance (RODS),[8] the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Lombardo et al., 2003), or a system they have developed themselves (GAO, 2008b). In the absence of bioterrorism attacks, these systems are being used to track the onset, relative impact, and sweep of annual seasonal influenza and norovirus outbreaks.

RODS, developed at the University of Pittsburgh Department of Biomedical Informatics, is a system that receives data in real time from patient registrations at hospitals and acute care clinics and classifies chief complaints into one of seven syndrome categories. Statistical detection algorithms are applied to the aggregated data to identify anomalous patterns in the syndrome counts (Tsui et al., 2003). The University of Pittsburgh group also maintains data on sales of over-the-counter health care products that are available to public health officials for use in conjunction with other surveillance resources. ESSENCE was initially developed to monitor clusters of symptoms from ambulatory care visits by military personnel and their families. The data collection and analysis system has been implemented at local, state, and regional surveillance programs.

Syndromic surveillance is still a young science, with much of its potential for success and problems yet to be determined. These surveillance systems present a growing challenge of sifting through and interpreting large quantities of data of uneven precision and accuracy to identify statistical evidence of disease clustering or increasing trends that might signify a potential disease outbreak. This has led to active development and analysis of algorithms to simplify the identification of significant spatial and temporal aberrations in the occurrence of symptoms and other health data.

But no consensus has been reached on the most appropriate data or methods. Model-based analyses show relatively substantial false-negative rates with syndromic surveillance, and some analyses of real data have shown that it may either generate mistaken signals or miss outbreaks (e.g., Steiner-Sichel et al., 2004; Balter et al., 2005). A review of studies of outbreak detection found that characteristics of both the system (representativeness, detection algorithm, and the specificity) and the outbreak

[8]Information about RODS is available at https://www.rods.pitt.edu/site/component/option,com_frontpage/Itemid,76/.

(magnitude, distribution, and timing) influenced detection (Buckeridge, 2007). The review also identified inconsistencies in the evidence currently available.

Nevertheless, two-thirds of the states and territories with syndromic surveillance systems have found them sufficiently valuable that they are likely to expand their use of syndromic surveillance over the next 2 years (Buehler et al., 2008). The committee heard testimony that some public health officials have used their syndromic systems to provide reassurance that outbreaks are *not* occurring, including the use of syndromic surveillance data as part of assessments they have conducted following actionable alerts from the BioWatch system.

Syndromic Detection of Bioterrorism

The effectiveness of syndromic surveillance for detection of a bioterrorist attack remains uncertain. Modeling studies have focused mainly on the threat of a large-scale airborne attack with anthrax spores released in a major metropolitan area. For example, Buckeridge and colleagues (2005, 2006) used a model-based analysis to compare syndromic surveillance to traditional diagnosis for detection of an aerosolized anthrax release. This analysis indicated that syndromic surveillance would detect an increase in febrile respiratory syndromes sooner than traditional diagnostic methods for 30 percent to 60 percent of large-scale releases, depending on the specificity of the detection algorithm. The syndromic signal preceded detection by traditional diagnosis by 8 to 24 hours, a benefit that is modest, although potentially important for a disease with a short incubation period and high fatality rate. However, the system generated frequent false alarms (one every 10 days) when it was sufficiently sensitive to detect a substantial proportion of outbreaks before clinical case finding.

The challenge is finding an appropriate balance between timeliness and completeness of epidemic detection and the potential for generating unacceptable numbers of false alarms. The ability of public health staff to mobilize an effective epidemiologic and laboratory investigation to confirm that a signal represents an outbreak that merits a public health investigation and response is an additional crucial determinant of the usefulness of syndromic surveillance. Health departments have processes to evaluate alerts and dismiss many that are unlikely to represent a disease outbreak. When a full-scale investigation is called for, it is challenging to accomplish because the patients whose conditions generated the statistical signal may not be available for testing, clinical records may have insufficient information, and microbiologic testing is rarely done, particularly for patients with respiratory syndromes who are not hospitalized.

Even if syndromic surveillance does not provide early warning that a bioterrorism event has occurred, it may provide public health officials with better situational awareness, helping them to track trends and assess the extent and geographic location of illness in their community. However, it is likely that once an event has been made public, visits to EDs and clinical testing will increase even in the absence of disease; this will have to be accounted for in the interpretation and use of the data.

The value of syndromic surveillance for detection of bioterrorism has not been evaluated comprehensively and remains unproved. In the absence of actual bioterrorist attacks, particularly large-scale attacks, its effectiveness for providing early epidemic detection relative to other epidemic detection methods will remain untested and unproved. Further modeling studies and insights from practical experience with the detection of seasonal illness and larger community outbreaks unrelated to bioterrorism are needed. In jurisdictions using syndromic surveillance, evaluation of experiences with detecting natural outbreaks unrelated to bioterrorism, such as the 2009 novel influenza A (H1N1) outbreak, can be expected to provide valuable insights into the effectiveness and limitations of syndromic surveillance versus traditional outbreak detection methods.

Examples of Collaboration in Surveillance

The link between health care laboratories and providers in hospitals and clinics is already established, as is the link between veterinary laboratories and veterinarians within academia and clinical practice. What must now be significantly improved nationwide are the working relationships between health care, public health, and veterinary laboratories, and the practice relationships between health care providers, public health epidemiologists, and veterinarians (Foldy, 2004). In addition, and of partcular importance, is the working partnership between the public health laboratory and the public health epidemiologists (Figure 4-2).

Not only must this partnership be strong, the workforce must be adequate and interdependent. A robust, near-real-time surveillance system requires effective laboratory and epidemiology personnel whose skills are reinforced not just by responding to atypical cases, but also through ongoing mutual efforts. Minnesota is an example of such real-time testing and investigation in practice. As isolates of infectious agents are routinely received from sentinel laboratories throughout the state, the agents are immediately identified and subtyped to detect clusters of genetically similar pathogens that may indicate the presence of an outbreak, either naturally occurring or as a potential act of terrorism. Daily, the laboratory provides the state health department's epidemiology staff with a report of all the

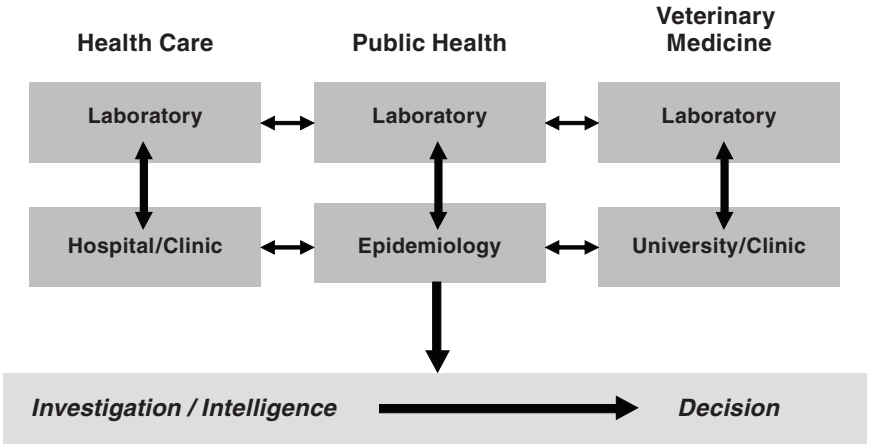


FIGURE 4-2 A schematic depiction of the relationships between functional components of biosurveillance and the associated flows of information. Information must flow effectively from the clinical and analytic elements of biosurveillance (the boxes in the upper portion of the figure) to the investigative and decision-making components of the public health system (the bar in the lower portion of the figure).

isolates tested. The report includes the genetic subtypes found linked to the patient's name and location, as well as a historical perspective for each subtype (i.e., whether or not it has been seen previously).

DATA INTEGRATION AND SITUATIONAL AWARENESS

The data needed to detect an infectious disease outbreak or bioterrorism may come from a variety of sources, and being able to aggregate data across these sources may be necessary to recognize the nature of a disease event or understand its scope (e.g., Proctor et al., 1998). One hope is that being able to effectively monitor multiple data sources may also increase the possibility of detecting warning signs that could allow for advance preparation or even, perhaps, preventive action. For example, the presence of avian influenza may initially be recognized in the veterinary community, whereas an indication of a potential bioterrorist attack may first come to the attention of the intelligence community. Access to multiple data sources is also seen as an important resource for monitoring the course of a disease outbreak (natural or intentional) and guiding the response. Building an integrated, near-real-time repository of information presents many challenges, however. At the national level, both HHS and DHS are pursuing data integration activities.

BioSense

CDC's BioSense program was initiated in 2002 in response to the threat of bioterrorism and other emerging diseases. It is being developed and administered by CDC's public health informatics program. The program's current aim is to serve as a resource for surveillance and situational awareness by assembling and analyzing health-related data from health care organizations, syndromic surveillance systems, and laboratories across the country and by providing access to that information to public health officials at federal, state, and local levels (CDC, 2009c). It is emphasizing secure and timely transmission of surveillance data, statistical analysis of surveillance data, reporting and display of information, and access to data for health departments to support investigation and response to disease outbreaks.

Currently, the program receives near-real-time clinical data from more than 590 health care facilities, mostly private or municipal hospital EDs (the majority via ED-based syndromic surveillance systems established by state or local health departments), ambulatory clinics, and clinical laboratories; more than 1,200 Department of Defense and Department of Veterans Affairs hospitals and clinics; and other sources, including major commercial diagnostic laboratories. At least some data are going to BioSense from the 50 largest metropolitan areas and all BioWatch jurisdictions (CDC, 2009c).

In general, state and local public health and hospital personnel have reported mixed views about the usefulness of BioSense, especially for early event detection, because of limited data relevant to their specific jurisdiction (Buehler et al., 2008, 2009; GAO, 2008b). Since late 2007, BioSense has been undergoing major changes in response to concerns of Congress and state and local health agencies about data protection and access, utility, and duplication of effort (TFAH, 2008). Rather than having hospitals report data directly to CDC, bypassing state and local health departments, the program is trying to achieve national coverage by fostering and integrating existing state and local syndromic surveillance systems (TFAH, 2008; CDC, 2009a,c). The goal is to have all levels of public health with jurisdiction over the 50 most populous metropolitan areas using the BioSense application for biosurveillance and situational awareness by accessing data directly from their health care facilities. This is to be accomplished by offering state and local public health agencies technical and financial support for developing and maintaining real-time surveillance systems; supporting formation of Regional Health Information Organizations and Health Information Exchanges to enable regional coordination of surveillance; developing a system of federated databases in which the data are stored locally but can be accessed by CDC and other authorized users; and developing better detection technologies (CDC, 2009a,c).

NBIS and NBIC

The National Biosurveillance Integration System (NBIS) was established in response to Homeland Security Presidential Directive 10, *Biodefense for the 21st Century* (The White House, 2004), which directed the Secretary of Homeland Security to create a national bioawareness system to detect a biological attack at the earliest possible moment and enable an effective response to reduce loss of life, economic impact, and social disruption. The purpose of NBIS is to acquire, integrate, analyze, and disseminate information from human disease, food, agricultural, water, meteorological, and environmental surveillance systems and relevant threat and intelligence information to provide continuous situational awareness, early warning of a possible attack, and a decision support system for outbreak and event response in the event of a biological incident, either intentional or naturally occurring (DHS, 2009b).

Establishing an effective NBIS has been difficult and time consuming (DHS, 2007; GAO, 2008a), and the National Biological Information Center (NBIC) was created to manage it. DHS opened NBIC in September 2008, but the program is still evolving. Currently, NBIC has permanent staff, it is implementing a new information technology system (NBIS 2.0), and it is developing a biological common operating picture in coordination with the other relevant federal agencies. Progress in building an interagency team has been slow. DHS identified 11 agencies to support NBIC operations but has memoranda of understanding with only 7 (DHS, 2009a,b). CDC has a detailee working in the center (DHS, 2009a), and NBIS has access to CDC's BioSense (CDC, 2009b). Most of the anticipated information exchange awaits interagency security agreements that had not been signed as of March 2009.

PUBLIC HEALTH RESOURCES FOR DISEASE SURVEILLANCE

Every state has a public health agency, and there are approximately 2,900 health departments serving "local" jurisdictions (e.g., counties, townships) (NACCHO, 2006). More than 60 percent of the local health departments serve populations of fewer than 50,000 people. In 2005, local health departments had a total of about 160,000 full-time equivalent (FTE) workers (NACCHO, 2006), and state health departments had another 100,000 workers (TFAH, 2009).

At the local level, a third of health departments employed fewer than 10 FTE workers. The median number of employees among departments serving a population of a million or more was about 500. Nearly all (98 percent) of these large health departments have epidemiologists (scientists trained in disease surveillance and control), and a similar percentage (96 percent)

have an emergency preparedness coordinator (NACCHO, 2006). But only 50 percent of health departments serving populations of 100,000–249,999 reported having an epidemiologist on staff. Overall, states employed about 2,500 epidemiologists in 2006 (CSTE, 2007). About 42 percent of the epidemiologists had assignments related to infectious diseases, and 14 percent were assigned to bioterrorism and emergency preparedness programs.

For 2005, a third of local health departments reported expenditures of less than $500,000 a year, and a fifth spent more than $5 million (NACCHO, 2006). Local health departments are typically funded by a mix of local, state, and federal funds. Overall, they received 29 percent of their funding from local sources, 23 percent from the state, and 20 percent from federal funds (either directly or through the state). Much of the remainder of their funding was derived from sources such as Medicare, Medicaid, and fees for services. A survey in late 2008 found that 44 percent of local health departments expected their new budgets to be smaller than the current one (NACCHO, 2008). Staff are also being lost, with 53 percent of health departments having lost staff in 2008 and 46 percent expecting to do so during 2009.

At the state level, public health agencies' budgets for fiscal year (FY) 2007–2008 ranged from $8.6 million to $3.0 billion (TFAH, 2009). On average, state health departments received approximately 49 percent of their funding from the federal government (ASTHO, 2009). In 2009, state health departments are facing substantial budget pressures. Nearly 30 percent had smaller budgets in FY 2008 than in FY 2007, and more than two-thirds expected their budgets to be reduced from FY 2008 to FY 2009, some by 10 percent or more (ASTHO, 2009). Forty percent of states reported expecting to lose staff in FY 2009.

The current financial problems at the state and local level reflect both the consequences of the current recession and declines in federal funding for emergency preparedness after a substantial infusion following the events of 2001. The Public Health Emergency Preparedness (PHEP) cooperative agreement program, for which states and territories as well as the New York City, Chicago, Los Angeles, and Washington, DC, health departments are eligible, increased from about $50 million a year to more than $900 million in FY 2002. The FY 2008 appropriation was $700 million, and the FY 2010 budget request is $715 million (CDC, 2009c). During this period, states also had access to funds from a total of $600 million appropriated for planning and preparedness for pandemic influenza. These federal funds have helped state and local health departments improve their capacity in disease surveillance and other preparedness areas over the past several years. Among other things, these increases in federal funding helped health departments hire additional staff, including epidemiologists to support improved surveillance capacity, but some of these positions may be lost as state and local budgets are reduced.

CONCLUDING REMARKS

Many novel and promising surveillance techniques and programs have been developed at the local, state, and federal levels in recent years, spurred in part by funding for bioterrorism and public health emergency preparedness since 2001. However, the nation's resources for surveillance have shortcomings.

- There is insufficient evidence regarding the public health utility of novel surveillance techniques, and funding for evaluation of surveillance approaches is insufficient.
- Surveillance capacities are unevenly distributed among states and localities.
- National standards for surveillance data and for interoperability between surveillance systems are incompletely developed and unevenly implemented; the important efforts underway to resolve this suffer from inadequate funding and focus.
- Insufficient attention has been paid to the timeliness and accuracy of case reporting, or how this process can be strengthened.
- Insufficient attention has been paid to effective methods for linking, integrating, analyzing, and displaying multiple surveillance platforms for optimal situational awareness, decision making, and response.
- Federal funding, while substantial after 2001, has been year-to-year, which disrupts orderly program planning and discourages recruitment of qualified personnel; more recently this funding has been declining. Meanwhile, the economic conditions in 2009 make it difficult for many state and local governments to support their current activities, let alone make investments in new systems or make up the loss in federal funding.

FINDING: Inconsistent local and state public health capabilities, combined with inadequate systems for information exchange and situational awareness spanning jurisdictions up to the national level, leave the nation with many holes in the ability to promptly detect, confirm, and respond to disease clusters or bioagent attack, as well as providing the opportunity for duplication of effort. The gaps are likely to worsen with recent reductions of federal funding for these functions in the face of a recession affecting local and state public health budgets.

REFERENCES

Ashford, D.A., R.M. Kaiser, M.E. Bales, K. Shutt, A. Patrawalla, A. McShan, J.W. Tappero, B.A. Perkins, and A.L. Dannenberg. 2003. Planning against biological terrorism: Lessons from outbreak investigations. *Emerging Infectious Diseases* 9(5):515–519. http://www.cdc.gov/ncidod/EID/vol9no5/pdfs/02-0388.pdf (accessed March 9, 2009).

ASTHO (Association of State and Territorial Health Officials). 2009. Impact of budget cuts on state public health. http://www.astho.org/Advocacy/2009-Advocacy-Materials/Impact-of-Budget-Cuts-on-State-Public-Health/ (accessed June 28, 2009).

Balter, S., D. Weiss, H. Hanson, V. Reddy, D. Das, and R. Heffernan. 2005. Three years of emergency department gastrointestinal syndromic surveillance in New York City: What have we found? *Morbidity and Mortality Weekly Report* 54(Suppl.):175–180.

Buckeridge, D.L. 2007. Outbreak detection through automated surveillance: A review of the determinants of detection. *Journal of Biomedical Informatics* 40(4):370–379.

Buckeridge, D.L., P. Switzer, D. Owens, D. Siegrist, J. Pavlin, and M. Musen. 2005. An evaluation model for syndromic surveillance: Assessing the performance of a temporal algorithm. *Morbidity and Mortality Weekly Report* 54(Suppl.):109–115.

Buckeridge, D.L., D.K. Owens, P. Switzer, J. Frank, and M.A. Musen. 2006. Evaluating detection of an inhalational anthrax outbreak. *Emerging Infectious Diseases* 12(12):1942–1949.

Buehler, J.W., A. Sonricker, M. Paladini, P. Soper, and F. Mostashari. 2008. Syndromic surveillance practice in the U.S.: Findings from a survey of state, territorial, and selected local health departments. *Advances in Disease Surveillance* 6:3. http://www.isdsjournal.org/article/view/2618/2517 (accessed March 20, 2009).

Buehler, J.W., E.A. Whitney, D. Smith, M.J. Prietula, S.H. Stanton, and A.P. Isakov. 2009. Situational uses of syndromic surveillance. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 7(2):165–177. http://www.liebertonline.com/doi/pdf/10.1089/bsp.2009.0013

CDC (Centers for Disease Control and Prevention). 2008a. Effect of electronic laboratory reporting on the burden of Lyme disease surveillance—New Jersey, 2001–2006. *Morbidity and Mortality Weekly Report* 57(2):42–45. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5702a4.htm (accessed March 9, 2009).

CDC. 2008b. *Justification of estimates for appropriation committees: FY 2009*. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY09_CDC_CJ_Final.pdf (accessed March 25, 2009).

CDC. 2008c. Outbreak of *Salmonella* serotype Saintpaul infections, associated with multiple raw produce items—United States, 2008. *Morbidity and Mortality Weekly Report* 57(34):929–934.

CDC. 2008d. Potential effects of electronic laboratory reporting on improving timeliness of infectious disease notification—Florida, 2002–2006. *Morbidity and Mortality Weekly Report* 57(49):1325–1328. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5749a2.htm?s_cid=mm5749a2_e (accessed December 22, 2008).

CDC. 2009a. *FY 2008 CDC annual performance report*. Atlanta, GA: CDC. http://www.cdc.gov/fmo/PDFs/FY_2008_CDC_Annual_Performance_Report.pdf (accessed March 20, 2009).

CDC. 2009b. *IOM review.* Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, January 13, Washington, DC.

CDC. 2009c. *Justification of estimates for appropriation committees: FY 2010*. Atlanta, GA: CDC. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2010_CDC_CJ_Final.pdf (accessed July 21, 2009).

CDC. 2009d. Multistate outbreak of *Salmonella* infections, associated with peanut butter and peanut butter-containing products—United States, 2008–2009. *Morbidity and Mortality Weekly Report* 58(4):85–90.

CDC. 2009e. Status of state electronic disease surveillance systems—United States, 2007. *Morbidity and Mortality Weekly Report* 58(29):804–807.

CSTE (Council of State and Territorial Epidemiologists). 2007. 2006 National assessment of epidemiologic capacity: Findings and recommendations. Version 1.0. Atlanta, GA: CSTE. http://www.cste.org/pdffiles/2007/2006CSTEECAFINALFullDocument.pdf (accessed July 28, 2009).

CSTE. 2008. *National Electronic Disease Surveillance System: A status report on implementation*. Atlanta, GA: CSTE. http://www.cste.org/dnn/LinkClick.aspx?fileticket=BJJMGWMITb8%3d&tabid=173&mid=712 (accessed July 14, 2009).

Dato, V., M.M. Wagner, and A. Fapohunda. 2004. How outbreaks of infectious disease are detected: A review of surveillance systems and outbreaks. *Public Health Reports* 119(5):464–471. http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1497658&blobtype=pdf (accessed March 9, 2009).

Dausey, D.J., A. Chandra, A.G. Schaefer, B. Bahney, A. Haviland, S. Zakowski, and N. Lurie. 2008. Measuring the performance of telephone-based disease surveillance systems in local health departments. *American Journal of Public Health* 98(9):1706–1711. http://www.ajph.org/cgi/reprint/AJPH.2007.114710v1 (accessed March 24, 2009).

Dey, A.N., J.I. Tokars, P. Hicks, M. Miller, and R. English. 2008. *Automated monitoring of injuries due to falls using the BioSense system*. Public Health Informatics Conference 2008. http://www.cdc.gov/biosense/files/Automated_Monitoring.pdf (accessed July 14, 2009).

DHS (Department of Homeland Security). 2007. *Better management needed for the National Bio-Surveillance Integration System program*. OIG-07-61. Washington, DC: Office of Inspector General, DHS. http://www.dhs.gov/xoig/assets/mgmtrpts/OIG_07-61_Jul07.pdf (accessed March 25, 2009).

DHS. 2009a. *Department of Homeland Security annual performance report: Fiscal years 2008–2010*. Washington, DC: DHS http://www.dhs.gov/xlibrary/assets/cfo_apr_fy2008.pdf (accessed March 26, 2009).

DHS. 2009b. *Department of Homeland Security FY 2010 congressional justification budget*. http://www.dhs.gov/xlibrary/assets/dhs_congressional_budget_justification_fy2010.pdf (accessed July 28, 2009).

Doyle, T.J., M.K. Glynn, and S.L. Groseclose. 2002. Completeness of notifiable infectious disease reporting in the United States: An analytical literature review. *American Journal of Epidemiology* 155(9):866–874.

Effler, P., M. Ching-Lee, A. Bogard, M.C. Ieong, T. Nekomoto, and D. Jernigan. 1999. Statewide system of electronic notifiable disease reporting from clinical laboratories: Comparing automated reporting with conventional methods. *Journal of the American Medical Association* 282(19):1845–1850. http://jama.ama-assn.org/cgi/reprint/282/19/1845 (accessed March 9, 2009).

FEMA (Federal Emergency Management Agency). 2008a. *Biological incident annex*. http://www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf (July 24, 2009).

FEMA. 2008b. *Emergency support function #8—Public health and medical services annex*. http://www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf (accessed July 13, 2009).

Foldy, S.L. 2004. Linking better surveillance to better outcomes. *Morbidity and Mortality Weekly Report* 53(Suppl.):12–16. http://www.cdc.gov/mmwr/PDF/wk/mm53SU01.pdf (accessed March 23, 2009).

Foldy, S., E.N. Barthell, J.C. Silva, P. Biedrzycki, D. Howe, M. Erme, B. Keaton, C. Hamilton, L. Brewer, G. Miller, E. Eby, R. Coles, K. Pemble, and C. Felton. 2004. SARS surveillance project: Internet-enabled multi-region syndromic surveillance for rapidly emerging disease. *Morbidity and Mortality Weekly Report* 53(Suppl.):215–220. http://www.cdc.gov/mmwr/preview/ind2004_su.html (accessed July 14, 2009).

GAO (Government Accountability Office). 2008a. *Biosurveillance: Preliminary observations on Department of Homeland Security's biosurveillance initiatives*. GAO-08-960T. http://www.gao.gov/new.items/d08960t.pdf (accessed March 26, 2009).

GAO. 2008b. *Health information technology: More detailed plans needed for the Centers for Disease Control and Prevention's redesigned BioSense program*. GAO-09-100. Washington, DC. http://www.gao.gov/new.items/d09100.pdf (accessed March 20, 2009).

Ginsberg, J., M.H. Mohebbit, R.S. Ptel, L. Brammer, M.S. Smolinski, and L. Brilliant. 2009. Detecting influenza epidemics using search engine query data. *Nature* 457:1012–1014.

Henning, K.J. 2004. Overview of syndromic surveillance: What is syndromic surveillance? *Morbidity and Mortality Weekly Report* 53(Suppl.):5–11. http://www.cdc.gov/mmwR/preview/mmwrhtml/su5301a3.htm (accessed July 14, 2009).

Jajosky, R.A., and S.L. Groseclose. 2004. Evaluation of reporting timeliness of public health surveillance systems for infectious diseases. *BioMed Central Public Health* 4:29. http://www.biomedcentral.com/content/pdf/1471-2458-4-29.pdf (accessed March 9, 2009).

Klompas, M., R. Lazarus, R. Platt, X. Hou, F. Campion, B. Kruskal, G. Haney, J. Daniel, A. DeMaria, and S.J.N. McNabb. 2008. Automated detection and reporting of notifiable diseases using electronic medical records versus passive surveillance—Massachusetts, June 2006–July 2007. *Morbidity and Mortality Weekly Report* 57(14):373–376. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5714a4.htm (accessed March 9, 2009).

Lazarus, R., M. Klompas, F.X. Campion, S. McNabb, X. Hou, J. Daniel, G. Haney, A. DeMaria, L. Lenart, and R. Platt. 2009. Electronic support for public health: Validated case finding and reporting for notifiable diseases using electronic medical data. *Journal of the American Medical Informatics Association* 16(1):18–24. http://www.jamia.org/cgi/reprint/16/1/18 (accessed February 28, 2009).

Lombardo, J., H. Burkom, E. Elbert, S. Macgruder, S.H. Lewis, W. Loschen, J. Sari, C. Sniegoski, R. Wojcik, and J. Pavlin. 2003. A systems overview of the Electronic Surveillance System for Early Notification of Community-based Epidemics (ESSENCE II). *Journal of Urban Health* 80(2 Suppl. 1):i32–i42.

Malakmadze, N., I.M. Gonzalez, T. Oemig, I. Isiadinso, D. Rembert, M.M. Mccauley, P. Wand, L. Diem, L. Cowan, G.J. Palumbo, M. Fraser, and K. Ijaz. 2005. Unsuspected recent transmission of tuberculosis among high-risk groups: Implications of universal tuberculosis genotyping in its detection. *Clinical Infectious Diseases* 40(3):366–373.

Mandl, K.D., J.M. Overhage, M.M. Wagner, W.B. Lober, P. Sebastiani, F. Mostashari, J.A. Pavlin, P.H. Gesteland, T. Treadwell, E. Koski, L. Hutwagner, D.L. Buckeridge, R.D. Aller, and S. Grannis. 2004. Implementing syndromic surveillance: A practical guide informed by the early experience. *Journal of American Medical Informatics Association* 11(2):141–150. http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=353021&blobtype=pdf (accessed March 24, 2009).

Moore, K.M., V. Reddy, D. Kapell, and S. Balter. 2008. Impact of electronic laboratory reporting on hepatitis A surveillance in New York City. *Journal of Public Health Management and Practice* 14(5):437–441.

NACCHO (National Association of County and City Health Officials). 2006. *2005 national profile of local health departments*. Washington, DC: NACCHO. http://www.naccho.org/topics/infrastructure/profile/upload/NACCHO_report_final_000.pdf (accessed December 31, 2008).

NACCHO. 2008. *Preliminary findings: NACCHO survey of local health departments' budget cuts and workforce reductions*. December. Washington, DC: NACCHO. http://www.naccho.org/advocacy/upload/LHDbudgetsjobsDec08.pdf (accessed January 2, 2009).

Nguyen, T.Q., L. Thorpe, H.A. Makki, and F. Mostashari. 2007. Benefits and barriers to electronic laboratory results reporting for notifiable diseases: The New York City Department of Health and Mental Hygiene experience. *American Journal of Public Health* 97 (Suppl. 1):S142–S145.

Olson, D.R., R.T. Heffernan, M. Paladini, K. Konty, D. Weiss, and F. Mastashari. 2007. Monitoring the impact of influenza by age: Emergency department fever and respiratory complaint surveillance in New York City. *PLoS Medicine* 4(8):e247. http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040247 (accessed July 29, 2009).

Overhage, J.M., S. Grannis, and C.J. McDonald. 2008. A comparison of the completeness and timeliness of automated electronic laboratory reporting and spontaneous reporting of notifiable conditions. *American Journal of Public Health* 98(2):344–350.

Polgreen, P.M., Y. Chen, D.J. Pennock, and F.D. Nelson. 2008. Using internet searches for influenza surveillance. *Clinical Infectious Diseases* 47:1443–1448. http://www.journals.uchicago.edu/doi/abs/10.1086/593098 (accessed July 15, 2009).

Proctor, M.E., K.A. Blair, and J.P. Davis. 1998. Surveillance for waterborne illness detection: An assessment following a massive waterborne *Cryptosporidium* outbreak. *Epidemiology and Infection* 120(1):43–54.

Steiner-Sichel, L., J. Greenko, R. Heffernan, M. Layton, and D. Weiss. 2004. Field investigations of emergency department syndromic surveillance signals—New York City. *Morbidity and Mortality Weekly Report* 53(Suppl.): 184–189.

TFAH (Trust for America's Health). 2008. *Ready or not? Protecting the public's health from diseases, disasters, and bioterrorism*. Washington, DC: TFAH. http://healthyamericans.org/assets/files/bioterror-report-2008.pdf (accessed July 17, 2009).

TFAH. 2009. *Shortchanging America's health: A state-by-state look at how federal public health dollars are spent and key state health facts*. Washington, DC: TFAH. http://healthyamericans.org/report/61/shortchanging09 (accessed July 26, 2009).

Thacker, S.B., and R.L. Berkelman. 1988. Public health surveillance in the United States. *Epidemiologic Reviews* 10:164–190.

Tsui, F.-C., J.U. Espino, V.M. Dato, P.H. Gesteland, J. Hutman, and M.M. Wagner. 2003. Technical description of RODS: A real-time public health surveillance system. *Journal of the American Medical Informatics Association* 10(5):399–408.

The White House. 2004. *Homeland Security Presidential Directive (HSPD) 10: Biodefense for the 21st Century*. Washington, DC. http://www.exercise.dhs.gov/xabout/laws/gc_1217605824325.shtm#1 (accessed July 24, 2009).

5

Enhancing Surveillance to Detect and Characterize Infectious Disease Threats

Infectious disease surveillance is conducted at all levels of government, with most surveillance legally authorized and performed by a heterogeneous set of state and local public health departments that voluntarily collaborate with the federal government (see Chapter 4). In practice, many separate systems are engaged in activities that contribute to public health surveillance at local, state, and national levels.

The multiplicity of surveillance systems (many of them monitoring specific diseases), the unevenness of their capabilities, and both the strengths and limitations of current approaches to surveillance through public health and health care systems have been the subject of many different studies, task forces, commissions, and other efforts both to assess the status of the situation and to propose changes to remedy current problems and bring about improvements (e.g., CDC, 2001; Baker and Koplan, 2002; IOM, 2003; Baker et al., 2005; Lurie et al., 2006).[1] These analyses share some broad themes.

- The nation is facing an increased threat from infectious disease outbreaks, both intentional from terrorists and natural from emerging and re-emerging pathogens.
- The nature of many bioterror threats (e.g., a high degree of infectiousness or severe morbidity, short incubation period, decreasing effectiveness of

[1]As this committee began its work, an effort to develop a National Biosurveillance Strategy, mandated by Homeland Security Presidential Directive 21 (HSPD-21), was getting under way through the coordination efforts of the Centers for Disease Control and Prevention (CDC, 2008a). This effort is described below.

treatment as the disease progresses) necessitates a very rapid medical response to prevent most of the casualties.

- Local and state public health agencies play a vital role in monitoring disease trends and outbreaks but do not all have sufficient staff, tools, and resources to be as effective as they need to be for rapid detection and response to outbreaks (e.g., adequate numbers of trained personnel, modernized information and communication systems, access to and capacity to fully use epidemiologic data systems and analysis tools, expanded and modernized public laboratories).
- The sharing of surveillance information between the health care system and state and local public health agencies needs to be improved to detect health threats and detect them earlier.
- Automated systems to improve the sharing of surveillance information between the health care system and state and local public health agencies to detect widespread outbreaks earlier and manage them better also need to be improved.
- The integration of human health information with information about infectious agents derived from surveillance of animal disease, water quality, and air quality—or "biosurveillance"—is needed to defend against bioterrorism and natural pandemics.

With its focus on the BioWatch system and a short timeframe in which to conduct its work, this committee acknowledges the large number of completed and ongoing efforts over the past decade, especially since 2001, to improve infectious disease surveillance and detection of disease outbreaks. In this chapter, the committee describes opportunities it has identified for further enhancing the detection of public health threats, especially threats from biological hazards, including bioterrorism. Many of the enhancements derive from the increasing digitalization of health information and resulting opportunities for better information technology systems and tools to aid case recognition, reporting, and analysis of information. A central and desirable aspect of the enhancements—in the context of bioterrorism surveillance—is to improve the *timeliness* of individual case and outbreak recognition, reporting, and analysis of information.

The opportunities for enhancement of surveillance through the public health and health care systems fall into broad and overlapping categories of improving legally mandated reporting, establishing automated linkages between health care information systems and public health systems, increasing laboratory and diagnostic testing capacity, and promoting information integration and knowledge sharing. These enhancements bring with them the risk of information overload, which must also be addressed through improved information and knowledge management (the field of public health informatics) (Yasnoff et al., 2000). Information tools to manage

such floods of information must be specifically designed for the end user to ensure that salient information is correctly interpreted in a timely manner (Endsley et al., 2003).

Skilled staff and other infrastructure resources are needed to use these systems effectively on a day-to-day basis and to evaluate and respond to these additional or enhanced information streams. Automated connections between health care and public health systems are unlikely to be fully effective in the absence of mutual trust, deserved respect for one another's expertise, and effective personal communication links between the health care providers and public health officials, particularly at the local level. In the final portion of the chapter, the committee provides recommendations for making the most of the enhancements and providing critical baseline capabilities to benefit from them.

LEGALLY MANDATED REPORTING

As discussed in Chapter 4, each state has laws requiring health care providers, laboratories, and other entities to report certain diseases and other conditions to local or state public health authorities. Typically, state laws also mandate reporting of unusual clusters of disease or outbreaks, even if the disease in question is not on the list of reportable conditions.

The Council of State and Territorial Epidemiologists (CSTE) has proposed the establishment of a common list of nationally notifiable conditions to be reported to *all* levels of the public health system (CSTE, 2007). CSTE has also proposed establishment of a list of "immediately notifiable conditions" in addition to routinely notifiable conditions (CSTE, 2008). Immediately notifiable conditions would be those that might constitute a "public health emergency of international concern," as defined in International Health Regulations (WHO, 2008). They include such conditions as smallpox, a novel strain of influenza, wild-type polio, and severe acute respiratory syndrome (SARS). The list also includes diseases caused by pathogens in Category A on the Centers for Disease Control and Prevention's (CDC's) list of possible bioterrorism agents and toxins (e.g., anthrax, plague, tularemia). These immediately notifiable diseases have been largely eliminated in the United States (e.g., measles) or globally, or are otherwise designated by the Nationally Notifiable Disease process.

In addition, standardized disease investigation forms with required data elements are needed for all notifiable diseases. CSTE and CDC are currently working together to establish an updated list of Nationally Notifiable Conditions, which will include nationally standardized case definitions,[2] forms,

[2]Many case definitions are now available at http://www.cdc.gov/ncphi/disss/nndss/casedef/case_definitions.htm.

and disease-specific codes and data elements, so that information can be readily and quickly shared, compared, and analyzed. This standardized approach to reporting the diseases of greatest concern is important, because a biothreat or naturally emerging infectious disease may strike more than one location, or terrorists may target an airport, state fair, sports arena, or other place with people travelling to and from multiple jurisdictions.

Electronic Laboratory Reporting Systems

Electronic reporting of laboratory results to public health officials can improve the timeliness and completeness of information regarding notifiable diseases and other agents of potential concern (Effler et al., 1999; Panackal et al., 2002; Babin et al., 2007). Such systems can reduce the delays and incompleteness of reporting based on busy laboratorians having to fill out and submit paper forms by mail or fax. While the benefits of more prompt reporting will vary by disease, depending on the urgency of beginning prophylaxis or treatment, electronic reporting can at least shorten one critical step in the transfer of information about the occurrence of notifiable diseases (CDC, 2008b). As of late 2008, about 85 percent of the states have some capacity for electronic laboratory reporting (ELR) (TFAH, 2008).[3]

In order for ELR systems to be deployed in a jurisdiction, standardized information exchange is needed between laboratories and public health reporting systems (i.e., standard vocabularies and codes and electronic messaging and transmission formats). The main impediment is the time required for both laboratory information technology (IT) staff and public health staff to map out a customized interface from each laboratory information system to the standardized format required for each notifiable disease, especially if a disease is confirmed by more than one test. This interface problem is reduced when regional health information exchanges (HIEs) electronically transmit information, including laboratory reports, between multiple users across the community. These information exchange systems can be politically and technically challenging, but they offer the possibility of creating a limited set of interfaces rather than unique interfaces for every entity and every application. Thus they can speed the process of establishing ELR in a community where it is not yet established. ELR has substantially increased the speed of delivery, the number of case reports, and the quality

[3]A 2007 survey of the 50 states, the District of Columbia, and five large cities (New York, Los Angeles, Denver, Chicago, and Indianapolis) found that 38 (68 percent) had at least partially operational ELRs, 9 (16 percent) were testing an ELR system, and 6 (11 percent) were planning an ELR system. Only 3 were not planning, testing, or operating an ELR system (Magnuson, 2008).

of patient-level information (e.g., address, demographics) provided in case reports (Overhage et al., 2008).

Better case ascertainment from ELR also creates higher information flow and workload demands on public health staff. For this to translate into better public health response, sufficient numbers of skilled public health professionals and high-quality information management systems are needed to quickly assess if reports meet disease case criteria and to implement appropriate case and contact investigations.

Notifiable Disease Reporting by Health Care Providers

As discussed in Chapter 4, all states mandate that physicians, veterinarians, laboratories, and other health care providers report certain health conditions—mainly infectious diseases—to their local or state department of public health, or both. Although health care providers are generally aware of the requirement to report, compliance is a problem (Jajosky and Groseclose, 2004). Providers may not be fully aware of the scope of reporting requirements, may assume that others (such as the laboratory or hospital infection control staff) will report, or be too busy with patient care to stop work and report a disease. Some may also doubt that their input is necessary or would be used effectively.

The challenge of complying with reporting requirements is even greater in clinical environments such as busy hospital emergency departments (EDs) and acute care clinics. Because these sites provide readily accessible care 24 hours a day, clinicians working in these settings may be the first to encounter patients with signs or symptoms of illness from a bioterror agent or an emerging infectious disease (IOM, 2007). The crowded conditions that characterize many EDs are also a problem, because they can extend the waiting time to see a physician and promote patient-to-patient spread of virulent infectious diseases, such as SARS (Augustine et al., 2004; Cass, 2005). Clinicians working in these environments are expected to diagnose and treat a wide range of conditions of widely varying severity, from immediately life-threatening to chronic. The frequent interruptions, need for multitasking, and circadian stress of shift work reduce the probability that a busy emergency physician or nurse will quickly report a diagnosis. In addition, the results of microbiologic tests may not be available for hours or days after they are submitted. Reporting rates from EDs could be enhanced if steps were taken to raise awareness among clinicians of the importance of case reports in monitoring public health and identifying disease outbreaks, or to provide additional support from infectious disease physicians or infection control staff who have somewhat more time to review differential diagnostic information.

Recognizing and diagnosing unusual diseases in EDs and acute care clinics is also a challenge. For bioterrorism preparedness, primary care provid-

ers and key specialists (e.g., in emergency medicine, infectious disease, dermatology, radiology, and microbiology) need to acquire and maintain "front of mind" awareness of the clinical manifestations of infection with Category A and B agents, which for many clinicians may be a once-in-a-lifetime diagnosis. Health alert systems, such as Health Alert Networks (HANs) located at CDC and all state and some local health departments, which broadcast email and faxes to health care providers and systems, have been put in place to rapidly notify providers of potential or breaking public health emergencies, but the task of signing up all providers is not complete in most places. In the event of an outbreak, HAN alerts should be used to increase the index of suspicion for providers by providing them with the specific clinical and epidemiologic criteria, public health contact information for reporting cases, and instructions for obtaining confirmatory laboratory testing.

In addition to maintaining provider outreach efforts on the requirements for reporting of notifiable diseases, local and state public health departments should take steps to ease the burden of reporting and ensure that staff who triage calls from providers are responsive and adequately trained. These steps, which have been taken by many but still not all public health systems, include:

- 24/7 toll-free call lines at the local or state health departments with the capability to rapidly connect providers with an appropriate staff person to triage their calls, including an on-call medical epidemiologist if indicated;
- easy-to-use Internet-based reporting systems; and
- feedback to clinicians regarding local disease trends and the impact of their reporting.

Enhancing the Infection Control Professional Workforce

Infection control professionals (or infection preventionists) are an important human link connecting the clinical and public health sectors. They often report notifiable conditions to public health, assist clinicians with definitive diagnosis, assist public health authorities with case investigation, and improve the speed and consistency of the application of infection control measures such as isolation. While common in hospitals, they are less often present in ambulatory care settings. Strengthening the system of infection control professionals across the health care system could provide an important tool to improve capacity for surveillance and response to bioterrorism or emerging infectious diseases, while simultaneously reducing health care-associated infections.

Electronic Death Reporting Systems

Making death reporting systems electronic may speed the detection of unusual trends in mortality. Tracking causes of mortality is the oldest form of public health surveillance and has been done for centuries. Ironically, the data systems in place to track mortality in most states use the same technology employed in these earlier centuries—i.e., paper—and are therefore slow. Electronic death reporting could improve timeliness of detection of clusters of deaths, identification of cases of infectious disease that should have been reported to public health by the treating physician, and identification of seasonal trends in infectious causes of death (Fallon and Boone, 2004).

In New Hampshire, death certificates are filed electronically within 24 hours of being signed by a physician. A surveillance coordinator in the New Hampshire Department of Health and Human Services reviews death certificates daily using a query developed to identify more than 50 illnesses potentially related to terrorism (Fallon and Boone, 2004).

The Los Angeles coroner reports on each day's cases to the Los Angeles County Department of Public Health (LACDPH). Of the approximately 70,800 coroner's cases reported between 2003 and 2006, the LACDPH investigated 424, and among the investigated cases, 196 (46 percent) had an infectious disease as the cause of death. Of these infectious disease cases, 81 (41 percent) had not been properly reported prior to death, including cases of hantavirus and rabies. There were also 505 cases with causes of death attributed explicitly to reportable communicable diseases, of which more than half (56 percent) had not been previously reported (Peterson and Terashita, 2008).

AUTOMATION OF HEALTH CARE INFORMATION SYSTEMS AND PUBLIC HEALTH LINKAGES

Advances in IT make it possible to collect and analyze public health information more quickly, accurately, and comprehensively than is possible with traditional manual methods. IT can greatly ease the demands of reporting for providers, as discussed above, especially for initiating case reports. However, additional input from clinicians is likely to continue to be necessary to complete case reports in many instances (e.g., to obtain information on patients' modes of exposure or more nuanced information necessary to verify that patients meet surveillance case definitions). Electronically reported data can be more easily aggregated and analyzed for patterns that indicate a possible outbreak of naturally occurring or bioterrorism-caused disease. Early trend detection by public health can be shared with clinicians using HAN and other notification systems, thus creating a circle of enhanced diagnosis, case reporting, infection control, and treatment.

Clinical Decision Support Tools

Many outbreaks are identified and reported by astute clinicians who encounter cases or clusters of cases with suspicious features, such as monkeypox in 2003 (Reed et al., 2004), anthrax in 2001, West Nile virus in 1999 (Fine and Layton, 2001), and hantavirus in 1993. In fact, the most crucial step in disease detection is the first one—recognizing that an ill patient has a potentially unusual disease or disease manifestation that warrants further investigation and notification of public health officials. Although it is widely assumed that all clinicians working in busy acute care settings intrinsically possess the knowledge, skills, and means to promptly identify, isolate, and report suspicious cases, this is not necessarily so. Most health care providers—particularly those who work in EDs and other acute care settings—constantly juggle competing demands for their time and attention. Yet it is vital that these same clinicians promptly recognize index cases that might signify a bioterrorist attack or an emerging outbreak of a dangerous infectious disease.

Traditionally, health departments and professional societies have relied on continuing education, posters, and pocket cards to educate health care professionals about the signs and symptoms of an illness caused by bioterrorism agents and other dangerous diseases. Although these measures are useful, they are not enough (IOM, 2000). Health care providers need decision support tools in their clinical environments that are designed to help them with their daily tasks (IOM, 2007). Examples include rapid dissemination of paper triage screening forms for a particular disease of concern (e.g., for SARS [Foldy et al., 2004b]), computer-assisted triage systems (e.g., Dong et al., 2007; Bullard, 2008), web-based interfaces or other electronic tools to help clinicians formulate differential diagnoses and access guidance about the clinical management of patients with rare or highly dangerous diseases (e.g., Papier, 2008), and electronic medical records (EMRs) with imbedded decision prompts that remind busy clinicians to consider certain diagnoses and report particular diseases (see Recommendation 10, below). Computer-assisted triage systems, for example, could be enhanced by programming them to automatically alert the triage nurse if an ED patient has history, symptoms, or clinical signs suggestive of exposure to a bioterrorism agent or other public health threat (IOM, 2007). In addition to reducing medical errors and streamlining patient flow, routine use of decision support systems should increase the likelihood that index cases of bioterrorism or emerging infectious disease are recognized in the earliest stages of an outbreak of potential public health significance. Although diagnosis of most diseases caused by bioterrorism agents will require more information (e.g., from a physician's examination, laboratory tests, or X-rays), the decision support tool may raise the index of suspicion to make appropriate

care more likely. This could enhance prompt reporting, use of appropriate diagnostic tests, institution of appropriate isolation measures, and swift treatment of both ill and exposed individuals.

Technologies exist to assist busy ED clinicians and hospital-based adult internal medicine and pediatric specialists in making clinical decisions concerning prevention and monitoring guidelines, prescribing of drugs, and diagnosis and management (IOM, 2001). Studies show that clinical decision support systems can increase clinician compliance with clinical guidelines and drug selection, screening for interactions, and monitoring for adverse side effects; but their utility in improving diagnosis is still unclear, especially in the ED setting (IOM, 2007). Further development of these systems is warranted, because of their promise in improving diagnosis and treatment, but additional research on their accuracy, effectiveness, and safety is also warranted.

Ideally, these tools should be modifiable and also allow for a multidirectional information flow. It should be possible to modify triage protocols to be specific for outbreak-related cases when warranted. And in addition to facilitating reporting of suspicious cases to the health department, they should allow the health department to alert front-line health care providers of a real or potential outbreak. For example, when a BioWatch Actionable Result (BAR) is declared or aberrancy is detected by syndromic surveillance, planners invariably want timely information from hospital EDs and other acute care providers to assess the validity of the signal.

This process could be dramatically enhanced in a setting of better bilateral electronic communication between clinicians and public health agencies. Unfortunately, the care settings in which this information exchange must occur (hospital EDs, intensive care units, and acute care adult and pediatric wards in hospitals and clinics) often have weak links with health departments, which tend to have more established ties with infectious disease departments. This represents a major opportunity for improvement in our nation's disease surveillance system. One approach is the use of regional emergency medical Internet (REMI) systems to communicate with and collect information from emergency services providers on a near-real-time basis, on scales ranging from local to multistate alerting and surveillance (Barthell et al., 2003; Foldy et al., 2004c).

Electronic Medical Records

Greater use of information from EMRs and other electronic health information sources, with linkages to public health, could enhance disease surveillance by detecting unusual cases of disease, clusters, or trends (Klompas et al., 2008; Lazarus et al., 2009). While adoption of EMRs is

proceeding slowly (Jha et al., 2009), their widespread adoption would help improve bioterrorism preparedness, but only if the standards for linking EMR and public health systems provide for timely reporting to public health and include the information needed to rapidly detect and respond to potential biothreats.

Electronic health record systems that are linked together by regional health information systems and to local and state public health departments could accomplish a number of essential tasks, including:

- increasing the capacity to prompt or automate key steps in notifiable disease reporting for patients meeting certain criteria (e.g., an ICD-9 diagnosis or laboratory report);
- increasing the capacity to prompt enhanced surveillance in response to a suspected or confirmed outbreak (e.g., automatic prompts to consider specific diagnostic testing for patients meeting clinical criteria); and
- increasing the capacity for public health officials to review more detailed clinical information (e.g., radiologic and laboratory findings) when a suspect disease cluster is detected or conduct more detailed chart reviews electronically.

Regional Health Information Exchanges

In a growing number of communities, information from EMRs, electronic laboratory reporting, hospital and other clinical registration systems, and other electronic health data are securely shared across organizational boundaries in regional health information exchanges (eHealth Initiative, 2008). In 2008, there were 42 operational HIE systems in the United States (eHealth Initiative, 2008).

These systems offer many opportunities to enhance both surveillance and information sharing between clinical providers and public health authorities. In Wisconsin, for example, data from over 10 hospitals and many clinics are made available (with personal identifiers removed) for real-time syndromic surveillance by local and state health departments (Foldy et al., 2008). CDC is preparing to pilot electronic feeds from three other HIEs into the BioSense syndromic surveillance system (Lenert, 2007). In Indianapolis, the Indiana Health Information Exchange has facilitated a great increase in the completeness and timeliness of electronic laboratory reporting to public health (Overhage et al., 2008). Indeed, in 2008, 6 of the 42 operational HIEs indicated that they were providing surveillance information to public health agencies, and 5 were exchanging electronic laboratory results with public health agencies (eHealth Initiative, 2008).

If HIEs are more widely adopted and become a universal medium for sending and receiving information in regional health care markets, they

may replace existing stand-alone public health alerting systems for communicating with clinicians and offer two-way communication between public health and health care partners to improve completion of case reports and similar collaborative communications. In the future, as the interoperability of HIEs with medical practice support systems like EMRs becomes more sophisticated, HIEs may offer the opportunity for public health officials to adjust electronic decision support systems that guide clinician practice (e.g., a rising incidence of pertussis or suspicion of an terrorist release of anthrax spores leading to specific prompts in the decision support tool to raise the provider's index of suspicion and prompt requests for diagnostic tests for a particular symptom complex) (Hanrahan et al., 2006). While such opportunities are currently speculative, if HIEs do survive and thrive, there are few technical reasons why public health systems and health information exchange could not converge over time, allowing more real-time and less labor-intensive information sharing between health care and public health professionals.

The federal government has already recognized the advantages of standardizing health information exchange at the national level. The second goal of the *Federal Health IT Strategic Plan: 2008–2012* reads, "Population Health—supports the use of electronic health information—primarily, but not exclusively, generated as a by-product of health care delivery—for critical national needs relating to public health, biomedical research, quality improvement, and emergency preparedness. Such use would promote early and effective management of infectious disease outbreaks, improved tracking of chronic disease management, the ability to gather data for research purposes, and the evaluation of health care based on value, by way of comparable price and quality information" (ONC, 2008, pp. 2–3). This commitment has been made more concrete by the health information technology programs passed in the 2009 American Recovery and Renewal Act, which created economic incentives for health care providers to use electronic medical records and engage in "meaningful use" of regional health information exchange.

The standardization of health information necessary to facilitate such clinical information exchange will similarly facilitate the horizontal transmission of critical public health information between jurisdictions as well as vertically from local to state to federal levels. As HIEs develop further, continued involvement of public health professionals will be needed to facilitate and evaluate this enhanced information sharing.

Although regional health information exchange systems can reduce the need for many unique and expensive interfaces tying EMR feeds and other data to public health systems, achieving wider adoption must overcome important barriers. Some of the barriers include establishing a basis for financial sustainability, addressing concerns about preserving privacy and

confidentiality of shared patient data, reaching agreements between public and private contributors on governance of the exchange system, and creating incentives for participation.

LABORATORY AND DIAGNOSTIC TESTING CAPACITY

Technology is expected to increase the availability, speed, accuracy, and utility of diagnostic tests, which would contribute to recognition of natural and terrorist disease outbreaks.

Rapid "Point-of-Care" Diagnostic Tests

The development and appropriate use of rapid, multiplexed "point-of-care" diagnostic tests seem likely to strengthen both surveillance and bedside patient care by helping clinicians pinpoint the cause of an infection (e.g., Mahony, 2008). This is still an emerging technology. In 2008, the Food and Drug Administration (FDA) approved the first multiplex system that simultaneously tests for 12 different respiratory viruses (FDA, 2008), as well as at least one other system that tests for a smaller set of respiratory viruses. Many bioterrorism agents produce nonspecific prodromes such as fever, cough, and myalgia that make it difficult to promptly diagnose the source of an infection if a patient presents for care in the first few days of illness before more characteristic signs and symptoms appear. In theory, the availability and use of validated multiplex point-of-care bioassays at frontline acute and primary care clinical settings would allow clinicians to test patients in response to public health alerts for persistent and seasonal pathogens, as well as bioterrorism agents and other pathogens of potentially great public health significance (e.g., avian influenza, SARS). In the event of a BAR or a public health alert, such testing might be used to detect or rule out a potential outbreak.

However, several factors can be expected to influence the implementation of such testing, especially for the purpose of detecting infections related to bioterrorism. Tests to be used in a clinical setting must be approved by the FDA, and the path to FDA approval of such diagnostic tests has not yet been made clear. Studies are needed to assess the costs of widespread use of such testing and how those costs will be met. For testing to be routinely conducted in a clinical setting, it may be necessary for the Medicare program and other insurers to agree to cover these costs to make their adoption economically attractive. As the current generation of multiplex tests for respiratory viruses are adopted, their contribution to surveillance will need to be evaluated. Rapid tests for clinical settings still need to be developed for the bioterrorism agents of greatest concern. If they are developed and approved, they, too, will require piloting and evaluation to establish their usefulness (see Recommendation 10, below).

Characterization of Pathogens

Many efforts are under way to extend capacities to molecularly characterize pathogens and compare findings to identify the emergence or spread of related cases of infectious disease (e.g., PulseNet model). Laboratories that diagnose and report cases now often send specimens to public health laboratories for phenotypic analysis or genetic "fingerprinting" (e.g., pulsed-field gel electrophoresis, insertion segment analysis, and nucleotide sequencing), which can be compared to other isolates around the nation or world. This has allowed cases of illness to be linked to common sources that would otherwise have gone unnoticed, and it has permitted the detection and characterizations of several recent national and international outbreaks of food-related disease (e.g., CDC, 2006, 2009b).

Collection and Testing of Clinical Specimens

The ability and capacity to collect and test clinical specimens as part of public health surveillance systems, either as an ongoing process or in response to possible alerts, needs to be expanded or enhanced. This involves improving the capability of hospital and commercial laboratories to serve as sentinel facilities to conduct preliminary testing of suspect bioterrorism agents and to rapidly recognize and transport suspect specimens to the nearest public health reference laboratory in the Laboratory Reference Network (LRN) for standardized confirmatory testing. It should be noted that attempts to constrain health care costs make it likely that microbiology tests will be used less frequently, especially in situations in which the clinical management of individual patients is unlikely to be dependent on definitive diagnostic testing. Thus, such surveillance may need to be supported financially by methods separate from personal health insurance.

There is a critical need to increase public health reference laboratory capacity in every state for

- molecular subtyping by DNA fingerprinting and DNA sequencing and serologic type testing;
- participation in networked comparisons of fingerprinting, such as CDC's PulseNet (which compares pulse-field gel electrophoresis of enteric organisms). This allows detection of the emergence of similar bacterial isolates from patients across state or even national boundaries, which may indicate widely separated cases in a disease cluster resulting from a single source, such as a contaminated food product;
- rapid molecular confirmation of Category A and B agents and other known infectious disease agents of public health significance (e.g., SARS and avian influenza [H5N1]);

- rapid development and deployment of molecular tests for new pathogens as they emerge (e.g., as was accomplished for novel influenza A [H1N1]); and
- electronic linking of public health laboratory information management systems with epidemiology and surveillance systems to enhance rapid reporting and detection of patterns of disease over time and space.

INFORMATION INTEGRATION AND KNOWLEDGE SHARING

In many public health systems, there are multiple surveillance systems and databases, typically created piecemeal over time for specific diseases and conditions or other purposes. Integrating these across local and state levels would permit greater awareness of patterns and trends and increase the likelihood that anomalies that might indicate a disease outbreak are detected and investigated.

Similarly, joining public health information with the information from other sources, such as information from law enforcement on terrorist activities, from surveillance of animal health, and from monitoring air and water quality, would enhance biosurveillance. Issues of privacy, confidentiality, and security must be carefully managed for such "fusion" of health information with other intelligence information (Riegle, 2009).

Integration of Public Health Information

Integration and analysis of public health information within and across public health jurisdictions promises to enhance surveillance by making it possible to associate related phenomena that otherwise would remain isolated. It might provide situational awareness of normal events, such as the beginning of the influenza season, while potentially enabling earlier detection of unexpected disease outbreaks caused by terrorism or that occur naturally. It may also help inform the response to an outbreak. As with other tools discussed here, its best use should be an area of cautious implementation and active evaluation.

Public health information originates from a variety of sources external to public health agencies, and even within a public health agency surveillance information is often compartmentalized by program (e.g., communicable disease, maternal and child health, environmental health). The major external source of public health information, of course, is the health care sector. Generally, health care providers are already required to report suspected cases of disease with major public health consequences, and approaches to enhancing the reporting of cases to public health have been discussed above. But other external sources of information important for biosurveillance do not necessarily report information to public health

authorities. These include law enforcement and intelligence agencies, agriculture and wildlife agencies that monitor animal health, municipal water authorities that monitor water quality, and air pollution agencies.

There is an urgent need for better situational awareness, both to detect anomalies that might signal a disease outbreak, and, in the event of an outbreak, to help responders monitor the spread of the disease and institute mitigating actions. This is specifically mandated in the Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417), which states that the Secretary of Health and Human Services shall "establish a near real-time electronic nationwide public health situational awareness capability." In response, CDC established a public health information fusion center in 2008, BioPHusion, to "incorporate information from multiple disparate data sources, facilitate the exchange of information across programs, and analyze aggregated interpreted data (information) from existing surveillance systems in order to enhance agency-wide situational awareness" (Rolka et al., 2008, p. 3). Currently, BioPHusion receives information from CDC programs, including BioSense and Epi-X, and from open sources outside CDC. It distributes a daily situational awareness report to the CDC director, division directors, and branch chiefs, and to selected external partners regarding infectious disease outbreaks, toxic spills and other accidental exposures, and natural disasters such as earthquakes and hurricanes. BioPHusion receives information about BioSense anomalies and the BioSense news digest. The program is working out memoranda of agreement to share information with other federal agencies with public health-related data, including the U.S. Department of Agriculture, which conducts veterinary surveillance. The plan for the future is to create online communities of public health practitioners who collect and exchange real-time information for situational awareness at the state and local levels (Rolka et al., 2008).

In 1994, problems with the local water supply in the Milwaukee area resulted in a cryptosporidium outbreak that sickened approximately 400,000 residents. The outbreak was not recognized until shortages of diarrhea medications and enteric culture media were reported (Proctor et al., 1998). The outbreak might have been detected earlier if information held by different agencies and organizations had been shared (Foldy, 2004). In response to that experience, the City of Milwaukee Health Department successfully piloted data integration, including information "dashboards" in which multiple data streams could be compared in the same time sequence. Information was accumulated opportunistically, including ED chief complaints, laboratory reports, hospital ED diversions, ambulance runs, medical examiner reports of unusual or suspicious deaths, poison control and nursing hotline call volumes, and over-the-counter pharmacy sales (Foldy et al., 2004a). In addition to analyzing this information in the public health agency, results were also supplied to the various data providers. Such "situ-

ational awareness" or "fusion" systems are increasingly common in public health, but must be well designed to support decision making rather than drown the user with data of limited value (Endsley et al., 2003).

Integration of Public Health with Other Information Sources

A further step is to integrate public health information with other information that provides contextual information for interpreting public health events. For example, information from intelligence sources on potential or actual threats of bioterrorism could be used to enhance the interpretation of public health surveillance data or prompt active surveillance. A syndromic surveillance alert based on an unexpected increase in influenza-like symptoms might be seen as a stronger signal if intelligence information were available that a terrorist group was planning an attack. Active surveillance for cases would no doubt be instituted, and, if the intelligence could identify the biological agent, the surveillance could be focused on signs and symptoms associated with that agent.

At the national level, the Department of Homeland Security (DHS) has established the National Biosurveillance Integration Center (NBIC) to integrate biosurveillance information with intelligence information about threats to improve situational awareness and early warning of bioterrorism. As noted in Chapter 4, NBIC has been slow to achieve full operational capability and exemplifies the complexity of integrating surveillance data across agencies.

Most states and some localities have established fusion centers, which are in various stages of development. Most of them are headed by law enforcement agencies (GAO, 2007). State and local fusion centers work most closely with the Federal Bureau of Investigation and, to a lesser extent, DHS, which assign personnel to the centers. The original impetus for fusion centers was the threat of terrorism, but most of them also collect, analyze, and disseminate criminal information. State health departments are partners in a number of fusion centers, but these centers are not generally viewed as the locus of situational awareness for public health agencies.

NATIONAL BIOSURVEILLANCE STRATEGY

In October 2007, Homeland Security Presidential Directive 21 (HSPD-21) directed the Secretary of Health and Human Services to establish an "operational national epidemiologic surveillance system for human health" (The White House, 2007). According to HSPD-21, the national surveillance system should be built on existing federal, state, and local surveillance systems; provide incentives for public health agencies to implement local surveillance systems where they do not exist; be built using electronic health information

systems; enable two-way information flow between federal, state, and local government public health authorities and clinical health care providers; and integrate the data into a national biosurveillance common operating picture (Box 5-1).

HSPD-21 also calls for the Secretary of Health and Human Services to establish an Epidemiologic Surveillance Federal Advisory Committee, including representatives of state and local public health and private-sector health care, "to ensure that the federal government is meeting the

BOX 5-1
Biosurveillance: A Critical Component of Public Health and Medical Preparedness

Homeland Security Presidential Directive 21 *Public Health and Medical Preparedness* says, in part:

> The United States must develop a nationwide, robust, and integrated biosurveillance capability, with connections to international disease surveillance systems, in order to provide early warning and ongoing characterization of disease outbreaks in near real-time. Surveillance must use multiple modalities and an in-depth architecture. We must enhance clinician awareness and participation and strengthen laboratory diagnostic capabilities and capacity in order to recognize potential threats as early as possible. Integration of biosurveillance elements and other data (including human health, animal health, agricultural, meteorological, environmental, intelligence, and other data) will provide a comprehensive picture of the health of communities and the associated threat environment for incorporation into the national "common operating picture." A central element of biosurveillance must be an epidemiologic surveillance system to monitor human disease activity across populations. That system must be sufficiently enabled to identify specific disease incidence and prevalence in heterogeneous populations and environments and must possess sufficient flexibility to tailor analyses to new syndromes and emerging diseases. State and local government health officials, public and private sector health care institutions, and practicing clinicians must be involved in system design, and the overall system must be constructed with the principal objective of establishing or enhancing the capabilities of State and local government entities.

SOURCE: The White House (2007).

goal of enabling state and local government public health surveillance capabilities." The National Biosurveillance Advisory Subcommittee (NBAS) was established in May 2008 as a subcommittee to the Advisory Committee to the Director of CDC to meet this mandate. CDC expects NBAS to "review, research, guide, and endorse the National Biosurveillance Strategy for Human Health on an annual basis" and "serve as an innovative engine for advancing nationwide biosurveillance capability" (Sosin, 2009).

CDC was assigned the lead in the interagency effort to develop the operational national surveillance system. CDC's Biosurveillance Coordination Unit worked with CDC biosurveillance strategy management and advisory teams; a state, local, territorial, and tribal work group; the interagency HSPD-21 Federal Biosurveillance Work Group, and representatives of other organizations to develop a working draft, *National Biosurveillance Strategy for Human Health 2008–2013* (*The Strategy*), which was released for public review and comment in December 2008 (CDC, 2008a).

The Strategy summarizes the well-known shortcomings of current surveillance systems in a short paragraph (CDC, 2008a, p. 10):

> Notifiable disease reports are often accurate, but not timely. Syndromic surveillance systems can be timely, but may lack specificity needed to validate and interpret signals and cues. Communication between laboratorians and epidemiologists is sometimes poor and all too frequently still manual and paper-based. Cues to human health threats from animal, plant, and environmental sources are inconsistently identified and shared. In addition, professionals within the public health system may have pieces of information that are not being effectively integrated or shared to achieve accurate situation awareness for themselves and other responders.

The Strategy identifies the following six priority areas "to address critical gaps and opportunities."

1. *Electronic Health Information Exchange*: strengthening and expanding upon multidirectional health information exchanges with health care and public health entities.
2. *Electronic Laboratory Information Exchange*: strengthening information exchanges between and among clinical and public health laboratories and between laboratories and public health programs for use in investigations. This is a part of electronic health information exchange but was broken out to underscore the importance of laboratories in biosurveillance.
3. *Unstructured Data*: leveraging digital information (e.g., text and image) that is not in a database format for biosurveillance for human health (e.g., mentions of disease names or symptoms in media reports)

4. *Integrated Biosurveillance Information*: generating actionable health intelligence by increasing access to information resources and synthesizing multiple streams of information into one coherent picture.

5. *Global Disease Detection and Collaboration*: ensuring the United States' ability to contribute to and participate in global disease detection and response through increased global capacity and coordinated international action.

6. *Biosurveillance Workforce of the Future*: addressing the need for a workforce that is available, prepared, and collaborating to adapt to evolving threats and crises.

The six priority areas could be considered to be the Department of Health and Human Service's (HHS's) plans to enhance the current surveillance system (i.e., take advantage of new opportunities), but the priorities also include efforts to complete the basic infrastructure (i.e., fill gaps).

The committee finds *The Strategy* to be very compatible with its views of areas that should and could be enhanced to improve early detection of biological threats. For example, *The Strategy* acknowledges that biosurveillance includes early detection of environmental threats as well as early suspicion and confirmation of cases of human infection and disease. In other words, environmental monitoring systems such as BioWatch are to be considered an integral part of surveillance of public health threats and should be integrated with surveillance by public health agencies and the health care system. (This topic is addressed more fully in Chapter 6.)

The intent of *The Strategy* is laudable, but it needs to be accompanied by details of its execution and, importantly, its funding. Furthermore, investment in surveillance systems should be accompanied by investment in the evaluation of their effectiveness. The main barriers to a national system, even a federated system of systems, are organizational and financial rather than technical (not that the technical issues are easy to resolve). A concept of operations document is planned for completion in 2009, and it may provide more detail on federal, state, and local responsibilities (Sosin, 2009).

COSTS OF INFECTIOUS DISEASE SURVEILLANCE AND ENHANCEMENTS

Part of the charge to the committee was to "assess the costs and benefits of an enhanced national surveillance system that relies on U.S. hospitals and the U.S. public health system . . . and its effectiveness compared to that of the current BioWatch approach." The committee engaged Industrial Economics, Incorporated (IEc), to collect and analyze information on the costs of the public health system as it currently exists and the costs of an

enhanced public health surveillance system. After its effort, IEc reported on available cost data and concluded that "the available data do not support a comprehensive cost analysis of either current or enhanced public health activities related to biosurveillance and outbreak response" (IEc, 2009; see Appendix C).

IEc identified several significant obstacles to performing a cost analysis of public health programs in general or public health surveillance programs specifically. The primary obstacle is the lack of financial transparency. Information on spending by functional category (e.g., surveillance) is not comparable across jurisdictions. Unlike hospitals and health systems, schools and school districts, and institutions of higher education, public health departments generally do not have (1) uniform classifications for revenues and expenditures, (2) electronic management information systems, (3) nationwide standardized financial analysis and reporting practices, or (4) professional associations of financial analysts and managers (Honoré et al., 2007). This lack of standardization is reinforced by the absence of a universally accepted agreement regarding what practices or activities constitute surveillance (despite general acceptance of the standard definition promulgated by CDC) and by the organizational variability of public health agencies in terms of program mix, division of labor between state and local agencies, and accounting systems (Sensenig, 2007).

In addition, most public health agencies order their budgets and financial reports by organizational unit (e.g., Communicable Disease Bureau, Laboratory Science Bureau, etc.) or object classification (e.g., personnel, supplies, etc.) rather than by function or mission (e.g., monitoring community health status, surveillance and identification of health threats, disease prevention and health promotion, personal health services, regulation of health and safety, etc.). Moreover, CDC (2009a) does not currently collect or track estimates of the costs at the federal, state, and local levels for the CDC disease surveillance programs relevant to biodefense and other public health emergencies.

Some past efforts to assess the costs of surveillance and other public health activities (Eilbert et al., 1996; Barry et al., 1998, 2000) tried using a set of 10 "essential public health services" (Box 5-2) as a basis for apportioning costs. Surveillance and detection of infectious disease threats is part of the second of these services: "Diagnose and investigate health problems and health hazards in the community." While these studies concluded that public health expenditures can be measured reliably and consistently using the essential services framework, they noted a number of serious limitations in this approach, including differences in state and local public health agency organizational structures, variability in the interpretation of terminology, lack

BOX 5-2
The 10 Essential Public Health Services

1. Monitor health status to identify community health problems
2. Diagnose and investigate health problems and health hazards in the community
3. Inform, educate and empower people about health issues
4. Mobilize community partnerships to identify and solve health problems
5. Develop policies and plans that support individual and community health efforts
6. Enforce laws and regulations that protect health and ensure safety
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable
8. Assure a competent public health and personal care workforce
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services
10. Conduct research to attain new insights and innovative solutions to health problems

SOURCE: Public Health Functions Steering Committee (1995).

of information on public health expenditures by non-public health agencies, and variability in the quality of local health department data.

In 2004, the Missouri Department of Health and Senior Services (MDHSS) categorized its expenditures using the essential services framework and compared them with performance measures. One of the limitations noted in that study was the difficulty of determining which expenditures should be assigned to each essential function. MDHSS had to use a crosswalk between its accounting categories and the essential services categories, which introduced an element of subjectivity and arbitrariness (Honoré and Schlechte, 2007).

In 2003, the IOM recommended that HHS conduct an annual assessment of the state of the nation's public health infrastructure and capacity to provide the 10 essential public health services to every community and report on the assessment to Congress. "The assessment should include a thorough evaluation of federal, state, and local funding for the nation's governmental public health infrastructure" (IOM, 2003, p. 7). This recommendation was not adopted.

CDC and six other public health organizations have been promoting standardization through the National Public Health Performance Standards Program (NPSPHP) since 2002.[4] NPSPHP is organized around the 10 essential services of public health. Under essential service #2 ("Diagnose and investigate health problems and health hazards in the community"), NPSPHP (no date) has identified three primary types of activities at the local level:

1. *Identification and Surveillance of Health Threats*. This includes surveillance systems to monitor health problems and identify health threats, timely submission of reportable disease information, and adequate resources to support surveillance and investigation activities.
2. *Investigation and Response to Public Health Threats and Emergencies*. This includes written protocols for case finding, contact tracing, source identification, and containment; current epidemiological case investigation protocols; a designated emergency response coordinator; capacity of personnel to respond quickly in emergencies or disasters; and periodic evaluations of public health emergency response preparedness and performance.
3. *Laboratory Support for Investigation of Health Threats*. This includes ready access to laboratories for routine diagnostic and surveillance needs; ready access to laboratories able to support investigation of public health threats, hazards, and emergencies; licensed and/or credentialed laboratories; and maintenance of guidelines or protocols for handling laboratory samples.

To date, the NPSPHP has been used by public health agencies in more than 35 states for self-assessment. However, the program does not collect or assess data on expenditures in relation to performance, making it impossible to conduct cost-effectiveness analyses. For example, a performance measure might be the number of graduate-level epidemiologists or the development or expansion of an ELR system or the number of Category A agents the state laboratory can test for; but it is not possible to determine the cost-effectiveness of improvements in these measures without cost information.

Given the lack of nationally comparable expenditure data, IEc concentrated on collecting examples of cost data for enhanced surveillance and outbreak response activities or programs under way at the state or local level. The intent was to provide some insight into the potential orders of

[4]The other organizations are the American Public Health Association, Association of State and Territorial Health Officials, National Association of County and City Health Officials, National Association of Local Boards of Health, National Network of Public Health Institutes, and Public Health Foundation. Information about the program is at http://www.cdc.gov/od/ocphp/nphpsp/index.htm.

magnitude or range of costs of developing and maintaining systems that improve biosurveillance and response.

IEc obtained one national-level cost estimate—the cost of implementing a national ELR infrastructure to enable quicker communication of results from public health and private laboratories to the appropriate public health authorities. Local, state, federal, and private-sector experts at a 2007 Association of Public Health Laboratories meeting sponsored by CDC estimated it would cost $25 million to plan the system, $25 million to build state public health laboratory information systems where needed,[5] $600 million to implement the system, and $100 million per year to operate and maintain it (APHL, 2007).

IEc was most successful in identifying cost information for the larger IT-related efforts: ELR systems, syndromic surveillance systems, HIEs, and electronic disease surveillance and outbreak management software. However, these data were often incomplete. For example, in some cases the systems are too new to provide operations and maintenance costs. IEc was least successful in obtaining cost estimates for marginal expansion of laboratory testing and diagnostic capabilities; clinical decision support tools and point-of-care diagnostic tools; health alert networks; and fusion centers. In some instances, anticipated costs varied greatly between two different localities' planned implementation of enhancements (e.g., regional health information exchanges in Tarrant County, Texas, and planned by Pennsylvania and Ohio), illustrating the difficulties in arriving at costs for nationwide implementation and operation. Appendix C provides details regarding the costs for specific examples of enhancements to surveillance in the public health and health care systems.

RECOMMENDATIONS

In this chapter, the committee considered several potential enhancements of public health and health systems for surveillance for the detection of bioterrorism and other significant infectious disease threats. The emergence of the novel influenza A (H1N1) outbreak in April 2009, as this report was being finished, highlighted many of the challenges of infectious disease surveillance as well as opportunities to apply enhanced approaches like those discussed in this chapter. Box 5-3 illustrates the experience of one state (Wisconsin) at the early stages of the outbreak. Other states experiences will vary, and these differences can be explored to learn more about strengths and weakness of a range of disease surveillance resources.

[5]At that time, approximately half the states did not have any form of public health laboratory information management system in place.

BOX 5-3
Pandemic Influenza A (H1N1):
Implications for Enhanced Surveillance

On April 21, 2009, the Centers for Disease Control and Prevention (CDC, 2009c) confirmed that two children had been infected in late March by a pandemic influenza A (H1N1) strain. Within a week, CDC had disseminated a set of working case definitions and strategies for testing, isolation, and treatment of suspect cases, and it had received approval for use of a new real-time PCR test to confirm pandemic influenza A (H1N1) infection. Many suspected cases that were previously "untypable" could be confirmed as the novel H1N1 virus.

The surveillance challenges facing states and communities have illustrated many of the concerns highlighted in this report. But the rapidity of the response also reflects past funding and innovation directed specifically at the management of a widely anticipated influenza pandemic. It does not necessarily reflect the state of the nation's capability to mount surveillance and response for other types of biological threats, including bioterrorism. Events in Wisconsin during the first few weeks of the outbreak serve as an early case study.

With the late-April information from CDC, the Wisconsin Division of Public Health and the Wisconsin State Laboratory of Hygiene implemented a new system of surveillance and proactively took steps to manage a possible outbreak of uncertain virulence. An around-the-clock incident command system was established. Instructions regarding the recognition and reporting of suspect cases, the submission of specimens for testing, isolation and other infection control measures, and treatment were disseminated to clinicians, hospitals, local health departments, and infection control professionals using email-lists, Wisconsin's Health Alert Network, and the Wi-Trac website for health care situation awareness and alerting.

Existing influenza surveillance systems, including sentinel clinic networks for assessing visits for influenza-like illness (ILI) and death record reviews for pneumonia or influenza, shifted from weekly to daily reporting. The Wisconsin Health Information Exchange (WHIE) provided near-real-time information on Milwaukee emergency department visits, hospital admissions, and the proportions of ILI among both. The Wisconsin Electronic Disease Surveillance System (WEDSS) (in use by approximately one-third of local health jurisdictions) incorporated reporting and case management for pandemic H1N1, and state and local public health laboratories implemented electronic laboratory reporting of test results. Remaining local health jurisdictions were provided reading rights on WEDSS to view laboratory results and other epidemiologic information in real time on suspected and confirmed cases in their jurisdictions.

Wisconsin's first three probable cases (untypable Influenza A) were reported on April 29. Many probable cases were also identified by a Milwaukee-area private research laboratory whose methods were validated by the state

Laboratory of Hygiene, and virtually all probable cases were later confirmed by additional analysis. The number of probable cases increased daily, including many among Milwaukee school children. National guidance then in effect recommended consideration of partial or total school system closure to reduce community transmission of the virus when multiple schools experienced cases—a high-consequence action for schools, families, and employers. Analysis of multiple surveillance systems showed that while emergency department visits for ILI were above normal and rising (with surges noted after major press announcements), no major increase had occurred in hospitalization for respiratory illness or deaths from pneumonia or influenza. This finding was consistent with information from CDC and other national authorities and with public health workers' interviews of patients with probable or suspect illness. Taken together, this information showed the virulence of the new virus might not warrant such extraordinary social distancing measures as school-system closings, and Milwaukee schools remained open.

By early May, three Wisconsin laboratories (two public and one private) were validated to confirm cases, speeding results and reducing the load on CDC laboratories. The number of laboratory-confirmed cases increased rapidly, making Wisconsin's case count the highest in the nation. However, Wisconsin also had significantly lower case-hospitalization and case-mortality rates than the national average, suggesting more complete ascertainment of mild illness. ILI rates and other measures of disease incidence remained similar to other states. The state's surveillance and laboratory capacity helped improve understanding the virulence of the virus. At the beginning of June 2009, however, Wisconsin's ILI rates began to rise, peaking the week of June 20. Comparison of syndromic, hospitalization, and death surveillance between Wisconsin and other states appeared to confirm that Wisconsin experienced exceptionally high H1N1 activity during this period. Three weeks later, at the conclusion of the public school year, the Wisconsin rates declined markedly.

The emergence of pandemic influenza A (H1N1) in Wisconsin illustrates several conclusions by the committee. Early warning from international and national authorities prompted rapid establishment and refinement of state and local surveillance systems. Clinicians were alerted electronically to initiate case finding and informed about how to recognize cases. LRN laboratories provided standardized and reliable testing capability within days of the first report of the virus. Electronic laboratory reporting into a shared electronic case-management environment facilitated case investigation and management; managing the rush of thousands of cases on paper would have been impossible. Near-real-time monitoring of ILI in primary care, emergency rooms, and hospitals, including information from a regional Health Information Exchange, helped gauge the spread of the outbreak, and more importantly provided valuable, if preliminary, information regarding the virulence of a novel pathogen. Rudimentary systems for comparing Wisconsin's syndromic information with other areas (e.g., BioSense and ILINet) proved helpful in distinguishing spurious from real differences in disease incidence.

The committee tried to assess the benefits and costs of these enhancements, based on examples around the country. In all but one case, however, it was unable to determine the costs of adopting them nationally or to quantify their benefits with any rigor. Although the committee could not recommend enhancements based on a formal benefit-cost analysis, a consensus exists that certain steps should be taken because of the urgent need to fill gaps and strengthen the infrastructure for surveillance of infectious disease. These steps are the subject of the four recommendations that follow.

Enhancing Methods for Surveillance

Infectious disease surveillance is a key public health practice, and it is the responsibility of state and local government. One federal role—aggregation and analysis of surveillance data—is achieved primarily through mutual agreement and cooperation with the state and local public health agencies and through federal funding incentives. Many novel and promising surveillance techniques and programs have been developed rapidly at the local, state, and federal level in recent years, spurred in part by funding for bioterrorism and public health emergency preparedness since 2001. However, as noted in Chapter 4, there has been limited evaluation of surveillance approaches, and national standards for surveillance data and interoperability between systems are incompletely developed. Surveillance capacities are unevenly distributed among states and localities, and limited year-to-year funding has made long-term planning and recruitment of qualified personnel difficult. This complex series of problems must be addressed by a dedicated, strategic, integrated, and adequately funded program. The CDC definition of surveillance is explicit in noting that surveillance is an activity intended to inform specific prevention or control programs; thus, it is essential that efforts to reform surveillance be led by those responsible for the programs the surveillance systems are intended to serve.

RECOMMENDATION 8: HHS should support the development, testing, and evaluation of improved methods for surveillance for infectious disease outbreaks. HHS, through CDC, should take a stronger leadership role in evaluating and enhancing efforts for automating both traditional provider and laboratory reporting and syndromic and other approaches to surveillance, including the development of standards, coordination of state and local initiatives, and integration of federal programs with state and local activities. HHS should assign this leadership role to those responsible for the prevention and control programs these surveillance systems are intended to serve, and it should rigorously evaluate these surveillance efforts.

HHS should coordinate a strategic, goal-oriented, integrated program of intra- and extramural research and development, pilot-testing, and operational evaluation of improved public health surveillance methods. This program should be implemented in partnership with DHS, the Agency for Healthcare Research and Quality, the National Institutes of Health, and other federal, state, and local agencies that have a role in monitoring threats to human health. Program planning should identify the need for additional evidence regarding effectiveness, identify gaps in the geographic deployment and quality of public health surveillance, identify and evaluate promising methods and technologies, and integrate and harmonize approaches across the many surveillance programs used by CDC and others in the public health community.

The focus of this effort should be to improve

- notifiable condition reporting by clinicians and laboratories, including automated, electronic reporting methods;
- syndromic and other automated health information monitoring;
- environmental surveillance;
- public health reference laboratory services;
- situational awareness based on integration of multiple surveillance and other information streams, including intelligence on terrorism threats;
- efficiency, effectiveness, and agility of information management at the state and local levels;
- horizontal and vertical information sharing across jurisdictions;
- surveillance support for rapid decision making and response; and
- methods to compare the utility and cost-effectiveness of surveillance methods.

Effective methods resulting from this effort should be deployed across state and local jurisdictions through a combination of federal funding and local investments.

Enhancing Mechanisms for Information Sharing

The threat of bioterrorism is just one of several reasons for the United States to improve means for sharing disease surveillance information. Another reason is to enhance detection of naturally occurring diseases, including emerging infectious diseases such as SARS and possibly avian influenza, and the re-emergence of traditional threats such as tuberculosis. At the same time, scientific and technological advances make such information sharing more effective and useful. Some advances make it quicker and easier to collect and transmit data and others make it easier to analyze them for

patterns and anomalies. Others, such as genetic sequencing and polymerase chain reaction (PCR) allow new tests to be developed rapidly. The sharing of phenotypic and genotypic fingerprinting results enables molecular epidemiology—comparing and linking strains to connect widely separated cases—in ways not possible before.

In addition to quicker and more effective outbreak detection, information sharing can be expected to improve situational awareness and response capabilities. It should enable a jurisdiction to better track an outbreak, focus its response activities, and determine the effectiveness of response efforts. Better information sharing should also enable affected jurisdictions to see the bigger picture and coordinate their actions for their mutual benefit.

RECOMMENDATION 9: DHS and HHS should enhance the efforts to develop a mechanism for providing a national situational awareness of biological threats and significant disease outbreaks, to better inform rapid decision making and response through cross-jurisdictional data sharing and analysis of data. To this end, DHS and HHS should facilitate the development of an interoperable, secure, bidirectional, nationwide information-sharing infrastructure and ensure that local and state health officials have ready access to the system.

"National" in this context does not mean federal or centralized, although an important feature of such an information-sharing infrastructure is the ability to analyze data aggregated across multiple jurisdictions. This can sometimes make it possible, for example, to recognize a disease outbreak when the number of cases in any one jurisdiction is too small to generate concern. Or, if the exposure is in a transportation hub such as an airport or train station, it may make it possible to recognize that geographically scattered cases are the result of exposure in a single incident.

A nationwide information-sharing infrastructure that is decentralized and a cooperative effort by multiple jurisdictions will also require a bidirectional information flow. Higher levels of data aggregation and analysis may be necessary to detect an outbreak in its earliest stages, but an effective response depends on well-informed actions by and cooperation among the state and local public health agencies where people are sick. A decentralized cooperative infrastructure should also enhance data sharing because the data providers would find it to be useful in carrying out their missions.

Accordingly, CDC and the states should focus their efforts on developing and deploying methods for intra- and interstate, cross-jurisdictional integration, sharing, analysis, and display of public health surveillance information. This system should function to monitor the presence of naturally occurring or deliberately introduced infectious agents, discover emerging or yet undefined threats to public health, and integrate data from the

BioWatch program and the public health and health care sectors. Priority should be given to results of tests for laboratory-reportable diseases, LRN biothreats, and BioWatch samples.

Improving Technologies for Clinical Case Recognition and Reporting

If environmental surveillance systems such as BioWatch do not detect a bioaerosol attack (or if a biological attack takes another form), early detection may depend upon an astute clinician's recognition of history, symptoms, or signs that are consistent with exposure to a bioterrorism agent. However, most clinicians will be seeing what amounts to a rare disease for the first time and may not recognize it, especially in the early stages when symptoms are still consistent with other, much more common (and less dangerous) diseases. The availability, and use, of valid and reliable automated assistance may aid in recognizing rarely encountered diseases that pose a large threat to public health.

RECOMMENDATION 10: HHS should promote the development, testing, and evaluation of technologies that strengthen the accuracy, timeliness, consistency, and completeness of clinical diagnosis of infectious diseases of public health importance, and that facilitate timely reporting of these diagnoses to public health authorities.

Promising strategies, described earlier in this chapter, include

- computer-assisted emergency department triage;
- bedside decision support tools with automated case reporting;
- rapid point-of-care laboratory testing; and
- multiplex assays that could be used for epidemiologic investigations, surveillance, or clinical applications, especially in the context of suspected outbreaks or concerning signals from syndromic systems or BioWatch.

HHS, under the auspices of the Office of Assistant Secretary for Preparedness and Response, should identify and support the deployment of web-based clinical decision support tools to help triage nurses and acute care clinicians identify, report, and manage suspicious cases of diseases of public health concern. These systems should be clinically useful for more routine diseases and, therefore, be employed on an ongoing basis. They should be bidirectional so they can quickly and reliably communicate public health alerts to front-line providers as well as enable busy clinicians to easily report suspect or confirmed cases to the local health department. The systems should be easily modifiable so they can be updated to reflect evolving knowledge of a bioterrorist attack or infectious disease outbreak

and provide event-specific recommendations to providers on recognizing and managing outbreak-associated cases.

Enhancing Public Health Surveillance Capacity

Before the terrorism events of 2001, the governmental public health infrastructure was unevenly, but generally inadequately, staffed and funded to accomplish its traditional tasks, including surveillance (IOM, 2003). During the 1990s, some states and localities began to use information technologies to develop new techniques to counter biological threats, such as syndromic surveillance, monitoring of health-related behaviors such as over-the-counter pharmacy sales and absenteeism, and electronic laboratory information management and reporting systems. CDC began to encourage and subsidize electronic reporting of surveillance data. Congress began to fund state and local public health preparedness in 1999 through CDC's Public Health Emergency Preparedness Program (PHEP). The events of 2001, however, made the general weakness in the capacity of the public health system painfully evident to policy makers (IOM, 2003).

At that time, there were plans under the Public Health Improvements Act of 2000 to provide grants to improve basic state and local public health infrastructure and under the Public Health Threats and Emergency Act of 2000 to provide grants for state and local bioterrorism preparedness. After 2001, the two efforts were combined and focused on preparedness for bioterrorism and other health emergencies (IOM, 2003). The Health Resources and Services Administration in HHS began a Hospital Preparedness Program (HPP) in 2002. Federal funding for public health and hospital preparedness rose from less than $50 million in fiscal year (FY) 2001 to more than $1 billion in FY 2002.

The substantial infusion of federal funds for public health and medical preparedness has improved the general level of preparedness, but the categorical nature of the funding and the uncertainty of its continuation has generally discouraged public health agencies from integrating these new capacities with traditional programs. At the same time, the basic public health infrastructure, such as staffing and electronic information management and analysis systems, did not experience the same level of investment in most places. This uneven level of basic organizational capacity reduces the national level of preparedness to detect and, especially, to respond to and manage the consequences of a major health emergency. The need for a minimum standard of local public health services to detect public health emergencies, as demonstrated by the rapid global spread of illnesses like SARS and the novel influenza A (H1N1), is also now codified in the World Health Organization's International Health Regulations (WHO, 2008). Thus there is an enforceable treaty obligation to improve the capability of local health services across the United States.

Meanwhile, the current economic recession is causing significant cutbacks in state and local government programs, including basic public health programs. PHEP and HPP funding has also declined for several years, even though much of the federal investment in capacity building requires continued financial support to be effective. Even with continuing federal investments, achieving the desired minimum state and local capacities for surveillance for bioterrorism and infectious disease threats will be challenging. The task is substantial and will require effective coordination and collaboration across the diversity of configurations of state and local public health systems and across complexities of state and federal relationships and interagency action at the federal level.

RECOMMENDATION 11: HHS and DHS should give high priority to building and sustaining sufficient public health workforce strength and competencies, along with associated laboratory and information management capacities, needed by all states and communities to detect a bioterrorism attack or other public health emergency. They should pursue a nationally consistent minimum level of disease surveillance and communication sufficient to provide early warning and tracking of bioagent attacks and outbreaks of natural disease. Key state and local capacities should include the following:

- **Adequate amounts and types of staff expertise, including infectious diseases, veterinary health, laboratory science, environmental health, applied epidemiology and biostatistics, and health informatics;**
- **Adequate public health reference laboratory capacity;**
- **Electronic laboratory reporting systems to ensure timely and complete transmission of notifiable disease reports from commercial and hospital-based laboratories to public health;**
- **Universal access to public health reference laboratory services for detecting and confirming biothreats and other emerging infectious diseases and performing molecular typing to link cases in outbreaks;**
- **Robust surveillance and outbreak management information systems;**
- **Electronic death registration systems;**
- **Health alert networks that connect public health departments with all health care facilities and providers in their jurisdictions; and**
- **Integration of public health needs and systems into emerging health information exchanges.**

For maximum benefit this investment should be directed at developing and maintaining staff expertise, informed decision making, and response capabilities that would serve in both natural and bioterrorism-related disease outbreaks.

REFERENCES

APHL (Association of Public Health Laboratories). 2007. *Framework for electronic laboratory reporting: Recommendations to policymakers*. A report of the Electronic Laboratory Reporting Consensus-Building Meeting held October 30, 2007, in Arlington, VA. http://www.aphl.org/policy/Documents/Electronic_Lab_Reporting_2007.pdf (accessed March 26, 2009).

Augustine, J.J., A.L. Kellermann, and J.P. Koplan. 2004. America's emergency care system and severe acute respiratory syndrome: Are we ready? *Annals of Emergency Medicine* 43(1):23–26.

Babin, S., S. Magruder, S. Hakre, J. Coverly, and J.S. Lombardo. 2007. Understanding the data: Health indicators in disease surveillance. In: *Disease surveillance: A public health informatics approach*, edited by J.S. Lombardo and D.L. Buckeridge. Hoboken, NJ: Wiley-Interscience. Pp. 43–90.

Baker, E.L., Jr., and J.P. Koplan. 2002. Strengthening the nation's public health infrastructure: Historic challenge, unprecedented opportunity. *Health Affairs* 21(6):15–27. http://content.healthaffairs.org/cgi/reprint/21/6/15 (accessed March 25, 2009).

Baker, E.L., M.A. Potter, D.L. Jones, S.L. Mercer, J.P. Cioffi, L.W. Green, P.K. Halverson, M.Y. Lichtveld, and D.W. Fleming. 2005. The public health infrastructure and our nation's health. *Annual Review of Public Health* 26:303–318.

Barry, M.A., L. Centra, E. Pratt, Jr., C.K. Brown, and L. Giordano. 1998. *Where do the dollars go? Measuring local public health expenditures*. Washington, DC: Public Health Foundation. http://www.phf.org/reports/Expend1/loclexpn.pdf (accessed February 23, 2009).

Barry, M.A., R. Bialek, M.R. Fraser, C.K. Brown, and S. Vogel. 2000. *Statewide public health expenditures: A pilot study in Maryland*. Washington, DC: Public Health Foundation. http://www.phf.org/reports/Expend1/MDmain.pdf (accessed February 23, 2009).

Barthell, E.N., S.L. Foldy, K.R. Pemble, C.W. Felton, P.J. Greischar, R.G. Pirrallo, and W.J. Bazan. 2003. Assuring community emergency care capacity with collaborative Internet tools: The Milwaukee experience. *Journal of Public Health Management and Practice* 9(1):35–42.

Bullard, M. 2008. *Emergency department potential for biosurveillance and BioWatch*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 3, November 3–5, Washington, DC.

Cass, D. 2005. Once upon a time in the emergency department: A cautionary tale. *Annals of Emergency Medicine* 46(6):541–543.

CDC (Centers for Disease Control and Prevention). 2001. *Public health's infrastructure: A status report*. Atlanta, GA: CDC. http://www.uic.edu/sph/prepare/courses/ph410/resources/phinfrastructure.pdf (accessed February 12, 2009).

CDC. 2006. Surveillance for foodborne-disease outbreaks—United States, 1998–2002. *Morbidity and Mortality Weekly Report* 55(SS-10):1–34. http://www.cdc.gov/mmwr/PDF/ss/ss5510.pdf (accessed August 7, 2009).

CDC. 2008a. *National biosurveillance strategy for human health, 2008–2013*. Working Paper Version 1.0. December 15. http://sites.google.com/site/nbshh10/graphics-and-documents/NationalBiosurveillanceStrategyv10_121508-1650.pdf?attredirects=0 (accessed March 3, 2009).

CDC. 2008b. Potential effects of electronic laboratory reporting on improving timeliness of infectious disease notification—Florida, 2002–2006. *Morbidity and Mortality Weekly Report* 57(49):1325–1328. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5749a2.htm?s_cid=mm5749a2_e (accessed December 22, 2008).

CDC. 2009a. *IOM review*. Document submitted to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, January 13.

CDC. 2009b. Multistate outbreak of *Salmonella* infections, associated with peanut butter and peanut butter-containing products—United States, 2008–2009. *Morbidity and Mortality Weekly Report* 58(4):85–90. http://www.cdc.gov/mmwr/PDF/wk/mm5804.pdf (accessed August 7, 2009).

CDC. 2009c. Swine influenza A (H1N1) infection in two children—Southern California, March–April 2009. *Morbidity and Mortality Weekly Report* 58(5):400–402. http://www.cdc.gov/mmwr/PDF/wk/mm5815.pdf (accessed August 7, 2009).

CSTE (Council of State and Territorial Epidemiologists). 2007. *CSTE official list of Nationally Notifiable Conditions*. CSTE Position Statement 07-EC-02. http://www.cste.org/PS/2007ps/2007psfinal/EC/07-EC-02.pdf (accessed February 27, 2009).

CSTE. 2008. *Criteria for inclusion of conditions on CSTE Nationally Notifiable Condition list and for categorization as immediately or routinely notifiable*. CSTE Position Statement 08-EC-02. http://www.cste.org/PS/2008/2008psfinal/08-EC-02.pdf (accessed February 27, 2009).

Dong S.L., M.J. Bullard, D.P. Meurer, S. Blitz, E. Akhmetshin, A. Ohinmaa, B.R. Holroyd, and B.H. Rowe. 2007. Predictive validity of a computerized emergency triage tool. *Academic Emergency Medicine* 14(1):16–21.

Effler, P., M. Ching-Lee, A. Bogard, M.C. Ieong, T. Nekomoto, and D. Jernigan. 1999. Statewide system of electronic notifiable disease reporting from clinical laboratories: Comparing automated reporting with conventional methods. *Journal of the American Medical Association* 282(19):1845–1850. http://jama.ama-assn.org/cgi/reprint/282/19/1845 (accessed March 3, 2009).

eHealth Initiative. 2008. *Fifth annual survey of health information exchange at the state and local levels: Overview of 2008 findings*. Washington, DC: eHealth initiative. http://www.ehealthinitiative.org/HIESurvey (accessed March 3, 2009).

Eilbert, K.W., M. Barry, R. Bialek, and M. Garufi. 1996. *Measuring expenditures for essential public health services*. Washington, DC: Public Health Foundation. http://www.phf.org/reports/Expend1/Measuring_Expenditures_for_Essential_Public_Health_Services.pdf (accessed February 23, 2009).

Endsley, M.R., B. Bolté, and D.G. Jones. 2003. *Designing for situation analysis: An approach to user-centered design*. Boca Raton, FL: Taylor & Francis Group.

Fallon, K.K., and D. Boone. 2004. Death certificate surveillance—New Hampshire. *Morbidity and Mortality Weekly Report* 53(Suppl.):236. http://www.cdc.gov/mmwr/preview/mmwrhtml/su5301a48.htm (accessed February 28, 2009).

FDA (Food and Drug Administration). 2008. *FDA clears first test designed to detect and identify 12 respiratory viruses from single sample*. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116829.htm (accessed July 8, 2009).

Fine, A., and M. Layton. 2001. Lessons from the West Nile viral encephalitis outbreak in New York City, 1999: Implications for bioterrorism preparedness. *Clinical Infectious Diseases* 32(2):277–282.

Foldy, S. 2004. Linking better surveillance to better outcomes. *Morbidity and Mortality Weekly Report* 53(Suppl.):12–17. http://www.cdc.gov/mmwr/preview/mmwrhtml/su5301a4.htm (accessed March 30, 2009).

Foldy, S., P. Biedrzycki, E. Barthell, N. Haney-Healy, B.K. Baker, D.S. Howe, D. Gieryn, and K.R. Pemble. 2004a. Syndromic surveillance using regional emergency medicine Internet. *Annals of Emergency Medicine* 44(3):242–246.

Foldy, S.L., P.A. Biedrzycki, B.K. Baker, G.R. Swain, D.S. Howe, D. Gieryn, E.N. Barthell, and K.R. Pemble. 2004b. The public health dashboard: A surveillance model for bioterrorism preparedness. *Journal of Public Health Management and Practice* 10(3):234–240.

Foldy, S., E.N. Barthell, J.C. Silva, P. Biedrzycki, D.S. Howe, M. Erme, B. Keaton, C.L. Hamilton, L.K. Brewer, G. Miller, R. Bernstein, E. Eby, K. Pemble, and C. Fenton. 2004c. SARS surveillance project: Internet-enabled multi-region syndromic surveillance for rapidly emerging disease. *Morbidity and Mortality Weekly Report* 53(Suppl.):215–220.

Foldy, S., K. Pemble, R.T. Heffernan, E.N. Barthell, and J. Beix. 2008. Whoosh!: Building and controlling Wisconsin HIE's clinical data stream for local and state health departments. Public Health Information Network annual meeting, Aug. 28. Atlanta, GA: Centers for Disease Control and Prevention. http://cdc.confex.com/recording/cdc/phin2008/pdf/free/4db77adf5df9fff0d3caf5cafe28f496/paper17528_1.pdf (accessed July 30, 2009).

GAO (Government Accountability Office). 2007. *Homeland security: Federal efforts are helping to alleviate some challenges encountered by state and local information fusion centers*. GAO-08-35. http://www.gao.gov/new.items/d0835.pdf (accessed March 30, 2009).

Hanrahan, L.P., S. Foldy, E.N. Barthell, and S. Wood. 2006. Medical informatics in population health: Building Wisconsin's strategic framework for health information technology. *Wisconsin Medical Journal* 105(1):16–22.

Honoré, P.A., and T. Schlechte. 2007. State public health agency expenditures: Categorizing and comparing to performance levels. *Journal of Public Health Management and Practice* 13(2):156–162. http://journals.lww.com/jphmp/Fulltext/2007/03000/State_Public_Health_Agency_Expenditures_.11.aspx (accessed August 7, 2009).

Honoré, P.A., R.L. Clarke, D.M. Mead, and S.M. Menditto. 2007. Creating financial transparency in public health: Examining best practices of system partners. *Journal of Public Health Management and Practice* 13(2):121–129. http://journals.lww.com/jphmp/Fulltext/2007/03000/Creating_Financial_Transparency_in_Public_Health_.7.aspx (accessed August 7, 2009).

IEc (Industrial Economics, Incorporated). 2009. *Summary of research into the costs of enhanced public health surveillance systems*. Commissioned paper. Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Washington, DC.

IOM (Institute of Medicine). 2000. *To err is human: Building a safer health system*. Washington, DC: National Academy Press.

IOM. 2001. *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academy Press.

IOM. 2003. *The future of the public's health in the 21st century*. Washington, DC: The National Academies Press.

IOM. 2007. *Hospital-based emergency care at the breaking point*. Washington, DC: The National Academies Press.

Jajosky, R.A., and S.L. Groseclose. 2004. Evaluation of reporting timeliness of public health surveillance systems for infectious diseases. *BMC Public Health* 4:29.

Jha, A.K., C.M. DesRoches, E.G. Campbell, K. Donelan, S.R. Rao, T.G. Ferris, A. Shields, S. Rosenbaum, and D. Blumenthal. 2009. Use of electronic health records in U.S. hospitals. *New England Journal of Medicine* 360(16):1628–1638.

Klompas, M., R. Lazarus, R. Platt, X. Hou, F. Campion, B. Kruskal, G. Haney, J. Daniel, A. DeMaria, and S.J.N. McNabb. 2008. Automated detection and reporting of notifiable diseases using electronic medical records versus passive surveillance—Massachusetts, June 2006–July 2007. *Morbidity and Mortality Weekly Report* 57(14):373–376.

Lazarus, R., M. Klompas, F.X. Campion, S. McNabb, X. Hou, J. Daniel, G. Haney, A. DeMaria, L. Lenart, and R. Platt. 2009. Electronic support for public health: Validated case finding and reporting for notifiable diseases using electronic medical data. *Journal of the American Medical Informatics Association* 16(1):18–24. http://www.jamia.org/cgi/reprint/16/1/18 (accessed February 23, 2009).

Lenert, L. 2007. *The evolution of public health surveillance to a GRID model*. Presentation to the 2007 International Society for Disease Surveillance Sixth Annual Conference. http://www.syndromic.org/conference/2007/powerpoint/5%20CDC.Linert.ppt (accessed July 27, 2009).

Lurie, N., J. Wasserman, and C.D. Nelson. 2006. Public health preparedness: Evolution or revolution? *Health Affairs* 25(4):935–945. http://content.healthaffairs.org/cgi/reprint/25/4/935 (accessed March 25, 2009).

Magnuson, J.A. 2008 (unpublished). 2007 *National electronic laboratory reporting snapshot survey: Summary of results*. Portland, OR: Oregon State Public Health, Acute and Communicable Disease Prevention.

Mahony, J.B. 2008. Detection of respiratory viruses by molecular methods. *Clinical Microbiology Reviews* 21(4):716–747.

NPHPSP (National Public Health Performance Standards Program). No date. Local Public Health System Performance Assessment – Model Standards. Version 2. http://www.cdc.gov/od/ocphp/nphpsp/documents/FINAL%20Local%20MS.pdf (accessed July 27, 2009).

ONC (Office of the National Coordinator for Health Information Technology). 2008. *Federal health IT strategic plan: 2008–2012*.Washington, DC: Department of Health and Human Services. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848083_0_0_18/HITStrategicPlan508.pdf (accessed July 27, 2009).

Overhage, J.M., S. Grannis, and C.J. McDonald. 2008. A comparison of the completeness and timeliness of automated electronic laboratory reporting and spontaneous reporting of notifiable conditions. *American Journal of Public Health* 98 (2):344–350.

Panackal, A.A., N.M. M'ikanatha, F.-C. Tsui, J. McMahon, M.M. Wagner, B.W. Dixon, J. Zubieta, M. Phelan, S. Mirza, J. Morgan, D. Jernigan, A.W. Pasculle, J.T. Rankin, Jr., R.A. Hajjeh, and L.H. Harrison. 2002. Automatic electronic laboratory-based reporting of notifiable infectious diseases at a large health system. *Emerging Infectious Diseases* 8(7):685–691. http://www.cdc.gov/ncidod/EID/vol8no7/pdf/V8n7_final.pdf (accessed March 3, 2009).

Papier, A. 2008. *Bioterrorism: The challenge of early diagnosis*. Presentation to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 3, November 3–5, Washington, DC.

Peterson, A., and D. Terashita. 2008. The unusual death surveillance system: Real time monitoring of deaths using coroner's data, 2003–2006. In: *2007 Special Studies Report*, Acute Communicable Disease Control Program, Los Angeles County Department of Public Health. Pp. 67–72. http://www.lapublichealth.org/acd/reports/annual/2007%20Special%20Studies%20Report%20for%20Web%20Posting.pdf (accessed August 7, 2009).

Proctor, M.E., K.A. Blair, and J.P. Davis. 1998. Surveillance data for waterborne illness detection: An assessment following a massive waterborne outbreak of *Cryptosporidium* infection. *Epidemiology and Infection* 120(1):43–54.

Public Health Functions Steering Committee. 1995. *Public health in America: The essential public health services*. Washington, DC: Public Health Functions Steering Committee, U.S. Public Health Service. http://www.health.gov/phfunctions/public.htm (accessed February 27, 2009).

Reed, K.D., J.W. Melski, M.B. Graham, R.L. Regnery, M.K. Sotir, M.V. Wegner, J.J. Kazmierczak, E.J. Stratman, Y. Li, J.A. Fairley, G.R. Swain, V. Olson, E.K. Sargent, S.C. Kehl, M.A. Frace, R. Kline, S.L. Foldy, J.P. Davis, and I.K. Damon. 2004. The initial detection of human monkeypox in the western hemisphere: Association with infected prairie dogs. *New England Journal of Medicine* 350(4):342–350.

Riegle, R. 2009. *The future of fusion centers: Potential promise and dangers*. Testimony before the Committee on Homeland Security, Subcommittee on Intelligence, Information Sharing, and Terrorism Risk Assessment, April 1. http://www.dhs.gov/ynews/testimony/testimony_1238597287040.shtm (accessed July 30, 2009).

Rolka, H., J.C. O'Connor, and D. Walker. 2008. Public health information fusion for situation awareness. In: *Lecture Notes in Computer Science: Biosurveillance and Biosecurity*, edited by D. Zeng, H. Chen, H. Rolka, and W.B. Lober. Raleigh, NC: Springer. Pp. 1–9.

Sensenig, A.L. 2007. Refining estimates of public health spending as measured in national health expenditures accounts: The United States experience. *Journal of Public Health Management and Practice* 13(2):103–114. http://journals.lww.com/jphmp/Fulltext/2007/03000/Refining_Estimates_of_Public_Health_Spending_as.5.aspx (accessed August 7, 2009).

Sosin, D. 2009. *Enhancing nationwide biosurveillance for human health*. Presentation at the Integrated Surveillance Seminar, CDC, February 11. http://www2a.cdc.gov/ncphi/disss/seminars/docs/2-11-09DanSosin.ppt (accessed March 3, 2009).

TFAH (Trust for America's Health). 2008. *Ready or not? Protecting the public's health from diseases, disasters, and bioterrorism*. Washington, DC: TFAH. http://healthyamericans.org/assets/files/bioterror-report-2008.pdf (accessed July 17, 2009).

The White House. 2007. *Public health and medical preparedness*. Homeland Security Presidential Directive (HSPD) 21. Washington, DC. http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm#1 (accessed March 3, 2009).

WHO (World Health Organization). 2008. *International health regulations (2005)*, 2nd ed. Geneva, Switzerland: WHO.

Yasnoff, W.A., P.W. O'Carroll, D. Koo, R.W. Linkins, and E.M. Kilbourne. 2000. Public health informatics: Improving and transforming public health in the information age. *Journal of Public Health Management and Practice* 6(6):67–75.

6

BioWatch and Enhanced National Biosurveillance Resources

The previous chapters describe aspects of the current and planned environmental monitoring technology of the Department of Homeland Security's (DHS's) BioWatch program and current and potentially enhanced surveillance practices in the public health and health care systems. Here the committee compares the BioWatch program to enhancing current surveillance practices in the public health and health care systems.[1]

EXPLORING THE EFFECTIVENESS OF BIOSURVEILLANCE RESOURCES

Evaluating the effectiveness of the BioWatch program is problematic for several reasons.

- Definitive information about the likelihood of a catastrophic bioterrorist attack of the kind that BioWatch is intended to detect and about the specific nature, costs, and effectiveness of an enhanced surveillance system implemented through the public health and health care systems is not available.
- No bioterrorism events have tested the currently deployed Generation 2 BioWatch system, and risk-management analyses do not appear to be available for all of the pathogens currently included in BioWatch testing.

[1]As noted in Chapter 1, the public health and health care "systems" of the United States are highly decentralized.

- The Generation 3 BioWatch system has not yet been selected, so its assessment can be based only on the proposed operational requirements (DHS, 2008, 2009).
- The public health and health care systems regularly face the need to recognize and respond to naturally occurring disease outbreaks and seasonal illness and are also expected to be able to detect and respond to bioterrorism events. Assessments of the effectiveness of surveillance systems in detecting disease outbreaks are limited, especially for newer syndromic surveillance techniques (Bravata et al., 2004; CDC, 2004; Buckeridge, 2007). In trying to determine their effectiveness in the event of bioterrorism, it is necessary to rely on simulations because actual data are not available.
- Biosurveillance within the public health system is composed of numerous separate systems, varying in maturity, whose integrated cost and performance is difficult to assess for detection of either natural disease outbreaks or bioterrorist events, whether alone or in conjunction with BioWatch.
- Natural outbreaks are heterogeneous, differing in size, location, agent, and mechanism of spread, as are the capabilities of state and local public health departments to recognize and respond to outbreaks and the availability of health care resources to provide treatment. Assessing the effectiveness of a potentially enhanced surveillance system is even more challenging.
- The digitalization of health information that could improve the speed and ease of disease surveillance remains incomplete.

Despite these challenges, it is possible to make a basic but informative comparison of BioWatch with surveillance through the public health and health care systems.

Performance of the BioWatch System

A fundamental question is whether BioWatch can perform in a useful way. Answering this question requires considering several interrelated events that are necessary for BioWatch to contribute to the reduction of illness and loss of life (see Table 6-1). The official estimates of the probabilities of some of these events, especially that a bioterrorism attack will occur, that it will take place in a BioWatch jurisdiction, and that it will be delivered in a manner that BioWatch has the potential to detect, have not been made available to the committee. With the understanding that judgments about these probabilities will be crucial to policy decisions that must be made about the refinement and further deployment of BioWatch, the committee looked at the system's potential performance assuming there is a detectable attack, that is, a large-scale airborne release of one of the

TABLE 6-1 Steps Necessary for BioWatch to Help Reduce Illness and Loss of Life

Necessary Step	Likelihood	Evidence
Large airborne release of a bioagent	Uncertain*	
Release occurs in BioWatch jurisdiction	Uncertain*	
Bioagent among those detectable by BioWatch	Uncertain*	
Bioagent remains viable and is of suitable particle size for infection	Depends on agent processing method, dissemination method, agent vulnerability to ultraviolet light, and other environmental factors	Military testing
Bioagent plume reaches a BioWatch detector	Depends on size and location of release relative to location and density of detectors; and on meteorological conditions that control dispersion (e.g., wind velocity, stability)	Military testing, modeling
Analysis of BioWatch sample produces positive reading when target agent is present (result of many substeps)	Likely (?)	Genetic material from naturally occurring organisms successfully identified from Generation 2 filters
Decision makers receive positive BioWatch result and other information sufficient to promptly recognize a BioWatch signal as indication of a true bioterror event	Variable, by jurisdiction; in general, uncertain	No experience yet with a BAR later determined to result from a bioterror event Testimony from public health officials
Effective prophylaxis or treatment exists	Depends on the agent	Medical literature
Decision makers initiate prophylaxis or treatment	Depends on the detected agent, other available information, and circumstances	Experience from multiple BARs, but response to a BAR for anthrax may differ Testimony from public health officials
Prophylaxis or treatment is carried out in time to reduce mortality and morbidity	Depends on the agent, dose, time elapsed since human exposures, ability to define and target prophylaxis to the population exposed, and dispensing capabilities	Modeling Exercises

NOTE: BAR, BioWatch Actionable Result.

*Information about this step may be available to those conducting the threat analysis but was not part of this committee's review.

pathogens included in the BioWatch assays in a location where a BioWatch device can obtain a sample for analysis.

The BioWatch system currently operates in more than 30 major metropolitan areas, with most of the collectors deployed in outdoor locations. Given the relatively modest number of devices available for BioWatch jurisdictions, their placement is a major factor in determining whether at least one collector would be in the path of an aerosol release. But their allocations were based upon dispersion models of urban environments that are especially challenging and sensitive to assumptions about parameter values (GAO, 2008b). Operational testing will be important to better understand collector efficacy and aerosol behavior in the complex microclimates of the urban environments of BioWatch jurisdictions, and the probability of plume detection.

On a few dozen occasions since implementation the BioWatch system, samples have produced positive findings that were interpreted as being genetic material from an organism among those currently being monitored. These BioWatch Actionable Results (BARs) have demonstrated that the current BioWatch technology can collect analyzable genetic material and that the current laboratory assays can detect this genetic material. In each BAR, BioWatch jurisdictions concluded that no terrorist release had occurred and that there was no indication of increased human illness. (The committee notes that it heard testimony from public health officials in some of these jurisdictions, but it did not have the opportunity to review the information available to the public health authorities in each case.)

However, as discussed in Chapter 3, several concerns about the BioWatch system's technical performance remain, including questions about sample collection, laboratory analysis, siting practices, and program priorities.

One concern is the usefulness of the analyses of the BioWatch air samples. The information provided to the committee about BARs does not indicate whether viable organisms were collected. In addition, more needs to be learned about the genetic near neighbors of the pathogens that BioWatch targets and about the microbial ecology of the areas where BioWatch operates.

All of the BARs to date appear to be the result of procedurally accurate analyses of BioWatch samples. Although none of them has been determined to be due to bioterrorism, these BARs have been unplanned opportunities to test the BioWatch program's plans and procedures. Nevertheless, they amount to false alarms that are costly to evaluate. Repeated false alarms may eventually create a sense of skepticism or complacency that could delay or hinder an appropriate response to a true bioterrorism event. The opposite, but related concern is determining the likelihood that the BioWatch collection and analysis process may fail to detect the presence of targeted organisms.

Realizing Benefits from the BioWatch System

The expected benefits from the BioWatch system derive primarily from the anticipation that it will decrease the time that elapses between a large-scale airborne release of a bioterrorism agent and the distribution and use of post-exposure prophylaxis and post-infection treatment. For BioWatch Generation 2, the time from the release of a biological agent to confirmation of positive results—the declaration of a BAR—would typically be 10 to 36 hours (depending on when an event occurs during the 24-hour collection cycle and allowing for filter recovery, primary screening, and agent-specific testing). As discussed in Chapter 3, plans for BioWatch Generation 3 include a 4- to 6-hour time to detect a pathogen.

The committee is most confident about the potential for early detection via BioWatch to reduce morbidity or mortality in the event of a massive aerosol attack using *Bacillus anthracis* spores, assuming an effective public health response capability is in place. This conclusion is based on evidence that includes the environmental stability of *B. anthracis* spores; empirical findings about infection and mortality rates from natural outbreaks, the Sverdlovsk release, and the 2001 anthrax letters; the relatively rapid incubation period of anthrax (during which victims have no symptoms); the potential for effective post-exposure antibiotic prophylaxis; and the rapidly decreasing efficacy of treatment after the onset of symptoms (e.g., Jernigan et al., 2001; Inglesby et al., 2002; Holty et al., 2006; Wilkening, 2006, 2008).

Several modeling analyses suggest that the timing of the start and completion of a prophylaxis effort following detection of an anthrax release are critical factors in determining subsequent morbidity and mortality (e.g., Hupert et al., 2002; Buckeridge et al., 2005, 2006; Wein and Craft, 2005; Yang et al., 2006; Baccam and Boechler, 2007; Zaric et al., 2008). Early notice of a potentially catastrophic release of anthrax may speed a range of actions up to and potentially including initial distribution of prophylaxis from local supplies while further investigation proceeds and dispatch of prophylactic and therapeutic medications from the national stockpile is arranged. But such presumptive actions have to be weighed against the potential for adverse reactions if antibiotics or vaccines are administered and other negative consequences should the BioWatch signal ultimately prove to be a false alarm.

For agents other than *B. anthracis*, however, there is less information and less confidence that the BioWatch system's early detection potential will result in decreasing morbidity and mortality. Better evidence and thoughtful consequence analysis are needed on other agents' environmental stability in an aerosol attack, the effectiveness of post-exposure prophylaxis, and the time course and virulence of infection.

Although a BAR may present an opportunity to hasten the delivery of prophylactic or therapeutic care, it does not automatically trigger a public health response. The type and timing of a response are likely to depend on public health officials' judicious interpretation of not only the BAR but also other information that may include the number of the BioWatch collectors affected, the strength of the real-time PCR signal in affected collectors, the availability of corroborating information (including follow-up environmental sampling or information from law enforcement or intelligence sources), the effectiveness of public notification, and the resources available to set up distribution centers. Testimony to the committee suggests that, depending on the circumstances, some public health officials may be hesitant to launch a high-regret action that may cause unnecessary alarm or even harm, such as initiating the widespread distribution of prophylaxis or treatment, without confirmed cases of disease in humans or animals. This may reduce but does not necessarily negate the value of BioWatch environmental detection. A BioWatch alert may trigger outreach to health care providers and help them identify early cases of illness that might otherwise be missed or ascribed to other causes. It could also trigger preparation for the delivery of medical countermeasures and shorten the interval from later confirmation to chemoprophylaxis. Plus, a BAR in one jurisdiction may be important context for the interpretation of a closely timed BAR in another location. Thus, a BAR may enhance response even if it does not automatically trigger distribution of prophylaxis. In addition, a BAR can spur investigation and collection of evidence needed in the national security and law enforcement response to bioterrorism.

Qualitative Assessment of Enhanced Surveillance Through Public Health and Health Care Systems

Detection of bioterrorism or a disease outbreak through the public health and health care systems is, by definition, the detection of symptoms or infection (or behavior related to the onset of illness). Because almost all infectious agents require an incubation period of hours to weeks before signs or symptoms of illness appear, none of the potential enhancements discussed in Chapter 5 can be expected to provide earlier notice of the potential for exposure than rapid environmental detection can. However, to varying degrees, many of these enhancements may facilitate earlier recognition of an outbreak that BioWatch cannot or does not detect, or provide confirmatory information after a BAR, and thus they may allow for earlier mobilization of a response than is possible now. These enhancements may also improve the effectiveness of the response by improving decision makers' situational awareness.

The most important enhancements are those that will facilitate rapid diagnosis of infections, and that enable public health authorities to detect

incidence patterns consistent with an outbreak. For example, enhancement of public health laboratories' capability and capacity to conduct molecular subtyping to detect clusters of genetically similar pathogens isolated from cases is used to link cases that might otherwise not be connected to a point source, such as accidental or intentional contamination of food products. Another desirable enhancement is the development and use of effective clinical decision support tools for diagnosis, reporting, and case management, because these may enable rapid identification and reporting of the index case in an outbreak. As is true with BioWatch, the benefits of such earlier detection are contingent on informed interpretation and decision making by health care providers, public health personnel, and other officials.

CDC has described attributes that should be considered in an evaluation of surveillance systems generally (CDC, 2001) and has recommended a framework specifically for evaluating surveillance systems for early detection of outbreaks (CDC, 2004). The overall attributes include a surveillance system's usefulness, simplicity, flexibility, data quality, acceptability to data contributors, sensitivity, representativeness, predictive value, timeliness, and stability. The expectations for, and the importance of, any given attribute may vary, depending on the purpose of the surveillance system. Sensitivity, timeliness, and predictive value are of particular significance for early detection of outbreaks.

With the specific challenges of rapid detection of bioterrorism and other serious infectious disease threats in mind, the committee framed 10 related performance features that could be used to evaluate the potential contributions of BioWatch or enhanced surveillance tools that may be integrated into the public health and health care systems. These performance features are:

1. Facilitates early detection of an attack or the onset of an outbreak
2. Minimizes "false positive" alerts for an attack or outbreak
3. Improves recognition of an index case
4. Facilitates validation of signals of a possible bioterrorist attack or other outbreak and facilitates initial response decisions (e.g., whether to initiate mass prophylaxis)
5. Improves situational awareness during an event (e.g., the extent of exposure, disease trends and characteristics, available health care capacity) and allows characterization of the scale and scope of the incident so that mitigation can be effectively targeted
6. Improves communication among public health personnel and clinicians (e.g., event or case detection, event status, patient evaluation or treatment, infection control)
7. Improves communication among public health laboratories, clinical laboratories, and public health epidemiologists (e.g., event or case

detection, event status, specimen management, test procedures, quality assurance)

8. Detects bioterrorism attacks unlikely to be detected by existing environmental surveillance

9. Detects emerging infectious disease and other natural (unintentional) outbreaks

10. Aids surveillance of noninfectious health problems (e.g., injuries, chronic disease, intoxication)

Specific measures for enhancing surveillance in the public health and health care systems are discussed in Chapter 5 and listed in Box 6-1. Because formal evidence for the benefits of each proposed enhancement is limited and varies depending upon the enhancement, this qualitative assessment is largely based on expert opinion on the potential for improvement.

Note that the merits of expanding BioWatch to smaller localities need to be explored in risk-based analyses that account for many factors, including the probability of an attack in additional localities and the size of the potentially exposed population. With the current deployment in large urban areas, the BioWatch program has had the advantage of working with larger health departments that tend to have greater expertise and response capability than smaller health departments. Expanding BioWatch to more localities would require DHS to work with local health departments that are likely to need more federal interaction and support to be capable of analyzing and responding to a BAR.

EXAMINING THE POTENTIAL FOR EARLIER DETECTION TO IMPROVE OUTCOMES

To explore the impact of the timeliness of BioWatch detection and compare it with other surveillance approaches, the committee commissioned a simulation model to represent the timing of events in the detection of an aerosolized release of *B. anthracis*. In addition, a committee member (Stephen Pollock) developed an analytic approach (using the same model assumptions and parameters) as an alternative method to address these issues.

An anthrax attack was selected as a case study because timely response to inhalation anthrax is critical and because concerns about the threat from anthrax have driven much of the planning and action for bioterrorism preparedness. The model approaches were not designed to determine the likelihood that an anthrax attack would be detected by environmental sampling, but rather to assess the potential benefit from environmental detection, should an airborne attack occur and be detected. The model

BOX 6-1
Potential Enhancements to Surveillance Through Public Health and Health Care

Legally Mandated Disease Reporting

- Enhance electronic laboratory reporting systems
- Enhance notifiable disease reporting by clinicians (outreach, electronic reporting procedures, 24/7 call lines)
- Enhance electronic death reporting systems

Automated Health Care Information Systems and Public Health Linkages

- Enhance/use clinical decision support tools for diagnosis, reporting, and management (e.g., triage, infection control, and treatment)
- Enhance use of information from EMRs and other electronic health information sources to detect reportable conditions, unusual cases or trends (public health collects and collates information from multiple institutions)
- Enhance use of regional health information exchanges to detect reportable conditions, unusual cases or trends (public health interfaces with area-wide exchange that involves multiple institutions)
- Enhance public health capacity to electronically alert health care sector of important public health events (e.g. inform evaluation, triage, infection control, treatment)

Laboratory and Diagnostic Testing

- Expand development and use of rapid multiplexed and point-of-care diagnostic tests for both common pathogens and bioterrorism agents
- Extend capacities to characterize pathogens and collate reports from geographically dispersed sources to identify related cases of infectious disease (e.g., PulseNet model for enteric pathogens)
- Expand/enhance capacity to collect and test clinical specimens as part of public health surveillance systems, either ongoing or in response to possible alerts

Information Integration and Knowledge Sharing

- Improve integration and analysis of public health information within and across jurisdictions
- Enhance integration and analysis of public health information with other types of information (e.g., intelligence, law enforcement)

evaluation does not address the potential merits of environmental sampling for pathogens other than anthrax.

A brief overview of the approach and results of the models is presented here.

Modeling Approach

The models evaluated three approaches for the detection of an anthrax release: clinical case finding, syndromic surveillance, and environmental air sampling. These approaches are defined as follows:

- *Clinical case finding*: Diagnosis may be made each time a patient seeks clinical care following the onset of symptoms. Blood cultures may be ordered as part of routine testing. The time to detection is the time from exposure until the first positive blood culture among all people who seek care.
- S*yndromic surveillance*: Centralized collection and processing of data from primary care settings and emergency departments related to visits for respiratory conditions. For these models, detection is defined as occurring when an alert from a statistical algorithm indicates a higher than expected number of visits. (In practice, such an alert would have to be investigated, and an outbreak identified, to be considered a detection.)
- *Environmental air sampling*: Fixed aerosol monitoring devices (e.g., BioWatch air samplers) may be "hit" by airborne spores. Detection occurs when the presence of *B. anthracis* is confirmed through polymerase chain reaction (PCR) testing of samples collected by one or more monitors.

The specific objectives of the modeling were:

1. To estimate, for each approach to detection, the average time (and, in the analytical model, the distribution of time) to detection and the time to response, defined as the initiation of mass antibiotic prophylaxis.
2. If all three approaches operate in parallel, to estimate the average time to response and the contribution of each approach to early detection.
3. If only clinical case finding operates, to estimate the incremental benefit of adding syndromic surveillance, environmental sampling, or both.

Detection through any approach results in a subsequent investigation and preparation to initiate mass antibiotic prophylaxis. Two scenarios are defined for these investigations and preparations: (1) following a "strong" hit and (2) following a "weak" hit. An example of a strong environmental hit would be BARs from multiple environmental monitoring devices; a strong clinical hit

might be numerous positive blood cultures. A weak hit, in contrast, might be a BAR from a single monitoring device or a single positive blood culture. Clinical case finding and environmental sampling are assumed to have either a weak or strong hit while syndromic surveillance is assumed to have only a weak hit. For this simulation, a hit is assumed to trigger prophylaxis after a defined interval, and the disease is assumed to respond to prophylaxis or treatment, with subsequent reduction in morbidity and mortality.

The discrete-event Monte Carlo simulation model produces many replications of output variables of interest (e.g., time to first detection, time to prophylaxis). Model input parameters and probability distributions for various random times are based on the literature and expert opinion provided by committee members. The analytic model uses identical inputs to provide a direct, numerical computation of probability distributions for the output variables. The simulation model approach has the advantage of flexibility and ability to represent complex probabilistic events. The analytic approach provides exact values of outputs of interest and facilitates the use of sensitivity analyses to understand how assumptions and input parameters affect these outputs.

Results of the Modeling Analyses

The analyses indicate that, under highly favorable scenarios, BioWatch environmental sampling has the *potential* to lead to dispensing of antibiotics 2 to 3 days sooner after an aerosolized anthrax release than does syndromic surveillance or clinical case finding. Such an advantage in the time to dispensing may have a substantial impact on mortality from an anthrax attack, *assuming* that a prompt and effective mass dispensing program can be implemented. A critical uncertainty in these scenarios is whether an airborne attack would be detected by environmental sampling. Although environmental monitoring need not detect a release with certainty to provide a population benefit comparable to other means of detection, the probability of detection must be substantial to provide such a benefit.

The benefit from including syndromic surveillance in addition to clinical case finding depends on the sensitivity and specificity of the syndromic surveillance system, and on the time between exposure and patients' presenting with symptoms. Based on prior research that indicated that syndromic surveillance would detect an anthrax attack in a mean of 84 hours (Buckeridge et al., 2006), the current analysis found that the probability that an attack would be identified by syndromic surveillance before clinical case finding ranged from 30 percent (strong hit for clinical case finding) to 50 percent (weak hit for clinical case finding) when the specificity of syndromic surveillance was 0.9. This level of specificity resulted in a false alarm every 10 days. The average time to dispensing was improved only

modestly by the addition of syndromic surveillance to clinical case finding, by a half day or less. Depending on how long it takes to confirm a signal from syndromic surveillance, this modest advantage in detection may not lead to faster antibiotic dispensing.

Recent analyses suggest that the incubation period of anthrax is dose dependent, and that people with massive exposures may be ill within 24 to 48 hours (Wilkening, 2008). Preliminary analyses performed for the committee, involving reanalysis of a previous study (Buckeridge et al., 2006) with the addition of a dose-dependent incubation period, suggest that the addition of syndromic surveillance to clinical case finding may have the potential to result in dispensing of antibiotics up to a day earlier than with case finding alone. These results require confirmation with additional analyses, but they suggest that there may be circumstances in which syndromic surveillance provides an important early indication of an aerosol release of *B. anthracis*.

The effect of earlier initiation of antibiotic dispensing on mortality is complex, depending on not only the reduction in time until dispensing but also when the reduction occurs and assumptions about the efficiency of the dispensing process. For example, a 24-hour reduction in time until initiating dispensing will reduce mortality to a different extent if it occurs at day 2 after exposure versus day 5 after exposure. Different authors have used different assumptions about the timing of antibiotic dispensing and other factors to estimate different mortality curves for anthrax (e.g., Kaufman et al., 1997; Wilkening, 2006, 2008; Yang et al., 2006; Baccam and Bechler, 2007). As reflected in the discussions in previous chapters, an important component of this interval is likely to be the time public health officials need from the detection of a threat (from whatever source) to determine that distribution of antibiotic prophylaxis is an appropriate response. It is also uncertain whether public health officials would be able to provide antibiotic prophylaxis to hundreds of thousands, if not several million, people within 48 hours of determining that a large-scale aerosol attack with anthrax spores has occurred—the time frame that CDC has recommended as the planning target in its Cities Readiness Initiative.

Despite the uncertainty surrounding the effect of earlier dispensing on mortality, the mortality models can still be used to qualitatively illustrate the explicit trade-offs in mortality reduction between reducing the detection time and increasing the likelihood of detection by environmental sampling.

Modeling Conclusions

These model-based analyses indicate that environmental sampling may have, with two important caveats, the potential to provide an advantage

in early response to an anthrax release. The advantage is only realized if the release is detected and if a relatively rapid and effective response subsequently occurs. Thus, in the restricted scenario discussed above, aerosolized anthrax spores released in a jurisdiction with deployed BioWatch detectors that generate a BAR provides a "best case" scenario for the performance of the BioWatch system in terms of gaining time to make decisions and deploy antibiotic prophylaxis. However, other scenarios may lead to different conclusions about the value of the BioWatch system. For example, BioWatch may show greater benefit if a pathogen causing a contagious disease is detected and effective quarantine and isolation procedures can be implemented to limit the spread of the disease. With pathogens having longer incubation periods, the interval between detection by environmental sampling and clinical case finding or syndromic surveillance could be greater than it is for anthrax, giving public health officials more time to implement their response. For noncontagious illnesses that may respond well to treatment even after diagnosis (unlike anthrax), the opportunity for earlier detection with BioWatch may contribute relatively little to improvements in survival because waiting until clinical recognition may still result in high survival rates, but a BioWatch detection may have other benefits.

Finally, the analyses suggest that, in some circumstances, syndromic surveillance may provide an important warning of an anthrax attack earlier than clinical case finding. Quantifying the magnitude of this benefit requires analyses that were not possible within the time frame of this study. A major limitation of these analyses is that they do not account for potential synergies between the different detection approaches; signals from separate systems may be used to corroborate the occurrence of an outbreak.

These models are first-cut simplifications, but nevertheless useful in identifying critical aspects of, and parameters governing, the response to a release. A more thorough modeling endeavor would have considered including more fidelity in the response modeling—in particular the probabilistic dependence between and among the random variables characterizing detection delays and response times, the size of an attack, and the state of readiness of the responders (a function of previous experience with false alarms, or alerts from other sources, etc.).

In summary, models can indicate certain circumstances, such as the anthrax scenario presented here, in which enhancement of the BioWatch system appears to provide benefits in terms of lives saved and illness avoided compared with traditional means of outbreak detection. The challenge, however, is to value this *potential* capability, given the uncertainties about (1) the likelihood of an attack, (2) the identity of the hazardous pathogens (either natural or intentionally released) that may be encountered, (3) the placement of detectors compared with the path of the release, (4) the performance of the various existing and proposed detection systems and methods, (5) the

capability of the public health and health care systems to respond rapidly and effectively to detection of a pathogen or the resulting illness, and (6) the probabilistic dependence among the critical variables involved in the response and in modeling the response, most critically the size of the attack and the consequent sensor detection times, and system response times.

Need for Formal Modeling and Evaluation of the BioWatch System

As emphasized in Chapter 3, there is a critical need for a more formal, detailed, and systematic approach to assessing various aspects of the effectiveness of BioWatch (see Recommendation 6). A definitive analysis was not performed during the course of this study, but the modeling framework presented here has the potential, in conjunction with information from the DHS Bioterrorism Risk Assessment (BTRA), to aid in understanding and comparing the relative benefits of environmental sampling, syndromic surveillance, and improved clinical case finding.[2]

Although rapid implementation of the BioWatch program was judged necessary in 2003, at this stage in the life of the program, DHS should be using available information and analytic tools to shape the program in a way that maximizes its potential benefits. This includes developing models that are more detailed to address the questions assessed in the modeling exercise described here. Such analyses should be performed for all pathogens that BioWatch is intended to detect. The value of including a particular pathogen in the BioWatch portfolio should reflect clear evidence of health benefits from earlier detection and minimal risk of detecting DNA fragments from organisms that are naturally present in the environment of BioWatch jurisdictions, as well as evidence of the probability of attack and detection sufficient to support the additional cost of surveillance for the pathogen. The results of these analyses should be used as part of the documentation presented for justifying enhancements for BioWatch or other approaches to achieving early detection of biothreats.

DHS should conduct these assessments in close coordination with HHS and state and local public health partners, and with the advice of the recommended advisory panel, because these partners are crucial in realizing the potential benefits of BioWatch. The scenarios contained in the BTRA provide a foundation upon which to base an evaluation of the contribution of the BioWatch program to its public health goals. With several years of operational experience in hand, the models can now

[2]In carrying out its modeling, DHS could draw on work such as that carried out by Craft, Wein, and Wilkins to determine the smallest attack size that can be detected by sensors with a given detection limit deployed at a given sensor density (Craft et al., 2005).

include realistic assumptions about the use of BioWatch results by public health authorities.

AN ECONOMIC PERSPECTIVE ON COSTS AND BENEFITS OF BIOWATCH

The committee was also asked to examine the costs of surveillance through BioWatch and through the public health and health care systems. The explicit federal program costs for BioWatch since 2003 can be tracked in the aggregate through DHS budget documents, but as discussed in previous chapters, the costs of other surveillance activities across federal, state, and local levels and the public and private sectors are much harder to document (Hebert et al., 2007; GAO, 2008a; Franco, 2009).

To gain some perspective on the costs of the BioWatch program, the committee used the framework of a "break even analysis." The reasonableness of the costs can be considered from three points of view: (1) whether the expected benefits from BioWatch are likely to be greater than its costs for the country as a whole, (2) how the economic and logistical burdens of operating BioWatch are distributed, and (3) whether this distribution is acceptable to the affected parties. It is particularly important to understand the impact of BioWatch on state and local governments because they have the front-line responsibility for making most public health response decisions. Their perceptions of the reasonableness of the costs associated with BioWatch can be expected to strongly influence the acceptability and usefulness of the program.

National Perspective on Costs and Benefits of BioWatch

The most direct benefits expected from BioWatch are marginal reductions in the risk of loss of life or morbidity from early detection of a bioterrorism event. This is the life-saving contribution of a BioWatch alert over and above the normal functioning of public health and health care system surveillance and response. The modeling analysis presented earlier in this chapter offers some information on potential benefit in the form of an estimate of the expected reduction in time between attack and treatment that could result from BioWatch deployment, given a detectable attack. To make some assessment of the value of achieving the potential benefits of BioWatch, the committee considered the program's costs, as discussed in Chapter 2, and estimates of the public's willingness to pay for reduction in mortality risks. This is a widely accepted practice in evaluation of proposed health and safety regulations (The White House, 1993; EPA, 2000). Formally, estimates of willingness to pay for reductions in mortality risk are called "value of statistical life" (VSL) measures.

The Value of a Statistical Life

A "statistical life" is a population-level measure of mortality risk. It aggregates changes in individual, annual mortality risk to a population level. To illustrate, an action that reduces the annual mortality risk by 1/100,000 for each member of a population of 100,000 saves 1 statistical life over a year (Robinson, 2008). This change in mortality risk can be valued by looking at trade-offs people regularly make between expenditure of time or money and risk to safety and health. For example, many people trade off the benefit from saving the time it would take to walk to the corner to use a crosswalk against the increased risk of injury or death from jay-walking. Time can be given a monetary value based on wage rates and on a growing literature on the value people attach to time spent in nonwork activities. VSL estimates measure the magnitude of these trade-offs. For example, if on average people in a population of 100,000 are each willing to pay $60 to reduce mortality risk by 1/100,000, the implied VSL is $6 million [$60 ÷ (1/100,000)].

Under guidance from the Office of Management and Budget (OMB), agencies have leeway to develop their own criteria for regulatory economic analysis, including the choice of VSL estimates, but the choice must be based on a review of available research. OMB recognizes that best practices will therefore change with further research. Federal agencies currently use VSL estimates with midpoints ranging from $5 million to $7.6 million in their regulatory impact assessments (Robinson, 2008). In 2008, a component of DHS adopted use of a VSL of $6.3 million (Coast Guard, 2008; Robinson, 2008). These VSL values are used to monetize the value of benefits of government programs and are then compared to the expected costs of the program to society as means of determining the reasonableness of programs in regulatory impact analysis.

A significant body of research, in both the risk perception literature and the health valuation literature, strongly suggests that people are willing to pay more to reduce risks that they cannot control and risks that they dread (Chilton et al., 2006; Jenkins, 2006). An example of this might be the risk of illness and death from exposure to radiation from a nuclear accident. Evaluations of this literature conclude that VSLs for these types of risk are twice as high as those for commonplace risks that may be higher but over which individuals feel that they have some control, such as driving a car (Robinson, 2008).

Assessing the "Value" of the BioWatch Program

The committee used the VSL adopted by DHS to explore the costs of the BioWatch program in relation to the number of lives the program would

need to save over a specified period of time—10 years in this case—to "break even" if the only benefit were an incremental reduction in mortality risk. Making this calculation is complicated by not knowing the probability of an attack, the timing of an attack, the scale of an attack, the likelihood that an attack is in a form detectable by BioWatch, or the number of people exposed in an attack. If, for example, the probability of an attack over the 10-year interval is very low, a decision maker may have expectations that for a given program cost, the benefit in additional lives saved would need to be greater than if the probability of an attack during that period were high. Alternatively, if the dread of a bioterrorist event means that a higher VSL is acceptable, the number of additional lives that BioWatch would be expected to save to break even would be perhaps half as high as the standard VSL suggests.

Because of the fundamental unknowns, the committee chose to make simplifying assumptions that (1) the likelihood of attack is the same each year over the next 10 years and (2) the annual probability of a single, BioWatch-detectable attack is .1, .01, or .001. These assumptions are used solely because they are transparent and easily understood. The calculations also assume $6.3 million for a VSL, a 7 percent real discount rate as used in the cost analysis in Chapter 2, and income growth of 3 percent per year. To "break even" with an annual probability of attack of .1 per year, or 1 attack expected in 10 years, BioWatch Generation 2 would need to save 134 additional lives if an attack occurs; Generation 3 (configured according to the proposed acquisition and deployment plans) would have to save an additional 447 lives. With an annual probability of attack of .001 (a .01 chance of an attack in 10 years), BioWatch would need to save 13,398 additional lives with Generation 2 and 44,661 additional lives with the full acquisition and deployment of Generation 3. Table 6-2 shows the results of this simplified break even analysis.

The committee's calculation is a conservative assessment of the potential benefits of the BioWatch system because it accounts only for reducing mortality in the event of a bioterrorism attack. Other benefits may include illnesses avoided and social and economic disruption averted. However, even successful detection of an attack would not completely prevent economic and social disruption. One estimate of the global costs in 2003 of the SARS outbreak is at least $40 billion (Lee and McKibbin, 2004). Another possibility not reflected in these calculations is the possible deterrent effect of BioWatch, which might lead a terrorist to choose another location or method of attack that puts fewer lives at risk. The committee did not undertake the complex task of estimating the potential impact of BioWatch on social and economic consequences of a biological attack, but such analyses should be part of the work that the committee recommends DHS perform in evaluating the BioWatch system (see Chapter 3, Recommendation 6).

TABLE 6-2 Implied Number of Additional Lives That BioWatch Would Have to Save in the Event of an Attack to "Break Even" on Program Costs

BioWatch deployment	Present Value Cost of BioWatch (10-year forecast) ($ millions)	Present Value of 1 Statistical Life per Year over 10 Years ($ millions)	Additional Lives to Save to "Break Even" Annual Probability of Attack .1	.01	.001
Generation 2	600	44.8	134	1,340	13,398
Generation 3, full acquisition and deployment	2,000	44.8	447	4,466	44,661
Generation 3, acquisition and deployment without geographic expansion	800	44.8	179	1,786	17,864

NOTE: The calculations use a value of $6.3 million in 2009 dollars for the value of a statistical life (Robinson, 2008). Present value for the 10-year period is calculated in 2009 dollars using a 7 percent real discount rate and a 3 percent annual growth in income.

State and Local Impact

As noted in Chapter 2, the committee was able to obtain only limited information on the unreimbursed costs to states and localities where BioWatch operates. The data that were obtained cover only two types of in-kind contributions: (1) for laboratory support and analysis and (2) for public health support and response planning (e.g., participation on the BioWatch Advisory Committee, planning for responses to detection of true bioterrorism events, and planning and conducting exercises and responses to BARs). In each case, the costs were small relative to the jurisdictions' total public health budgets.

Yet the committee heard representatives from multiple local and state jurisdictions raise concern about the burden placed on them by BioWatch. This concern does not seem to be based solely on the actual costs of BioWatch, but rather on a sense of skepticism about the public health value of BioWatch. Two factors appear to be fueling this skepticism. First, local and state public health departments are under increasing budgetary and staffing pressure. When confronted with a trade-off between expending time and energy to meet a steady stream of immediate public health needs, such as surveillance, treatment, and prevention of sexually transmitted diseases or detection of outbreaks of foodborne illness, and planning for high-impact but very rare, and perhaps hypothetical, events, such as a catastrophic airborne bioterrorism attack, the value of meeting the immediate need may seem greater.

Second, officials in some local and state public health jurisdictions do not appear confident that BioWatch would enhance their ability to reduce illnesses and death if an attack were to occur. Because interpretation of BARs is not straightforward, gathering sufficient information to determine an appropriate course of action may consume valuable lead time and staff resources. DHS may be able to boost state and local confidence in the value of BioWatch through thorough analyses and field testing of the technology and operating plans, along with informed participation by the users of BioWatch information in planning and decisions about BioWatch system operations.

COMPLEMENTARY SURVEILLANCE ROLES FOR BIOWATCH AND PUBLIC HEALTH AND HEALTH CARE

With certain reservations, the committee concluded that the BioWatch system in its current form (Generation 2) can fill a unique and complementary functional niche in the nation's resources for detecting a potentially high-consequence biological risk, especially from a large-scale release of aerosolized anthrax spores. BioWatch has the potential to provide an earlier warning of the airborne presence of specific pathogens before the onset of human illness than surveillance tools based on clinical findings. By the same token, because BioWatch is so narrowly focused as a detection tool, it does not eliminate the need for the broad-based surveillance activities that can detect bioterrorism or naturally occurring disease outbreaks that BioWatch (enhanced or not) cannot or does not detect.

The Generation 3 deployment of BioWatch, as described to the committee, is expected to analyze air samples more frequently than the current system and therefore should be able to produce more timely alerts. But determining the appropriate public health response will still require expert synthesis of additional information to interpret the significance of the BAR. Such information may include which pathogen is detected, the number of BioWatch collectors producing alerts, whether the pathogen detected is known to be endemic to the area, or whether there is relevant intelligence information indicating the potential for an attack. Although the absence of a signal from BioWatch collectors cannot be taken as firm evidence that no release has occurred, positive signals from multiple collectors in a single jurisdiction, or information that collectors in other jurisdictions have produced BARs, could influence interpretation of the significance of a signal and decisions regarding the speed and scope of the public health response.

Enhancements to surveillance carried out through the public health and health care systems may also improve the timeliness of recognition of disease or even prodromal symptoms, whether from a bioterrorist event or

from a naturally occurring outbreak. But because these surveillance tools depend on detecting infections that follow exposure by hours or days, they cannot match the potential for earlier awareness provided by the BioWatch system.

With or without BioWatch, the public health and health care systems need to be capable of rapid and thoughtful review of clinical, animal, environmental, and law enforcement data by local experts with knowledge of the specific features of the area and its population. Figure 6-1 illustrates the variety of information sources that contribute to detection of significant public health threats. *At best, BioWatch will only be one of these sources.* Experience over the past few years with the emergence of the mosquito-borne West Nile virus, the international spread of SARS, repeated episodes of multistate foodborne illness, and the 2009 influenza pandemic demonstrates the importance of having many other surveillance resources to facilitate quick understanding of the nature and extent of the health threat.

FINDING: BioWatch and surveillance through the public health and health care systems are complementary. If a large-scale aerosol attack using certain pathogens were to occur in specific localities, BioWatch has the potential to provide a more timely alert than the public health

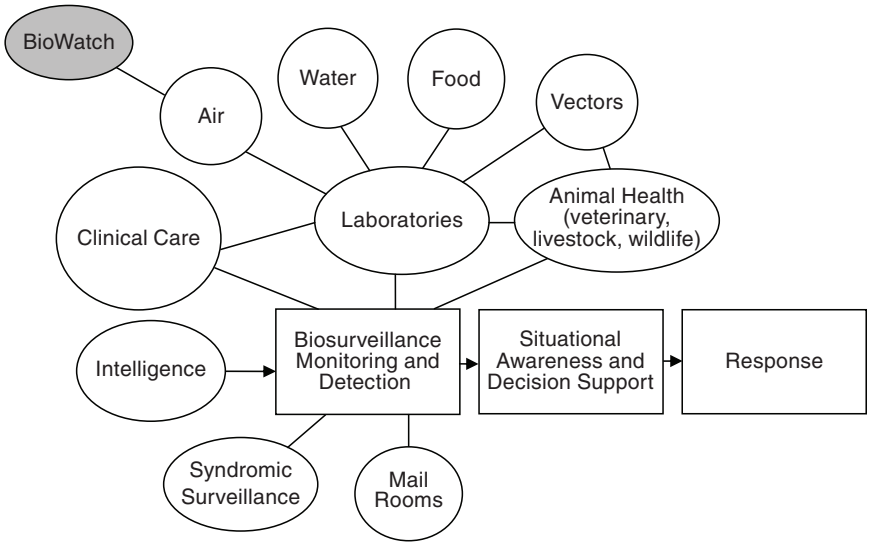


FIGURE 6-1 A schematic illustration of the relation between the BioWatch program and other sources of information needed for infectious disease surveillance in the public health and health care systems.
SOURCE: Adapted from Hooks (2008).

and health care systems. Surveillance through the public health and health care systems is broader and more flexible and is an essential element of daily activities at local, state, and federal levels to fully meet the public's health needs.

Table 6-3 provides a broad-brush summary of key features of the narrowly targeted BioWatch and the wide scope of more traditional surveillance systems. It is challenging to make this kind of summary comparison because of the vast differences in the purpose and scope of the BioWatch system and infectious disease surveillance activities through the public health and health care systems.

The cost comparison is especially problematic. The BioWatch program is a relatively well-defined federal program, with some unidentified but limited costs incurred by the states and localities where it operates. On the other hand, the committee was unable to obtain information that would allow a determination of the costs of infectious disease surveillance for significant biological threats, or specifically for bioterrorism threats. These costs cannot be readily separated from other health surveillance programs, and as discussed in Chapter 5, the costs of the broader surveillance activities in the public health and health care systems are also difficult to estimate because current budgeting and accounting systems at the local, state, and federal levels do not use classifications that provide this information. The surveillance costs incurred by hospitals, outpatient services, laboratories, and the other private-sector components of the health care system are even less readily captured. In addition, the development costs and longer-term financial impact of enhancements to infectious disease surveillance, such as those discussed in Chapter 5, are unclear at the national level, and the costs may vary considerably for individual states and localities.

The only readily available reference point is a federal government estimate that total expenditures for federal, state, and local government public health activities amounted to $64.1 billion for 2007 (Hartman et al., 2009). This includes all types of public health activities, ranging from public health education to restaurant inspection as well as disease surveillance. The committee urges further examination of the costs of developing, operating, and modifying surveillance systems and related public health activities. Better cost information will be essential for officials at the federal, state, and local levels to assess the effectiveness of current and future approaches. In addition, new analytic approaches may be needed to study the cost-effectiveness of the broader disease surveillance infrastructure and its infectious disease components.

FINDING: The annualized direct costs of the current BioWatch Generation 2 program over the next 10 years will be approximately $80 million;

TABLE 6-3 Capabilities and Costs of the BioWatch System and Surveillance Through the Public Health and Health Care Systems

System	Detection Capability	Coverage	Sensitivity and Specificity
BioWatch System			
Generation 2	Certain biological agents; environmental presence of airborne genetic material	> 30 major metropolitan areas (i.e., BioWatch jurisdictions)	Not publicly available Dozens of BARs to date; none linked to bioterrorism
Generation 3 *(proposed)*	Biological agents covered by Generation 2, with goal of including additional agents; environmental presence of airborne pathogens	Expanded coverage	System not yet selected
Public Health and Health Care Systems			
Disease recognition and reporting by health care providers and laboratories to health departments	All human health hazards (e.g., biologic, chemical, environmental) that result in clinically recognized disease or injury	Entire country, reports of uneven quality submitted to nearly 3,000 local and state health departments	Not readily quantified; varies by disease, provider, location, reporting system, epidemiologic expertise, and other resources

	Timeliness	Benefits	Annual Costs	Other Considerations
	Typical 24-hour sample collection cycle; 10- to 36-hour window from release to confirmation of screening test	If aerosolized pathogen is detected, potential reduction in casualties if distribution of prophylaxis and treatment can be started sooner; potential interruption of contagion or environmental spread*	$80 million (10-year average) Costs of recommended program changes not included	Need for testing and evaluation of technology, holistic evaluation of goals, better tools to aid public health response, and assessment of environmental risk after a BAR
	Proposed 4- to 6-hour time to detect; automated sample processing and testing and reporting of results	Potential for reduction in casualties may be greater than with Generation 2 because of plans for more frequent testing*	$200 million (10-year average) for acquisition, deployment, and operation Costs of recommended program changes not included	System not yet selected; actual performance may differ from proposed specifications; significant technological hurdles must be overcome to achieve desired system capabilities
	May depend on disease, skill of health care provider, availability of appropriate analysis tools, scale of pathogen exposure, reporting system; depends on evidence of infection, so not likely to detect before environmental surveillance	Provide ongoing detection of intentional and naturally occurring outbreaks for prevention or treatment	Unknown; data necessary to estimate costs of disease surveillance systems or marginal cost of surveillance for significant infectious disease threats not available	Need for additional integration and information sharing across federal, state, and local levels; need for evaluation and incorporation of new techniques

continued

TABLE 6-3 Continued

System	Detection Capability	Coverage	Sensitivity and Specificity
Syndromic surveillance	Varies by system design and application	Currently > 80% of state, tribal, large local jurisdictions have some form	Varies by system design and application, scale of outbreak

NOTE: BAR, BioWatch Actionable Result.

*As described in the text, achieving a reduction in mortality with the BioWatch system depends not only on the BioWatch technology and communication of a BioWatch Actionable Result, but also on expeditious information gathering to confirm a bioterrorist event and having the capability to distribute mass prophylaxis or treatment to prevent or reduce illness and mortality. Also see Table 6-1.

over the same 10 years, the annualized direct costs for acquiring and operating the planned Generation 3 enhancement are projected to be roughly $200 million. The committee was unable to obtain information that would allow a determination of the costs attributable to infectious disease surveillance in the public health and health care systems. Better data are needed on these costs as part of any effort to assess the cost-effectiveness of infectious disease surveillance and measure improvements. In addition, innovative methods may be needed for assessing the impacts of a multifaceted and multipurpose public health infrastructure such as infectious disease surveillance.

INCORPORATING BIOWATCH INTO AN ENHANCED NATIONAL SURVEILLANCE SYSTEM

The nation lacks a clear, overarching architecture of interlocking interagency goals, metrics, and accountability to support a seamless process from detection of biological threats through response and recovery. This architecture will require strong, high-level leadership along with strong and consistent engagement of on-the-ground experts in federal, state, and local agencies. This architecture is both critical to, and must also be supported by, robust operational capabilities and information systems that allow for merging data from multiple sources and providing critical emergency planning and decision support to biodefense partners across local, state, and federal levels.

Timeliness	Benefits	Annual Costs	Other Considerations
May depend on scale of pathogen exposure, but not likely to detect before environmental surveillance	May help detect and track sporadic and recurring infectious disease outbreaks	Would be included in costs of disease surveillance; cost of developing and operating individual systems expected to vary widely	Requires further testing and evaluation to assess strengths and limitations as tool to aid detection of infectious disease outbreaks

Improving the Integration of BioWatch into Biosurveillance

BioWatch is a federally developed, implemented, and directed program to *detect* certain airborne biological pathogens, but it depends on state and local health departments to *act* on the information it produces. This configuration invites tensions from competing interests. Some of the challenges of integrating BioWatch functions into surveillance and decision making carried out by the public health community may stem in part from its superimposition onto existing systems that serve other important priorities. Local and state public health departments have diverse responsibilities that include both routine and outbreak surveillance activities, independent of the responsibilities that come with participation in the BioWatch program. As Figure 6-1 illustrates, BioWatch is just one of the many sources of information that health departments must monitor and evaluate on a continuing basis.

The imposition of new responsibilities for low probability events may be seen by local jurisdictions as detracting from their daily duties and responsibilities, and therefore may potentially be perceived as inappropriately burdensome. The occurrence to date of numerous BARs, all of which were determined to be unrelated to bioterrorism and each of which required an official and time-consuming response by local and state officials, has served to increase skepticism of the value of the program. Moreover, some communities may have been reluctant to participate in BioWatch because of its low perceived value but could not readily decline.

The apparently top-down approach that DHS has taken in its interaction with public health departments may be symptomatic of a departmental mindset. DHS has been urged before in other arenas to improve its partnerships with state and local stakeholders (e.g., GAO, 2008c). DHS has noted its plans to increase the involvement of state and local officials in their BioWatch planning, and it has taken some steps in this direction through a contract with the Center for Infectious Disease Research and Policy (CIDRAP) to promote communication among epidemiologists in BioWatch jurisdictions and between the epidemiologists and the BioWatch program (CIDRAP, no date).

Differences in priorities between local and federal entities are natural and are explicitly acknowledged in the *National Response Framework*: "Planning for low-probability, high-consequence scenarios is a [f]ederal focus and complements a [s]tate, tribal, and local focus on more likely and frequently experienced smaller-scale events" (FEMA, 2008, p. 71). The committee also recognizes that the BioWatch system was fielded rapidly and had to meet numerous technological, operational, and organizational challenges. Although the deployment of the BioWatch system has been somewhat rocky in terms of coordination and integration with local public health officials, there is a continuing national effort to achieve a more integrated system from the multitude of local and state systems for infectious disease surveillance. All told, the BioWatch system needs to be better integrated into local surveillance systems that themselves are ultimately better integrated into a whole that resembles more of a national biosurveillance system. With multiple demands on the attention and resources of public health authorities, such integration may be vital to the sustainability of the BioWatch system and its counterterrorism mission. This challenge is only made more urgent under the current conditions of increasing economic constraint.

An Enhanced National Biosurveillance System

A major challenge to meeting the goal of a "national" biosurveillance system is that authority for public health action resides primarily at the state and local levels, where a multitude of systems and approaches make for a fragmented and difficult-to-coordinate national picture. The federal government has operational responsibilities in certain limited areas of public health protection, but it wields considerable influence through leadership in developing tools and guidance and especially through funding programs that reflect federal priorities.

How can progress be made toward a national system when a top-down approach is not possible? National priorities should include ensuring that state and local health departments can meet and sustain basic performance

standards for surveillance and analysis, in conjunction with essential capabilities to respond both to the often unpredictable demands of public health emergencies and to the array of ongoing obligations to protect the public's health. It is also important that BioWatch be factored into this view. But with programmatic and budgetary responsibility for BioWatch resting with DHS, the challenges of coordinating related responsibilities and systems that are dispersed across other federal departments only adds to the complexity of coordinating biosurveillance across federal, state, and local levels.

It is equally essential that the linkages between the public health and health care systems be strengthened. Health care providers in the public and private sectors, along with the large community of clinical and commercial laboratories, are essential partners with public health. Because the surveillance needs of the public health system are not their first priority, it is essential that the public health perspective be effectively represented as health care and laboratory information systems evolve so that technologies are created that serve needs in both enhancing the care of individual patients and protecting the health of the public.

In the committee's view, a national biosurveillance system should aid in protecting the nation from significant, time-critical biological threats of all types, whether intentionally released (i.e., bioterrorism), accidentally dispersed, or naturally arising (i.e., emerging or re-emerging infectious disease). This system would employ a layered approach that includes

1. judicious use of environmental surveillance tools, such as BioWatch, to detect a small number of current and potential future airborne threats that could harm a large number of people;
2. an enhanced capacity to recognize, isolate, and report index cases from clinical settings;
3. refined approaches to analyzing epidemiologic data to detect aberrant signals that may indicate a disease outbreak and track its spread;
4. improved and more rapid methods for use in the laboratory or at the point of care to detect, verify, and characterize a biological threat;
5. improved tools for information management and communication among all appropriate stakeholders (e.g., electronic laboratory reporting systems);
6. streamlined approaches at the federal, state, and local levels to (a) intelligence and information sharing, (b) decision making to minimize delay between the emergence of a threat and appropriate action to minimize its consequences, and (c) timely after-action analysis to identify strengths and weaknesses in policies and procedures; and
7. sustainable funding that encourages program integration (in contrast to categorical funding streams).

The committee sees an important federal role in at least three critical areas: (1) helping to develop and validate improved methods for infectious disease surveillance, (2) developing a mechanism to achieve and sustain national situational awareness of biological threats, and (3) building and sustaining critical public health workforce competencies.

Improved Methods for Infectious Disease Surveillance

Surveillance is an essential public health practice, but it has long rested on multiple independent data collection activities, often constrained by limited resources and narrow programmatic requirements. As information and communication technologies have evolved and become more accessible to health departments and health care providers, they are making it possible to improve the collection, integration, and analysis of surveillance data. Many novel and promising surveillance techniques and programs have been developed rapidly at the local, state, and federal levels, spurred in part by funding for bioterrorism and public health emergency preparedness.

At present, national standards for surveillance data and for interoperability between surveillance systems are incompletely developed and unevenly implemented because of limited funding and inconsistent direction. Insufficient attention has been paid to linking, analyzing, and displaying multiple surveillance platforms for optimal situational awareness, decision making, and response. In addition, many new systems and techniques have not yet received sufficient evaluation to ensure that they are effective and being used appropriately.

The committee believes that this complex series of problems must be addressed by a dedicated, strategic, integrated, and adequately funded program. If the federal government, working collaboratively with state and local officials, were able to strengthen and streamline and, where possible, automate core public health surveillance functions such as clinical case finding and laboratory reporting, this could reduce the daily operational stress felt by many local and state health departments and foster better working relationships.

Situational Awareness

In addition to new and improved surveillance tools, there is a critical need for a means to bring information together to provide situational awareness regarding potential or active threats to the public's health. Most of the information that enables detection, characterization, and ongoing management and mitigation of both natural and bioterrorism-related outbreaks is generated at the local or regional level and typically assembled at a statewide level. Compartmentalization of this information based on geography,

agency, or professional subject area may impede detection and interpretation of events that are unfolding on a national or international scale.

Health departments also have increased access to electronic information on animal health, vector control, water and air quality, meteorology, and other information to aid in monitoring threats to human health. Resources for situational awareness also need to facilitate communication between public health officials and clinical providers. In addition, efforts are being made to increase information sharing between public health agencies and others with a role in emergency preparedness and response, including the intelligence, law enforcement, emergency management, and business communities.

At the federal level, activities in both DHS and HHS are aimed at more effective integration of information to improve situational awareness. In DHS, the National Biosurveillance Integration Center (NBIC) is intended to bring together national and international information that could enhance awareness of potential and active biological threats of all types. In HHS, the BioSense program is focusing on assembling and sharing data from public health and health care sources to support situational awareness at local, state, and federal levels. Another effort to promote information exchange and situational awareness is the development of state and local "fusion" centers, which facilitate access to and sharing of information between federal, state and local officials.

These information-sharing activities face several challenges. On the informatics and technology side, the challenges include reconciling data structures and vocabularies from independent information systems. Policy concerns include finding an appropriate balance between the national security concerns of DHS and the intelligence community, which have tended to favor limited access to the information, and the need for an effective partnership with state and local officials who need better access to information that will help them recognize and respond to bioterrorism and other significant biological threats. Another consideration is the need to ensure that the exchange of health-related information appropriately calibrates the need for personally identifiable information so that individual privacy is protected. In addition, there is a need to encourage local and state authorities to share information within a state, with other states, and with federal agencies. Their willingness to do so will typically be related to the net value they obtain from such exchanges.

Public Health Workforce Levels and Competencies

The committee has recommended (see Chapter 5, Recommendation 11) that HHS and DHS make bolstering the public health workforce a priority. Benefits from new methods or tools will be limited without sufficient, and adequately trained, personnel to employ and deploy them. Public

health surveillance to detect and investigate potential bioterrorism events or naturally occurring infectious disease outbreaks requires the continuous availability of well-trained laboratory and epidemiology staff in sufficient numbers to be able to conduct advanced laboratory analyses and epidemiologic investigations in real time.

State and local health departments have faced persistent difficulties in hiring and retaining personnel and now face new budget constraints that are forcing further staff reductions in many places. Moreover, as new technologies and analytic techniques become the norm, there is a need to ensure access to training in their use for the existing workforce and to ensure that academic programs are adequately preparing the workforce of the future to use them. Cooperation between academia and the public health practice community can help identify appropriate competencies and develop credentials that foster readiness to respond to biothreats.

CONCLUDING OBSERVATIONS

BioWatch is a federal program designed by DHS to be operated by the public health system at the state and local levels in order to serve national security interests. This is an awkward and organizationally challenging arrangement. Because the potential for BioWatch to help limit morbidity and mortality depends so heavily on the ability of health departments and the health care system to analyze the nature of the threat and take quick and decisive action, it is essential that the operation and management of BioWatch be well integrated with the jurisdictions in which it operates.

State and local authorities, whose knowledge of endemic health risks and available resources cannot be replicated at the federal level, need to be recognized as essential and valuable partners not only in the BioWatch program but also in broader national biosurveillance and biodefense efforts. Likewise, recognizing that a bioterror attack is a threat against the entire population of the United States, state and local officials need to remain open and willing to partner with the federal government to ensure that resources, expertise, and decisions are used in the most appropriate way to ensure our national security.

Finally, it is essential that policy makers recognize that the benefits of any form of infectious disease surveillance will not be realized if states and communities do not also have the capability to respond effectively to a public health emergency. Despite the substantial progress that many localities have made in advancing their mass dispensing capacity, having the ability to administer antibiotic prophylaxis to hundreds of thousands, if not several million, urban area residents within a few days following detection of a bioterrorist attack remains a challenge.

REFERENCES

Baccam, P., and M. Boechler. 2007. Public health response to an anthrax attack: An evaluation of vaccination policy options. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 5(1):26–34.

Bravata, D.M., K.M. McDonald, H. Szeto, W.M. Smith, C. Rydzak, and D.K. Owens. 2004. A conceptual framework for evaluating information technologies and decision support systems for bioterrorism preparedness and response. *Medical Decision Making* 24(2):192–206.

Buckeridge, D.L. 2007. Outbreak detection through automated surveillance: A review of the determinants of detection. *Journal of Biomedical Informatics* 40(4):370–379.

Buckeridge, D.L., P. Switzer, D. Owens, D. Siegrist, J. Pavlin, and M. Musen. 2005. An evaluation model for syndromic surveillance: Assessing the performance of a temporal algorithm. *Morbidity and Mortality Weekly Report* 54(Suppl.):109–115.

Buckeridge, D.L., D.K. Owens, P. Switzer, J. Frank, and M.A. Musen. 2006. Evaluating detection of an inhalational anthrax outbreak. *Emerging Infectious Diseases* 12:1942–1949.

CDC (Centers for Disease Control and Prevention). 2001. Updated guidelines for evaluating public health surveillance systems: Recommendations from the Guidelines Working Group. *Morbidity and Mortality Weekly Report* 50(RR-13):1–29. http://www.cdc.gov/mmwr/PDF/rr/rr5013.pdf (accessed August 7, 2009).

CDC. 2004. Framework for evaluating public health surveillance systems for early detection of outbreaks: Recommendations from the CDC Working Group. *Morbidity and Mortality Weekly Report* 53(RR-5):1–16. http://www.cdc.gov/mmwr/PDF/rr/rr5305.pdf (accessed August 7, 2009).

Chilton, S., M. Jones-Lee, F. Kiraly, H. Metcalf, and W. Pang. 2006. Dread Risks. *Journal of Risk and Uncertainty* 33(3):165–182. http://www.springerlink.com/content/p02538767t15252r/fulltext.pdf (accessed April 10, 2009).

CIDRAP (Center for Infectious Disease Research and Policy). No date. *Public health and BioWatch*. http://www.cidrap.umn.edu/cidrap/center/mission/articles/biow.html (accessed April 2, 2009).

Coast Guard. 2008. Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System. Proposed Rule. *Federal Register* 73(242):76295–76318.

Craft, D.L., L.M. Wein, and A.H. Wilkins. 2005. Analyzing bioterror response logistics: The case of anthrax. *Management Science* 51(5):679–694.

DHS (Department of Homeland Security). 2008. *BioWatch Gen-3 autonomous detection system: Operational requirements document (ORD)*. Version 1.0, December 11. Washington, DC: Office of Health Affairs.

DHS. 2009. *BioWatch Gen-3 request for proposal: HSHQDC-09-R-00045*. https://www.fbo.gov/download/54e/54e9ae25a4a9d2d39a9e9e836955001f/HSHQDC-09-R-00045_(5-27-2009).pdf (accessed August 5, 2009).

EPA (Environmental Protection Agency). 2000. *Guidelines for preparing economic analyses*. EPA 240-R-00-003. Washington, DC: EPA. http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/homepage (accessed July 16, 2009).

FEMA (Federal Emergency Management Agency). 2008. *National response framework*. Washington, DC: DHS. http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf (accessed August 7, 2009).

Franco, C. 2009. Funding biodefense. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 7(1):1–2.

GAO (Government Accountability Office). 2008a. *Health information technology: More detailed plans needed for the Centers for Disease Control and Prevention's redesigned BioSense program*. GAO-09-100. Washington, DC: GAO. http://www.gao.gov/new.items/d09100.pdf (accessed March 20, 2009).

GAO. 2008b. *Homeland security: First responders' ability to detect and model hazardous releases in urban areas is significantly limited*. GAO-08-180. Washington, DC: GAO. http://www.gao.gov/products/GAO-08-180 (accessed July 16, 2009).

GAO. 2008c. *National response framework: FEMA needs policies and procedures to better integrate non-federal stakeholders in the revision process*. GAO-08-768. Washington, DC: GAO. http://www.gao.gov/products/GAO-08-768 (accessed July 16, 2009).

Hartman, M., A. Martin, P. McDonnell, and A. Catlin. 2009. National health spending in 2007: Slower drug spending contributes to lowest rate of overall growth since 1998. *Health Affairs* 28(1):246–261. http://content.healthaffairs.org/cgi/content/short/28/1/246 (accessed July 16, 2009).

Hebert, K., N. Henderson, and E.A. Gursky. 2007. Building preparedness by improving fiscal accountability. *Journal of Public Health Management and Practice* 13(2):200–201.

Holty, J.E., D.M. Bravata, H. Liu, R.A. Olshen, K.M. McDonald, and D.K. Owens. 2006. Systematic review: A century of inhalational anthrax cases from 1900 to 2005. *Annals of Internal Medicine* 144(4):270–280.

Hooks, R. 2008. Presentation and public comments to the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, Meeting 1, July 30–31, Washington, DC.

Hupert, N., A.I. Mushlin, and M.A. Callahan. 2002. Modeling the public health response to bioterrorism: Using discrete event simulation to design antibiotic distribution centers. *Medical Decision Making* 22(Suppl. 1):S17–S25. http://mdm.sagepub.com/cgi/reprint/22/suppl_1/s17 (accessed February 12, 2009).

Inglesby T.V., T. O'Toole, D.A. Henderson, J.G. Bartlett, M.S. Ascher, E. Eitzen, A.M. Friedlander, J. Gerberding, J. Hauer, J. Hughes, J. McDade, M.T. Osterholm, G. Parker, T.M. Perl, P.K. Russell, K. Tonat, and the Working Group on Biodefense. 2002. Anthrax as a biological weapon, 2002: Updated recommendations for management. *Journal of the American Medical Association* 287(17):2236–2252.

Jenkins, C.M. 2006. Risk perception and terrorism: Applying the psychometric paradigm. *Homeland Security Affairs* 2(2):1–14.

Jernigan, J.A., D.S. Stephens, D.A. Ashford, C. Omenaca, M.S. Topiel, M. Galbraith, M. Tapper, T.L. Fisk, S. Zaki, T. Popovic, R.F. Meyer, C.P. Quinn, S.A. Harper, S.K. Fridkin, J.J. Sejvar, C.W. Shepard, M. McConnell, J. Guarner, W.J. Shieh, J.M. Malecki, J.L. Gerberding, J.M. Hughes, B.A. Perkins, and members of the Anthrax Bioterrorism Investigation Team. 2001. Bioterrorism-related inhalational anthrax: The first 10 cases reported in the United States. *Emerging Infectious Diseases* 7(6):933–944.

Kaufmann, A.F., M.I. Meltzer, and G.P. Schmid. 1997. The economic impact of a bioterrorist attack: Are prevention and post-attack intervention programs justifiable? *Emerging Infectious Diseases* 3(2):83–94. ftp://ftp.cdc.gov/pub/EID/vol3no2/adobe/kaufman.pdf. (accessed November 2, 2008).

Lee, W., and J.W. McKibbin. 2004. Estimating the global economic costs of SARS. In *Learning from SARS*. Washington, DC: The National Academies Press. Pp. 92–109.

Robinson, L. 2008. *Valuing mortality risk reductions in homeland security regulatory analyses*. Final Report to U.S. Customs and Border Protection, Department of Homeland Security. June 2008. Cambridge, MA: Industrial Economics, Inc.

Wein, L.M., and D.L. Craft. 2005. Evaluation of public health interventions for anthrax: A report to the Secretary's Council on Public Health Preparedness. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 3(4):348–356.

The White House. 1993. *Executive Order 12866 – Regulatory Planning and Review.* http://www.whitehouse.gov/omb/inforeg/eo12866.pdf (accessed August 7, 2009).

Wilkening, D.A. 2006. Sverdlovsk revisited: Modeling human inhalational anthrax. *Proceedings of the National Academy of Sciences* 103(20):7589–7594.

Wilkening, D.A. 2008. Modeling the incubation period of inhalational anthrax. *Medical Decision Making* 28(4):593–605.

Yang, L., I. Chumfong, T. West, H. Ammerlahn, and A. Yoshimura. 2006. *Earlier detection in emergency response to an anthrax attack*. SAND2006-1740. Livermore, CA: Sandia National Laboratories. http://www.prod.sandia.gov/cgi-bin/techlib/access-control.pl/2006/061740.pdf (accessed February 12, 2009).

Zaric, G.S., D.M. Bravata, J.C. Holty, K.M. McDonald, D.K. Owens, and M.L. Brandeau. 2008. Modeling the logistics of response to anthrax bioterrorism. *Medical Decision Making* 28(3):332–350.

Appendix A

Study Activities

COMMISSIONED WORK

In two areas, the committee commissioned additional work by outside experts. David L. Buckeridge of McGill University conducted a modeling exercise to compare the timeliness of detection of biological threats via environmental air sampling, clinical case finding, and syndromic surveillance. Industrial Economics, Incorporated (IEc), a professional services firm, conducted an analysis of costs of the BioWatch program and of surveillance activities to detect biological threats through the public health and health care sectors.

COMMITTEE MEETINGS

The committee held three information-gathering meetings in Washington, DC, during the period July 2008 through November 2008. During these meetings the committee received briefings from federal, state, and local government officials; medical and laboratory professionals; and academic and private-sector researchers regarding biological threats, bioaerosol detection technologies, clinical diagnostic testing, and surveillance and detection of disease threats in clinical settings and through public health systems.

The first meeting, held on July 30–31, 2008, included speakers involved in creating the legislation relevant to the committee's charge and speakers from selected federal agencies and professional organizations, as well as

speakers presenting the scientific perspective on bioaerosol detection technology and testing and a review of federal biosurveillance activities.

At the second meeting, held September 22–24, 2008, the committee heard from speakers on the topics of bioterrorism risk and risk analysis, BioWatch as a risk-management response, the basis for the BioWatch approach, the current operational approach and future plans, environmental monitoring and public health surveillance and response, surveillance in public health and health care, and laboratory roles in BioWatch and in infectious disease surveillance in the public health and health care systems. Speakers were chosen for their expertise in their fields.

At the third meeting, held November 3–5, 2008, the committee heard from speakers on the topics of critical information needs for decision makers, index case recognition, point-of-care diagnostics, and other operational approaches to environmental monitoring for bioterrorism. The committee also heard briefings on aspects of the threat, on aerosol plume modeling, and on past and projected costs for BioWatch.

The fourth and fifth meetings, held December 2–3, 2008, in Irvine, California, and January 26–27, 2009, in Washington, DC, respectively, were deliberative and writing meetings during which the committee developed and refined its recommendations and the members of the committee worked together to draft the report. The committee also kept in close contact by telephone and electronic communication throughout the study.

Invited Speakers

The following individuals were invited speakers at meetings of the committee:

Amy Altman, Ph.D.
Luminex Corporation

Atar Baer, Ph.D.
Seattle-King County Department of Health, WA

Vickie Baselski, Ph.D.
University of Tennessee

Paul Benda
Pentagon Force Protection Agency

Steven Bennett, Ph.D.
Department of Homeland Security

Diane Berry, Ph.D.
Department of Homeland Security

Debora Boyle, D.V.M., Ph.D.
University of Minnesota

Michael Brown, Ph.D.
Los Alamos National Laboratory

David Buckeridge, M.D., Ph.D.
McGill University

Michael Bullard, M.D.
University of Alberta, Edmonton

Svetlana Deyneka, M.D., M.P.H.
North Carolina Division of Public Health

Pamela Diaz, M.D.
Centers for Disease Control and Prevention

Jeffrey Engel, M.D.
North Carolina Department of Health and Human Services

Hawazin Faruki, Dr.P.H.
Laboratory Corporation of America

Martin Fenstersheib, M.D., M.P.H.
Santa Clara County Health Department, CA

P. Joseph Gibson, Ph.D., M.P.H.
Marion County Health Department, IN

Mary Gilchrist, Ph.D.
Massachusetts Department of Public Health

Chevelle Glymph, M.P.H.
Washington, DC, Department of Health

Ray Gordon
Department of Homeland Security

James Hadler, M.D., M.P.H.
Public Health Consultant

Steven Hanna, Ph.D.
Harvard School of Public Health

Katherine Heilpern, M.D.
Emory University

Penny Hitchcock, D.V.M.
Department of Homeland Security

Harvey Holmes, Ph.D.
Centers for Disease Control and Prevention

Robert Hooks
Department of Homeland Security

Richard Hopkins, M.D., M.S.P.H.
Florida Department of Health

William Jenkins, Jr.
Government Accountability Office (GAO)

CAPT Malcolm Johns
Department of Homeland Security

Robert Kadlec, M.D., M.T.M.H., M.A.
White House

Lawrence Kerr, Ph.D.
National Counterproliferation Center

Sara Klucking, Ph.D.
Department of Homeland Security

Gerald Kost, M.D., Ph.D.
University of California, Davis–Lawrence Livermore National Laboratory

Frances Ligler, D.Phil., D.Sc.
Naval Research Laboratory

COL Mark Malatesta
Department of Defense

Patrick Mendonca
U.S. Postal Service

Michael Osterholm, Ph.D., M.P.H.
University of Minnesota

Tara O'Toole, M.D., M.P.H.
Center for Biosecurity, University of Pittsburgh Medical Center

Herminia Palacio, M.D., M.P.H.
Harris County Public Health and Environmental Services, Texas

Art Papier, M.D.
Logical Images, Inc.

Sudha Pottumarthy, Ph.D.
Houston Public Health Laboratory, Texas

Rep. David Price, Ph.D.
U.S. House of Representatives

Stephen Quake, D.Phil.
Stanford University

Barry Rhodes, Ph.D.
Centers for Disease Control and Prevention

Edward Rhyne
Department of Homeland Security

Jeffrey Runge, M.D.
Department of Homeland Security

Mary Shaffran, M.P.A.
Association of Public Health Laboratories

Denise Sockwell, M.S.P.H.
Virginia Department of Health

Daniel Sosin, M.D., M.P.H.
Centers for Disease Control and Prevention

Jeffrey Stiefel, Ph.D.
Department of Homeland Security

Jerome Tokars, M.D., M.P.H.
Centers for Disease Control and Prevention

INTERIM REPORT

As called for by the Statement of Task, the committee prepared an interim report that outlined initial progress on addressing the major issues under consideration by the committee. The report was prepared at a point before conclusions or recommendations had been developed. It was released on February 10, 2009, and it is available at http://www.nap.edu/catalog.php?record_id=12599.

Appendix B

Glossary

Active surveillance: Public health surveillance in which the health agency solicits reports of cases of disease, injury, or other conditions.

Agent: see *Biological agent*.

Air sampling: Determining quantities and types of atmospheric contaminants by collecting and measuring a representative sample of air.

Alarm: A signal that warns or alerts to the presence of danger or a malfunction.

Assay: A quantitative or qualitative evaluation of the presence or amount of a given substance in a particular sample.

BAR false negative: Failure to declare a BAR when a bioterrorist attack has occurred.

BAR false positive: Declaration of a BAR when a bioterrorist attack has not occurred.

Biodefense: Procedures involved in taking defensive measures against attacks using biological agents.

Biological agent: A microorganism (or a toxin derived from it) that causes disease in humans, plants, or animals and is used in bioterrorism or biological warfare.

Biological terrorism: The intentional use of microorganisms, or toxins derived from living organisms, to produce death or disease in humans, animals, or plants.

Biosurveillance: The process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health—whether infectious, toxic,

metabolic, or otherwise, and regardless of intentional or natural origin—in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity.

Bioterrorism: See *Biological terrorism*.

BioWatch Actionable Result: A determination that occurs when analysis of a filter from a BioWatch sampler indicates the confirmed presence of a target organism's nucleic acid signature.

BioWatch jurisdiction: A major metropolitan area—which may include one or more city, county, state, or regional decision-making bodies—where BioWatch air samplers are operating.

BioWatch program: An activity funded by the Department of Homeland Security that uses sets of air samplers in more than 30 jurisdictions to collect airborne particles onto filters that are subsequently transported to laboratories for analysis for the presence of genetic material from certain biological agents.

BioWatch system: The collection of operational components (which are themselves systems) that produce information from air sampling and feed it into a public health decision-making process to determine the appropriate response to a BioWatch Actionable Result (BAR).

Catastrophic health event: Any natural or man-made incident, including terrorism, that results in a number of ill or injured persons sufficient to overwhelm the capabilities of immediate local and regional emergency response and health care systems.

Contagious: Transmissible by direct or indirect contact with an infected organism.

Detection: The determination or recognition of the presence of an object or state of interest.

Detector: A data collection and processing technology that both collects and evaluates data.

Environmental sampling: In the context of the BioWatch system, physical sampling of the environment where a BAR was declared to provide decision makers with a more accurate situational assessment of a BAR and to inform appropriate public health response action.

Environmental surveillance: Monitoring of the environment to evaluate potential exposure to harmful agents and damage to living organisms.

Epidemiologic surveillance: The process of actively gathering and analyzing data related to human health and disease in a population in order to obtain early warning of human health events, rapid characterization of human disease events, and overall situational awareness of disease activity in the human population.

False negative: A negative result for a given target when the target is present.
False positive: A positive result for a given target when the target is not present.

High-regret decision: A decision that results in major disruption or has important health or economic risks.

Incidence: A measure of the frequency with which new cases of illness, injury, or other health condition occurs among a population during a specified period.
Index case: The earliest documented case of a disease that is included in an epidemiological investigation of a disease outbreak.

Laboratory Response Network (LRN): A national network of local, state, and federal public health, health care, food, agriculture, veterinary, and environmental testing laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism and other public health emergencies.
Lidar: The word comes from the acronym for light detection and ranging. Lidars transmit and receive pulses of laser radiation and use the time between transmission and the reflected pulse to determine the distance of an object.
Low-regret decision: A decision that does not result in large risks to the public's health, convenience, or confidence in the decision maker.

Monitoring: Periodic or continuous surveillance or testing to determine the presence or level of a substance of interest in various media or in humans, plants, and animals.
Multiplex (assay): A type of laboratory procedure that performs multiple, molecular-based assays concurrently. It is distinguished from procedures that perform one or a few molecular assays at a time.

Outbreak: The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period. Usually, the cases are presumed to have a common cause or to be related to one another in some way. Sometimes distinguished from an epidemic as more localized or as a term less likely to evoke public panic.

Panel: A set of assays used to test for the presence or absence of a particular target organism or set of organisms.
Passive surveillance: Public health surveillance in which data are sent to a health agency without prompting.

Pathogen: An organism capable of causing infection and disease.

Polymerase chain reaction (PCR): A technique in molecular genetics that is used to reproduce (amplify) selected sections of DNA enzymatically. It permits the analysis of any short sequence of DNA (or RNA) without the need for cloning.

Prevalence: The number of cases of a specific disease or attribute present in a given population at a specified point in time or during a specified period of time.

Public health: The science and practice of protecting and improving the overall health of the community through disease prevention and early diagnosis, control of communicable diseases, health education, injury prevention, sanitation, and protection from environmental hazards.

Public health and medical preparedness: The existence of plans, procedures, policies, training, and equipment necessary to maximize the ability to prevent, respond to, and recover from major events, including efforts that result in the capability to render an appropriate public health and medical response that will mitigate the effects of illness and injury, limit morbidity and mortality to the maximum extent possible, and sustain societal, economic, and political infrastructure.

Public health surveillance: Ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control.

Screening: In the context of the BioWatch system, analysis of air sampler filters for a genetic signature of a particular pathogen.

Sensitivity: The probability that a system will correctly indicate the presence of a particular substance when the substance is present above a certain concentration.

Sensor: A device that detects, qualitatively or quantitatively, the presence of a physical entity and produces a signal that can be read by an observer or an instrument.

Situational awareness: The perception of environmental elements within a given time and space, the comprehension of their meaning, and the projection of their status in the near future.

Specificity: The ability to correctly identify the absence of a target substance when it is not present.

Surveillance: Surveillance is a systematic method for continuous monitoring to detect changes in trend or distribution to initiate investigative or control measures.

Syndromic surveillance: A system for early detection of outbreaks whereby health department staff, assisted by automated acquisition of data

routinely collected for other purposes and computer generation of statistical signals, monitor disease indicators, particularly those associated with possible terrorism-related biologic and chemical agents, continually or at least daily to detect outbreaks earlier than would otherwise be possible with traditional public health methods.

Technology Readiness Level: An element of a classification scheme used by the Department of Defense and other U.S. government agencies to characterize the maturity of evolving technologies before incorporating that technology into a system or subsystem.

Appendix C

Summary of Research into the Costs of Enhanced Public Health Surveillance Systems

Henry Roman
Industrial Economics, Incorporated

In 2003, the U.S. Department of Homeland Security (DHS) initiated an environmental surveillance system intended to detect the intentional aerosolized release of biological pathogens. The program, called "BioWatch," deploys air samplers, primarily in outdoor locations, in more than 30 jurisdictions throughout the United States. Over the next 4 years, DHS intends to upgrade the capabilities of the current system through improved technology and expanded coverage, both of existing BioWatch jurisdictions and expansion to additional jurisdictions and indoor facilities.

At the request of the Congress, the Institute of Medicine (IOM) and the National Research Council (NRC) have been asked by DHS's Office of Health Affairs (OHA) to evaluate the effectiveness of the current BioWatch program (BioWatch) relative to planned improvements to the existing program and to current surveillance performed through the U.S. public health and hospital systems. This effort will be conducted by the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System (the committee). The committee consists of experts in areas that include biological threat assessments, evaluation of biological detection systems, environmental monitoring technologies, biological assays, microbiology, virology, epidemiology, syndromic surveillance, health information technology, the U.S. public health sector, hospital systems, emergency medicine, laboratory operations, statistical methods, systems engineering, operations research, and economic analysis.

IOM/NRC engaged Industrial Economics, Incorporated (IEc), to provide analytical support to the committee to address cost-related aspects of its charge. This support included (1) an assessment of the costs of imple-

menting current and future realizations of the BioWatch monitoring system; and (2) research into the costs of "the current and a potential 'enhanced national surveillance system' to provide a basis for a rapid response to bioterrorist attacks or other biothreats, including initiation of pre-infection prophylaxis and expedited response and recovery."[1] This memo focuses on IEc's efforts to acquire and analyze cost data on the public health system both as it currently exists and for cutting-edge programs aimed at improving surveillance and response capabilities. Note that this memorandum is not intended to provide information about the merits of the current or "enhanced" public health system or provide a snapshot of current public health surveillance capabilities nationwide. Furthermore, for the reasons detailed below, IEc and the committee have concluded that the available data do not support a comprehensive cost analysis of either current or enhanced public health activities related to biosurveillance and outbreak response. Thus, this memo does not present such an analysis; instead, it describes the major challenges to performing a cost analysis of public health programs, describes IEc's effort to obtain cost data for example programs operating at the state or local level that match key biosurveillance and response activities identified by the committee, and discusses IEc's observations regarding the limited data set we were able to obtain.

We include example costs for specific state and local programs in Table C-2.

OBSTACLES TO COST ANALYSIS

Significant obstacles preclude our ability to generate a comprehensive cost estimate for the current or an enhanced U.S. public health system's biosurveillance and response efforts. The primary problem is a general lack of financial transparency and accountability across the U.S. public health system. A number of papers and reports have documented this issue (e.g., Hebert et al., 2007; Honoré et al., 2007; TFAH, 2008). In part, this lack of transparency reflects differences in the organization of the public health system from state to state, where some have a more centralized system of public health responsibilities and others spread those responsibilities across multiple agencies. More importantly, there is no uniformly recognized classification system for expenditures on public health, leading to confusion about what constitutes public health spending. The report from the Trust for America's Health (TFAH, 2008) presents examples of inconsistencies in cost accounting for specific public health initiatives both across states and

[1] "Statement of Task" provided to the committee by the Institute of Medicine and the National Research Council.

also year-to-year within the same state.[2] This lack of transparency makes it difficult to do a top-down analysis of the portion of federal bioterrorism preparedness funds that are spent on biosurveillance and response activities by state and local health departments. It also precludes a "bottom up" approach to estimating funds spent on bioterrorism surveillance and response, given the difficulties both identifying and isolating spending in specific public health categories.

Another challenge for the committee is defining the entity—the "enhanced national surveillance system"—for which costs are to be assessed. No current definition of such a system exists, though efforts to define such a system are ongoing. Given the tight time frame of the committee's analysis, and not wishing to preempt current efforts in this area, the committee opted to instead highlight opportunities for enhancement of surveillance through the public health and health care systems in broad categories of legally mandated reporting, automation of health care information systems and public health linkages, laboratory and diagnostic testing capacity, and information integration. We have used these categories to guide our cost research.

APPROACH AND DATA SOURCES

Faced with these challenges and the timeframe of this analysis, IEc adapted its cost analysis to focus on providing example cost data for activities or programs at the state or local level that match the surveillance- and response-related categories described above. The results were intended to provide some insight into the potential order of magnitude or range of magnitudes of the costs of developing and maintaining systems that improve reporting, surveillance, and response. IEc focused its analysis on state or local public health programs and initiatives, though it did review one source reporting cost estimates for implementing electronic laboratory reporting (ELR) nationwide.

Data Sources

The cost information we obtained came from two categories of sources:

- **Published reports and journal articles.** IEc conducted a thorough review of all cost-related documents on the IOM/NRC portal website submitted by committee members, IOM/NRC staff, and the U.S. Centers for Disease Control and Prevention (CDC) for relevant cost estimates for the categories provided by the committee. IEc also searched for additional pub-

[2]For a discussion of the difficulties of measuring the value of services provided by public health departments, see Neumann et al. (2008).

lic health cost analyses using the National Library of Medicine's PubMed database.[3] A table listing all the documents reviewed by IEc has been previously submitted to the committee.[4]

- **Telephone interviews.** Most of our data came from e-mail exchanges and telephone interviews with state and local health officials and representatives of public health organizations such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Laboratories (APHL). The individuals contacted in December 2008 and January 2009 were identified through discussions with the aforementioned organizations, the committee, and IOM/NRC staff. IEc sent inquiries to individuals from state public health departments in Florida, Massachusetts, Michigan, Minnesota, Nebraska, New York, North Carolina, Pennsylvania, and Washington. IEc obtained cost data or conducted follow-up interviews with representatives of all of these states except Michigan, New York, and Pennsylvania. IEc also spoke with committee member James Buehler, who provided cost information about health departments in Georgia. At the local level, IEc interviewed a representative of the Tarrant County, Texas, health department, and we obtained data for the New York City health department from committee member Marci Layton. IEc also spoke with a University of Pittsburgh researcher currently developing a biosurveillance grid covering areas of Pennsylvania and Ohio. Individuals contacted by IEc are shown in Table C-1.

RESULTS AND OBSERVATIONS

The results of IEc's research efforts are included in Table C-2. The data are quite limited; however, we can make a few observations.

- The level of detail of these costs was generally rather broad, as expected, with responses often given in terms of development and operations and maintenance (O&M) costs.
- To the extent we can tell from limited data, the relative scale of the magnitude of costs across states and localities appears reasonable.
- We obtained one national-level cost estimate—the cost of implementing a national ELR infrastructure, as estimated during a 2007 meeting of

[3]IEc also reviewed CDC budget documents online (http://www.cdc.gov/fmo/topic/Budget); however, due to the difficulties in tracking CDC funding to the state and local level, we did not derive any cost estimates from these data.

[4]See e-mail messages from Henry Roman, IEc, to Lois Joellenbeck, NAS/IOM, dated December 20, 2008, and January 24, 2009.

local, state, federal, and private-sector experts sponsored by CDC through its cooperative agreement with APHL. The initial estimates included $50 million for planning and building basic infrastructure where needed, $600 million for development, and $100 million per year for O&M costs.

- IEc was most successful in identifying cost information for the larger information technology (IT)-related efforts—ELR, syndromic surveillance systems, health information exchanges (HIEs), and electronic disease surveillance and outbreak management software. However, these data were often incomplete—for example, missing O&M costs in some cases because the systems are too new. IEc was least successful obtaining cost estimates for marginal expansion of laboratory testing and diagnostic capabilities, clinical decision support tools and point-of-care diagnostic tools, health alert networks, and fusion centers.
- The interconnectedness of some of these systems makes it difficult to separate out costs of individual systems. For example, to implement ELR in North Carolina, the health department needed to develop a National Electronic Disease Surveillance System (NEDSS) function in order to receive ELR information. To do this, North Carolina funded the development of the Maven software system at a cost of over $3 million, with $650,000 annually in O&M costs. To estimate costs across the current categories, one would need to develop an approach to dividing the development (or purchase) and O&M costs of Maven across categories when such overlap exists, to avoid double-counting.
- Another complicating factor in assessing the costs of these initiatives relates to accounting for costs to all parties involved. For example, the true costs to hospitals that participate in ELR or syndromic surveillance systems may not be included in these estimates. Also, in the case of Washington State, one of their major syndromic surveillance systems (Electronic Surveillance System for the Early Notification of Community-based Epidemics, or ESSENCE) was provided to them by Johns Hopkins University at no cost, including an estimated $50,000 in hardware (Wayne Turnberg, WADOH, personal communication).
- Customization can be a driving factor in the costs of syndromic surveillance systems, and the difference in cost can be dramatic. In addition to the ESSENCE example above, the Real-time Outbreak and Disease Surveillance (RODS) system, developed at the RODS laboratory at the University of Pittsburgh, is an open-source system that is available at no cost to health departments. If a department wishes to customize RODS, it either needs to have the IT resources available in-house to modify the code, or it needs to contract out the modifications to an IT firm (Rich Tsui, University of Pittsburgh, personal communication). The Outbreak Detection Information Network (ODIN) syndromic surveillance system, developed by Washington State to complement ESSENCE, features greater customization

options and incorporates additional data sources; the cost of developing ODIN was approximately $5 million over 4 years.

- In some cases, notably the HIEs, we observe a significant range in development costs—from a Tarrant County system with development costs under $200,000 to the PA-OH surveillance grid system ($1 million) to the Washington State HIE, which is being developed under a $5 million CDC grant. The Tarrant County effort, described as a "rudimentary" HIE that covers 50 to 60 hospitals, illustrates a less highly tailored approach, using open-source syndromic surveillance systems (RODS and ESSENCE) "off the shelf" to implement surveillance (William Stephens, Tarrant County (TX) Health Department, personal communication). While some of the cost differences with the other systems may be due to scope or other factors, we expect much of the difference reflects a focus on front-end development, providing greater customization and flexibility and features.

REFERENCES

Hebert, K., N. Henderson, and E. Gursky. 2007. Building preparedness by improving fiscal accountability. *Journal of Public Health Management and Practice* 13(2):200–201.

Honoré, P.A., R.L. Clarke, D.M. Mead, and S.M. Menditto. 2007. Creating financial transparency in public health: Examining best practices of system partners. *Journal of Public Health Management and Practice* 13(2):121–129.

Neumann, P.J., P.D. Jacobsen, and J.A. Palmer. 2008. Measuring the value of public health systems: The disconnect between health economists and public health practitioners. *American Journal of Public Health* 98(12):2173–2180.

TFAH (Trust for America's Health). 2008. *Shortchanging America's health 2008: A state-by-state look at how federal public health dollars are spent*. Washington, DC: Trust for America's Health. http://healthyamericans.org/reports/shortchanging08/ (accessed March 27, 2009).

TABLE C-1 Public Health Cost Data Contacts

Health Department/ Organization	Contacts
APHL	Scott Becker Chris Mangal Michelle Meigs Patina Zarcone (January 23, 2009)
ASTHO	James Blumenstock
CSTE	Lisa Dwyer
Emory University	James Buehler* (December 17, 2008)
Florida	Richard Hopkins (January 14, 2009)
Massachusetts	Dina Caloggero
Michigan	James Collins
Minnesota	Richard Danila
NACCHO	Jack Herrmann, William Stephens (Tarrant County (TX) Public Health, December 18, 2008)
Nebraska	Thomas Safranek (January 14, 2009)
New York City	Marci Layton*
New York State	Robert Burhans
North Carolina	Jeffrey Engel (January 16, 2009)
Pennsylvania	Veronica Urdaneta
University of Pittsburgh	Fu-Chiang (Rich) Tsui (December 18, 2008)
Washington State	Michael Davisson John Erickson Margaret Hansen Judy May Wayne Turnberg (all January 20, 2009)

NOTE: Interview dates in parentheses. APHL, Association of Public Health Laboratories; ASTHO, Association of State and Territorial Health Officials; CSTE, Council of State and Territorial Epidemiologists; NACCHO, National Association of County and City Health Officials.

*IOM/NRC committee member.

TABLE C-2 Public Health Cost Matrix: Examples of Surveillance Program Costs

Category	Example Programs
Environmental Monitoring Programs	
Enhance animal, wildlife, vector testing	Canada's National Wildlife Disease Strategy
Legally Mandated Reporting and Surveillance Systems: Notifiable Diseases, Outbreak Reporting, Vital Event Registration	
Enhance electronic laboratory reporting systems	1. APHL/ANSER/CDC estimate for developing a national ELR system
	2. NC (online for 2 labs)
	3. WA: PHRED (online for 5 of larger hospital labs, about 50% of test results)
	4. NE (developing)
	5. MA

Cost Information	Cost Information Reference	Comments
No data yet on Canadian program. Paper identified by committee member Seth Foldy suggests $4–5 million over 3 years to design and implement global animal surveillance system for zoonotic pathogens	Kuiken et al. (2005)	
1. Development: $650 million to plan ($50 million) and implement ($200 million/yr over 3 years). Planning includes building state public health LIMS where needed ($25 million). O&M: $100 million/yr estimated O&M costs	1. APHL et al. (2007)	MA values assume ~$53,000 labor, $140,000 in software, and ~$3,000 in hardware support for 6 servers
2. Development: $400K for STARLIMS product for labs; cost per hospital can vary, can be as much as $40,000. O&M: no data yet. Costs to Receive ELR: needed to develop NEDDS systems; Development: $3.25 million to develop and implement Maven system; O&M: $650,000 ($500,000/yr for Maven; $150,000/yr for ELR coordinator)	2. Jeffrey Engel, NC, personal communication	
3. Development: do not have yet; O&M: about $200,000/yr (half technology, half operations)	3. Michael Davisson, Wayne Turnberg, Judy May, WA, personal communication	
4. Development: estimates $600,000 ($20,000 per lab); O&M: estimates $50,000–75,000/yr personnel costs	4. Thomas Safranek, NE, personal communication	
5. Development: pending; O&M: $196,000/yr	5. Dina Caloggero, MA, personal communication	

continued

TABLE C-2 Continued

Category	Example Programs
Enhance notifiable disease reporting by clinicians (outreach, electronic reporting procedures, 24/7 call line)	
Enhance electronic death reporting systems	1. Boston surveillance system receives death certificate data issued in City of Boston
	2. WADOH (5 counties)
Automation of Healthcare Information Systems and Public Health Linkages	
Enhance use clinical decision support tools for diagnosis, reporting, & management (e.g., triage, isolation, treatment)	eTriage VisualDx

Cost Information	Cost Information Reference	Comments
Outreach programs generally involve 1 staff member working full-time as liaison (~$54,000/yr) Outreach materials can cost up to several hundreds of thousands of dollars per year (upper bound, NYC) For Internet-based systems, there is a startup cost plus 1 IT FTE to maintain it (~$48,000/yr).	Assume 1 junior epidemiologist FTE for Outreach "liaison" in public health department in GA (James Buehler, personal communication) "though staff varies with size of department, e.g., percentage of several MDs' time employed in outreach in NYC" (Marci Layton, personal communication). Outreach materials: Marci Layton, personal communication Cost of full-time staff from the State of Hawaii Department of Health Bioterrorism Preparedness Response Program–FY 2005 Salary Survey	
1. $74,389 (development; also includes costs for 911 and EMS data)	1. Kirkwood et al. (2007)	
2. Development: awaiting costs on latest version; O&M: unknown	2. Michael Davisson, WADOH, personal communication	
VisualDx: $20,000 per hospital		

continued

TABLE C-2 Continued

Category	Example Programs
Enhance use of information from EMRs and other electronic health information sources to detect unusual cases of disease or trends (public health collects and collates information from multiple institutions)	Syndromic Surveillance systems such as RODS, ESSENCE Systems in many states, including MA, NY, NC (NCDetect), WA Also local HIE efforts to increase integration with EHRs, beyond typical syndromic surveillance features—more public health user control over data reporting, reachback features (e.g., WA state, Indiana, NY?) Electronic Support for Public Health (ESP): an automated, secure, portable public health detection and messaging system for cases of notifiable diseases. Uses electronic medical data and supports an optional case management workflow system for case notification control. All relevant clinical, laboratory, and demographic details are transferred to the local health authority

Cost Information	Cost Information Reference	Comments
Boston, MA: An electronic, emergency department-based syndromic surveillance system for the Boston Public Health Commission cost $422,899 between December 2003 and July 2005. This included: $141,227 in development costs $74,389 for enhancements $196,302 in annual O&M costs	Kirkwood et al. (2007)	
NYC: O&M for syndromic surveillance system estimated to be $130,000–$150,000/yr	Heffernan et al. (2004)	
NC: NCDetect, statewide. Development: $1.9 million over 3 years (does not include some costs to hospitals); O&M: $600,000/yr. Also, 60 hospitals have reachback enhancement for an extra $3 million ($50,000 per hospital)	Jeffrey Engel, NC, personal communication	
WA: uses ESSENCE and ODIN; ESSENCE provided at no cost to WADOH; minimal staff maintenance/review time. ODIN (Kitsap and Pierce counties) Development: ~$5 million over 4 years; O&M: unclear, some minimal staff maintenance and review time. HIE with EMR extraction for syndromic surveillance Development: $5 million in CDC grant over 3 years	Michael Davisson, Wayne Turnberg, Judy May, WA, personal communication	40 hospital partners for HIE in WA; CDC grant for HIE went to University of Washington, INHS (a RHIO), SAIC
No cost data yet on ESP		ESP developed through a collaboration between CDC, the CDC-funded Center of Excellence in Public Health Informatics based at Harvard, Harvard Vanguard Medical Associates, and the Massachusetts Department of Public Health

continued

TABLE C-2 Continued

Category	Example Programs
	Massachusetts eHealth Collaborative, which uses health information technology through community-based implementation of EHRs and health information exchange
Enhance use of regional health information exchanges to detect unusual cases of disease or trends (public health interfaces with area-wide exchange that involves multiple institutions)	1. Tarrant County, TX system
	2. PA-OH BiG (under development)
Enhance public health capacity to electronically alert healthcare sector of important public health events (e.g., inform evaluation, triage, isolation, treatment)	
Laboratory and Diagnostic Testing Capacity	
Expand access to rapid diagnostic tests, "point of care" tests	Luminex
Extend capacities to characterize pathogens and coalesce reports to identify emergence or spread of related cases of infectious disease (e.g., PulseNet model)	

Cost Information	Cost Information Reference	Comments
eHealth Collaborative: $50 million was pledged by Blue Cross Blue Shield of Massachusetts to establish an all-stakeholder organization that would implement three full funded community-wide EHR demonstration projects across Massachusetts over 3 years	Goroll et al. (2009)	
1. Development costs: $150,000; O&M: $70,000–$75,000/yr; Future enhancements (includes adding ELR): $150,000–$200,000	1. William Stephens, manager, Southwest Center for Advanced Public Health Practice; Tarrant County Public Health, personal communication	
2. Development costs: $1 million ($500,000 over 2 years); O&M: similar to maintenance costs in current public health system	2. Rich Tsui, University of Pittsburgh, RODS laboratory, personal communication	
NYC: Several million in startup costs plus 3–4 FTEs to operate/maintain (~$200,000/yr)	Marci Layton, personal communication Cost of full-time staff from the State of Hawaii Department of Health Bioterrorism Preparedness Response Program, FY 2005 Salary Survey	
Development costs: $4–6 million over 2 years; unit cost: <$50,000		

continued

TABLE C-2 Continued

Category	Example Programs
Expand/enhance capacity to collect and test clinical specimens as part of public health surveillance systems, either ongoing or in response to possible alerts	
Information Integration	
Improve integration and analysis of public health information (e.g., epidemiologic, laboratory, environmental, program)	1. Maven Electronic Disease Surveillance and Outbreak Management (Consilience Software) in NY, MA, MN
	2. WATrac: checks ED status and bed availability, and has incident management functions for disaster response; includes patient tracking (no users yet)
Enhance integration and analysis of public health and other information sources that characterize public health threats (e.g., BioPHusion model, fusion centers)	BioPHusion, BWIC project, NBIS/NBIC (DHS)

NOTES: APHL, Association of Public Health Laboratories; BWIC, Biological Warning and Incident Characterization; CDC, Centers for Disease Control and Prevention; DHS, Department of Homeland Security; ED, emergency department; EHR, electronic health record; ELR, electronic laboratory reporting; EMR, electronic medical record; ESP, Electronic Support for Public Health; ESSENCE, Electronic Surveillance System for the Early Notification of Community-based Epidemics; FTE, full-time equivalent; FY, fiscal year; HIE, health information

Cost Information	Cost Information Reference	Comments
1. Maven in NC: Devevelopment: $3 million; O&M: $500,000/yr (overlap with ELR?); Maven in MN: $800,000 to purchase; no O&M given	1. Jeffrey Engel, NC, personal communication; Rich Danila, MN, personal communication	
2. WATrac Development: $160,000; O&M: $45,000	2. Margaret Hansen, WADOH, personal communication	WATrac: bed tracking and ED status in 82% of WA hospitals; resource and pharmaceutical tracking anticipated to be implemented in 2009 statewide

exchange; IT, information technology; LIMS, laboratory information management system; NEDSS, National Electronic Disease Surveillance System; NBIC, National Biosurveillance Information Center; NBIS, National Biosurveillance Information System; O&M, operation and maintenance; PHRED, Public Health Reporting of Electronic Data; RHIO, regional health information organization; RODS, Real-time Outbreak and Disease Surveillance; WADOH, Washington State Department of Health.

REFERENCES

APHL (Association of Public Health Laboratories), ANSER, and CDC (Centers for Disease Prevention and Control). 2007. *Framework for electronic laboratory reporting: Recommendations to policymakers*. A report of the Electronic Laboratory Reporting Consensus-Building Meeting, October 30, 2007. Arlington, VA: Analytic Services Inc. http://www.aphl.org/policy/Documents/Electronic_Lab_Reporting_2007.pdf (accessed March 26, 2009).

Goroll, A.H., S.R. Simon, M. Tripathi, C. Ascenzo, and D.W. Bates. 2009. Community-wide implementation of health information technology: The Massachusetts eHealth Collaborative experience. *Journal of the American Medical Informatics Association* 16:132–139. http://www.jamia.org/cgi/content/full/16/1/132 (accessed August 10, 2009).

Heffernan R., F. Mostashari, D. Das, M. Besculides, C. Rodriguez, J. Greenko, L. Steiner-Sichel, S. Balter, A. Karpati, P. Thomas, M. Phillips, J. Ackelsberg, E. Lee, J. Leng, J. Hartman, K. Metzger, R. Rosselli, and D. Weiss. 2004. New York City syndromic surveillance systems. *Morbidity and Mortality Weekly Report* 53(Suppl.):23–27.

Kirkwood, A., E. Guenther, A.T. Fleischauer, J. Gunn, L. Hutwagner, and M.A. Barry. 2007. Direct cost associated with the development and implementation of a local syndromic surveillance system. *Journal of Public Health Management Practice* 13(2):194–199.

Kuiken, T., F.A. Leighton, R.A.M. Fouchier, J.W. LeDuc, J.S.M. Peiris, A. Schudel, K. Stohr, and A.D.M.E. Osterhaus. 2005. Public health: Pathogen surveillance in animals. *Science* 309(5741):1680–1681.

Appendix D

Biographical Sketches of Committee Members

Bernard D. Goldstein (*Chair*) is a professor in the Department of Environmental and Occupational Health at the University of Pittsburgh Graduate School of Public Health, where he previously served as dean. Before coming to Pittsburgh, he was the director of the Environmental and Occupational Health Sciences Institute, a joint program of Rutgers, The State University of New Jersey, and the University of Medicine and Dentistry of New Jersey (UMDNJ)–Robert Wood Johnson Medical School. Dr. Goldstein was assistant administrator for research and development, U.S. Environmental Protection Agency, 1983–1985. His past activities include serving as a member and chairman of the NIH Toxicology Study Section and EPA's Clear Air Scientific Advisory Committee. He is a member of the IOM, where he has co-chaired the section on Public Health, Biostatistics, and Epidemiology and is current head of the Environmental and Occupational Health and Toxicology Interest Section. He is also chair of the NRC Standing Committee on Risk Assessment Issues and Review. Dr. Goldstein is a fellow of the American Association for the Advancement of Science, the American College of Physicians, the American College of Preventive Medicine, and the Academy of Toxicological Sciences. He is a past recipient of the Robert A. Kehoe Award of Merit of the American College of Occupational and Environmental Medicine, the Katherine Boucot Sturgis award from the American College of Preventive Medicine, the Distinguished Service Award from the American College of Toxicology, and the Distinguished Achievement Award from the Society for Risk Analysis. He received an M.D. from New York University School of Medicine, and he is board certified in internal medicine, hematology, and toxicology.

Joseph M. DeSimone (*Vice Chair*) is the Chancellor's Eminent Professor of Chemistry at the University of North Carolina at Chapel Hill and the William R. Kenan, Jr. Professor of Chemical Engineering at North Carolina State University. He also serves as director of the National Science Foundation Science and Technology Center for Environmentally Responsible Solvents and Processes and is co-principal investigator for the Carolina Center for Cancer Nanotechnology Excellence. He is also the director of the Institute for Advanced Materials, Nanoscience, and Technology at UNC-CH. Among Dr. DeSimone's notable inventions is an environmentally friendly manufacturing process that relies on supercritical carbon dioxide for the creation of fluoropolymers, such as Teflon®. More recently, he worked with a team to design a polymer-based, fully bioabsorbable, drug-eluting stent, which helps keep a blocked blood vessel open after a balloon-angioplasty and is absorbed by the body within 18 months. Dr. DeSimone's current interests are focused on applied fabrication technologies from the microelectronics industry to make nanocarriers for use in medicine. Dr. DeSimone holds more than 115 issued patents with more than 70 new patent applications pending, and he has published more than 240 peer-reviewed scientific articles. In 2005, Dr. DeSimone was elected into both the National Academy of Engineering and the American Academy of Arts and Sciences. He has received numerous awards and recognition, including the Lemelson-MIT Prize (2008), the Presidential Green Chemistry Challenge Award (1997), the Engineering Excellence Award by DuPont (2002), and the American Chemical Society Award for Creative Invention (2005). He is the cofounder of Liquidia Technologies, Inc., and a cofounder of BioStent, which was sold to Guidant (now Abbott Vascular). At the National Academies, he has served on the Division on Earth and Life Studies' Board on Chemical Sciences and Technology. Dr. DeSimone earned his B.S. in chemistry from Ursinus College and his Ph.D. in chemistry from the Virginia Polytechnic Institute and State University.

Michael S. Ascher is the Senior Medical Advisor to the California Emergency Management Agency (CALEMA) and a visiting researcher in the Department of Medicine and Epidemiology, University of California (Davis) School of Veterinary Medicine. Previously, he has been the lead for biological defense activities in the California Department of Health Services and principal investigator of the CDC grant to the state for preparedness and response. Other past positions include chief of the Viral and Rickettsial Laboratory, Division of Communicable Disease Control, at the California Department of Health Services. He also served in the U.S. Army as chief of medicine and in the Bacteriology Division at the U.S. Army Medical Research Institute of Infectious Diseases. In the area of biological defense, he has served on the Armed Forces Epidemiological Board and an interagency advisory panel on Biological Warfare Preparedness for the 21st Century. He has consulted for the Department of Defense, the Centers for Disease Control and Prevention, MITRE Corporation, the National Domestic

Preparedness Office of the FBI, and others. Dr. Ascher's research interests include mechanisms of protective immunogenicity of microbial vaccines and advanced methods for diagnosis of infectious diseases. He currently serves on the National Academies' Standing Committee on Biodefense at the U.S. Department of Defense. Dr. Ascher received his M.D. from Harvard Medical School.

James W. Buehler is a Research Professor in the Department of Epidemiology and a member of the Center for Public Health Preparedness and Research at the Rollins School of Public Health at Emory University. Prior to joining the Emory faculty in 2002, he served for 21 years in the U.S. Public Health Service as a medical epidemiologist at the Centers for Disease Control and Prevention (CDC), where he worked in the areas of general field epidemiology, maternal and child health, HIV/AIDS, and, for a brief period in 2001, anthrax. His work in public health surveillance—population health monitoring—has spanned analysis, development, management, application of surveillance information to programs and policies, and ethics. Dr. Buehler's applied research interests center on improving public health capacity to detect and respond to epidemics and other community health emergencies and on improving the use of epidemiology in public health systems and practice. In August 2009, he accepted an assignment at CDC as a consultant epidemiologist for influenza surveillance.

Karen S. Cook is the Ray Lyman Wilbur Professor of Sociology at Stanford University, chair of the Department of Sociology, and director of the Institute for Research in the Social Sciences (IRISS). She joined the faculty of the Department of Sociology in academic year 1998–1999. Before coming to Stanford, she was on the faculties of the University of Washington and of Duke University. Professor Cook was elected vice president of the American Sociological Association in 1994–1995. She also has served as vice-president of the International Institute of Sociology and as chair of Research Committee 42 (social psychology) in the International Sociological Association. In 1996, she was elected to the American Academy of Arts and Sciences, and in 1998–1999, she was a fellow at the Center for Advanced Study in the Behavioral Sciences. In 2004, she received the Cooley-Mead Award for career contributions to social psychology from the American Sociological Association. She was elected to the National Academy of Sciences in 2007. Professor Cook has a long-standing interest in social exchange, bargaining, and social justice and is currently involved in a large interdisciplinary project focusing on trust in social relations. She is a co-author of *Cooperation Without Trust?* (2005) and her edited or jointly edited books include *The Limits of Rationality* (1990), *Sociological Perspectives on Social Psychology* (1995), *Trust in Society* (2001), and *Trust and Distrust in Organizations* (2004). Currently she also serves as co-editor of the *Annual Review of Sociology*. In the past, she has served on many editorial boards and as editor of *Social Psychology Quarterly* (1988–1992). Her research has been

supported by the National Science Foundation and the Russell Sage Foundation, and articles based on this work have appeared in the *American Journal of Sociology*, the *American Sociological Review*, *Social Psychology Quarterly*, and other journals in sociology. Professor Cook received her B.A., M.A., and Ph.D. from Stanford University.

Norman A. Crouch retired in early 2009 as the assistant commissioner at the Minnesota Department of Health. In this position he was responsible for overseeing the department's Health Protection Bureau, which included the Office of Emergency Preparedness and Response, as well as the Divisions of Environmental Health, Infectious Disease Epidemiology, Prevention and Control, and the Public Health Laboratory. Previously, he was director of the department's Public Health Laboratory Division. Prior to his involvement in the practice of public health at the state level, with interest in the development of emergency response networks to detect and respond to emerging biological and chemical health threats, Dr. Crouch was on the faculty in the Department of Microbiology at the University of Iowa and the Department of Biomedical Sciences at the University of Illinois College of Medicine in Rockford, Illinois. He has served as a member of the Board of Directors and as president of the Association of Public Health Laboratories (APHL). He currently serves on several APHL committees, which includes being chairman of the APHL Emergency Preparedness and Response Committee and a member of the APHL Finance Committee. In addition, he serves on the APHL subcommittee for Continuity of Operations Planning and the steering committee for Laboratory Performance Standards. He is board certified in medical and public health virology by the American Board of Medical Microbiology. Dr. Crouch received his B.S. in bacteriology from the University of Wisconsin–Madison, and his Ph.D. in medical microbiology, also from the University of Wisconsin. He conducted post-doctoral studies at the Baylor College of Medicine in Houston, the Pennsylvania State University College of Medicine in Hershey, and the Mayo Clinic in Rochester, Minnesota.

Francis J. Doyle III holds the Duncan and Suzanne Mellichamp Chair in Process Control in the Department of Chemical Engineering at the University of California, Santa Barbara (UCSB), as well as appointments in the Electrical Engineering Department, and the Biomolecular Science and Engineering Program. He is the associate director of the Institute for Collaborative Biotechnologies. Prior to his appointment at UCSB, he held faculty appointments at Purdue University and the University of Delaware, and he held visiting positions at DuPont, Weyerhaeuser, and Stuttgart University. Dr. Doyle's research interests are in systems biology, network science, modeling and analysis of circadian rhythms, drug delivery for diabetes, model-based control, and control of particulate processes. He is currently the editor-in-chief of the *IEEE Transactions on Control Systems Technology*, and he holds associate editor positions with the *Journal of Process*

Control, the *SIAM Journal on Applied Dynamical Systems*, and *Interface*. In 2005, he was awarded the Computing in Chemical Engineering Award from the American Institute of Chemical Engineers for his innovative work in systems biology. He received his B.S.E. from Princeton, Certificate of Post-graduate Studies from Cambridge, and Ph.D. from California Institute of Technology, all in chemical engineering.

Seth Foldy is State Health Officer and administrator of the Division of Public Health for the State of Wisconsin. Until recently, he served as an associate professor in the Department of Family and Community Medicine at the Medical College of Wisconsin and principal of health.e.volution consulting. He also cofounded and served as chief medical officer of the Wisconsin Health Information Exchange, which recently began supplying public health agencies with real-time hospital and clinic data. In addition, he assisted the Argonne National Laboratory Decision and Information Sciences division on emergency public health response exercises, trainings, modeling and information fusion systems. Dr. Foldy was previously Commissioner of Health in Milwaukee, Wisconsin, and had earlier practiced and taught urban family medicine in Worcester, Massachusetts, and Cleveland, Ohio. He helped create the SURVNET, a 14-jurisdiction communicable disease surveillance network; the SARS Surveillance Network, which deployed syndromic surveillance rapidly across four states; and a regional emergency medicine internet for surveillance and clinician alerting. He led the local elimination of monkeypox at the center of its first hemispheric appearance in 2003 and participated in a joint health task force responding to the 2005 Indian Ocean tsunami. He chaired the National Association of County and City Health Officials' Information Technology Committee and served on the board of the eHealth Initiative Foundation and on the CDC Information Council. He also facilitated the formation of the Joint Public Health Informatics Taskforce. Dr. Foldy holds degrees from Stanford University, Case Western Reserve University, and the Medical College of Wisconsin; board certifications in family and preventive medicine; and the Roemer Prize for Creative Local Public Health Work.

Elin A. Gursky is a fellow and principal deputy for Biodefense, National Strategies Support at ANSER. She has held various senior-level government and private-sector positions. As director of Epidemiology and Communicable Disease Control (1987–1995) for Prince Georges County, Maryland, Dr. Gursky addressed and helped reverse epidemic rates of communicable diseases, including infectious and congenital syphilis, enteric pathogens, and multidrug-resistant tuberculosis. Dr. Gursky subsequently served as deputy health commissioner for New Jersey (1995–1998), building and leading the Public Health Protection and Prevention Programs. She designed and implemented a statewide interactive electronic communication system to improve the accuracy and timeliness of

disease reporting, surveillance, and response. She developed a fax-based Health Alert system for immediate dissemination of urgent infectious disease information to the medical community. She also instituted a comprehensive review and rewriting of practice standards for the state's 117 local health departments to rebuild the state's public health infrastructure. Dr. Gursky has also served as vice president for public health for a 10-hospital system and as a private consultant on hospital business strategies. She received a D.Sc. from Johns Hopkins University in 1985.

Sandra Hoffmann is a fellow at Resources for the Future. Before joining Resources for the Future, she served on the faculty of the University of Wisconsin–Madison LaFollette School of Public Affairs. She also practiced law with the Washington, DC, office of McKenna, Conner, and Cuneo, specializing in chemical and pesticide regulatory law. Dr. Hoffmann's research focuses on the economics of health and environmental risk management, in particular, health valuation and integration of economics and health risk assessment. Her research on health valuation includes studies assessing the social cost of environmental pollution in China, assessments of the social cost of foodborne illness in the United States, and a series of studies on parental decision making affecting children's risk of developmental harm from environmental neurotoxins. She has advised the EPA and the OECD on improving regulatory economic analysis related to children's environmental health. A significant body of her work has focused on enhancing the usefulness of foodborne illness disease surveillance to public health decision makers. She has testified on this issue before USDA and FDA. She is co-editor with Michael Taylor of *Toward Safer Food: Perspectives on Risk and Priority Setting*, which sets out a systematic structure for designing a more science/risk-based approach to food safety regulation in the United States. Dr. Hoffmann received a Ph.D. in agricultural and resource economics from the University of California at Berkeley and a J.D. from the University of Michigan Law School.

Calvin B. Johnson is vice president and chief medical officer of the Temple University Health System in Philadelphia. Previously he was secretary of the Pennsylvania Department of Health, a position he held from 2003 to 2008. He is a board-certified pediatrician. Before his appointment at the Department of Health, Dr. Johnson was a physician in the Pediatric Emergency Department at Temple University Children's Medical Center in Philadelphia and an assistant professor of pediatrics at the Temple University School of Medicine. In Philadelphia, he served on the board of directors of the Philadelphia Health Management Corporation. He has also served as medical director of the Division of Family Health Services in the New York City Department of Health. Dr. Johnson was a commissioned officer in the Medical Corps of the U.S. Army Reserve/National Guard, achieving the rank of major. Dr. Johnson received

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Paul Keim holds the Cowden Endowed Chair in Microbiology and is the Arizona Regents Professor at Northern Arizona University (NAU). He is the director of NAU's Microbial Genetics and Genomics Center. He also directs the Pathogen Genomics Division at the Translational Genomics Research Institute (TGen), a nonprofit research institute. He maintains his Laboratory Affiliate at Los Alamos National Laboratory in the Division of Biosciences. Dr. Keim's current research interests include genomic analysis of bacterial pathogens and the application of genomic technology to clinical diagnostic problems. He currently serves as principal investigator or co-principal investigator for three projects unrelated to the BioWatch program that are funded by the Homeland Security Advanced Research Projects Agency (HSARPA): (1) Microbial Forensic Signatures on the TIGR system, (2) Forensic Assays for the Analysis of *Ricinus communis*, and (3) High Resolution Forensic Assays–Phase II award. Dr. Keim's laboratory has developed high-resolution strain-typing analysis methods for the forensic analysis of *B. anthracis*, *Y. pestis*, and *F. tularensis*. He has participated in collaborative projects with scientists from the former Soviet Union to understand the ecology and epidemiology of these pathogens. Dr. Keim has served on grant review panels for USDA and NIH; on advisory groups for the FBI, GAO, and HHS; and on three previous NRC committees. He is currently a member of the FBI's Scientific Working Group on Forensic Analysis of Chemical, Biological, Radiological, and Nuclear Terrorism; the National Science Advisory Board for Biodefense; and the executive advisory committee for the Pacific Southwest Regional Center for Biodefense. He is a fellow of the American Academy of Microbiology. Dr. Keim received a B.S. in biology and chemistry from Northern Arizona University and a Ph.D. in botany from the University of Kansas. He has done post-doctoral work in genetics, genomics, and biotechnology.

Arthur L. Kellermann is professor in the Department of Emergency Medicine and associate dean for Health Policy at Emory University School of Medicine. He also holds an appointment as a professor in the Department of Environmental and Occupational Health at the Rollins School of Public Health, Emory University. He has conducted landmark research on prehospital cardiac care, use of diagnostic technology in emergency departments, and health care for the poor. His papers have been published in many of the nation's leading medical journals. He is a recipient of the Hal Jayne Academic Excellence Award from the Society for Academic Emergency Medicine, the Excellence in Science award from the Injury Control and Emergency Health Services Section of the American Public Health Association, and the Scholar/Teacher Award from Emory University. He was a Robert Wood Johnson Health Policy Fellow at the Institute of

Medicine (IOM) for 2006–2007. Dr. Kellermann is a member of the IOM. He has served as co-chair of the IOM Committee on the Consequences of Uninsurance and as a member of the IOM Committee on the Future of Emergency Care in the United States Health System.

Kenneth P. Kleinman is associate professor of Ambulatory Care and Prevention at Harvard Medical School and Harvard Pilgrim Health Care. Before joining the faculty of the Harvard Medical School in 2000, Dr. Kleinman was an associate research scientist at the New England Research Institutes, Watertown, Massachusetts. His research focuses on public health surveillance, particularly the statistical identification of aberrations that signal the onset of events of public health significance, and evaluating such statistical methods, including syndromic surveillance. He serves as director of the statistical core of a CDC program grant for a Center for Excellence in Public Health Informatics. He earned his B.A. in sociology and anthropology from Oberlin College, and his S.M. and Sc.D. in biostatistics from the Harvard School of Public Health.

Marcelle Layton is the assistant commissioner for the Bureau of Communicable Disease at the New York City Department of Health and Mental Hygiene. The bureau is responsible for the surveillance and control of 71 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. She completed an internal medicine residency at the University Health Science Center in Syracuse, New York, 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. She has previously served on the IOM Forum on Microbial Threats. Dr. Layton received her medical degree from Duke University.

Eva K. Lee is an associate professor in the H. Milton Stewart School of Industrial and Systems Engineering at Georgia Institute of Technology, and director of the Center for Operations Research in Medicine and HealthCare. She is also a senior research professor at the Atlanta VA Medical Center. Dr. Lee earned a Ph.D. at Rice University in the Department of Computational and Applied Mathematics and received her undergraduate degree in mathematics from Hong Kong Baptist University, where she graduated with Highest Distinction. Dr. Lee was awarded a NSF/NATO postdoctoral fellowship on Scientific Computing and a postdoctoral fellowship from Konrad-Zuse-Zentrum Informationstechnik

Berlin in 1995 for Parallel Computation. Dr. Lee works in the area of mathematical programming and large-scale computational algorithms with a primary emphasis on medical and health care decision analysis and logistics operations management. She tackles challenging problems in health systems and biomedicine through systems modeling, algorithm and software design, and decision theory analysis. Specific research areas include health risk prediction, early disease prediction and diagnosis, optimal treatment strategies and drug delivery, health care outcome analysis and treatment prediction, public health and medical preparedness, and large-scale health care and medical decision analysis and quality improvement. Dr. Lee's research in logistics focuses on large-scale optimization and algorithmic advances for optimal operations planning and resource allocation. She has developed decision support systems for inventory control; large-scale truck dispatching, scheduling, and transportation logistics; telecommunications; portfolio investment; and emergency treatment response and facility layout and planning.

Shane D. Mayor is a research professor in the departments of physics and geosciences at California State University, Chico. From 2003 to 2008, he served as scientist at the Earth Observing Laboratory at the National Center for Atmospheric Research (NCAR), Boulder, Colorado. Dr. Mayor completed his Ph.D. at the University of Wisconsin–Madison in 2001 with a focus on using volume image lidar (VIL) data to improve fine-scale numerical simulations of atmospheric boundary layer turbulence. After completing his Ph.D., Dr. Mayor worked at NCAR through the Advanced Studies Program and the Atmospheric Technology Division to develop REAL—an eye-safe version of the Wisconsin VIL. Through a technology-transfer effort, commercial versions of REAL now operate for urban aerosol plume surveillance and at a military test range. Prior to his years at Wisconsin, Dr. Mayor worked at NASA Langley on differential absorption lidars and at NCAR on heterodyne Doppler lidars. Dr. Mayor previously served on the NRC Committee on Testing and Evaluation of Biological Stand-off Detection Systems.

Timothy F. Moshier is senior principal scientist in the Environmental Science Center of Syracuse Research Corporation. Previously, he was a staff member in the Biodefense Systems Group at the MIT Lincoln Laboratory. Other former positions were with tactical and research, development, and acquisition (RD&A) organizations for the U.S. Army. Mr. Moshier also served 6 months with the United Nations Special Commission (UNSCOM) in 1995, investigating Iraq's biological weapons program. Among his RD&A assignments, Mr. Moshier has served at U.S. Army Dugway Proving Ground (Installation Biological Safety Officer and Operations Officer), the Joint Program Office for Biological Defense (Detection Project Officer and manager for the Critical Reagents Program), and as the project manager for the Joint Biological Point Detection System. Mr.

Moshier has also worked for SPARTA, Inc., as chief, Homeland Security Division, where he was responsible for the daily operation of an organization consisting of threat and international relations specialists; chemical, biological, and nuclear defense experts; and a group of explosive ordnance disposal experts. He has served on three other NRC committees: Biodefense at the U.S. Department of Defense, Testing and Evaluation of Biological Standoff Detection Systems, and Committee on Review of Testing and Evaluation Methodology for Biological Point Detectors. He received a B.A. in biology from the State University of New York College at Oswego, an M.S. in biology from Syracuse University, and a Masters in Military Art and Science from the U.S. Army Command and General Staff College.

Frederick A. Murphy is professor, Department of Pathology, University of Texas Medical Branch (UTMB) at Galveston. At UTMB he is also a member of the Institute for Human Infections and Immunity, the Galveston National Laboratory, the Center for Biodefense and Emerging Diseases, and the McLaughlin Endowment Program. Previously, he served as dean and distinguished professor, School of Veterinary Medicine, and distinguished professor, Department of Internal Medicine, School of Medicine, University of California, Davis. Dr. Murphy received a B.S. and D.V.M. from Cornell University and a Ph.D. from the University of California, Davis. He served as chief, Viral Pathology Branch, then director of the Division of Viral and Rickettsial Diseases, and later director of the National Center for Infectious Diseases of the Centers for Disease Control and Prevention. His honors include elected membership in the Institute of Medicine, the Presidential Rank Award from the U.S. government, and membership in the German Academy of Natural Sciences and the USSR Academy of Medical Sciences. Recently he has served as a member of the U.S. Department of Health and Human Services Secretary's Council on Public Health Preparedness. Currently he serves on the NRC/IOM Committee on Biodefense at the U.S. Department of Defense. He also has been co-chair of the NRC Committee on Occupational Health and Safety in the Care and Use of Nonhuman Primates, and a member of the IOM Committee on Microbial Threats; the NRC Committee on Public Health, Agriculture, Basic Research, Counter-terrorism and Non-proliferation Activities in Russia; and the IOM Committee on Transmissible Spongiform Encephalopathies.

Royce W. Murray is Kenan Professor of Chemistry at the University of North Carolina at Chapel Hill (UNC-CH). He was educated at Birmingham Southern College (B.S., 1957) and Northwestern University (Ph.D., analytical chemistry, 1960), joined the University of North Carolina faculty in 1960, and became Kenan Professor of Chemistry in 1980. He served as Chemistry Department chairman for the period 1980–1985. Dr. Murray has been colleague to nearly 150 graduate and post-graduate students, with

whom he has published over 425 papers. Among his many awards are the Olin Palladium Medal (The Electrochemical Society), the Charles N. Reilley Award (Society for Electroanalytical Chemistry), the Faraday Medal (Royal Society of Chemistry, UK), the Breyer Medal (Royal Australian Chemical Institute), the American Chemical Society Award in Analytical Chemistry, the North Carolina Award in Science, the Pittsburgh Analytical Chemistry Award, and the Luigi Galvani Medal of the Italian Chemical Society. He is an elected member of the National Academy of Sciences and of the American Academy of Arts and Sciences. He has served since 1991 as editor-in-chief of the journal *Analytical Chemistry*. Dr. Murray's research interests include electroanalytical methods, the molecular design of electrode surfaces and nanoparticles, electrochemically reactive semi-solid media, mass transport and electron transfer dynamics, electrocatalysis, and voltammetry in extreme media.

Douglas K. Owens is a general internist; a senior investigator at the VA Palo Alto Health Care System; a professor of medicine and, by courtesy, of health research and policy at the Stanford School of Medicine; and a core faculty member at the Center for Health Policy/Primary Care and Outcomes Research (CHP/PCOR). He directs the Stanford–UCSF Evidence-based Practice Center; the Program on Clinical Decision Making and Guideline Development at PCOR; the Palo Alto VA's Postdoctoral Informatics Fellowship Program; and the Palo Alto VA's Health Services Research Fellowship Program. Dr. Owens' research focuses on technology assessment, cost-effectiveness analysis, evidence synthesis, biodefense, and methods for clinical decision making. Dr. Owens received a B.S. and an M.S. from Stanford University, and an M.D. from the University of California, San Francisco. Dr. Owens is chair of the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. He is past-president of the Society for Medical Decision Making; he was elected to the American Society for Clinical Investigation and the Association of American Physicians. He received the Under Secretary's Award for Outstanding Achievement in Health Services Research from the Department of Veterans Affairs.

Stephen M. Pollock is Herrick Emeritus Professor of Manufacturing and Professor Emeritus of Industrial and Operations Engineering at the University of Michigan. He has been involved in applying operations research and decision analysis methods to understand and influence a variety of operational phenomena, including military search and detection, criminal recidivism, manufacturing process monitoring, sequential allocation of resources, predictive and proactive maintenance, networks of queues, the stochastic behavior of infectious disease epidemics, and the optimization of radiation oncology plans. He has authored over 60 technical papers, co-edited two books, and has served as a consultant to over 30 industrial, governmental, and service organizations. Professor Pollock

was associate editor and area editor of *Operations Research*, senior editor of *IIE Transactions*, associate editor of *Management Science*, and on the editorial boards of other journals. He has served on various advisory boards for the National Science Foundation and on the Army Science Board. He was president of the Operations Research Society of America in 1986 and awarded the 2001 INFORMS Kimball Medal for contributions to operations research and the management sciences. He is a fellow of INFORMS and the AAAS and is a member of the National Academy of Engineering. He was a member of the NRC's Committee on Applied and Theoretical Statistics. Among other NRC activities, he chaired the CNSTAT panel on Operational Test Design and Evaluation of the Interim Armored Vehicle, served on the panel on Statistical Methods for Testing and Evaluating Defense Systems, the Committee on Technologies to Deter Currency Counterfeiting, and the Panel on Methodological Improvements to the DHS Biological Agent Risk Analysis.

I. Gary Resnick is the Bioscience Division Leader at Los Alamos National Laboratory. He is an internationally recognized scientist in the area of chemical and biological defense, with extensive leadership and management experience. His scientific and technical accomplishment encompasses all aspects of research, development, and testing of chemical warfare agents and chemical/biological defense systems. In addition, he has been an active member of the interagency and international chemical and biological arms control communities. His previous positions include associate center director for Chemical and Biological (CB) Defense, Center for Homeland Security at Los Alamos National Laboratory; director of CB Defense, Defense Threat Reduction Agency; director of research and technology, Edgewood Chemical and Biological Center; technical director, U.S. Army Dugway Proving Ground; and staff scientist at the U.S. Environmental Protection Agency. He holds a B.S. from Cornell University, an M.S. from Long Island University, and a Ph.D. in microbiology from the University of Rhode Island.

R. Paul Schaudies is president and CEO of GenArraytion, a company that is developing products and services for rapid identification of infectious disease agents, including those underlying sepsis and hospital-acquired infections. Previously, he founded and managed the Biological and Chemical Defense Division at Science Applications International Corporation (SAIC). His expertise is in biotechnology and nanotechnology. Dr. Schaudies spent 4 years with the Defense Intelligence Agency as collections manager for biological and chemical defense technologies. As such, he initiated numerous intra-agency collaborations that resulted in accelerated product development in the area of biological warfare agent detection and identification. He has served on advisory panels for the Defense Intelligence Agency, the Defense Advanced Research Projects Agency, and the Department of Energy. He has bench research experience managing

laboratories at Walter Reed Army Medical Center and Walter Reed Army Institute of Research, and as a visiting scientist at the National Cancer Institute. Dr. Schaudies was the science advisor to the EPA on-scene coordinator and incident commander at the anthrax incident in Washington, DC. He received a B.S. in chemistry from Wake Forest University and a Ph.D. from Temple University School of Medicine in the department of biochemistry. Dr. Schaudies is currently a member of the NRC/IOM Committee on Biodefense Analysis and Countermeasures and has served on the NRC Committee on Protecting Occupants of DOD Buildings from Chemical or Biological Release and the NRC Committee on Materials and Manufacturing Processes for Advanced Sensors.

Jerome S. Schultz is on the faculty at the University of California, Riverside, where he is Distinguished Professor in the Bourns College of Engineering, chair of the Bioengineering Department, and director of the Center for Bioengineering Research. He founded the Department of Bioengineering when he joined the UC Riverside faculty in 2004. Dr. Schultz began his career in the pharmaceutical industry (Lederle Laboratories) and then joined the University of Michigan, where he was chairman of the Department of Chemical Engineering. He spent 2 years at the National Science Foundation as deputy director of the Engineering Centers Program. In 1987, he joined the University of Pittsburgh as director of the Center for Biotechnology and Bioengineering, and he was the Founding Chairman of the Department of Bioengineering. He recently spent a year at NASA's Ames Research Center as a senior scientist in their Fundamental Biology Program. He is a member of the National Academy of Engineering and a fellow of the Biomedical Engineering Society, and he was a founding fellow and president of the American Institute for Medical and Biological Engineering. Dr. Schultz received his B.S. and M.S. in chemical engineering from Columbia University and his Ph.D. in biochemistry from the University of Wisconsin.