COORDINATING ENHANCED NATIONWIDE BIOSURVEILLANCE FOR HUMAN HEALTH

National Biosurveillance Strategy for Human Health

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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A more complete list of contributors is provided in Appendix A.

Executive Summary: National Biosurveillance Strategy for Human Health

The United States faces many potential threats to human health, including natural disease outbreaks, environmental exposures, and acts of terrorism. In today's modern world of high-density population centers and global mass transit such threats and hazards can significantly impact human health. These potential threats speak to the need for an integrated all-hazards approach to health security by all sectors of society. At the same time, the broader and more sophisticated use of information technology, new information sources, and analytic techniques holds the potential to accelerate recognition of health threats and improve the accuracy of assessments. With greater availability and real-time delivery of health information it may be possible to maintain a comprehensive picture of the nation's health and detect aberrations in illness patterns faster and more accurately.

These new opportunities and increasing threats demand a national vision for biosurveillance that builds on existing capabilities and relationships while investing in innovative and science-driven tools and methods. Effective biosurveillance embraces a complementary "system of systems" that leverages the data collection and analyses performed at the local level while incorporating broader national perspectives.

Biosurveillance in the context of human health is a new term for the science and practice of managing health-related data and information for early warning of threats and hazards, early detection of events, and rapid characterization of the event so that effective actions can be taken to mitigate adverse health effects. It represents a new health information paradigm that seeks to integrate and efficiently manage health-related data and information across a range of information systems toward timely and accurate population health situation awareness.

The scope and function of biosurveillance includes the following:

- All hazards: including biological, chemical, radiological, nuclear and explosives

- Defined by urgency and potential for multi-jurisdictional interest

- Urgent notifiable conditions and non-specific and novel health events

- Ad hoc data gathering, analysis, and application of information

- Functions: Case Detection, Event Detection, Signal Validation, Event Characterization, Notification and Communication and, Quality Control and Improvement

- Supports rapid and efficient discharge of responsibilities for the International Health Regulations [IHR (2005)]

The National Biosurveillance Strategy for Human Health (hereafter *The Strategy)* articulates a vision for enhanced biosurveillance and is intended to guide national interests to:

- Implement a national enterprise of complementary biosurveillance systems that provides relevant, accurate and timely information for government, healthcare, business, and personal decision-making for planning and responding to population health emergencies;

- Coordinate health-related information sharing, according to defined data sharing policies, both vertically and horizontally across all levels of government, jurisdictions, and health-related disciplines to improve the effectiveness of disease monitoring and response;

- Prioritize improvements to existing biosurveillance efforts and infrastructures;

- Ensure biosurveillance data is available for local use, where it is best understood and managed;

- Develop new relationships while continuing to leverage and maintain existing ties between local public health professionals and data providers;

- Engage a diverse consortium of governmental, non-governmental, academic, and business sector stakeholders in the complex and distributed national enterprise of biosurveillance for human health;

- Optimize resources to support biosurveillance and broader public health needs; and

- Address all hazards while assuring flexibility and specificity of biosurveillance methods as required to monitor and investigate cases at the local level.

The Strategy provides the foundation for a long-term effort to improve a nationwide capability to manage health-related data and information. It is grounded in U.S. laws and Presidential Directives, including Homeland Security Presidential Directive-21 (HSPD-21), "Public Health and Medical Preparedness", which names biosurveillance as one of four critical priorities for improving public health preparedness. HSPD-21 also mandates the development of a nationwide integrated biosurveillance capability, as well as the establishment of a federal advisory committee. As a result, the National Biosurveillance Advisory Subcommittee (NBAS), which includes private sector representatives, and state and local government public health authorities, was established to help carry out these mandates. This subcommittee to the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), produced their first report which includes recommendations to strengthen the nation's biosurveillance capability and provides counsel to the federal government regarding a broad range of issues affecting a nationwide biosurveillance strategy for human health. That report has helped shape *The Strategy* document.

The continued development and implementation of *The Strategy* is informed by the following principles that define how stakeholders will plan and work together:

- Building on current capabilities and relationships

- Establishing data and technical standards and promoting interoperability of platforms

- Respecting multi-organizational and multi-disciplinary perspectives

- Building Federal, State and Local trust

- Assuring value for stakeholders

- Ensuring protection of rights and authorities

The Strategy is a product of collaboration across several multi-disciplinary working groups, and engagements with additional biosurveillance stakeholders. *The Strategy* will continue to evolve through stakeholder input and will be periodically updated as requirements change and

opportunities for improvement are recognized. The network of stakeholders includes Federal
Agencies and State, Local, Territorial and Tribal Governments, the Healthcare Industry and
International Partners. While having broader missions, the professional communities protecting
Animal, Plant and Environmental Health also have direct impact on human health security and
are stakeholders as well. Private Sector, Academia, and Community-based Organizations are also
vital partners in creating the biosurveillance capability necessary to prevent and mitigate urgent
health threats.

Priority Areas

The multi-dimensional challenges—and opportunities—for creating a more robust
biosurveillance system are substantial. At the same time, competition for limited resources is
intense and there is a need to identify priorities. Six priority areas are put forward in *The Strategy*
to address critical gaps and suggest opportunities for improvement. They are as follows:

- **Electronic Health Information Exchange** – strengthening and expanding upon multi-
  directional health information exchanges with healthcare and public health entities.

- **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.

- **Unstructured Data** – leveraging digital information (e.g., text and image) that is not in a
  database format for biosurveillance for human health.

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

- **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.

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

Summary

The Strategy represents the foundation for a long-term effort to improve a nationwide capability
to manage health-related data and information for early warning of threats and hazards, early
detection of events, rapid characterization, and overall situation awareness so that necessary
actions can be taken to mitigate health effects. It will be maintained and periodically updated in a
manner that reflects progress, new ideas, increased knowledge, and shifts in the healthcare
industry and the related political environment. In this way, *The Strategy* will unite and integrate
the work of all interested stakeholders who contribute to and will benefit from the products of
biosurveillance.

The Strategy is not intended as a mechanism to dictate policy within agencies, but is written
under the premise that each agency will plan and implement programs to fulfill its respective
responsibilities in biosurveillance and maintain performance accountability. Baseline and
investment-oriented measures will be utilized to evaluate the effectiveness of the activities and

programs, allowing agencies to justify their investments, make resource allocation decisions, and adjust priorities accordingly.

Through the implementation of *The Strategy*, the United States can take significant steps toward fulfilling the vision of Biosurveillance in the 21st Century. However, this vision can only be achieved through work performed at all levels of government, in healthcare, academia and the private sector. Active participation is required of all stakeholders and sustained leadership and action is needed at the federal level.

Introduction

The scientific foundations of public health surveillance have been advancing rapidly, triggered by new technology, increasingly digital data and information, and emerging, reemerging and novel health threats that require earlier warning and detection. Containing the spread of disease or responding to other human health hazards in an interconnected world requires active vigilance for signs of an adverse public health event, rapid validation of its presence, and swift characterization so that resources and adaptive strategies can be employed effectively. Greater information sharing and strengthened collaborations among public health, healthcare, environmental, animal and plant health communities along with partnerships with private sector organizations addressing common goals can unleash the power of health-related information to prevent, protect, and mitigate the health threats and hazards that Americans face.

The broader and sophisticated use of information technology, new information sources, and analytic techniques holds the potential to accelerate recognition of health threats and improve the accuracy of assessments, creating an invaluable resource for health decision-making. With greater availability and real-time delivery of digital health information it is possible to create and maintain a comprehensive picture of the nation's health and detect aberrations in normal illness patterns faster and more accurately. New opportunities and increasing threats demand a national vision for biosurveillance that builds on existing capability and relationships while investing in new innovative and science-driven tools and methods. *The National Biosurveillance Strategy for Human Health* (*The Strategy)* first articulates a vision for enhanced biosurveillance in the 21st century, then suggests goals and objectives to be met to make that vision a reality.

Legislative and Regulatory Background

The impetus for *The Strategy* can be found in a series of legislative documents. Biosurveillance for human health is one component of a larger federally mandated initiative for better preparedness and response on a national level. Nationwide preparedness and response is not new, although our current technological capacity allows for a greater degree of planning for possible health threats and situation awareness during a public health emergency.

In 2002, Congressional legislation created a bipartisan commission to prepare a complete account of the circumstances surrounding the September 11, 2001 terrorist attacks. The 9/11 Commission released its public report on July 22, 2004. The Commission's report led to the development of Public Law (P.L.) 110-53 (Implementing Recommendations of the National Commission on Terrorist Attacks upon the United States Act of 2007), which mandates the federal government to develop a system to:

> *Rapidly identify, characterize, localize, and track a biological event of national concern by integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems (both national and international).*

Prior to P.L. 110-53, Congress passed and the President signed the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 (Public Law 109-417). PAHPA focused on public health and medical preparedness and response for public health emergencies. The purpose of the Pandemic and All-Hazards Preparedness Act is "to improve the Nation's public health and

medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural."

In 2004, the President issued two directives to improve coordination across federal agency bio-awareness programs. Homeland Security Presidential Directive (HSPD)-9, *Defense of United States Agriculture and Food* (January 30, 2004), charged federal agencies to create a new biological threat awareness capacity. HSPD-10, *Biodefense for the 21ˢᵗ Century* (April 28, 2004), called for an integrated and comprehensive warning system that assists in recognizing and responding to biological attacks on humans, animals, food, water, agriculture, and the environment. HSPD-10 directed the Department of Homeland Security (DHS) to integrate all federal agency efforts to create a national bio-awareness system that will detect a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic impact, and social disruption.

To harness the potential of biosurveillance in the United States the President issued HSPD-21, *Public Health and Medical Preparedness* in October 2007. This directive names biosurveillance as one of four critical priorities for improving public health preparedness and charges the Secretary of Health and Human Services to:

> *"establish an operational national…[bio]surveillance system for human health, with international connectivity where appropriate, that is predicated on State, regional, and community-level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers." (HSPD-21, paragraph 21)*

Additionally, in December 2006, the United States committed to comply with provisions of the revised International Health Regulations [IHR (2005)]. These regulations are designed to prevent and protect against the international spread of diseases while minimizing interference with world travel and trade. IHR (2005) requires countries to implement core capacities for detecting and responding to events, to share information about known diseases and public health events of potential international concern, and to collaborate by providing technical, logistical, and financial support to ensure compliance.[1] The regulations clarify the World Health Organization's (WHO) authority to recommend measures to member states to contain the international spread of disease, including public health actions at ports, airports, borders, and on means of transport that involve international travel. As the United States is an important contributor to global health, *The Strategy* is mindful of the nation's responsibilities in planning improvements and connections for the global exchange of health-related information.

The Strategy is a critical component of a comprehensive national approach to biosurveillance. It is intended to align with other strategies called for in HSPD-21, such as the recently published National Health Security Strategy,[2] and other federal government strategies, e.g., Project Horizon.[3] Additionally, *The Strategy* supports and supplements plans such as those associated

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[1] World Health Organization. *International Health Regulations 2005*. Geneva: World Health Organization.
[2] *National Health Security Strategy of the United States of America*, U.S. Department of Health and Human Services, December 2009
[3] Project Horizon posits a new approach to long-term interagency planning for United States Government (USG) agencies whose missions have significant global components to develop realistic interagency strategies and to

with the National Response Framework.[4] The presidential directives along with other related agreements and statutory authorities, such as Public Law 109-417 and Public Law 110-53, provide a foundation for development of *The Strategy.*

What is Situation Awareness?

Central to the vision for Biosurveillance in the 21st Century is 24/7, real-time[5] situation awareness. Adopted from other domains, such as aviation, situation awareness is defined as "the perception of elements in the environment within a volume of time and space, the comprehension of their meaning, and the projection of their status in the near future."[6] Situation awareness is at a premium in work environments where (a) the environment is often dynamic and information rich; (b) workers may experience high mental workload; (c) extensive training is required; (d) problems are ill-structured; and (e) time is constrained.[7] Like pilots taking off and landing at busy airports, public health professionals process innumerable bits of data, assign meaning, ascertain significance, determine implications, act, and adjust accordingly. In order to put together the many pieces of the epidemiological puzzle, health professionals, surveillance systems, and data at multiple levels have to be interconnected and integrated. The timeliness goal for biosurveillance information in urgent situations is generally considered to be at least daily (i.e., near-real-time).

What is Biosurveillance?

Biosurveillance in the context of human health is a term for the science and practice of managing health-related data and information for early warning of threats and hazards, early detection of events, and rapid characterization of the event so that effective actions can be taken to mitigate adverse health effects. Biosurveillance represents a new health information paradigm for public health that seeks to integrate and efficiently manage health-related data and information across a range of information systems with the primary goal of timely and accurate population health situation awareness (SA).

The nation's current biosurveillance capability rests primarily in the functions of public health surveillance and investigation and is widely distributed across local, tribal, territorial, state, federal and international jurisdictions. While public health surveillance contributes to biosurveillance, it is in itself not sufficient to meet the overall information needs for SA across the phases of an event (pre-event forecasting, detection, response, recovery). Other domains and

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identify capabilities in which the government should invest to prepare for unforeseen threats and opportunities that the nation will face during the next 20 years.

[4] The National Response Framework presents guiding principles that enable all response partners to prepare for and provide a unified national response to disasters and emergencies; http://www.fema.gov/emergency/nrf/.

[5] For the purposes of this document real-time operation is defined as straight-through processing as seen in trades and instant payment processes.

[6] Endsley, M. R. Design and evaluation for situation awareness enhancement. In <u>Proceedings of the Human Factors Society 32 Annual Meeting</u>. 1988; 97-101. Santa Monica, CA: Human Factors Society.

[7] Uhlarik J, Comerford, DA. "A review of situation awareness literature relevant to pilot surveillance functions," March 2002. Report No. DOT/FAA/AM-02/3. Available through National Technical Information Service, Springfield, VA 22161.

disciplines are also required to establish a comprehensive biosurveillance capability, including, but not limited to the health of animals and plants, and environmental monitoring.

The scope and function of biosurveillance includes the following:

- All hazards: including biological, chemical, radiological, nuclear and explosives

- Defined by urgency and potential for multi-jurisdictional interest

- Includes urgent notifiable conditions and non-specific and novel health events

- Includes ad hoc data gathering, analysis, and application of information

- Functions include: Case Detection, Event Detection, Signal Validation, Event Characterization, Notification and Communication and, Quality Control and Improvement

- Supports rapid and efficient discharge of responsibilities for the International Health Regulations [IHR (2005)]

Biosurveillance is dependent on quality data and information. It should be flexible to balance and meet the needs for speed, scale, and specificity. It musst adapt to the information needs of an event, having needed capabilities that extend beyond public health surveillance to support the breadth of information requirements across phases of an event. Biosurveillance also must be scalable to allow for the needed granularity of information at the operational level while addressing the need for situation awareness at other levels based on roles, responsibilities, and assets. A goal of biosurveillance is effective situation awareness. The biosurveillance enterprise should support the sharing of data across all levels of government but not necessitate the sharing of data across all levels for all acute events. Notification and reporting channels and information products should not be unique, but well characterized, explicit, and designed to optimize situation awareness among all those with a need-to-know. As required by the IHR (2005), the enterprise should provide the ability to capture unanticipated incidents through reliance on human judgment. A skilled workforce is an underlying requirement for all biosurveillance activities.

The National Biosurveillance Strategy for Human Health

Because biosurveillance for human health is integral to the Centers for Disease Control and Prevention's (CDC) mission, the Department of Health and Human Services (HHS) assigned CDC a key role in coordinating and leading development of *The Strategy*. In executing this charge, CDC established and/or consulted with a number of biosurveillance workgroups and an advisory committee comprised of federal, state and local governmental, as well as non-governmental, stakeholders. Working with advisory groups and stakeholders, version 1.0 (2008) of *The Strategy* was released. Their ongoing consultation has provided input on the current version of *The Strategy*. *The Strategy* will continue to be updated as requirements, opportunities and circumstances evolve.

The Strategy is intended to guide national interests to:

- Implement a national enterprise of complementary systems that provides accurate and timely information regarding emerging public health threats to enhance decision-making

and response in the government, healthcare, and business communities, as well as by individuals;

- Coordinate health-related information sharing both vertically and horizontally across all levels of government, jurisdictions and health-related disciplines to improve the effectiveness of disease monitoring and response while allowing biosurveillance data to remain local where it is best understood and managed;

- Leverage and maintain existing relationships between local public health staff and data providers;

- Engage a diverse consortium of governmental, nongovernmental, academic, and business sector stakeholders in the complex national enterprise of biosurveillance for human health to build local, regional, and national views of population health;

- Optimize resources that support not only biosurveillance information flow but a wide variety of public health needs;

- Prioritize improvements to existing biosurveillance efforts and infrastructures;

- Address all hazards while assuring flexibility and specificity of methods as required to monitor and investigate cases and events at the local level;

- Embrace a complementary "system of systems" that leverages the robust data collection and analyses performed at the local level. Biosurveillance efforts distributed at the state and local level allow data to be interpreted, understood, and applied in a local context. Local interpretation can be complemented and enhanced by national perspectives that synthesize multiple data streams and provide a broad picture across jurisdictions.

Development and implementation of *The Strategy* is dependent on the collaborative efforts of a wide range of public health stakeholders which have influence over and will be influenced by *The Strategy's* activities. An example of a key collaboration supported by *The Strategy's* goals and objectives is cited in the text box below:

National Biosurveillance Integration System (NBIS):   NBIS is a national interagency biosurveillance integration body led by the Department of Homeland Security (DHS) in accordance with a series of U.S. laws and directives. HHS plays a key role as a member of NBIS because of its expertise in the medical and public health arenas. *The Strategy,* in setting out details of a collaborative approach to biosurveillance coordination for human health, is in full accord with NBIS' efforts to fulfill its required integration tasks. *The Strategy's* underlying themes of cooperation in support of biosurveillance, derived from broad stakeholder input, ensure the document will be used to reinforce biosurveillance integration role being played by DHS in accordance with legislative and executive mandates.

As background, DHS was tasked by the President in 2002 to develop a national biosurveillance integration system in coordination with appropriate Federal departments and agencies for rapid recognition and warning of an intentional dispersal of biological agents. In 2004, the President issued two directives, HSPD 9 and 10, to improve coordination across federal agency bio-awareness programs. In 2006, PAHPA required HHS to develop and sustain essential public health security capabilities, including disease detection and investigation. Shortly thereafter, Congress codified the federal government's expectations for biosurveillance integration and coordination in Sec 1101 of PL 110-53. The law directed the Secretary of Homeland Security to "establish, operate, and maintain a National Biosurveillance Integration Center (NBIC)" having a mission to (1) "enhance the capability of the Federal Government to rapidly identify, characterize, localize, and track a biological event of national concern and disseminate alerts and other information to Member Agencies and, in coordination with them to agencies of State, local, and tribal governments" and, (2) "oversee the development and operation of the National Biosurveillance Integration System (NBIS)." The NBIS "system" is currently defined as the joint enterprise consisting of federal departments and agencies that participate in biosurveillance development, operation, and governance. Members contribute resources, such as information, analysis, and information technology, which enable identification and characterization of biological events of national concern as rapidly as practicable. Assistant Secretary-level guidance for the efficient operation and evolution of the NBIS program is established through the NBIS Interagency Oversight Council (NIOC).

DHS involvement in leading the interagency initiative continues to move forward and remains unchanged under the guidance of various HSPDs and public law. This integrating mission is consistent with the Secretary of Homeland Security's continuing role as the principal Federal official for domestic incident management and responsibility for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks.

Examples of other important collaborative efforts include:

Biosurveillance Indications and Warning Analytic Community (BIWAC): BIWAC's mission is to provide an interagency forum for collaborative exchange of information among members regarding indications and warning of biological events that could threaten U.S. national interests. Sharing of real and near real-time data and the interpretation thereof among members provides actionable information to warn decision makers in order to mitigate possible adverse outcomes during rapidly evolving situations. Members include CDC's Global Disease Detection Operations Center, HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR), USDA's Center for Epidemiology and Animal Health, DHS' National Biosurveillance Integration Center, DOD's Strategic Command Center for Combating Weapons of Mass Destruction, Northern Command, National Center for Medical Intelligence, and the Department of State.

Integrated Consortium of Laboratory Networks (ICLN): Public health requires coordination of reporting requirements from clinical, veterinary, environmental and public health laboratories to state and federal agencies. Coordinated reporting requirements across all data sources will reduce the current reporting burden on labs and clear the path to define standards and vocabulary for automated exchange of test results. The Homeland Security Council established the ICLN and the Department of Homeland Security was assigned the Executive Secretariat to promote harmonization and coordination across multiple laboratory networks affiliated with federal agencies. The ICLN includes 10 federal departments/agencies: the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, State, and the Environmental Protection Agency. ICLN's mission is to create a U.S. homeland security infrastructure with a coordinated operational system of laboratory networks that provide timely, high quality and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response.

National Biosurveillance Advisory Subcommittee (NBAS)

In 2007, Homeland Security Presidential Directive 21 (HSPD-21) called for the establishment of a federal advisory committee that includes "representatives from state and local government public health authorities and appropriate private sector health care entities, in order to ensure that the federal government is meeting the goal of enabling State and local government public health surveillance capabilities." To accomplish this, the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention, established the National Biosurveillance Advisory Subcommittee (NBAS) on May 1, 2008 to provide an independent perspective on enhancing our nation's biosurveillance capacity. NBAS is comprised of public and private biosurveillance stakeholders from public health, healthcare, academia, and business. As a subcommittee to the ACD, the NBAS has helped shape the development of this version of *The Strategy* by providing recommendations and counsel to the federal government through the ACD regarding a broad range of issues affecting the development and implementation of a nationwide biosurveillance strategy for human health.

The NBAS divided into Task Forces to develop a report detailing recommendations that would have the greatest effect in establishing a well functioning and cost-efficient national biosurveillance capacity. The NBAS's report titled: *Improving the National's Ability to Detect*

and respond to 21st Century Urgent Health Threats was unanimously approved by the ACD and made public on October 16, 2009. The report is organized around the following broad and cross cutting recommendations:

- The Executive Branch must define the strategic goals and priorities of federal investments in biosurveillance activities and technologies, implement a plan to achieve, fund and periodically assess progress towards these goals. To accomplish this, the White House should establish an Interagency Biosurveillance Coordination Committee ("the Committee").

- The U.S. National Biosurveillance Enterprise must encompass and enable detection and awareness of global health threats.

- The federal government must make a sustained commitment towards ensuring adequate funding to hire and retain highly competent personnel to run biosurveillance programs at all levels of government.

- Government investments in electronic health records and electronic laboratory data should be leveraged to better serve biosurveillance and public health missions.

- The federal government must make strategic investments in new technologies to strengthen U.S. biosurveillance capabilities.

The NBAS is committed supporting the enhancement of the nation's biosurveillance capability in the future by providing advice and creative ideas to federal decision makers in the field of biosurveillance. As a major part of that effort, the NBAS will continue to prepare reports that contain recommendations on achieving biosurveillance improvements.

Planning Principles

The continued development and implementation of *The Strategy* is informed by the following principles that define how stakeholders will plan and work together:

Build on Current Capabilities and Relationships: Development of new biosurveillance systems should be coupled with the commitment to further develop and sustain the existing systems that provide the foundation for biosurveillance at the state and local levels. Clear information requirements for a national biosurveillance capability for human health are vital to purposeful design and prioritization of enhancement efforts. Cataloging of nationwide biosurveillance efforts that comprise the nation's current capability is necessary to identify gaps. Preliminary stakeholder requirements for national biosurveillance for human health and current capability assessments were gathered through key stakeholders interviews and working group members at the federal, state, local levels. Ongoing stakeholder input will allow for greater specification of requirements and current capability.

Federal, state, and local health departments are at various stages of implementing biosurveillance capabilities. Building on their strengths, taking advantage of emerging technologies, and expanding the array of biosurveillance information resources is essential to success. State and local health departments have established relationships with hospitals, physicians, and other healthcare providers to create an operational biosurveillance capability that the nation depends on today. Promising practices are emerging that can guide nationwide enhancements. Possible strategies will be evaluated for utility and feasibility before being implemented nationally.

Establish Standards and Interoperability: Data and technical standards provide the specifications for how electronic data are stored and securely exchanged. Interoperability of platforms is necessary in order to collect, analyze, and visualize data effectively and will enhance overall biosurveillance capability by leveraging current systems. Implementation of the biosurveillance use-case defined by the American Health Information Community (AHIC) as well as standards, specifications, and services advanced by the Nationwide Health Information Network (NHIN) and implementation of the Healthcare Information Technology Standards Panel (HITSP) standards recognized by the Department of Health and Human Services (DHHS) will help address these issues. *The Strategy* will build upon these relationships, systems, and capabilities.

Respect Multi-organizational and Multi-disciplinary Perspectives: An effective biosurveillance capability requires the involvement of individuals with different skills and organizations with diverse and sometimes overlapping responsibilities. Across government agencies (federal, state, local, territorial, and tribal), mechanisms will be pursued to foster a greater exchange of personnel, share expertise, remove policy barriers to information sharing, and improve communications. Frameworks are needed for the multi-directional exchange of information between the government and public and private sector entities to set the stage for expanding data resources and meeting common interests in protecting the health of Americans.

Build Federal, State and Local Trust: Principles of governance and data use will be as *The Strategy* is implemented. The governance structure will include Federal, state, local, territorial, and tribal representation. *The Strategy* seeks to optimize and leverage the strengths and contributions of all stakeholders and will include active involvement from a broad array of expertise. Consensus priorities and solutions will be sought. *The Strategy's* implementation will provide a supported environment that allows biosurveillance stakeholders to assume tasks, to allocate and manage resources, and to develop and enforce internal policies that allow them to contribute to the broader enterprise consistent with their interests, authorities, and resources.

Assure Value for Stakeholders: The value of a comprehensive and integrated approach to biosurveillance comes from exchanging timely, accurate, concise, and actionable information among stakeholders resulting in earlier and improved decisions for protecting human health. Critical to the quality of information arising from the front lines of public health and healthcare (e.g. local levels of clinical and public health practice) is assuring the value of biosurveillance information and data *before* it is aggregated to state, regional, national and international levels. In addition, assuring that biosurveillance information exchange is valued by stakeholders during everyday responsibilities will improve preparedness for infrequent, high-consequence incidents.

Ensure Protection of Rights and Authorities: Biosurveillance data acquisition, reporting, and use should be responsive to ethical and legal obligations across government and between government and data providers. Ensuring the confidentiality, privacy, security, and appropriate use of the public's health information (i.e., data stewardship) is paramount to building trust necessary for effective re-use of this information for population health security at local, state, federal, and global levels. As information domains for biosurveillance expand, policies and agreements surrounding intellectual property will also need to be addressed. Additional work is needed to understand the implications of different state and federal legal frameworks for cross-

jurisdictional information sharing. The work of the AHIC Confidentiality, Privacy, and Security Work Group will be leveraged as additional work in this area is undertaken.

Audience and Key Stakeholders

This document was written for a broad audience that includes public health, healthcare, academic, and private sector stakeholders who contribute to and benefit from the products of biosurveillance. The document assumes that readers have varied levels of knowledge of the subject and thus this strategy includes both basic information and advanced content.
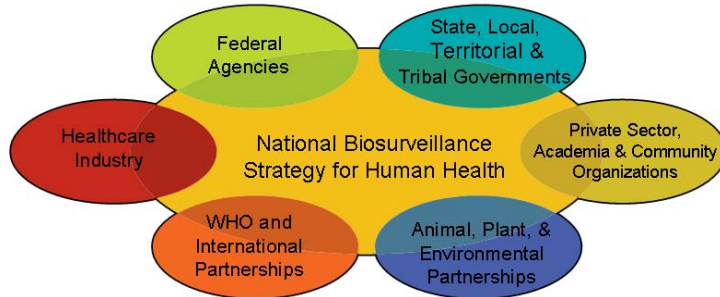
Biosurveillance for complex health emergencies requires collaboration across a diverse network of individuals and organizations. This stakeholders network includes **Federal Agencies** and **State, Local, Territorial and Tribal Governments**. The **Healthcare Industry** and **International Partners** are specifically recognized in legislative documents as core stakeholders. While having broader missions the professional communities protecting **Animal, Plant, and Environmental Health** have direct impact on human health security and are stakeholders as well.

Private Sector, Academia, and Community-based Organizations are also vital partners in creating the biosurveillance capability necessary to prevent and mitigate urgent health threats. Many members of these stakeholder groups are already working together to provide early indications and warnings that will inform health situation awareness for decision makers; others will require increased engagement efforts. Each of these stakeholders is vital to the development and implementation of an effective strategy.

Biosurveillance in the 21st Century

The first decade of the 21st Century has witnessed numerous public health crises that continue to challenge the United States and international public health infrastructures. Tuberculosis is increasingly resistant to first-line therapies. In an era of globalization and rapid transit, novel and emerging diseases, such as SARS, West Nile virus, H1N1 influenza, and the evolving antimicrobial resistance of many pathogens, signal the risk of diseases spreading rapidly through susceptible populations. Air-, food-, and water-borne disease outbreaks demonstrate the vulnerability of society's most basic needs to chemical and biological hazards, whether natural or man-made. Catastrophic natural disasters, such as Hurricane Katrina, made clear the need for timely and accurate health information to be shared seamlessly across organizations and disciplines to affect a coordinated and effective response.

Even relatively common exposures demand timely and accurate information to manage integrated responses. A derailed freight car carrying chlorine, an accidental release of ammonia from an industrial plant, smoke drifting from massive forest fires, errant radioactive materials, and numerous other scenarios hold the potential to threaten human health and human lives unless addressed quickly and effectively. Containing the spread of such threats and hazards in a susceptible and interconnected population requires active vigilance for signs of potential health emergencies. When a health emergency does occur, it must be rapidly recognized and characterized and its causative factors must be determined to guide strategies and resources for an appropriate and effective response. Continuing vigilant monitoring during event management or countermeasure intervention is also needed to assure effective outcomes.

Confronted with these emerging health threats, traditional public health surveillance systems, though extensive and sophisticated in many cases, are not set up to fully meet the need for comprehensive, near real-time information necessary to guide a rapid response. A new non-traditional approach based on preparedness, planning and collaboration is necessary to bring the full array of biosurveillance activities to bear on addressing such urgent events. New technologies are emerging in such fields as data mining, visualization methods, digital open source scanning, geo-coding for GIS mapping, electronic health records and laboratory data, among many other areas, as noted in the recent NBAS report. These developing capabilities, when joined with a better trained and multi-talented workforce, properly organized and coordinated, offer hope that the challenges presented by public health threats in the road ahead can be met effectively.

As it continues to evolve, the enhanced 21st Century biosurveillance environment will generate increasingly more useful information products that are timely, all-source, analyzed, concise, and actionable for federal, state, local, territorial, and tribal government decision-making. Reports will be shared through clearly defined and negotiated notification procedures that are rule-based whenever possible. Notification and response protocols will balance the tension between rule-based algorithms, built on critical information requirements that can be automated and timely, and broad rules, such as the International Health Regulations [IHR (2005)], that provide the flexibility to capture unanticipated incidents through reliance on human judgment.

The goal of the biosurveillance effort is to ensure that local jurisdictions have expanded capability and capacity to produce a near real-time common operating picture[8] of routine and emerging acute human health problems that can be easily shared with domestic and international entities to inform broader levels of situation awareness in the response community. The vision reflects a strategy that is robust and adaptable to future integration of new methods, sources of data, and analytical technology that will increase utility to stakeholders. It encompasses:

- An all-hazards approach to mitigate the full spectrum of public health emergencies;

- An all-population coverage which includes at-risk or special populations (e.g., children, older adults) who might be more susceptible to hazards and diseases;

- A strengthened and competent biosurveillance workforce and innovative programs for maintaining biosurveillance expertise;

- A vertically- and horizontally-networked enterprise of complementary systems providing biosurveillance capability and multi-directional information exchanges between and among domestic and international stakeholders. The complexity of the response to the 2009 Pandemic H1N1 illustrates how beneficial it is to the control of an outbreak that public health officials, healthcare providers, and the public exchange information across all relevant professional disciplines, levels of government, and global surveillance networks;

- A nationwide, robust and dynamic situation awareness capability with both ongoing and *ad hoc* data collection and real-time analyses and feedback processes to facilitate continuous evaluation and adaptation;

- Biosurveillance technology to support professional judgment. Electronic systems will support collection, integration, data sharing, management, analysis, modeling, and visualization of data, but will not replace human interpretation and judgment in an evolving situation;

- A multi-tiered comprehensive picture of the health of communities formed by the integration of all appropriate information that impacts human health, including those from animal, plant, and environmental domains;

- Enhanced case detection and disease reporting through electronic health information;

- Enhanced interoperability between laboratories and surveillance systems including nationwide electronic laboratory information exchange; and

- Evaluation and judicious integration of newer sources of biosurveillance data, such as those derived from news media, electronic discussion groups, call center logs, patient chief complaints, web-based social networks, and biosensor data.

The changing threat environment leaves little room for error or delay before negative health effects increase exponentially. Society has little tolerance for government shortcomings in protecting the populace from highly visible health threats and events. Biosurveillance provides the health intelligence that is the foundation of effective response actions. To understand where

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[8] A common operating picture is a single display of information used to support decision making that is dynamic, populated with real-time data, and enhanced through methods of data and information visualization.

enhancements are needed and feasible, it is important to contrast current capabilities with biosurveillance requirements.

Biosurveillance Today

In the United States, the healthcare system is the cornerstone of biosurveillance data including reportable disease surveillance. The reportable disease system has observers--primary care doctors, emergency departments, infection control professionals and laboratories--already in place in every community in the country. These observers make routine required reports and alert their local health department to unusual events. This system also has known disadvantages, but few, if any, of the alternatives have the geographic reach of this system.

In short, the healthcare system addresses all health hazards, it provides nationwide geographic coverage, and it produces the most precise health-related information for individuals that is subsequently aggregated for population health intelligence. The optimum surveillance approach for event detection varies by locality and is affected by such considerations as population density, healthcare provider density and distribution, geographic area under observation, nature of healthcare provision, availability of laboratories, endemic diseases, and other local factors. Nonetheless, case-based surveillance is the benchmark for public health monitoring. It is accomplished by clear and consistent criteria to achieve the definition of a case and the establishment of a reporting requirement when those criteria are recognized.

Critical sources of case-based surveillance include, but are not limited to, direct communications from clinicians and affected individuals, investigations by public health officials, and reports of laboratory data. These sources of data can provide specific (i.e., discriminatory) information about the case-patients and/or pathogens (e.g., laboratory subtype data) that is required to take public health action. The historical limitation of this methodology has been that it requires clinicians to recognize case criteria and actively report the information to the public health system. The quality of case reporting of notifiable diseases varies considerably by condition and by jurisdiction. Reporting is often incomplete or delayed. These limitations seriously hamper detection and situation awareness, especially in the early phases of an emerging health threat.

> A regional epidemiologist launches a routine daily query of the searchable multi-user database and learns that in recent interviews three patients with reported salmonellosis, in three different counties, all mentioned eating at the same restaurant at a regional mall within two days before onset of the illness. A record of a citizen complaint about unsanitary conditions at the same restaurant was also received by the state environmental health division. A foodborne outbreak investigation is launched.

Communities, like individuals, have a normal state of health,. Through routine health surveillance and epidemiologic investigations public health professionals learn what 'normal' looks like in their communities; they are then able to then detect deviations. Health professionals also monitor other elements of the biosphere[9]

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[9] The ecosystem comprising the entire earth and the living organisms that inhabit it -- Dictionary.com. *Dictionary.com Unabridged (v 1.1).* Random House, Inc. http://dictionary.reference.com/browse/biosphere (accessed: March 5, 2010).

to assure acceptable rates of exposure and injury. They monitor conditions such as restaurant food safety practices, animal diseases, and the need for animal and insect control to prevent communicable diseases. They monitor conditions such as industrial materials containment, waste disposal, air quality, soil quality, and plant health to prevent toxic exposures. They monitor climate conditions, especially temperature extremes, to prevent thermal injuries from heat and cold. They monitor occupational conditions such as sound levels, repetitive motion, and dosimeter readings to prevent mechanical and radiation injuries. They monitor hurricane behavior, earthquakes, and flooding to anticipate health problems from mixtures of microbes, toxins, and trauma. When detecting and responding to urgent events with near-real-time health information needs, these routine monitoring efforts can be intensified to meet biosurveillance needs. During the spring 2009 H1N1 outbreak several traditional influenza surveillance systems were successfully able to increase their frequency of reporting, which aided in the response. An example of how CDC leveraged existing surveillance systems in that period and CDC's lessons learned from the experience are given in the text box below:

Capabilities Today – Biosurveillance Systems in the Pandemic H1N1 (PanH1N1) Response, April - June, 2009

During the Pandemic H1N1 (PanH1N1) Influenza outbreak between April and June, 2009, public health practitioners throughout the nation worked diligently to respond. During the response, a broad range of surveillance systems, methods, and tools were used to gather, interpret, and communicate urgent health-related information; and outputs were used to inform decision making. The CDC conducted an in-process review of the biosurveillance systems, tools, and methods which were utilized for decision making. The results of that review provide a snapshot of how surveillance is viewed today within a key federal agency in dealing with a real-world response. Major findings of that review are provided below for purposes of illustration:

• Overall information exchange was good and the response was effective because of relevant and timely information. This was more a product of ability of experienced and talented people to adapt to the needs of the moment rather than the specific systems involved.
• Traditional influenza surveillance systems and laboratory capacity were flexible and scalable for the response; limitations in systems in achieving scalability/flexibility were overcome by trained, competent staff.
• Manual and labor intensive processes had a tendency to degrade as capacity was reached and the event grew; they are likely to be limiting factors unless alternatives are prepared.
• Familiarity was important to data use during the response. Systems and tools that were not familiar to influenza surveillance subject matter experts (SMEs) (i.e., validated and previously interpreted under similar conditions) tended not to be used in routine information sharing.
• While good balance was achieved, some responders expressed a sense that the information available was better than the conviction with which it was presented for action. Some of those responsible for presenting expressed concerns that the information requirements were continually changing, sometimes unrealistic, and demanded more certainty than the data supported. Stronger commitment to clear critical information requirements was urged for planning.
• Visibility of local conditions was a gap given the focal nature of this outbreak. People on the ground are the most important factor in getting specific and valid data. Epi-Aids and related field work yielded outstanding information.
• The international influenza data were held in very high regard. This appears to have been a combination of quality staff, quality relationships, and effective partnerships that integrated and reinforced critical thinking from multiple different perspectives.
• Problems in data sharing between states and federal agencies were a result of manual systems, duplicate entry requirements, and a strong desire to see federal agencies abide by the standards espoused in PHIN and notifiable disease surveillance. Automated systems were viewed as performing well. Manual linkage of laboratory and epidemiology data is a serious impediment that requires more long-term attention (e.g., establishment of a national patient identifier).
• Peer-to-peer (horizontal) communication was better than vertical communication. The more federal agencies can help partners define the critical information requirements needed to make decisions that are in scope for them, the less likely they will be to seek information not relevant to their role.

In the past decade, the science of surveillance has advanced rapidly in response to the need for early warning and detection of emerging, reemerging and novel health threats and hazards. New techniques are being introduced from diverse scientific fields to improve case-based reporting and situation awareness, as well as methods to identify and characterize events of public health interest that are not directly reportable as individual cases (e.g., food-borne outbreaks). Expanding dramatically beyond traditional notifiable disease reporting, methods now include managing data in electronic health records, electronic laboratory information exchange, environmental sensors, and health event indicators such as pharmacy sales data and call center logs.

Currently, these inputs provide an inconsistent mix of accuracy and timeliness. Communication between laboratorians and epidemiologists is sometimes poor and in many cases still manual, (e.g., in person or via telephone, and paper-based). Professionals within the public health system may have pieces of information that responders need in order to achieve accurate situation awareness. Notifiable disease reports are often not timely. Syndromic surveillance systems can be timely, but may lack specificity needed to validate and interpret signals and cues. Signals generated by these systems need rapid follow-up investigation and coordination with healthcare providers for the systems to provide a differential improvement over clinician-only surveillance.[10]

While today's U.S. biosurveillance capability has demonstrated effectiveness, as seen in the recent response to the spring 2009 H1N1 outbreak, too often success is dependent on the variability of human flexibility and effort; major vulnerabilities remain in the systematic ability to rapidly detect and mitigate health emergencies. Biosurveillance information still is not integrated, it does not flow as quickly or as efficiently as is necessary, and the trained workforce is in critically short supply.

Requirements for Biosurveillance

Successful biosurveillance capability must accomplish the following functions:

Case detection—discovery of the existence of a single instance of a specific disease or exposure. A front-line biosurveillance activity, it is typically accomplished as a by-product of routine medical or veterinary care, laboratory work, or via an astute observer.

Cluster detection—continuous analysis of health-related data to detect unusual patterns of conditions that may signal an outbreak. Cluster detection seeks to identify patterns in volume surveillance and unstructured data, rather than case reports, to identify potential events.

Signal validation—confirmation processes that ensure that cases, clusters, signals and other such cues represent acute public health events that require a response. These may be labor and time intensive.

Event characterization—includes the range of processes that support case investigation and tracing and are linked to early event detection to decipher and specify the causative biological agent, source, route of transmission and other characteristics of an outbreak or event. These

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[10] Steiner-Sichel L, Greenko J et.al. Field investigations of emergency department syndromic surveillance signals—New York City. *MMWR*. 2004. Sept 24;53 Suppl:184-9.

characteristics guide effective response actions, including the treatment of victims and the institution of control measures to prevent additional cases.

Notification and communication—processes, including notifiable disease reporting, that ensure that those with a need and right to know have information (event details as well as response guidance) as soon as possible, and all users understand their responsibilities for use and management of the information. State statutes, laws, regulations and, less frequently, ordinances at the local or county level determine which diseases and health conditions are reportable to public health authorities. These reporting requirements enable healthcare providers, laboratories, hospitals and other care facilities to report patient information to public health authorities so those authorities can investigate the source of the occurrence and prevent additional spread of disease. The reporting requirements may include name reporting, demographic information, and, in some instances, clinical information and laboratory results. Current reporting mechanisms include mail, phone, fax, and secure electronic reporting. These processes also support the mass administration of prevention and treatment measures, adverse event detection, and isolation and quarantine tracking.

Quality control/ improvement—ensuring data management, including protecting the privacy and confidentiality of biosurveillance data, and monitoring the system through performance measurement to confirm that objectives are being met.

These functions require capabilities at the state and local levels where follow-up investigation can take place, domain knowledge can be incorporated for accurate interpretation, information quality feedback loops can be executed, and ultimately, effective response actions can be taken. Close working relationships, resourcing, and training support will be needed to ensure a robust and effective biosurveillance capability resides at the state and local levels across the U.S.

Towards Implementation

The multi-dimensional challenges – and opportunities -- for creating a more robust biosurveillance system are substantial. The social and economic costs of recent disease outbreaks underscore the importance of biosurveillance in detecting, preventing, and mitigating adverse human health events. At the same time, competition for limited resources is intense. Consequently, there is an immediate need to identify priority areas. Six priority areas are put forward in *The Strategy* to address critical gaps and suggest opportunities for improvement. These are as follows:

- **Electronic Health Information Exchange –** to strengthen and expand upon multi-directional health information exchanges with healthcare and public health entities. This priority includes information available today and that will be available in the future as healthcare systems evolve.

- **Electronic Laboratory Information Exchange –** to strengthen information exchanges between and among clinical and public health laboratories and to improve integration of laboratory and epidemiologic data.

- **Unstructured Data –** to leverage digital information (e.g., text and image) that is not in a database format. Sources of unstructured data include digital news media and discussion forums as well as digitally-stored information in health departments and the healthcare

system that capture notifications and queries about potential events of public health concern.

- **Integrated Biosurveillance Information** – to generate actionable health intelligence by increasing access to information resources and synthesizing multiple streams of information into one coherent picture.

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

- **Biosurveillance Workforce of the Future – to** address the need for a workforce that is available, prepared, and collaborating to adapt to evolving threats and crises.

Priority Areas

Electronic Health Information Exchange[11]

Health information technology (HIT) and electronic health information exchange, including electronic health records (EHRs), have the potential to accelerate timely and accurate sharing of health data between clinical care and public health practice settings. Healthcare information provides the most specific and direct representation of the health of the nation's communities. At present the healthcare system has four critical roles in biosurveillance:

    1) report notifiable diseases and clusters of suspicious illness to state and local health departments;

    2) provide automated data streams that can be used to recognize and monitor outbreaks;

    3) assist health investigators through the provision of clinical information from patient medical records, screening services, diagnostic results, and other sources; and

    4) monitor patient and worker health and safety within its own facilities (especially hospitals and long-term care facilities).

Like biosurveillance, the practice of medicine is information intensive. The healthcare system records many types of data for every patient encounter. Access, however, is a significant barrier to the use of healthcare data for biosurveillance. The data needed for early detection and rapid characterization of an outbreak or other adverse human health event are stored in a variety of locations, often in paper-based form. Even when data are recorded electronically (as is typically the case for laboratory test results and radiology exams), they are encoded in non-standardized formats that present a barrier to data use and integration. Other data, such as symptom and physical exam data, are often recorded in unstructured formats (e.g., text strings). Data may also be of poor quality (e.g. when incorrect ICD-codes are used). Clinical care and public health practitioners exchange information primarily via fax, email, and phone for case, outbreak, and other adverse human health events reporting.

Progress toward expanding the use of EHRs offers promise for eliminating many of the existing inefficiencies in health care and public health settings. At its most basic level, EHRs convert paper charts to electronic ones, reducing paperwork, helping prevent medical errors, and adding efficiencies to the transmission of information such as prescription data. They also give health care providers a fuller picture of the patients' health by integrating their medical histories and by tracking more efficiently key aspects of patients' ongoing medical condition and treatment.

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[11] For the purpose of this document, electronic health information exchange is defined as the sharing of digitized human health data and information according to nationally recognized standards among organizations that can utilize the information to improve individual and community health security.

Enhanced electronic information flow to public health practitioners generated from EHRs can, in turn, help in the management of risks to entire groups and in the development of preventive measures that have broader applicability.

Health information technologies have been introduced to assist almost every aspect of medical practice, including scheduling, ordering of tests, recording of clinical observations, and processing billing and claims. Some of these departmental systems are widely deployed; others, such as electronic health records and e-prescribing systems, have more limited adoption. The success of electronic health information exchange is dependent on linking all those engaged in the care of the patient, whether individuals or communities, together in secure and interoperable environments. Widespread deployment of HIT systems, including the development of networks that support electronic health information exchange, while adhering to security and privacy standards, is the essential foundation to realizing clinical data's full potential for biosurveillance.

Mutual benefit is possible through the coordination of biosurveillance objectives with HIT for patient treatment and healthcare system improvement. Arming healthcare systems and health departments with strengthened case-finding approaches and bidirectional, real-time information about health threats and events in the community will allow health professionals to effectively adapt patient interventions to changing conditions and thus provide the best care possible. Aggregated population-based information will facilitate clinical research on new treatment options and implementation of quality improvement programs. Nonetheless, challenges exist to incorporating biosurveillance requirements into the information architecture of medical business systems and the workflow of medical practice. The business model for medical practices constrains implementation of new information system requirements until benefits outweigh the cost of installation and support. A favorable business case is needed.

Public support for e-health efforts is necessary to leverage the potential of electronic health information. Privacy protection and security measures are key components of success in the development and sustainability of electronic health information exchange and HIT. Ongoing successful experiences with the secure transfer of standardized electronic healthcare records are building the trust necessary for that support.

In an enhanced biosurveillance environment the healthcare system will exchange significantly more data and services with public health and will do so in real time. This trend is already unfolding in many jurisdictions in the United States and abroad. In support of this exchange, public health programs and professionals will assure security and appropriate use of the information, minimize the burden, and transmit information helpful to clinicians, such as automated support for reporting requirements, guidance on diagnosis and management, and situation awareness information.

The Nationwide Health Information Network (NHIN) and the standards for biosurveillance published by the Health IT Standards Panel (HITSP) are expected to serve as the foundation for a nationwide exchange. Interconnected networks will share common services and adhere to standards and requirements to enable interoperability. The enriched data-sharing environment will allow both clinical and public health professionals automated processes for entering information, access to health information when they need it, automated analyses that support notifiable disease detection and outbreak cues, query abilities for additional investigation when warranted, and feedback loops to validate findings and enact countermeasures.

Goals for this priority area include:

Goal A. Create Nationwide Capability for Health Information Exchange

A nation-wide data framework of health information sharing could enable the public health community to store data locally, in state and local public health departments and within the healthcare system, and allow stakeholders, including the federal government, to access and analyze those data with appropriate permissions. There are multiple technical approaches to such a data model including grid technology, service oriented architecture, and lightweight data integration. These approaches should be explored through collaborative proof-of-concept projects.

Proof-of-concept projects for different technological approaches for information sharing between existing health information databases are currently underway. Efforts are already underway at the national level to identify standards for HIT systems to ensure they are interoperable and have the necessary security and privacy capabilities. Promoting standards-based, interoperable technologies and certification may help overcome provider concerns and speed HIT and electronic health information exchange development. A large body of work exists that can be directly applied towards integrating clinical data into biosurveillance. The number of collaborative health information exchange initiatives at the state, regional, and community levels has grown considerably with a nearly 40 percent increase over 2008 in the number of advanced or operational initiatives.[12]

Several initiatives have been undertaken within the Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC) to provide incentives to healthcare entities. Through the American Recovery and Reinvestment Act of 2009 (ARRA), the Centers for Medicare and Medicaid Services (CMS) is authorized to provide reimbursement for healthcare providers who adopt electronic health records (EHRs) meeting "Meaningful Use" criteria. The reimbursements begin in 2011. By 2015, providers are expected to have adopted meaningful use of EHRs or face financial penalties.

Meaningful use of EHRs centers on the idea of improving clinical care through exchange and utilization of health information. As the definition of meaningful use evolves, it is essential that public health is an active participant to ensure that biosurveillance needs are addressed. This has further implications than just financial incentive programs for adoption, as meaningful use criteria may be used to define certification criteria for EHRs in the future. EHRs must have the capability to exchange information with public health without an additional burden on healthcare providers.

As health policy facilitates the adoption of HIT, the need for measurement is critical. ONC has partnered with George Washington University & Massachusetts General Hospital / Harvard Institute for Health Policy to measure the state of EHR adoption and determine the effectiveness of policies to increase adoption of EHRs and interoperability.

In addition to financial incentive programs to promote adoption of meaningful use of EHRs, grants are available under the ARRA to accelerate electronic exchange of information. Two priority areas have been released as of August 2009: 1) Health Information Technology Extension Program and 2) State Health Information Exchange Cooperative Agreement Program.

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[12] eHealth Initiative. *Sixth Annual Survey of Health Information Exchange. Migrating toward Meaningful Use: The State of health Information Exchange.* 2009. http://www.ehealthinitiative.org/HIESurvey/. Accessed March 5, 2010.

The Health IT Extension program provides grants to establish centers to support and accelerate adoption of meaningful use of EHRs by healthcare providers. These Health IT Regional Extension Centers will offer technical assistance, guidance and information on best practices to healthcare providers. The State Health Information Exchange (HIE) Cooperative Agreement Program provides grants to states or their designees to establish HIE capabilities in their jurisdictions. These efforts to build connectivity among health care providers and hospitals will improve quality of care. Both of these grant programs, and those yet to be announced, have the potential to enhance biosurveillance capacity and require that public health needs be incorporated from the outset.

Objectives:

1. **Ensure implementation of standards and specifications to support bidirectional exchange of biosurveillance data between clinical care, laboratories, and public health.**

2. **Provide input from a public health perspective in defining meaningful use of EHRs to assure biosurveillance needs are met.**

3. **Support incentive programs (e.g., reimbursement policies) that facilitate adoption of meaningful use of electronic medical record systems, to enable electronic health information exchange.**

4. **Encourage widespread adoption of meaningful use of electronic health record systems.**

5. **Create robust, interoperable linkages between clinical care, laboratories, and state/local public health, leveraging existing efforts and infrastructure as appropriate.**

Goal B. Strengthen Surveillance Processes and Notifiable Disease Reporting Mechanisms, Including Electronic Laboratory Results Reporting

Notifiable disease reports, including reportable disease laboratory findings and vital statistics, are among the most enduring types of data collected systematically for biosurveillance purposes. Automated and standardized electronic reporting processes for notifiable diseases can also greatly enhance the nation's biosurveillance capability. Electronic laboratory results reporting (ELR) has been shown to greatly increase the speed with which notifiable disease reports are received. Laboratory information exchange is a critical component of health information exchange, and so is addressed here. It also appears in *The Strategy* as its own priority area to underscore the extent to which laboratories are fundamental to biosurveillance and to recognize the importance of linkages to laboratories testing non-human specimens (e.g., environmental samples and animal specimens).

Advancing the timeliness and accuracy of reportable laboratory findings through automated electronic reporting from all clinical laboratories and advancing the timeliness and accuracy of death records through electronic registration in the United States are within reach. Death is the quintessential health metric and has served as the foundation of surveillance since the origins of public health. Work also needs to be done to improve, expand, and enhance biosurveillance systems for priority exposures and health events, for example, improve surveillance for chemical and radiologic exposures, improve the speed and quality of coding and reporting of nature-of-

injury and external-cause-of-injury data from emergency departments, and improve numbers of states covered by poison control center surveillance.

Public health must continue to work with healthcare and HIT vendors to ensure their applications are biosurveillance-enabled, having the capability to collect and exchange data at the point of care as part of the normal workflow. Emphasis will also be placed on collaboration to consolidate requests for clinical data and minimize the burden of collection. As adoption of HIT and electronic health information exchange widens and as healthcare systems become more integrated opportunities will arise to exchange additional data. Agreement on and widespread implementation of an expanded set of data elements, policies for data sharing that build trust, and mutually agreed upon business models will accelerate data exchange between clinical and public health systems. Additional functionality to enable decision support and to enable bidirectional communications among front-line clinicians and public health will also be needed.

Electronic reporting of cases of disease from EHRs has been shown to improve timeliness and completeness of reporting from healthcare entities. Throughout the past year, work has been undertaken by the Council of State and Territorial Epidemiologists (CSTE) and CDC to standardize data elements and case detection algorithms for identification and reporting of nationally notifiable conditions from healthcare entities to local and state public health. Implementation guides are being developed to enable electronic exchange of these data. This work, combined with widespread adoption of EHRs, has the potential to improve case detection capabilities for reportable public health conditions. Further development, testing, and implementation of algorithms and data exchange standards are necessary to enhance capabilities.

The benefits of having a national or global biosurveillance capability may be readily apparent on a societal level, although not at a healthcare businesses level. Both understanding and articulating the "value proposition" for healthcare providers are critical to forming productive collaborations.

Objectives:

6. **Develop a compelling business case for automated information exchange between public health and healthcare.**

7. **Evaluate real-time data management approaches for electronic health record systems to support case reporting, syndromic, and exposure data.**

8. **Support timely and accurate case detection and disease reporting capabilities in all clinical settings for all priority exposures and health events.**

9. **Develop decision-support tools for sharing biosurveillance information with clinical care providers (through work with software vendors) and prompting providers to request consultation from public health professionals.**

10. **Enable electronic reporting systems, with emphasis on the following areas: electronic real time death registration, automated transmission of laboratory reportable findings, and electronic real-time reporting from healthcare providers.**

11. **Establish informational architecture for the national biosurveillance capability, including but not limited to, interfacing with the Nationwide Health Information Network (NHIN), other federal networks and existing state and local health networks.**

Goal C. Strengthen Biosurveillance Communications in Healthcare

Web-based tools and voice and text messaging systems are used by stakeholders in healthcare as convenient means of providing alerts and notifications of health issues. Enhanced biosurveillance capability must leverage convenient mechanisms for information sharing to maximize the value of biosurveillance findings. More development and evaluation is needed to establish the most effective mechanisms.

Objectives:

12. **Evaluate existing approaches for advancing bidirectional communications between healthcare and public health.**

13. **Initiate and support pilot programs for improving communications for biosurveillance alerting, notification, and related actions.**

14. **Develop approaches to interface with existing networks and health information exchanges at all levels.**

Goal D. Address Health Information Privacy, Security, and Use

Consumer and provider trust are key to the success of electronic health information exchange. Privacy and security policies and standards are not applied consistently across healthcare entities at this time. Current state and federal privacy law requirements are inconsistent, further inhibiting electronic exchange. Privacy laws that govern information exchange and requirements for data disclosure vary across states and jurisdictions (e.g., federal and state). Requirements may vary by data type (e.g., general health, mental health, or infectious disease); purpose of use (e.g., treatment, public health reporting); and mechanism for compliance (e.g., ink signature, paper form, verbal). State privacy requirements are scattered into different chapters of legislation and regulation. Some are specifically written for a paper-based system.[13] Federal and state agencies must work together to better understand what privacy laws are supportive or prohibitive of electronic health information exchange and address unintended impediments these laws present.

New activities should build upon the ongoing work of many organizations, such as: The American Health Information Community Confidentiality, Privacy, and Security Work Group; Health Information Security and Privacy Collaboration; American Medical Informatics Association; American Quality Association; Connecting for Health; eHealth Initiative; National Committee on Vital and Health Statistics; the Workgroup for Electronic Data Interchange; and the Nationwide Health Information Network Data Use and Reciprocal Support Agreement Workgroup.

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[13] State Alliance for e-Health. *Accelerating Progress: Using Health Information Technology and Electronic Health Information Exchange to Improve Care*. Washington, DC: National Governors Association Center for Best Practices, 2008. http://www.nga.org/Files/pdf/0809EHEALTHREPORT.PDF. Accessed March 5, 2010.

Objectives:

15. **Create a set of common principles and policies for use of electronic clinical data.**

16. **Align policies and laws to support intra- and interstate data exchange while ensuring appropriate consumer protection.**

17. **Define data access, data use and data sharing policies to ensure the availability of biosurveillance information to identified and authorized users.**

Goal E. Establish a Governance Body to Guide Electronic Health Information Exchange

Leadership from government and the private sector is critical to the success of HIT and electronic health information exchange initiatives. A key ingredient in formulating these initiatives is building the trust needed to facilitate collaboration. Stakeholders (e.g., payers, providers, and consumers) engaged in e-health activities represent diverse, sometimes opposing viewpoints and have varying needs and missions. Visible and sustained government support that recognizes the value of HIT and electronic health information exchange in enhancing biosurveillance outcomes will help improve coordinated action.

As the National Health Information Network (NHIN) evolves and moves into production, operational policies, data use and reciprocal support agreements, and a model for governance will be required. NHIN policy and governance teams will address these requirements. The NHIN governance model should be leveraged to serve as a governance for both Electronic Health Information Exchange and Electronic Laboratory Information Exchange outlined in this document, as appropriate.

Objectives:

18. **Ensure leadership and support for HIT and electronic health information exchange exists at all levels of government.**

19. **Establish state-level roadmaps articulating state visions and strategies for electronic health information exchange using a collaborative approach involving appropriate stakeholders, including state public health departments..**

20. **Establish forums for the sharing of best practices, protocols and lessons learned.**

21. **Implement social and technical platforms to enable scientific collaboration, standardization and informatics development.**

22. **Explore data use policies that address privacy, security, data ownership and stewardship, and liability protection for data providers.**

Electronic Laboratory Information Exchange

The intent of electronic laboratory information exchange is to improve timeliness of reporting, accuracy, completeness, and availability of laboratory data for use by those who need the information for investigation and decision-making. Laboratory-based testing and surveillance provides a critical foundation for effective biosurveillance practice. Addressing the exchange of laboratory information within the human health domain is the initial focus of this priority area. Strengthening connections and promoting the use of data standards among laboratories (i.e., public health, clinical) and between laboratories and public health organizations across jurisdictions (local, state, regional, national, and global) and domains (human, animal, plant, food, and environmental) is important to biosurveillance.

The value of laboratory information lies in its diagnostic capability and key role in identifying cases and events of public health significance. Electronic data exchange between clinical laboratories and public health has demonstrated the potential to improve the timeliness of event detection and increase the number of reports received.[14]

Critical stakeholders in laboratory information exchange for human health include clinical laboratories (commercial and hospital), public health laboratories (local, state, and federal), clinicians, as well as public health programs (local, state, and federal) that use laboratory information for diagnosis, case and event detection, investigation, and confirmation. This community of stakeholders must be able to share information seamlessly in a manner that supports their specific business practices.

Within this priority, electronic laboratory information exchange has two critical components, exchange of information between laboratories for optimal laboratory practice and between laboratories and public health stakeholders for use in investigations and responses. Protocols and policies should be in place to ensure that the use of this information in investigations and responses - which facilitate a rapid response - adheres to privacy and confidentiality requirements.

First, laboratories must be able to exchange test orders and results with other laboratories. This includes sharing information related to the ordering of tests and reporting specific findings (e.g., organism identified, method performed, instrument used), as well as test interpretation (e.g., normal ranges). This exchange should occur electronically between laboratory information management systems (LIMS) (also known as laboratory information systems, or LIS). Such laboratory-to-laboratory exchanges are essential when large numbers of tests are performed. It is also critical in a continuity of operations situation in which one or more public health laboratories must support testing for a laboratory that is unable to perform testing for any reason. The spectrum of testing conducted within laboratory systems varies, lending complexity to messaging needs around test orders and results.

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[14] See, for example, Effler P, Ching-Lee M, Bogard A, Ieong MC, Nekomoto T, Jernigan D. Statewide system of electronic notifiable disease reporting from clinical laboratories: comparing automated reporting with conventional methods. JAMA 1999;282(19):1845-50; Häyrinen K, Saranto K, Nykänen, Definition, structure, use and impacts of electronic health records: a review of the research literature. Int J Med Inform 2008;77:291-304; Moore KM, Reddy V, Kapell D, Balter S. Impact of electronic laboratory reporting on Hepatitis A surveillance in New York City. J Public Health Manag Pract 2008;14(5):437-441;

Equally important, public health professionals must be able to receive laboratory results to support detection, confirmation, and investigation of case reports and outbreaks or other events of public health significance. This should be accomplished by automated transfer of electronic laboratory results from a LIMS to public health surveillance systems to reduce the time and labor involved and to facilitate epidemiologic analyses of laboratory data.

However, the transition from paper to electronic reporting has been slow despite a national movement to adopt standards for exchange. Many laboratories lack a modern LIMS to manage, track, and share laboratory results. Consequently they must provide reports via paper or other methods that require manual and repetitive data entry.

> The 2007 State of Technology Adoption Survey, conducted by the Association of Public Health Laboratories (APHL), surveyed the LIMS capabilities of state and local public health laboratories. Among the 68 respondents, only 57 percent reported having a functional LIMS. Among the 39 laboratories with a functional LIMS, 62 percent conduct automated electronic data exchange with an external partner such as CDC, another state laboratory, or a private laboratory. Seventy-four percent of labs with a functional LIMS conduct automated electronic data exchange with a state epidemiology program, and 62 percent exchange data using standard vocabulary, such as LOINC® or SNOMED.[15]
> *(Personal communication. Patina Zarcone, Association of Public Health Laboratories, APHL 2007 State of Technology Adoption Survey)*

These challenges exist at all levels (local, state, and federal), both for clinical and public health laboratories. Effective information technology tools and data standards exist to help address these challenges, but barriers to adoption persist, including limited resources and other organizational priorities.

Laboratories that have implemented LIMS face additional challenges. Data standards for messaging vocabulary have been established, but their application remains inconsistent. The use of different messaging formats and coding at the hospital and private clinical laboratory levels provides a striking example. Even when the same standard is used (e.g., HL7 2.3.1 for messaging or LOINC® for vocabulary[15]), how the standard is applied may vary slightly from laboratory to laboratory and across jurisdictions. This may include variability in the specific standards or codes used to represent the same concept, as well as the level of detail that is provided. Limitations of LIMS systems may also prevent laboratories from adhering to standards.

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[15]SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms) is a comprehensive clinical terminology originally created by the College of American Pathologists and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organisation. http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html.   Accessed March 5, 2010. LOINC® (Logical Observations Identifiers, Names, Codes), is a clinical terminology important for laboratory test orders and results produced by the Regenstrief Institute. LOINC is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information. http://www.nlm.nih.gov/research/umls/loinc_main.html. Accessed March 5, 2010.

Many public health programs lack biosurveillance systems capable of automatically populating case reports with electronic information from laboratories. The lack of connectivity makes duplicate data entry and manual cross-matching of records necessary. In addition, there are multiple stand-alone disease-specific systems with no ability to exchange laboratory information. Some were developed prior to widespread availability of standards and now are the sole system supporting vital programs. Facilitating interoperability of these systems would result in more efficient and effective data management across public health programs and jurisdictions.

The Public Health Laboratory Interoperability Project (PHLIP) advocates for collaborations that strengthen the public health laboratory community. The project includes components related to laboratory data vocabulary, messaging, security, and architecture and building community and collaboration around the critical issue of laboratory data messaging. This collaborative has reached a level of maturity where it has evolved from proof of concept status to production status and the project is poised to achieve bi-directional data messaging to and from CDC and its state laboratory partners. The public health impact of being able to effectively and efficiently share laboratory data electronically is fundamental to planning public health strategies and responding to all public health threats.

Challenges related to electronic laboratory information exchange have eluded quick solutions. Still, incremental progress has been made in setting national standards for interoperability, security, and data terminology; providing in-field state/local consulting expertise and training; and providing federal guidance on strategic initiatives and helping to procure funding. Solutions to challenges will consist of approaches that advance and expand work currently in progress while acknowledging the need for progressive implementation. Key goals for this priority area include:

Goal A. Ensure the Electronic Management and Exchange of Laboratory Test Orders, Specimens, and Results Information

Sharing electronic test orders and results across laboratories is effectively accomplished today in some but not all locations. There has been considerable work on the development of standards for electronic messages and vocabulary for laboratory information, but the translation of these into practice has not been coordinated. Multiple stakeholder groups implement coding schemes and develop localized standards to meet their needs, which results in disparate implementation.

An electronic mechanism for accepting test orders, sharing specimen information, tracking and reporting results would provide for more rapid, accurate, and efficient surveillance and consultation. Infrastructure investments are needed at all levels (local, state, federal) that contribute to the public health system (clinical, public health, and other laboratories) to develop LIMS systems capable of sharing this information. Investments are needed at local, state, and federal laboratories to assure that capabilities of the nationwide network of public health laboratories can be shared in a timely manner with those who are managing patients and the community response. Successful projects that are showing progress toward the consistent application of standards should be identified, promoted, and advanced.

Objectives:

23. Engage stakeholders to identify and resolve gaps in standards, share best practices, and promote consensus for implementing data standards.

24. **Identify incentives and ensure consistent application and use of standardized vocabulary and messaging, including standardized data elements for electronic laboratory reporting.**

25. **Engage commercial vendors and promote the implementation of LIMS in laboratories for functions of particular importance to biosurveillance for human health.**

Goal B. Ensure Reportable Laboratory Information is Combined Electronically with Clinical and Epidemiological Data

Laboratory reporting is required in all states for test results related to state reportable and nationally notifiable conditions. This information, when combined with other epidemiologic data, forms the basis for public health investigations. Building a public health case record is a component of case investigation that includes laboratory and clinical data as well as risk-factor data about the case. Although it is not expected that lab results would be accompanied by clinical information, many laboratory results that are messaged to public health entities do not contain enough information for public health professionals to begin an investigation (e.g., unique patient identifier shared to link laboratory data efficiently with epidemiologic data). One of the challenges of the 2001 anthrax attack response was integrating laboratory test orders and results with additional clinical and epidemiologic data held by infectious disease experts. In an effort that will facilitate interoperability between laboratory and epidemiology programs, the Council of State and Territorial Epidemiologists (CSTE), in partnership with CDC, has rewritten surveillance case definitions for Nationally Notifiable Conditions (effective January 2010) to include specifications for laboratory results. Efforts will:

> Investment at the state and local level has demonstrated success and resulted in significant progress. In 2007, the National Electronic Laboratory Reporting (ELR) Teleconference Group (sponsored by Council of State and Territorial Epidemiologists) conducted a survey of 50 states, one territory and 5 U.S. metropolitan areas on the status of electronic laboratory results reporting to public health organizations. Thirty-eight respondents were operational at some level, 14 of 38 were 50-100% operational. Fifty percent of respondents were receiving reports electronically from their reference public health laboratory. Eighteen of 52 respondents with local health departments in their jurisdiction reported being able to route the data to those users.

- Promote and strengthen interoperable platforms for information exchange;

- Advance consistent application of standards in the design of public health surveillance information systems to ensure that surveillance systems are capable of processing, managing, manipulating, and displaying electronic laboratory information in an automated way;

- Identify and address unique types of data files that need to be shared that may not yet utilize data standards (e.g., text string results, pulsed field gel electrophoresis (PFGE) pattern files);

- Explore identification strategies (e.g., the creation of globally-unique patient identifiers), to facilitate the early linkage of laboratory data with epidemiologic data.;

- Advance national-level incentives to ensure that commercial vendors have a return on investment for implementing systems that share standard laboratory information; and

- Explore the utility of legal mandates for laboratory reporting to public health epidemiology programs.

Objectives:

26. Identify and leverage best practices to enable laboratory data exchange with public health epidemiology programs.

27. Leverage the work of large private laboratories and establish information exchange between them and local public health programs.

Goal C. Create a Governance Structure for Electronic Laboratory Information Exchange

Coordinated planning and application of standards are necessary for a system that can share laboratory information successfully across jurisdictions, disciplines, and domains related to human health (veterinary, environmental, food, and agricultural). A governance structure implemented as part of the NHIN or other national initiatives should be leveraged to support Electronic Health Information Exchange and Electronic Laboratory Information Exchange. A governance structure administered at the national level will:

- Advance the consistent application of data standards for the exchange of lab information;

- Ensure that guidance vehicles include specific language to promote data standards (i.e., PHIN and NHIN standards);

- Determine priorities of goals to progressively and iteratively advance electronic exchange of laboratory information;

- Assure that state and local public health organizations are key stakeholders in this effort;

- Assure outreach to the clinical community to harmonize clinical and public health information needs;

- Advise on priorities;

- Leverage ongoing national efforts to address this topic (e.g., ICLN); and

- Support resolution of data stewardship agreements (when data should be shared; who can share data; what types of data can be shared; data use and re-release parameters; what data protections are sufficient; legal, statutory, and intellectual property considerations).

Objectives:

28. Coordinate planning and advance implementation of data standards.

29. Ensure data stewardship practices are in place.

Goal D. Ensure Interoperability and Collaboration Across Human Health-Relevant Laboratory Domains

Effective public health surveillance requires broad coordination across veterinary, environmental, food, and agricultural laboratory domains. Requirements will need to be defined to characterize the business needs and scope of data sharing among the different domains. Among other efforts, this goal includes close coordination with entities such as the ICLN, which

was formed by the Homeland Security Council and chaired by DHS to strengthen homeland security through a coordinated operational infrastructure of the national laboratory networks that encompass these domains. ICLN is working on several major initiatives to support interoperability:

- Development of a Standard Operating Procedure (SOP) for incident response across participating federal networks.

- Development of an Integrated Response Network (IRN).

- Development of a Data Exchange Architecture to support laboratory information sharing from federal networks with the National Biosurveillance Integration Center (NBIC).

These initiatives may not encompass the full spectrum of laboratories and tests needed for biosurveillance. Additional initiatives may be required for clinical laboratories to complete the electronic laboratory exchange.

Objectives:

30. **Develop a model to provide guidance to both public health and clinical laboratories on consistent representation of key data concepts such as sample, test, result, patient, and public health case.**

31. **Provide guidance and best practices on the implementation of laboratory data standards.**

Unstructured Data

Surveillance data have long been collected using a wide range of media (paper, voice, electronic) with much of it available in free-form text or unstructured formats that can be easily interpreted by a person but not by a computer. Unstructured data are pieces of information such as text strings that are not organized or integrated for direct entry into a database. The content is often qualitative rather than quantitative (e.g., a narrative description of a patient complaint). As technology has progressed and as more information is recorded onto digital media, access to a broader array of information is opening up across all levels of public health, healthcare, in the private sector and in open sources available through the Internet making it possible to supplement and build a more comprehensive picture of situation awareness.

Critical health information can be found in free-form text and other unstructured data in storage locations throughout public health and healthcare organizations. In a large complex public health agency, several workers may each know a different part of the story about an important health event, yet each alone does not realize the significance of the event. Key pieces of information that would provide context for a case report (such as the name of a restaurant) may lie in an epidemiology investigator's case notes, emails sharing information about consultations or investigations, consumer complaint logs, surveillance system reports, or media that are not yet readily searchable or computer-synthesized. Similarly valuable information may reside in emergency department triage nurse notes or free-text chief complaints, or in the narrative portions of electronic medical records or poison control center data systems.   Valuable information contained in unstructured data is not limited to infectious disease threats, but also include environmental data, such as chemical or radiological exposures and patient outcomes.

Unstructured data found in the private sector and in web-based sources can be used to augment public health and healthcare information. No matter how well the official reporting systems work, gaps in coverage and information still remain. Private health professionals may only see a single enigmatic case and not realize that other similar cases are presenting elsewhere in the healthcare system or the world. Recognizing this, sources such as the Public Health Agency of Canada's Global Public Health Intelligence Network (GPHIN) that continuously scrutinize global news media sources and health and science websites give healthcare professionals additional insights into what is happening in the environs around them. Similarly, Project Argus, developed and based at Georgetown University, is a biosurveillance system initiated in 2004. Argus was designed to detect and track biological events that may threaten human, animal, and plant health globally and in the United States by monitoring various types of social disruption evident in local, native-language media reports around the world. These reports range from traditional print and electronic media to internet based newsletters, in approximately 40 languages on every

> A citizen reports cloudy tap water to an environmental health worker. The worker enters the call notes directly into a searchable multi-user database, indicating the location, age range, zip code and general type of call as well as free-text narrative. At the same time, an epidemiologist located in a different office receives a call from an urgent care doctor describing an increase in clinic visits for gastro-intestinal illness in the past 24 hours. When the epidemiologist searches the database, the report of cloudy drinking water pops up from the zip code next to that of the urgent care center. A joint environmental-epidemiological investigation of a possible waterborne outbreak is launched.

continent, except Antarctica. Over 40 federal, state and local governmental entities use Argus on a daily basis.

More novel data streams, such as the number of searches for particular concepts on popular search engine sites, need to be further explored. Social networking technologies and web-based discussion forums, listservs, and blogs also have the potential to be mined for timely information about illness or health concerns.

All these sources provide potentially valuable information that if integrated with traditional surveillance data and shared more widely may aid earlier detection of public health threats. However, rigorous research, applied experience, and shared learning are needed to develop this capability, and additional technologies, tools, and skilled analysts are needed. Also, at all levels, public health entities will have to understand and weigh the benefits and limitations to investing in or utilizing unstructured data. Data and text-mining or knowledge discovery tools are needed to mine and convert the data into computer understandable format. Additional technologies are needed to facilitate analysis and integration and to detect patterns and associations. For example, free-text chief complaints in emergency department visit records are grouped into categories with software that looks for key word combinations indicating the presence of a syndrome such as gastroenteritis or rash with fever. These techniques have also been applied to emergency department triage nurse notes and could in principle be applied to other free-text data in electronic health records.

> A state-level epidemiologist receives a message with a request for information about testing for meningococcal disease. Before returning the call, the epidemiologist searches the database for records with similar characteristics. One state health department worker and two county health department staffers have recently handled consultations about three different people with suspected meningococcal disease in the same metropolitan area; none of them have talked with the others. The epidemiologist convenes a quick conference call and organizes a joint outbreak investigation and response. She also posts a health alert network item asking for additional case reports.

Best practices and lessons learned from federal and international systems can also help determine the tools and approaches that should be considered. In the United States, systems such as BioSense, the National Biosurveillance Integration System (NBIS), the USDA's Veterinary Services system for animal health, and the Office of the National Director of Intelligence already incorporate unstructured data into their analyses. Global activities include systems such as HealthMap, Epispider, MediSys, and BioCaster. These systems allow uptake of unstructured information to enhance disease surveillance activities.

While increased access to additional information is important for biosurveillance, so too is the professional judgment and skill, informed by proper local context, to validate and provide context to unstructured data analysis. For example, ProMED, a moderated listserv that serves as an early warning system covering human, animal, and plant disease, disseminates information from global news media, official national and international organizations, and direct reports from subscribers, including "astute clinicians". All reports are first vetted by a cadre of expert moderators providing interpretations and analyses as part of the information disseminated.

Additionally, creative and low-burden methods of sharing and exchanging both raw and synthesized unstructured information are needed for health professionals. For healthcare and

public health professionals, knowledge management tools and methods need to be explored to assist with managing information overload.

The value of access to and utilization of unstructured data will increase exponentially as the number of active participants using it increases. The information available will also increase with increased automation, integration and exchange across the healthcare environment and as more people are linked into these networks. The value will be best demonstrated as more and more public health professionals contribute to it, use it, and evaluate its usefulness.

Key goals that are intended to be addressed in order for this priority area include:

Goal A. Define and Evaluate Options for the Use and Management of Unstructured Data

The desired and feasible functionality of unstructured data systems needs to be clearly identified at all levels. An exploratory data source evaluation will then be needed to understand: the ability of various unstructured data (in public health agencies, medical records, and outside sources) to contribute to the earlier detection and assessment of threats; the level of precision supported by the data; and availability and cost.

Objectives:

32. **Determine appropriate technology tools to automate the collection, analysis, and visualization of unstructured data. Complete an inventory of methods and tools already in place across the nation.**

33. **Determine how, where, and what unstructured data would enhance situation awareness.**

34. **Determine what human resources will be needed to validate and analyze data for final analysis.**

35. **Determine what functions can and should be supported.**

Goal B. Develop the Capacity to Collect and Utilize Unstructured Data for Biosurveillance for Human Health Purposes

Intelligence and business communities both have well-developed tools and techniques for aggregating, analyzing, and using unstructured data and information. Health professionals can learn from these experiences and move ahead to obtain data, analyze them, and display information to assist decision making. As the use of unstructured data is not widespread across public health, active collaborations and sharing of best practices help accelerate progress in this area.

Objectives:

36. **Evaluate options for capturing information from existing and available sources in public health and healthcare.**

37. **Develop a public health ontology to be used in collecting web-based unstructured data.**

38. **Develop pilot systems that collect, manage, and support analysis of unstructured data as part of biosurveillance.**

39. **Evaluate effectiveness of various types of unstructured data in achieving the purposes of biosurveillance.**

Goal C. Promote Implementation and Use of Information Products and Technologies that Utilize Unstructured Data Most Effectively

Partnerships among federal, state, and international entities are necessary to achieve effective use of unstructured data. To achieve maximum impact, technologies for using unstructured data to enhance surveillance must be made widely available and must have the ability to collect data from a great variety of sources. For systems that depend on harvesting data already in public health agencies, there will be costs associated with assuring that data are captured electronically and made available to the surveillance engine that will be looking for patterns and anomalies. Training will also be needed in order to gain the best advantage from these systems. Systems that harvest and analyze data from publicly accessible sources (e.g., through the Internet) will need to be implemented nationally but will still require local- and state-level support and training in their use to be fully effective. Ongoing assessment of usefulness needs to be included in implementation plans so that science-based guidance can be shared to improve the utility of these data.

Integrated Biosurveillance Information

A critical function of biosurveillance is the ability to rapidly, reliably, and securely collect, synthesize, and share diverse biosurveillance information among public health, healthcare and other response entities. Integrated biosurveillance information can provide a more comprehensive picture of the health status of the nation's communities in order to enhance decision making. Because the responsibility for public health is shared across multiple levels of government, professional practice, and scientific disciplines, the timely exchange of reliable and actionable information is essential.

Public health leaders share a long history of working together to identify, prevent, monitor, and respond to health events. The need for a biosurveillance capability to support data integration, communication networking, and situation awareness has become more acute with globalization and the increasing availability and complexity of health-related information. Advances in technology and epidemiologic science hold the potential to support communication networks that lead to earlier awareness of hazards and events, real-time monitoring as events unfold, connectivity to the evidence, and greater access to knowledgeable public health and healthcare professionals. However, greater access to electronic health-related information comes with the responsibility to continuously evaluate what data and information are cost-effective and actionable. Integration occurs at all levels, from the local to international, and requires human interpretation and decisions at every stage. Enhancing the effort to integrate biosurveillance information is a dual challenge of creating networks to deliver data to people and simultaneously supporting networks of people to turn the data into actionable knowledge.

Situation awareness tools that support integrated biosurveillance are as simple as a telephone call between different sectors and as complex as common operating pictures that produce automated dashboards or visualization tools of community health hazards and public health events. Activities are needed to determine how to best use and build upon information sharing innovations. It is important to have a clear definition of requirements: what decisions are needed, what data may be needed, what data are not needed, what data are needed for, how data are to be collected, and what products need to be produced. This is critical for:

- Information integration and sharing at the state, local and tribal level
- Information integration and sharing at the federal level
- Information integration and sharing with the private sector
- Information integration and sharing with international partners

Key goals for this priority area include:

Goal A. Define Requirements for Multi-Level Situation Awareness Monitoring and Reporting

The critical information requirements for public health situation awareness must necessarily cast a wide net and be flexible, increasing in detail as an event unfolds. Requirements must provide for 1) identifying public health events or threats of all types worldwide; 2) monitoring potentially impacted jurisdictions when events that may be imminent; 3) estimating threat impacts to staff and resources; and 4) communicating newsworthy public health events, with appropriate qualification of validity.

Multiple types of information products for different types of clinical and public health decision makers will be needed. For example, stakeholders report a need for a common operating picture for human health accessible through Internet-based capabilities (e.g., dashboards and GIS maps) and offering varying stakeholder access rights to support differing levels of decision making. The common operating picture would be enhanced through human review and analysis coupled with computational tools capable of automated event detection through integration and analysis of multiple streams of information. This picture should offer a unique lens on human health that supplements and is augmented by other information sources. Further discussions are needed to understand and provide for this specific requirement.

Objectives:

40. **Assess existing approaches, tools, and techniques for biosurveillance information integration.**

41. **Define requirements necessary for situation awareness and bi-directional exchange of information at the local, state, federal, and international levels as well as between government and private sector.**

42. **Complete an inventory of existing sources of information, methods, and techniques and evaluate these for their effectiveness and appropriateness for a nationwide situation awareness capability.**

43. **Develop protocols for the integration of unstructured and other biosurveillance data to inform decisions before, during, and after significant health events.**

Goal B. Establish a Nationwide Capability for Integrated Biosurveillance Information Management and Exchange

Frameworks for expanded information sharing and data integration, guidelines, policies, and standard operating procedures are needed to guide public health, healthcare, and private sector stakeholders as they work together to analyze, interpret, and respond to information. Alignment with supporting frameworks for preparedness and response will be important in ensuring roles and responsibilities are understood and respected.

Objectives:

44. **Establish governance for federal programs for human health information standards and integration.**

45. **Articulate technical requirements for integration and key system improvements needed for existing health-related biosurveillance systems to ensure the usability of those systems for integration.**

46. **Leverage existing databases, systems, and networks available across federal agencies.**

47. **Develop the tools and infrastructure necessary for integration.**

Goal C. Create a Collaborative Environment for Sharing of Situation Awareness Information and Health Intelligence

Activities associated with this goal will reduce barriers to communications and create a collaborative environment for situation awareness dialogues and knowledge exchanges among multi-disciplinary experts and representatives of stakeholder groups. Biosurveillance information products will include complete and consistent guidance to direct prevention and control actions and will be developed with and distributed among state and local public health departments as trusted agents. Achieving improved situation awareness will only work with support from stakeholders. Memoranda of agreement (MOAs) or understanding (MOUs) are means by which to establish a clear delineation of working relations between organizations. These agreements are needed to ensure that a trusted environment for open and transparent discussions is established where preliminary and incomplete information can be posted without the need for stringent levels of clearance or editing.

Active outreach opportunities will be pursued to ensure that the private sector is also represented, meeting the needs of their constituents and identifying ways that they and their organizations can participate in biosurveillance efforts. Similarly, expanded communications—along with greater coordination and cooperation—will take place among the larger scientific, government intelligence, and industrial sectors (e.g. Epi-X). These synergies will prove vital in advancing basic knowledge of biosurveillance, in creating new approaches to early detection, in creating new technologies to improve environmental surveillance, and in fostering a shared responsibility for protecting the nation's health.

Objectives:

48. **Establish MOUs with agencies and stakeholders for participation and information sharing.**

49. **Develop multi-disciplinary communities of practice to foster learning and knowledge exchange.**

50. **Develop the policies, tools, and incentives necessary to collaborate and share knowledge and expertise.**

51. **Promote linkages and partnerships with other international, federal and state information-sharing processes and initiatives as appropriate.**

52. **Create a mechanism to provide nationally generated analyses and threat assessments to state, territorial, tribal, and local health authorities in a timely fashion.**

Goal D. Provide Technical Assistance and Support State and Local Health Departments to Integrate Biosurveillance Information Products and Processes

To achieve maximum impact, integration technologies, situation awareness information products, collaboration practices, and standards must be made widely available at all levels of public health and healthcare. States and local public health organizations must develop scientific agendas and programs to determine how these new tools will become part of routine public health practice. Where value can be demonstrated, state and local stakeholders must have the resources to implement these capabilities.

Global Disease Detection and Collaboration

The 2007 *World Health Report* notes that "the world is at increasing risk of disease outbreaks, epidemics, industrial accidents, natural disasters and other health emergencies which can rapidly become threats to global public health security."[16] The report recognizes that "since the 1970's, newly emerging diseases have been identified at the unprecedented rate of one or more per year." The 2008 document *World at Risk: Report of the Commission on the Prevention of WMD Proliferation and Terrorism* states "unless the world community acts decisively…it is more likely than not that a weapon of mass destruction (with high probability it will be a biological weapon) will be used in a terrorist attack somewhere in the world by the end of 2013." [17] Infectious diseases such as Ebola hemorrhagic fever, AIDS, and SARS are all recent arrivals on the world stage. The Institute of Medicine's 2003 report *Microbial Threats to Health* recommends actions necessary to meet these global health challenges. The report stresses that the United States should seek to enhance the global capacity for responding to infectious disease threats, and it should take a leadership role in promoting the implementation of a comprehensive system of surveillance for infectious diseases wherever they arise.

At the same time, advancements in transportation, communications, and manufacturing have made us an interconnected society, a global village, where events that impact one part of the world can spread rapidly to affect other regions. For example, in September 2008, melamine contaminated infant formula and related dairy products originating in China were found in locations world-wide.[18] The breadth of potential global public health threats is recognized in the provisions of the revised International Health Regulations [IHR (2005)] with its all-hazards approach to assessing serious public health threats. These regulations are designed to prevent and protect against the international spread of diseases while minimizing interference with world travel and trade. They prompt countries to work together to share information about known diseases and public health events of international concern.

Visibility of emerging health threats around the world is contingent on the local capability to detect and investigate those threats and on a continued connection to the international health workforce. Clinical surveillance of disease is inadequate in much of the developing world due to limited funding for public health infrastructure. Attention needs to be focused on improving response and detection capabilities in the developing world where infectious diseases are most prevalent and opportunities for spread are considerable.

A major challenge to global disease surveillance and detection is to not only detect and report well-characterized known infectious diseases, but also to detect novel, emerging, or reemerging diseases in relatively low-tech environments. There is a corresponding need to develop redundant and complementary systems for infectious disease detection that go beyond the yield of traditional surveillance systems and approaches.

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[16] World Health Organization, *The World Health Report 2007: A Safer Future: Global Public Health Security in the 21st Century* (Geneva: WHO, 2007):10.

[17] *World At Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008.

[18] FDA Updates Health Information Advisory on Melamine Contamination, http://www.fda.gov/bbs/topics/NEWS/2008/NEW01891.html. Accessed October 21, 2008; Melamine-contamination event, China, September - October 2008, http://www.who.int/foodsafety/fs_management/infosan_events/en/index.html. Accessed March 5, 2010.

The vision for global surveillance and collaboration is to have global surveillance capacity at home and abroad working collaboratively with WHO and other international partners to recognize, communicate, and respond to public health events of international concern. Actions to realize this vision include leveraging existing global surveillance systems, enhancing and building global surveillance and response capabilities at home and abroad, and strengthening partnerships between the United States and the international health community. Since many efforts exist across the federal sector, coordination is needed. The Executive Office of the President (EOP), along with a designated lead federal agency, should coordinate U.S. government policy and programs on global biosurveillance. The lead agency should improve communication across U.S. federal entities and should craft, coordinate, and implement multilateral initiatives that strengthen core capabilities in global biosurveillance and respond to public health emergencies as outlined in the revised IHR.

Key goals for this priority area include:

Goal A. Strengthen Partnerships and Leverage Resources of U.S. Government (USG) and Non-USG Partners

An integrated and coordinated global biosurveillance network is critical in achieving and containing emerging health threats. USG agencies will work with their partners to integrate activities and create synergies across existing programs and communications networks. These network partnerships include those associated with WHO and programs such as CDC's Global Disease Detection (GDD) program, the Early Warning Infectious Disease Surveillance program (EWIDS), the National Biosurveillance Integration System (NBIS), the Global Public Health Information Network (GPHIN), DoD's Global Emerging Infectious Surveillance and Response System (GEIS), the Program for Monitoring Emerging Diseases (ProMED-mail), Global Outbreak Alert and Response Network (GOARN), and others.

Objectives:

53. **Develop a strategic plan to strengthen partnerships between WHO, USG agencies, and non-USG partners in global disease detection efforts. Include collaboration across USG initiatives to leverage existing in-country programs and build links between them.**

54. **Collaborate with WHO to define responsibilities and integrate initiatives across WHO and USG agencies to strengthen core capacities in global disease detection and response efforts.**

55. **Explore additional partnerships with non-USG partners for furthering global disease detection activities.**

56. **Strengthen partnerships with non-risk/lower-risk countries that have strong resources for global surveillance and response (e.g., European Union member states, Canada, and Japan).**

Goal B. Adopt a Risk-Based Approach to Focus Efforts in Areas of Greatest Vulnerability, Need, and Impact

Adoption of a strategic risk-based approach will help to anticipate vulnerabilities and to detect and control the global spread of disease. A renewed effort focusing on geographic hotspots is needed because they have high population density or because they experience recurring

infectious disease outbreaks (e.g., Ebola outbreaks in Uganda, Kenya, and the Democratic Republic of Congo; or chikungunya, Nipah, and influenza outbreaks in Southeast Asia). A focus on the highest priority threats will ensure more rapid identification and response to a wide range of emerging infections, including respiratory syndromes, diarrheal diseases, food borne illnesses, and zoonotic diseases, through integrated disease surveillance, prevention, and control activities.

Objectives:

57. **Form a steering committee with infectious disease and other subject matter experts to assess and update the top priority threats or pathogens of global concern.**

58. **Develop and routinely update the top priority threats or pathogens to which biosurveillance capabilities should be directed on a global scale.**

59. **Identify the key regions of the world (e.g., regions with significant potential for emerging infectious diseases but with limited local capacity for detection and control) on which to concentrate global biosurveillance efforts.**

60. **Establish a standardized process for allocation of global biosurveillance resources. The process would use criteria such as record of past collaboration, ability of local government to ensure personnel safety, population density of region, availability of local resources, and history of emerging threats to assist in decision-making.**

Goal C. Build In-Country Public Health Facilities and Expertise in support of IHR 2005

Biosurveillance activities need to focus on building in-country capacity, especially in areas with limited local resources and/or infrastructure to support rapid disease detection and effective response activities. This includes ensuring appropriate containment facilities, equipment, policies/practices, security precautions, and occupational health programs to encourage working safely with highly pathogenic agents, and strengthening laboratory operations by standardizing test procedures, laboratory protocols, and management practices.

International workforce development, laboratory and epidemiology capabilities have been a cornerstone of U.S. foreign assistance and facilitate awareness of health threats and of the U.S. role as trusted consultants in the prevention and control of health emergencies in the international community. In addition, investments in disease detection and capacity development support the implementation of the revised International Health Regulations (IHR 2005).

Objectives:

61. **Strengthen international partnerships and educational programs that build surveillance and laboratory capability and capacity.**

62. **Strengthen partnerships with non-risk/lower-risk countries (e.g., European Union member states, Canada, and Japan) that have strong capacity building resources for global surveillance and response.**

Goal D. Support Efforts to Connect the Worldwide "Network of Networks" to Foster More Rapid Information Sharing and Earlier Detection

Although many developed countries are strengthening their surveillance systems and capacities, the required health information infrastructure is lacking in parts of the world that may be most vulnerable to emerging health threats. The existing network of surveillance by health ministries,

institutes of public health, multinational agencies, and laboratory and institutional networks has gaps in geographic coverage and often suffers from poor information flow across national borders. In addition, focused efforts are needed in health risk communication and technology to strengthen communication with affected populations during outbreaks and to assure that public health responses are culturally, technologically, and scientifically appropriate and disseminated in the most cost-effective, time-sensitive manner possible.

Objectives:

63. Develop regional mutual assistance arrangements for information and health alert resource sharing through interoperable electronic networks/systems to improve timely reporting for public health emergencies of international concern in support of the World Health Organization's 2005 revised International Health Regulations.

64. Determine requirements for field technologies that support situation awareness and real-time data analysis across international borders.

Biosurveillance Workforce of the Future

Championing the importance of the human element in biosurveillance is critical to the success of *The Strategy.* Maintaining current capabilities and meeting future challenges will require an extensive, well-trained, and strongly motivated workforce. Building capacity will require vision, commitment of resources, and creative solutions to extend the skills of the workforce.

The critical functions of public health surveillance and investigation of exposures and acute human health events are widely distributed across local, state, federal and international jurisdictions. Professionals from diverse disciplines provide the range of skills necessary for biosurveillance to work effectively. As we transition from biosurveillance today to biosurveillance of the 21st century, the nation will continue to need people trained in fields that traditionally have been associated with surveillance and investigation, such as in epidemiology, laboratory sciences, and environmental health. In the healthcare sector, astute clinicians, e.g., infection preventionists - formerly known as infection control professionals - remain a critical link in biosurveillance.

Professionals in other disciplines, such as pharmacists and medical examiners, play an increasingly important role as well. Animal and plant health experts, veterinarians, plant pathologists, and agricultural specialists also contribute to biosurveillance given their expertise in zoonotic and environmental-associated health events. The legal, justice, and security realms are important partners that are collaborating more closely with public health, especially since 9/11. Their participation has been apparent during recent pandemic influenza response planning efforts and will continue to be integral to biosurveillance. Specialized skills are needed to perform and support data analysis, statistical modeling and information fusion to achieve health intelligence. In addition, professionals are also needed from other diverse fields including physical, chemical, radiological, mathematical, informatics, and computational sciences. As we move forward, interdisciplinary knowledge and specialized expertise will be critical to assimilating traditional information sources with new systems and methods for collecting and analyzing health information.

The vision for the biosurveillance workforce needs to articulate both what the responsibilities will be for primary public health professionals (epidemiologists, laboratorians, environmental health specialists, and informaticians) and how to engage and coordinate frontline clinicians (physicians, veterinarians, nurses, and others) and the various other stakeholders involved. Innovative strategies that include working with health departments and schools of public health must be applied to recruit and retain workers from diverse fields. Cross-training of personnel should aid in incorporating new technologies into public health practice. New curricula are needed, and should be applied through proven and new public health fellowship programs, training centers, and mentorship opportunities to produce the next generation of public health professionals. Simultaneously, similar needs must be met for healthcare professionals and the range of other disciplines participating in biosurveillance. Comprehensive and systematic efforts to enhance workforce capability ideally would result in cohesive networks of competent professionals responsible for biosurveillance functions.

Significant gains in biosurveillance workforce capacity have been achieved at the state and local level since 2002. Public health emergency preparedness funding has enabled the establishment of trained epidemiologists, laboratorians, and other public health professionals. These efforts

have not addressed the issues of an older public health workforce, nor the cross-training of individuals in other disciplines. Combined with waning federal funding and strapped state budgets, the progress that has been made is threatened and additional critical progress is delayed. Workforce capacity must be maintained while a human capital strategy is developed as part of an integrated National Biosurveillance Enterprise.

A clearly delineated human capital strategy is needed to articulate an integrated workforce approach that views the many participants as a pool of talent to be configured and developed strategically to create the most public benefit. The coordinated governance structure will engage multidisciplinary stakeholders to facilitate planning and establishing workforce standards and competency levels across all jurisdictions and disciplines. Strengthened inter-sector collaboration is needed to leverage public health, healthcare, academia, the private sector and others to better articulate roles, determine appropriate training needs, and guide professional standards, policies, and funding to build the necessary human infrastructure.

A human capital strategy will provide an overarching framework for defining what is needed and for managing the multiple stakeholders and entities involved. This human capital strategy will need to address several pressing challenges including:

- **The magnitude of the human capital investment in biosurveillance.** To ensure a continuously strong biosurveillance workforce at the local, state and federal levels, an assessment is needed of the current workforce and the assets invested to achieve the current level of biosurveillance. The assessment must include those in public health agencies with the legal authority to conduct surveillance and investigate possible warning signals, as well as those in healthcare organizations and other key stakeholders. Doing so will enable a determination of what ongoing human capital infrastructural investment will be needed to maintain and enhance the workforce to meet the vision of the future.

- **Frameworks for continuous learning and training**. A broadened training and education framework is needed to ensure current and future workers are prepared to meet the challenges ahead. Such a system would articulate professional roles and competencies necessary for biosurveillance and offer training and career-development paths. Doing so in an efficient manner is a step toward ensuring availability of needed workers and job opportunities, training, and viable career paths for health professionals at the local, state, national and global levels.

- **Recruitment and retention of professionals**. Serious public health and healthcare workforce shortages already exist. States and communities nationwide report needing more public health nurses, epidemiologists, laboratory workers, informaticians, statisticians, and environmental health experts. The Association of Schools of Public Health (ASPH) estimates that 250,000 more public health workers will be needed by 2020 just to maintain current capacity.[19] Innovative strategies are needed to address the underlying factors behind the

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[19] ASPH 2007 State Public Health Survey Results, and 2004 and 2006 surveys by the Association of State and Territorial Health Officials

shortfalls, such as the exodus of retiring workers, an insufficient supply of trained workers, inadequate funding, and uncompetitive salaries and benefits.[20]

- **Access to specialists**. Professionals performing biosurveillance need access to specialists such as statisticians, epidemiologic and mathematical modelers, information and decision scientists, informaticians, natural language processing experts, analytic data management programmers, knowledge managers, and disease and GIS mapping experts. Insufficient numbers and competency in biosurveillance exist in these groups at a time when demands on the health system are increasing.

Key goals for this priority area include:

Goal A. Assess Current Biosurveillance Workforce Capability, Identify Gaps and Articulate Needs

Creating a stronger biosurveillance workforce begins with a solid assessment of workforce requirements and the interrelationships between local, state, federal, and other stakeholder agencies. Next comes an assessment of reliable and available workforce data and a keen awareness of trends at the local and national levels that have an impact on the workforce pool, affect the workforce's strengths and weaknesses, and influence the skills and resources needed. The assessment must recognize how biosurveillance events are typically detected and communicated. This includes an emphasis around the intersection of healthcare and public health. It is about ensuring that the nation has and will continue to have the right people with the right skills in the right job at the right time performing their assignments efficiently and effectively. Activities will leverage existing resources to create multi-level baselines and an integrated human capital workplan that will meet the following objectives:

Objectives:

65. **Define which biosurveillance workforce requirements and strategies (laboratory and electronic systems) are essential at each level of the public health system.**

66. **Catalog current human capital and technological investment in biosurveillance and initiatives to plan for the future biosurveillance workforce at the state, territorial, tribal and local levels.**

67. **Characterize and model staffing requirements in the current workforce across public health and healthcare; assess further need and future supply.**

68. **Develop a human capital plan as part of an integrated National Biosurveillance Enterprise.**

69. **Maintain local and state biosurveillance workforce until objectives and funding needs for the National Biosurveillance Enterprise have been defined.**

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[20] Public Health Workforce Shortages Imperil Nation's Health, Center for Studying Health System Change, Research Brief, No. 4, Apr 2008.

Goal B. Ensure a Competent Biosurveillance Workforce

A national training and education framework is needed to articulate professional roles and competencies necessary for the biosurveillance workforce, and to offer guidance on training needs as well as career-development paths. Competency frameworks defining the necessary skills and skill levels, such as one developed by CDC and CSTE for government public health epidemiologists, offer guidance for state and local education planning. Development of curricula based on competency models would expand into new areas important to biosurveillance including informatics, genomics, cultural competence, community-based participatory research, global health, and ethics. Entry level, continuing, and advanced training curricula must be provided for the biosurveillance workforce. Collaborations among public health, healthcare, academia, and the private sector must be strengthened to leverage resources, guide professional standards, and develop educational policies for continuing education and academic curricula.

Objectives:

70. **Develop competency models for key biosurveillance roles both for routine public health operations and adequate surge capacity, leveraging existing work when applicable.**

71. **Develop curricula based on competency models.**

72. **Expand proven educational programs such as fellowships and training networks.**

73. **Identify opportunities for cross-disciplinary training and education.**

74. **Identify opportunities and strategies for entry level, continuing, and advanced level education.**

75. **Enhance the capability within partner organizations and associations to influence professional standards and provide training and education.**

76. **Establish career tracks for interagency service and National Biosurveillance Information System (NBIS) participation among federal agencies that are part of the NBIS.**

Goal C. Develop Competitive Strategies to Recruit and Retain an Effective Biosurveillance Workforce

Effective biosurveillance requires more than training; building workforce capacity through better recruitment and retention strategies is also needed. The capacity-building function of the federal government will be crucial to ensuring that state and local levels of government have the resources—human, financial, and organizational—needed to carry out the responsibilities delegated to them by the federal government or for which they are responsible by law. New policies and incentives must also be created to make careers in public health, and especially those related to biosurveillance, an attractive professional path, particularly for the emerging workforce and for those changing careers. At the national level, the biosurveillance enterprise should include efforts to recruit, hire, and retain competent, trained personnel involved in planning, evaluation, designing, and executing biosurveillance programs at local, state, and federal levels.

The nation—and the world—will continue to need people trained in health fields, such as in epidemiology, laboratory sciences, biostatistics, environmental health, that traditionally have been associated with surveillance and investigation. In addition to addressing shortfalls in critical

biosurveillance positions, however, there is a need to recruit people from other diverse fields including physical, chemical, mathematical, informatics and computational sciences (to apply their expertise to biological questions); ecology and evolutionary biology (to help with an understanding of the human–microbe interface); and the plant and veterinary sciences (to help in understanding the flow of diseases between humans, animals, and plants).

Objectives:

77. **Develop model position descriptions (based on competencies) and job classifications, where lacking, to facilitate hiring processes.**

78. **Design and develop innovative recruitment strategies and related career paths for biosurveillance positions.**

79. **Promote use of internships, fellowships, career-experience opportunities, and tuition-for-service programs as recruitment and retention strategies.**

80. **Explore recruitment of technical experts to government through the use of Intergovermental Personnel Assignments (IPAs) and other mechanisms.**

Goal D. Establish a Governance Body for Biosurveillance Workforce

Active and timely communication and collaboration among workers representing all public health jurisdictions, agencies, and healthcare communities is a key feature needed for an effective biosurveillance environment. A governance structure administered at the national level will assure consistency in workforce planning and establishment of workforce standards and competency levels across jurisdictions and disciplines.

Activities will leverage governmental, public-private, and academic partnerships to build the necessary infrastructure and to reach and engage multi-disciplinary stakeholders. Collaborations among traditional public health partners (such as the Association of State and Territorial Health Officials, National Association of County and City Health Officials, Council of State and Territorial Epidemiologists, and Association of Public Health Laboratories) and other important professional organizations (such as the American Medical Association, National Environmental Health Association, and American Medical Informatics Association) must be strengthened.

Objectives:

81. **Ensure leadership and support for nationwide biosurveillance workforce initiatives.**

82. **Establish regional and cross-jurisdictional networks of biosurveillance professionals in public health and healthcare.**

83. **Strengthen academic partnerships and establish biosurveillance-related centers of excellence.**

84. **Strengthen communication and interactions with private sector.**

85. **Strengthen organizational capacity of key partners working in support of competency development, training, and biosurveillance workforce initiatives.**

The Way Forward

The Strategy provides the foundation for a long-term effort to improve nationwide capability to manage health-related data and information for early warning of threats and hazards, early detection of adverse human health events, and overall situation awareness so that effective actions can be undertaken to mitigate health effects. It is important in this effort to first recognize the current nationwide capability and then to build upon it.

Active Outreach and Continued Development

Within the federal government, HHS and CDC will continue to play an active coordinating role in developing and implementing *The Strategy*. In addition to executing its specifically assigned responsibilities and initiatives, CDC will serve as the primary federal point-of-contact for state and local governments, the private sector, and the American people on issues related to biosurveillance for human health.

In accordance with that role, CDC will disseminate *The Strategy* widely, at the same time seeking additional updated input from stakeholders across the nation who contribute to and will benefit from the products of biosurveillance for human health. *The Strategy* will continue to be maintained in a manner that reflects progress, new ideas, increased knowledge, and changes in the healthcare industry and the related political environment. In this way, it is intended that *The Strategy* will be a catalyst for the unification and integration of the work of all concerned stakeholders.

Planning activities will continue to reflect an emphasis on partnering closely with stakeholders, tapping into their knowledge, experience, and information requirements, and adapting information products that will be supportive of them in their daily activities, as well as in preparedness planning. It is hoped that such an open and transparent approach toward strategy development will build confidence in the nation's biosurveillance capability and its management. Nationwide dialogue will also be encouraged to reach agreement on those critical issues for which there is not yet consensus.

In support of collaboration and further development, the activities cited below, among other coordination activities, will occur:

- Biosurveillance for Human Health Work Groups will continue to collaborate on issues of critical interest in the field of biosurveillance and on refining *The Strategy,* its principles, priority areas, and goals.

- The Work Groups and other partners will also begin to focus on key elements of *The Strategy's Concept Plan for Implementation of the National Biosurveillance Strategy for Human Health (Concept Plan)*, including identifying a governance model for collaboration (see details below), compiling a comprehensive Registry of existing biosurveillance activities, and on developing an approach to communicating the efforts of this biosurveillance enterprise more widely.

- The National Biosurveillance Advisory Subcommittee (NBAS) will continue to provide guidance and recommendations that will influence *The Strategy*.

- Recommendations made by other key organizations concerned with biosurveillance activities, such as the Government Accountability Office and the Institute of Medicine, will be incorporated into *The Strategy* as appropriate.

- Work will continue on development of a "vision" for public health surveillance, as follow-on to a 2009 workshop which included leading CDC scientists and analysts, along with key partners. The meeting addressed the topics of lexicon, global surveillance, IT, workforce, data sharing, and analysis, and will result in a draft vision statement. This activity will, in turn, help shape *The Strategy's* overall approach to enhancing biosurveillance capability.

- Outreach will be undertaken to important disciplines, such as the veterinary, plant, and environmental health communities whose involvement and input are critical to a comprehensive strategy.

- *The Strategy* will continue to be integrated and aligned with relevant U.S. laws and executive orders which address biosurveillance and other related official policies such as those noted in the National Health Security Strategy and the National Response Framework.

- A governance structure will be proposed to address biosurveillance challenges and opportunities and to provide a forum for the voicing of concerns, offering of suggestions, and decision-making. It will enhance relationships, increase effectiveness via joint effort, provide leadership, and support cohesiveness among participants. The important role of governance for achieving success of *The Strategy's* overall goals and objectives is addressed below.

Governance

In the course of development of *The Strategy*, it has become evident that there is a need for the establishment of an overarching intergovernmental framework, (i.e., a governance "enterprise") to monitor and implement progress in *The Strategy's* priority areas, goals and objectives. There is currently no encompassing organizational structure that has an authoritative role in carrying out the objectives of a national biosurveillance system or in setting out a related implementation plan. The absence of authoritative governance has slowed progress in bringing into closer cooperation the many separate surveillance programs nationwide serving a variety of purposes.

Governance is a recurring theme underlying most of the important goals and objectives of *The Strategy*. Sometimes the call for governance is explicit. More pervasively, with regard to a host of other objectives (to create policies and principles, ensure leadership and support, establish forums, engage stakeholders, coordinate planning, recommend resources, etc.), all implicitly require some form of organizational framework to bring them to fruition. This conclusion has been reinforced repeatedly in discussions with *The Strategy* working groups and in wide-ranging consultations with stakeholders at all levels.

The NBAS report also highlights the need for a governance structure over the biosurveillance process as one of its most important recommendations. It calls for the Executive branch to define the strategic goals and priorities of federal investments in biosurveillance activities and technologies and for the White House to establish an Interagency Biosurveillance Coordination Committee to ensure implementation. "The Committee" would, in addition to setting strategic

goals and priorities, ensure that programs are subject to performance assessments and establish clear criteria to evaluate biosurveillance activities. The NBAS, in recommending that biosurveillance governance be elevated to a high level within the Executive branch, has touched on a key principle that is also implicit in *The Strategy*, that establishment of an empowered organizational oversight body is imperative to ensuring the realization of significant improvements in the national biosurveillance capability.

In response to this clear call for an overarching authority over biosurveillance improvement, the *Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health (Concept Plan)* sets out guidelines, optimum organizational traits, and a proposed model for governing the biosurveillance enterprise. The model structures which were reviewed and considered by stakeholders as noted in the *Concept Plan* include a non-federal entity, a federal interagency working group, and a federal advisory committee. The *Concept Plan* describes a preferred governance model, and because of estimates that the model may take time to implement due to organizational complications, it also lays out an interim model. Both the interim and optimum models adopt the federal advisory committee approach, and would consist of members representing varying levels of government and the private sector; however, the interim approach could be implemented more quickly.

Two principles should be maintained as discussions proceed on what governance model will ultimately be selected by stakeholders and decision makers. First, preserving the principle of collaboration and consensus among all levels of participants throughout the process is essential.. Second, wherever practical, the governance structure should be built upon existing surveillance structures rather than creating new organizations and mechanisms. The governance framework is intended to interact with other agencies and governance bodies in accordance with *The Strategy's* commitment to leverage existing surveillance systems and relationships when possible.

While the *Concept Plan* presents a preferred governance model recommendation, it is anticipated that there may be modifications to the basic approach and that alternative proposals may also emerge. This is all in accordance with the objective of welcoming broad input and fresh ideas into the process, and encouraging buy-in on the part of all stakeholders to the ultimate governance model to be utilized. It is also envisioned that stakeholders will provide regular feedback on the effectiveness of the governance model being employed, with the ultimate goal of continued enhancement of nationwide biosurveillance capability.

National Biosurveillance Registry for Human Health

The National Biosurveillance Registry for Human Health (NBRHH) is being developed as a means to enhance our nation's biosurveillance capability by first assessing what assets are currently available. The NBRHH is a comprehensive, electronic registry of information about five types of surveillance-related activities:

- Surveillance systems—electronic-based (Information Technology or IT) and paper-based
- Registries
- Surveillance programs
- Collaboratives established to advance surveillance science and practice

- Tools that support surveillance

The goal of the NBRHH is to provide information about currently available surveillance activities pertinent to human health across a number of different domains (e.g., human, animal, environmental, food, plant, and vector). These data will be most useful to decision makers at various levels of government who either engage in surveillance related activities or rely on timely data in response to a public health event. They will also be useful to program managers who are planning new systems or those who wish to partner with other programs conducting surveillance in the same area or using the same platform to collect surveillance data.

Populating the NBRHH will be done on a voluntary basis by program points of contact, via an online survey instrument. Each point of contact for a system or program will input descriptive information into this survey, such as: name, affiliation, funding and performance measures. Actual surveillance data will not be available through this registry. The NBRHH will include only information <u>about</u> these systems and activities. It will not contain any data collected by them.

Achieving a Common Purpose

With a public health system having decentralized authorities and capabilities for early warning, detection, and response, leadership is needed across the biosurveillance enterprise to ensure that jurisdictions at all levels are protected from health threats and vulnerabilities. Through shared information and standards of practice and performance, a nationwide biosurveillance capability for human health serves as a sentinel to herald early action and the foundation of competent decision-making as events evolve. At the same time, state and local governmental leadership, supported by sufficient federal funding, can continue their responsibilities for creating and sustaining local capacities.

Achieving the right balance between improving near-term biosurveillance capability and building for the future will require openness and consensus building. New biosurveillance requirements will increase the need for investments – both in building the national enterprise of complementary systems that produces integrated health intelligence and in strengthening the comprehensiveness, quality, and timeliness of individual biosurveillance systems in place across the nation. A balancing and prioritizing of new initiatives and existing programs, with appropriate trade-off decisions, will be needed. Use of *The Strategy's* goal framework will help integrate individual agency plans into a common, comprehensive, costed plan. With a common *Strategy* as a touchstone, coordinated guidance will be developed to simplify and harmonize the various existing and planned federal- and state-level biosurveillance activities for human health.

The Strategy will not dictate agency policy, but will allow each agency to plan and implement programs to fulfill its responsibilities in biosurveillance and be accountable for its performance. Baseline and investment-oriented measures will evaluate the effectiveness of the activities and programs, allowing agencies to justify their investments, make resource allocation decisions, and adjust priorities accordingly.

Through the implementation of *The Strategy*, the United States can fulfill the vision of Biosurveillance in the 21st Century. This vision will only be achieved through work performed at all levels of government, in healthcare, academia and the private sector. Active participation is required of all stakeholders and sustained leadership and action is needed at the federal level. *The Strategy* offers a way forward for such national leadership and action.

Appendix A: Lists of Contributors

We have relied heavily on our workgroups to provide feedback on *The Strategy*. Many in the workgroups below including individuals from federal agencies, state and local public health departments, academic and professional organizations, and the private sector provided extensive comments on this *Strategy* and we are grateful for their contributions. Membership in the workgroups is subject to periodic change. On-going involvement and comments from active participants will continue to guide *The Strategy's* evolution.

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Appendix B: Acronym Glossary

A
ACD	Advisory Committee to the Director of CDC
AHIC	American Health Information Community
AMIA	American Medical Informatics Association
APHL	Association of Public Health Laboratories
ARRA	American Recovery and Reinvestment Act of 2009
ASPH	Association of Schools of Public Health
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials

B
BGP	Biosurveillance Governance Partners
BIWAC	Biosurveillance Indications and Warning Analytic Community

C
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
COTPER	Coordinating Office for Terrorism Preparedness and Emergency Response
CSTE	Council of State and Territorial Epidemiologists

D
DHS	Department of Homeland Security
DOD	Department of Defense

E
EARS	Early Aberration Reporting System
EHR	Electronic Health Records
EIP	Emerging Infections Program
ELR	Electronic Laboratory Results
EOP	Executive Office of the President
ESSENCE	Electronic Surveillance System for Early Notification of Community-Based Epidemics
EWIDS	Early Warning Infectious Disease Surveillance

F
FACA	Federal Advisory Committee Act
FSIS	Federal Surveillance Inspection System
FTE	Full-time employee

G
GAO	Government Accountability Office
GEIS	Global Emerging Infectious Surveillance and Response System
GIS	Geographic Information System

GOARN   Global Outbreak Alert and Response Network
GPHIN   Global Public Health Intelligence Network

H
HHS   Health and Human Services
HIE   Health Information Exchange
HIMSS   Healthcare Information and Management Systems Society
HIT   Health Information Technology
HITSP   Healthcare Information Technology Standards Panel
HL7   Health Level Seven
HSPD-21   Homeland Security Presidential Directive -21

I
IBGHH   Interim Biosurveillance Governance for Human Health
ICD   International Classification of Diseases
ICLN   Integrated Consortium of Laboratory Networks
IHR   International Health Regulations
IRN   Integrated Response Network
ISDS   International Society for Disease Surveillance
IT   Information Technology

J
K
L
LIMS   Laboratory Information Management Systems
LIS   Laboratory Information Systems
LOINC   Logical Observations Identifiers, Names, Codes

M
MOA   Memoranda of Agreement
MOU   Memoranda of Understanding

N
NACCHO   National Association of County and City Health Officials
NBAS   National Biosurveillance Advisory Subcommittee
NBIC   National Biosurveillance Integration Center
NBIS   National Biosurveillance Integration System
NBRHH   National Biosurveillance Registry for Human Health
NHIN   Nationwide Health Information Network
NIOC   NBIS Interagency Oversight Council

O
OMB   Office of Management and Budget
ONC   Office of the National Coordinator for Health Information Technology
OPDIVS   Operating Divisions

OSTP   Office of Science and Technology Policy

P

PAHPA   Pandemic and All Hazards Preparedness Act
PFGE   Pulsed Field Gel Electrophoresis
PHIN MS   Public Health Information Network Messaging System
PHIS   Public Health Information System
PL   Public Law
PHLIP   Public Health Laboratory Interoperability Project
ProMED   Program for Monitoring Emerging Diseases

Q
R

RECs   Regional Emergency Coordinators
RSPH   Rollins School for Public Health

S

SA   Situation Awareness
SLTT   State, Local, Tribal and Territorial
SME   Subject Matter Expert
SOP   Standard Operating Procedure

T
U

USDA   United States Department of Agriculture

V
W

WHO   World Health Organization

X
Y
Z