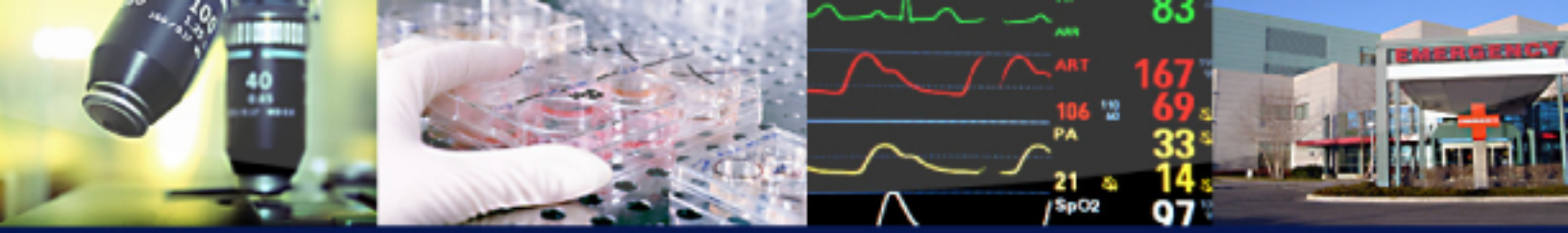

COORDINATING ENHANCED NATIONWIDE BIOSURVEILLANCE FOR HUMAN HEALTH

CONCEPT PLAN

For the Implementation of the National Biosurveillance Strategy for Human Health

January 2010

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Coordinating Office for Terrorism Preparedness and Emergency Response
Biosurveillance Coordination Unit

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EXECUTIVE SUMMARY

This *Concept Plan for Implementation of the National Biosurveillance Strategy for Human Health (Concept Plan)* responds to Homeland Security Presidential Directive 21 (HSPD-21), which was issued in recognition of significant health-related threats to the residents of our nation. Included in HSPD-21, as a critical component of public health and medical preparedness, is the development of a "nationwide, robust, and integrated biosurveillance capability." The U.S. Department of Health and Human Services (HHS) charged the Centers for Disease Control and Prevention (CDC) with leading the implementation of this component of HSPD-21. In 2008, CDC's Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) established the Biosurveillance Coordination Unit (BCU) to respond to the biosurveillance mandate of HSPD-21.

The basis for the efforts under HSPD-21 can be found in several prior executive and legislative actions. HSPD-9 and HSPD-10 created a new biological threat awareness capacity and established an integrated warning system. The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), among other recommendations, proposes new national surveillance methods. And finally, PL 110-53, which implemented the recommendations of the 9/11 Commission, mandates the federal government identify and track biological events of national concern by integrating and analyzing data. Each of these actions provided the building blocks for the foundation of biosurveillance.

Biosurveillance, as envisioned under HSPD-21, calls for integrating and efficiently managing health-related information across a wide range of information systems over the life cycle of an event. HSPD-21 also calls for integrating not only human health information but information about animals (domestic and wild), plants, and the environment when they are relevant to protecting human health. A successful biosurveillance capability requires quality data and information and relies on human judgment and a skilled workforce. Challenges in achieving an integrated and nationwide biosurveillance system include the need for the federal government to collaborate with the primary owners of these data, that is, with State, tribal, territorial, and local government and with organizations and individuals outside of government. Another challenge for creating an integrated nationwide biosurveillance capability is the wide range of sources of health-related data, including public health, environmental, plant, animal or vector monitoring systems, laboratories, medical records, administrative records, police records, vital records (e.g., birth and death certificates), and non-traditional sources such as open press and classified reporting. Another key requirement will be to develop methodologies, tools, and models to systematically harvest and contextualize all sources of biosurveillance data.

This broader definition necessitates interagency discussions to define the trigger points for policy decisions on countermeasure and response options, and planning exercises to incorporate all sources of biosurveillance information in those decisions.

A series of actions have been undertaken in response to HSPD-21, including development of the *National Biosurveillance Strategy for Human Health* (*Strategy*), working with the National Biosurveillance Advisory Subcommittee (NBAS), and development of this *Concept Plan*. The *Strategy* was developed with input on priority areas from multiple informal working groups representing Federal, State, local, tribal, public health, and clinical partners which provided individual ideas and input into the Strategy. The purpose of the *Strategy*, initially released in

December 2008, is to guide the development of capabilities that will safeguard the public by building on current programs and activities, particularly where they connect clinical health-care providers with public health professionals. The National Biosurveillance Advisory Subcommittee (NBAS) consists of prominent public and private biosurveillance stakeholders and contributors and makes recommendations to the CDC Advisory Committee to the Director on measures to improve biosurveillance capability nationwide. The initial report from the NBAS entitled "Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats" was released in October 2009.

This *Concept Plan* outlines the next steps to be taken in light of the *Strategy* and recommendations provided by the NBAS and accepted by the federal government. The *Concept Plan* is not a concept of operations. That is, it does not include specific operational processes for implementing the *Strategy*. It does however, present a conceptual framework for implementation and includes in broad strokes the major pillars to support the priority areas in the *Strategy*. Multiple groups representing Federal, State, local, tribal, public health and clinical partners were convened to provide input regarding current biosurveillance capability and requirements for the future. The *Concept Plan* proposes a framework to facilitate collaboration among federal agencies and other sectors in the creation of next-generation biosurveillance capabilities. It sets out the need for a governance structure to enable collaboration, establishes an approach to identify current biosurveillance activities that address priorities in the *Strategy*, and maps the communications activities needed for biosurveillance.

The development of a national biosurveillance capability depends on the collaborative efforts of partners and stakeholders across public health and at all levels of government. One possible governance structure for bringing diverse biosurveillance stakeholders together is a Federal Advisory Committee and an Interagency Working Group under the Executive Office of the President. Alternatively, a Federal Advisory Committee could undertake such activities under the direction of the Secretary of HHS with participants from across government and various other sectors.

The landscape of biosurveillance is complex, and understanding the national biosurveillance capability that addresses the priorities of the Strategy requires identification of the systems, tools, programs, and collaboratives currently in use. An electronic registry or catalog of the current biosurveillance activities is proposed to leverage capabilities that exist across Federal, State, local, tribal, and territorial governments and to identify data collection activities on the human, animal (domestic and wild), environmental, and plant domains that affect human health. The registry proposed in this plan will strengthen understanding across government and the private sector of how organizations collect, communicate, and use biosurveillance information and will capture data on surveillance activities related to human health.

Finally, implementing a broad communications strategy will enable a greater understanding among partners of the types of surveillance information available to decision makers and where it can be found. Communicating consistent information about biosurveillance will assist Federal, State, tribal, territorial, and local governments and international health agencies in making more informed decisions in terms of in early warning, rapid characterization, and overall situation awareness of public health events of national concern. CDC will work with partner organizations to (1) gather information about biosurveillance communications needs, (2) develop messages about biosurveillance for key stakeholders, and (3) educate partners and policy makers about the need for policies that facilitate the development of a national biosurveillance capability.

INTRODUCTION

This *Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health (Concept Plan)* is intended to further the implementation of Homeland Security Presidential Directive 21 (HSPD-21). HSPD-21: *Public Health and Medical Preparedness*, states that the U.S. Department of Health and Human Services (HHS) shall "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."[1] On November 16, 2007, the HHS Assistant Secretary for Preparedness and Response charged the Centers for Disease Control and Prevention (CDC), an agency within HHS, with leading the implementation of HSPD-21. In this role, CDC "will build from our existing strengths, take advantage of new and future technologies and methods, and connect with the rapidly expanding array of resources present or being developed in other organizations."[2] CDC also was charged with defining the human health component of the nationwide biosurveillance system, identifying information requirements, and determining how information could be analyzed and combined to provide a common operating picture that can inform the agency and HHS and provide situation awareness and support for decision analyses made by government responders at all levels. The basis for the efforts under HSPD-21 can be found in several prior executive and legislative actions. HSPD-9 and HSPD-10 created a new biological threat awareness capacity and established an integrated warning system. The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), among other recommendations, proposes new national surveillance methods. And finally, PL 110-53 implemented the recommendations of the 9/11 Commission for identifying and tracking biological events of national concern, and by analyzing data both nationally and internationally relating to human health, animal, plant, food and the environment.. Each of these actions provided the building blocks for the foundation of biosurveillance.

Biosurveillance for Human Health

"Biosurveillance," in the context of human health, is the science and practice of managing health-related data and information for early warning of threats and hazards and early detection and rapid characterization of emerging health threats so that adverse health effects can be mitigated. HSPD-21 defines biosurveillance as—

> *…the process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health—whether infectious, toxic, metabolic, or otherwise, and regardless or intentional or natural origin—in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity.*[3]

Biosurveillance represents a new paradigm for public health information that seeks to integrate and efficiently manage health-related data and information across a range of information resources. The primary goal is to create decision advantage over the life cycle of a health event by achieving timely and accurate situation awareness of population health. "Situation awareness"

is "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."[4] While traditional public health surveillance contributes to situation awareness, it alone is not sufficient to meet the information needs for situation awareness across the phases of an event (i.e., pre-event, detect, respond, recover).

There are a number of differences between traditional public health surveillance and biosurveillance for human health. Biosurveillance, for example, includes information about human health that can be preliminary and indicative of health problems, such as groups of disease symptoms (syndromes) and laboratory test orders. Biosurveillance also includes collecting relevant information about animals (domestic and wild), plants, and the environment and may be recorded in quantitative or qualitative form, such as in health-care provider notes and news reports. Traditional public health surveillance focuses on the collection, analysis, and dissemination of data on individuals (i.e. cases) diagnosed with or suspected of having a disease, injury, or an exposure of public health importance. Known as case-based surveillance, this type of surveillance is used when regular, frequent, and timely information on individuals is needed to make inferences about factors that increase the likelihood of illness among individuals, or, in other words, put them at risk of getting the illness. This information is needed to prevent or control the disease, condition, or exposure. Cases may be reported at the individual level or as aggregate counts. When reported as aggregate counts the data are used, not for drawing inferences about risk factors, but rather to monitor whether the amount of illness in the population is increasing or decreasing.

Biosurveillance processes and systems are characterized by the following:

- **Dependent** on quality data and information.
- **Flexible** to balance and meet the need for speed, scale, and specificity.
- **Adaptive** to the information needs of an event and has capabilities that extend beyond public health surveillance to support the breadth of information requirements across phases of an event.
- **Scalable**, allowing the needed granularity of information at the local level while addressing the need for situation awareness at other levels, based on their roles and responsibilities.
- **Supports** the sharing of data across all levels of government for acute events, but does not necessitate the sharing of all data across all levels.
- **Sustainable,** allowing activities that result in a successful biosurveillance initiative to be viewed as core activities of all the key stakeholders that comprise the system.
- **Possesses** notification and reporting channels and information products that are well characterized, explicit, and designed to optimize situation awareness among all public health responders with a need to know.
- **Provides** the ability to capture unanticipated incidents through reliance on human judgment.

- **Requires** a skilled workforce.

A successful biosurveillance capability comprises the following functions:

- **Case detection:** Discovery of the existence of single instances of a specific disease or exposure.
- **Cluster detection:** Continuous analysis of aggregate health-related data to detect unusual patterns or conditions that may signal an adverse human health event.
- **Integration:** The integration of multiple and disparate sources of data and information.
- **Signal validation:** Confirmation of acute public health events that require investigation or a response.
- **Event characterization:** Processes that specify the causative agent, source, route of transmission and other characteristics of an event in order to guide effective response actions.
- **Notification and communication:** Processes that ensure that persons with the need and right to know have the information they need as soon as the information is available and that all users understand their responsibilities for use and management of the information.
- **Quality control/ improvement:** Measurement to confirm that objectives are being met.

An integrated biosurveillance capability at all levels of government will enable more timely, comprehensive, all-source, analyzed, and accessible information for decision making.

Challenges in Achieving a Nationwide Biosurveillance System

There are many challenges to achieving a nationwide biosurveillance system. First, because the United States' public health system comprises decentralized authorities and capabilities for early warning, detection, and response, national leadership is needed to ensure that all jurisdictions are protected from health threats and vulnerabilities. The responsibility for public health is shared across levels of government, professional practices, and scientific disciplines. Because of this distributed responsibility, the timely sharing of multi-sector, all-hazards information is both essential and incredibly challenging.

Second, as efforts to build a national network of complementary biosurveillance systems advance, it will be necessary to balance and prioritize new initiatives and existing programs. New biosurveillance initiatives will require new funding from various sources and should not come at the expense of vital investments that have demonstrated value. Additionally, sustained funding must be provided across the biosurveillance enterprise to existing programs that have shown and continue to show improved biosurveillance capability or capacity to maintain current biosurveillance capabilities and also facilitate collaborative relationships across those programs and systems.

Third, because public health threats are often multifaceted, there is a need to integrate various types and forms of information in developing situation awareness capacity. This complex task includes identification of potential diseases, natural disasters, or hazardous exposures that would constitute a public health threat. States, Tribal, Territorial, local health departments, CDC, and

other Federal agencies collect public health or surveillance data from a wide range of sources, including traditional sources such as public health officials, environmental monitoring systems, animal or vector monitoring systems, laboratories, medical records, administrative records, police records, vital records (e.g., birth and death certificates). Health-related data may also come from non-traditional sources such as open press and classified reporting, media and other public domain internet sources. These data are collected in a variety of ways (i.e., passive, active, sentinel, special systems, and survey research) and require flexible approaches to biosurveillance system design and operating procedures. New databases may need to be developed, existing records may need to be merged, or historical analysis may need to be conducted to inform capacity.

The federal government will need to collaborate with the primary owners of much of these data, that is, with State, tribal, territorial, and local government and with organizations and individuals outside of government. Because these data come from a broad variety of both traditional and non-traditional sources, another key requirement will be to develop methodologies, tools, and models to systematically harvest and contextualize all sources of biosurveillance data. This broader definition necessitates interagency discussions to define the trigger points for policy decisions on countermeasure and response options, and planning exercises to incorporate all sources of biosurveillance information in those decisions.

CDC's Response to Homeland Security Presidential Directive 21(HSPD-21)

In 2008, CDC established the Biosurveillance Coordination Unit (BCU) to manage the response to the mandate of HSPD-21 regarding the development of a nationwide, robust, and integrated biosurveillance capability. Three broad efforts ensued. First, HSPD-21 required the establishment of a federal advisory committee. To meet this requirement, CDC's Advisory Committee to the Director (ACD) established the National Biosurveillance Advisory Subcommittee (NBAS) on May 1, 2008. The second effort resulted in CDC releasing the draft version of the *National Biosurveillance Strategy for Human Health (Strategy*) on December 15, 2008. The *Strategy*, developed with partners across Federal, State, local, tribal, and private agencies and organizations, outlines priorities for enhancing next-generation biosurveillance capability through collaboration with national and international public and private stakeholders. These priorities are designed to be considered by organizations across the biosurveillance enterprise. Third, this *Concept Plan* describes an approach to developing a nationwide biosurveillance capability. It is intended to outline the next steps to be taken to accomplish the *Strategy* and NBAS recommendations. The *Concept Plan* is not a concept of operations. That is, it does not include specific operational processes for implementing the *Strategy*. It does however, present a conceptual framework for implementation and includes in broad stokes the major pillars to support the priority areas in the *Strategy*.

To develop the *Concept Plan*, multiple groups representing CDC programs and leadership and Federal, State, local, tribal and clinical partners were brought together to provide input and ideas regarding current biosurveillance capability and requirements for the future. These workgroups include the Federal HSPD-21 Biosurveillance Workgroup; the State, Local, Tribal, and Territorial Workgroup; a group of senior CDC leaders; and a consultative group of CDC scientists, policy advisors, and communicators. The workgroups were developed taking into consideration individual recommendations from the Association of State and Territorial Health

Officials, the National Association of City and County Health Officials, and federal partners. The BCU opened all workgroups to individuals interested in participating without restriction. The workgroups were intended to provide individual input and a forum for discussion on biosurveillance activities around the country, but not to provide consensus recommendations. Members were invited to participate in bi-weekly conference calls at which time the BCU provided an update on the work in progress and sought individual recommendations on topics of interest to workgroup members.

The *Concept Plan* describes a proposed framework to facilitate collaboration among federal agencies and other sectors in the creation of next-generation biosurveillance capabilities. It describes some of the activities necessary to continue to develop biosurveillance, which include the need for creation of a governance structure to enable collaboration; development of an approach to identify and make accessible the biosurveillance systems that currently exist; communication about biosurveillance; and identification of other steps in the development or improvement of a national biosurveillance capability.

National Biosurveillance Advisory Subcommittee (NBAS)

NBAS consists of prominent public and private biosurveillance stakeholders and contributors. As a subcommittee of the ACD, NBAS provides recommendations to the parent Committee regarding the broad range of issues affecting the development and implementation of a nationwide biosurveillance strategy for human health. The membership of NBAS includes persons from public health, health-care delivery, academia, and others sectors. This ensures diverse perspectives. In developing their recommendations, NBAS conducted fact-finding activities, consulted with experts, and deliberated in small groups and as a whole to assess the state of the biosurveillance enterprise as it currently exists. NBAS found that there are wide variations in biosurveillance systems and capabilities. The use of these systems is not well defined, and there are not formal, coordinated, external mechanisms in place to evaluate systems and drive improvements. As part of their advisory activities, NBAS envisioned future technology opportunities, and sought to address issues of sustainability of these efforts.

"Improving the Nation's Ability to Detect and Respond to 21st Century Health Threats: First Report of the National Biosurveillance Advisory Subcommittee" was released publically by DHHS on October 16, 2009. Included in the report were five high-level, cross-cutting recommendations as approved by the parent Committee to be considered by federal leadership. The recommendations are as follows:

- 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 U.S. National Biosurveillance enterprise must include global health threats in its purview and scope.
- The federal government must make a sustained commitment toward 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 improve how they serve biosurveillance and public health missions.
- The federal government must make strategic investments in new technologies to strengthen U.S. biosurveillance capabilities.

NBAS members will continue to serve in an advisory capacity and will deliver an updated recommendations report on a regular basis to the ACD.

National Biosurveillance Strategy for Human Health (Strategy)

The *Strategy* was initially created by the CDC under the direction of the director at that time, Dr. Julie Gerberding. It was created to fulfill one of the mandates of HSPD-21 to develop a nationwide biosurveillance capability. The *Strategy* represents the first step in a long-term effort to improve nationwide capabilities for managing health-related data and information in order to provide early warning of threats and hazards, early detection and rapid characterization of events, and overall situation awareness—informing decisions to enable actions used to mitigate adverse health effects.

The *Strategy* presents goals and objectives in six priority areas in order to address critical gaps and opportunities for achieving the goals of HSPD-21. These priority areas are—

- **Electronic Health Information Exchange**: Strengthening and expanding multidirectional health information exchanges with health-care 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. Within the domain of human health, laboratory information exchange is a critical component of health information exchange.
- **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 and prepared to adapt to evolving threats and crises.

The *Strategy* will be periodically updated in a manner that reflects progress, increased knowledge, and shifts in the health-care industry and political environment. In this way, it is intended that the *Strategy* will unite and integrate the work of numerous stakeholders, including NBAS, who contribute to and will benefit from the products of biosurveillance. An updated version of the *Strategy* will be released in late 2009 or early 2010.

Concept Plan for Implementing Strategic Goals and Objectives

This *Concept Plan* outlines the initial considerations and steps to be taken to facilitate collaboration across federal agencies and other sectors in the creation of next-generation biosurveillance capabilities. These considerations include: the need for a governance structure to enable collaboration, development of an approach to assess what biosurveillance systems currently exist, and development of communication about biosurveillance. The following sections of this document reflect the overall proposed approach to implementation of a stronger biosurveillance capability.

ACHIEVING THE GOALS OF THE NATIONAL BIOSURVEILLANCE STRATEGY FOR HUMAN HEALTH

The *Concept Plan* was developed to outline a means to operationalize a national biosurveillance capability and achieve progress toward the goals and objectives identified in the *Strategy*. It describes, at the highest levels, the concept for integrating and synchronizing existing federal capabilities to accomplish the mission-essential tasks identified in the *Strategy* and describes how federal capabilities will support and be integrated with regional, state, local, territorial, and tribal capabilities.

Stakeholder Involvement in the Development of the Concept Plan

The development of a national biosurveillance capability depends on the collaborative efforts of partners and stakeholders across public health, private health care, and at all levels of government. Recognizing this need, multiple groups with diverse and wide-ranging opinions and experience were convened to provide input regarding current biosurveillance capability and requirements for the future. The workgroups are described briefly here and more fully in Appendix C.

The federal HSPD-21 Biosurveillance Work Group represents the interests of federal departments and agencies in human health-related biosurveillance and is comprised of members of the federal workforce.

The State, Local, Tribal, Territorial (SLTT) Work Group members provide input regarding the development of a national biosurveillance capability from the state and local public health and medical perspectives. This work group consists of both governmental public health and clinical medicine entities. Several members are employed by State, Tribal, Territorial, or local government agencies. Others, although they do not officially represent their organizations, are employed by academic, private, and national professional institutions.

Within CDC, there are three groups of stakeholders: CDC leadership, which includes the CDC Director and Center and Office Directors; policy and communications staff from biosurveillance-related programs; and interested CDC scientific staff and program leads for biosurveillance efforts. This third group comprises the Biosurveillance Advisory Team (BAT).

Through their discussions, these work groups have helped develop the *Concept Plan* and shared their vision for enhancing biosurveillance capability. Their discussions and ideas helped to shape the ideas reflected in this document.

Components of the Concept Plan

The *Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health* has three fundamental components: (1) a governance model for enhancing collaboration between stakeholders, (2) an approach to assess existing biosurveillance activities that comprise our collective investment in national biosurveillance for human health, and (3) an approach to communicating the efforts of this nationwide enterprise to a wider audience of policy makers and health professionals.

Governing the Development of the National Biosurveillance Enterprise

There is no overarching organizational structure currently that has governance responsibilities for a national biosurveillance system for human health or lays out the implementation plan for such a system. While CDC has been given the operational lead for coordination of HSPD-21 biosurveillance capability, it has limited authority for implementation of any specific activities. The absence of an overarching organizational structure has contributed to the creation of many separate surveillance programs serving a range of purposes, as well as confusion about the responsibilities of different federal agencies and of Federal, State, Tribal, Territorial and local governments.

A governance model should enable the development of cross-sector, intergovernmental and intra-governmental collaborative processes that are transparent and effective. The governance model should ensure State, local, Tribal, Territorial, and Federal public health, and private sector organizations work together, thereby increasing accountability, efficiency and sustainability of biosurveillance in the United States and leveraging ongoing efforts across the biosurveillance enterprise.

Governance Model

Governance should be based on a model that comprises consistent management practices, cohesive policies, and well-defined processes. The governance model should enable participants to make biosurveillance-related recommendations and prioritize implementation of adopted recommendations designed to reach the common goals of the *Strategy*. Participants in the governance model should reflect broad cross-sector, intergovernmental, and intra-governmental representation and should operate using a transparent, consensus-based approach. Participants in the governance structure will conduct regular assessments of the *Strategy* priority areas, goals, objectives, and performance measures; prioritize biosurveillance activities that improve public health; develop recommendations to advance biosurveillance; and assess governance operations and outcomes.

Those involved in biosurveillance governance should:

- Establish the basis for governance, approval and measurement, including defining roles and accountabilities, policies and standards (statutory, regulatory) and associated processes, and relationships of stakeholders.
- Assess current biosurveillance coverage, including overlaps, gaps, and opportunities for streamlining coverage.
- Evaluate recommendations and promote those that reflect the best balance of investment of funds and scarce resources.
- Enable the implementation of activities that will further the biosurveillance enterprise through recommendations on resource priorities.
- Define and measure the ‘desired outcomes’ (end states), benefits and value — including how they fit the goals, objectives and performance measures in the *Strategy*.

- Monitor progress, stakeholder participation, and results.
- Develop and implement policies for sharing of data and information across all stakeholders, as appropriate.

The Biosurveillance Governance Partners (BGP) Working Group was formed with volunteer members from several other standing working groups, including HSPD-21, SLTT, and CDC's BAT. The purpose of the workgroup was to gather individual input and ideas on the development of possible governance models. Members have a range of expertise in epidemiology, biosurveillance, public health informatics, public health law, and laboratory information management and represent the federal government, public health laboratories, state public health agencies, and professional public health organizations.

Approach for Developing a Biosurveillance for Human Health Governance Model

The BGP Working Group first conducted a review of existing governance structures to learn the attributes to be considered in a model for biosurveillance and to determine if any existing governance bodies could be augmented to address biosurveillance. The BGP Working Group sought several types of governance structures and used electronic sources to gather reference information describing each type. Following the review of more than two dozen governance structures, the BGP Working Group identified organizational traits common to all the structures. They then posed four questions that should be considered in developing a functional governance model for biosurveillance:

- What is the scope of the activities the governance body will address?
- Who are the appropriate members?
- What is the process and structure by which the governance will operate?
- How will the recommendation of the governance body be implemented?

The BGP Working Group determined that any governance model implemented for biosurveillance for human health should:

- Incorporate stakeholders from Federal, State, Tribal, Territorial, local, and private sectors, including healthcare, public health, animal health, environment, and health IT.
- Avoid duplicating, or overlapping with, existing governance models to the extent possible to accomplish the objectives.
- Utilize existing resources and expertise found within current governance models and working groups, as appropriate.
- Respect the existing relationship between Federal, State, local, tribal and territorial governments.
- Promote biosurveillance collaboration and coordination across government and other sectors.
- Set strategic direction and priorities, leaving the operational and day-to-day management of programs and systems to the owners of those systems.

- Be strategically positioned to have a broad influence on a range of sectors and organizations to accomplish the objectives of the *Strategy*.
- Provide a forum to advise Federal, State, Tribal, Territorial, and local entities on how public health needs could be addressed in a nationwide approach to biosurveillance.
- Provide an authoritative opinion on how federal biosurveillance initiatives should interact with other federal projects as well as current or emerging gaps.

Governance Model Development

The structures listed below could serve as models for governing the biosurveillance enterprise. These structures are flexible and can be adapted for use in the biosurveillance context.

Non-Federal Entity

The federal government could consider methods to support the development of a non-governmental association or organization of biosurveillance professionals. This organization would facilitate collaboration across all stakeholder groups in order to encourage the development, promotion, and enhancement of a national biosurveillance "systems of systems." The organization might consist of members or participants from all jurisdictions and sectors, including existing public health and healthcare associations and organizations such as the NACCHO, ASTHO, CSTE, APHL, ISDS, and private sector healthcare providers. The organization might be a sub-component of an existing public health partner organization, such as CSTE, or it might be incorporated as a separate legal entity in accordance with the requirements of the jurisdiction. Federal employees and organizations may participate in the organization in accordance with ethics rules. However, by definition, a nonfederal entity is an independent legal entity that is separate from and not directly controlled by the federal government. Such organizations have the flexibility to educate policy makers and develop relationships with partners that federal agencies may not have. A limitation of such a model is that non-federal entities have limited (to no) roles in federal operational activities and policies and may not make recommendations to the federal government.

Federal Interagency Working Group

The federal government could establish an interagency working group consisting of the federal departments and agencies that have a stake in biosurveillance. This group could be a formal or informal group, although federal interagency working groups are usually established by law or an executive order issued by the President. This group could coordinate and collaborate on the federal components of a national biosurveillance system for human health, such as the sharing of data and information between and among federal agencies. Support for an interagency group often is most effectively provided through a neutral convening agency or federal partner, such as the National Science Foundation or the National Academy of Sciences. The advantage of a federal agency working group is that it provides a mechanism for collaboration among federal officials who are engaged in day-to-day activities related to biosurveillance. The limitation of a federal interagency working group, if it were the sole model for governance in biosurveillance, is that vast groups of stakeholders important to biosurveillance, such as State, Tribal, Territorial

and local health departments and private healthcare providers, would not be adequately represented. Federal law generally requires that groups consisting of non-federal members providing consensus advice and recommendations to the federal government be established as formal Federal Advisory Committees.

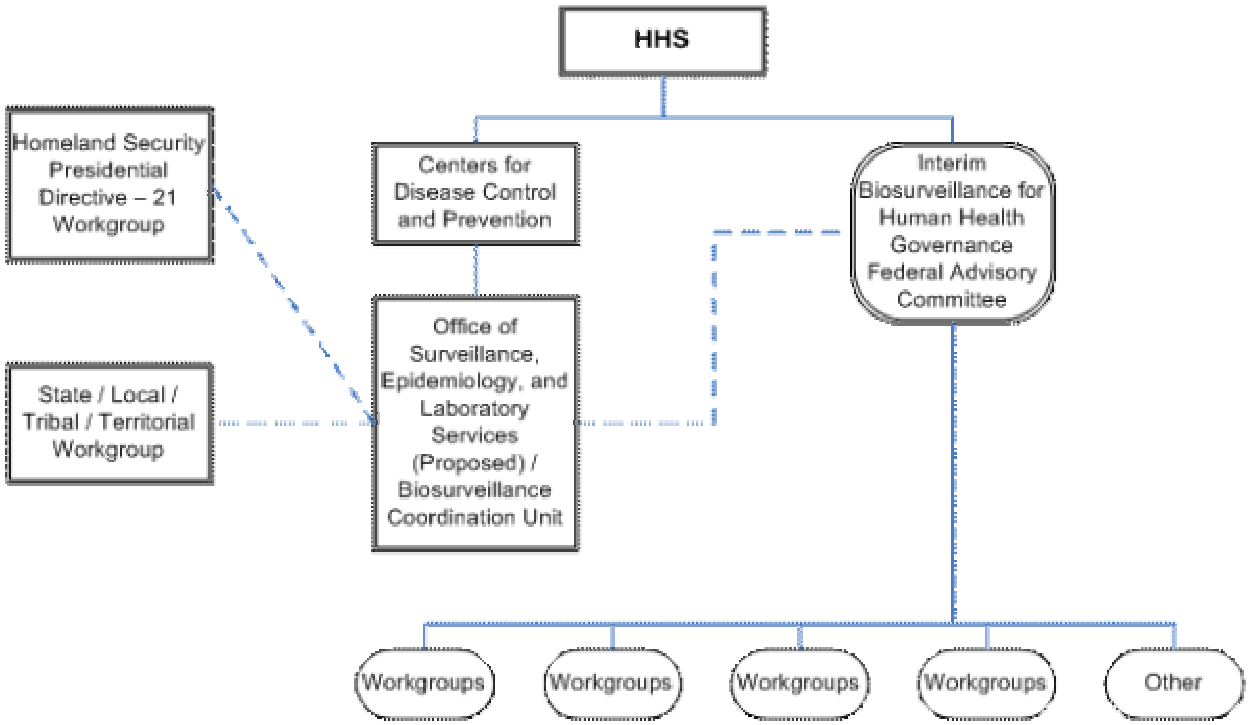
Federal Advisory Committee

The federal government could establish a federal advisory committee to address biosurveillance. Federal advisory committees are governed by the Federal Advisory Committee Act (FACA). FACA sets out the requirements for chartering an advisory committee, provides requirements for membership and representation, and limits how advisory committees can be used. In general, under FACA, an advisory committee consisting solely of federal employees falls outside the scope of the law. There are additional exceptions that may allow for the inclusion of Tribal, Territorial, State and local officials, or for groups not used to provide consensus advice to a federal agency or the President. There are over 1,000 federal advisory committees. These committees can be useful in ensuring a structured, legally compliant means for gathering input from nonfederal stakeholders regarding a federal program or activity. The limitation of a federal advisory committee is that it requires an extensive amount of time to establish due to the vetting process for proposed members, and requires the dedication of one federal FTE to manage the committee and its meetings in order to comply with the requirements of the FACA and its accompanying regulations.

Proposed Models

These three structures were considered by the BPG Working Group, which recognized that no single model offers a means for representing all desired stakeholders. Taking into account the principles that need to guide the development of a governance model, the BPG Working Group proposed a mixed governance model, which is described below. Recognizing that reaching the optimal model requires organizational decisions by the federal government that may not be quickly implemented and are not within the control of the BPG Working Group, they also proposed an interim model (Figure 1). The interim model adheres to the same criteria as the optimal model. However, it is based on a structure that will be established within HHS and relies on existing organizational entities.

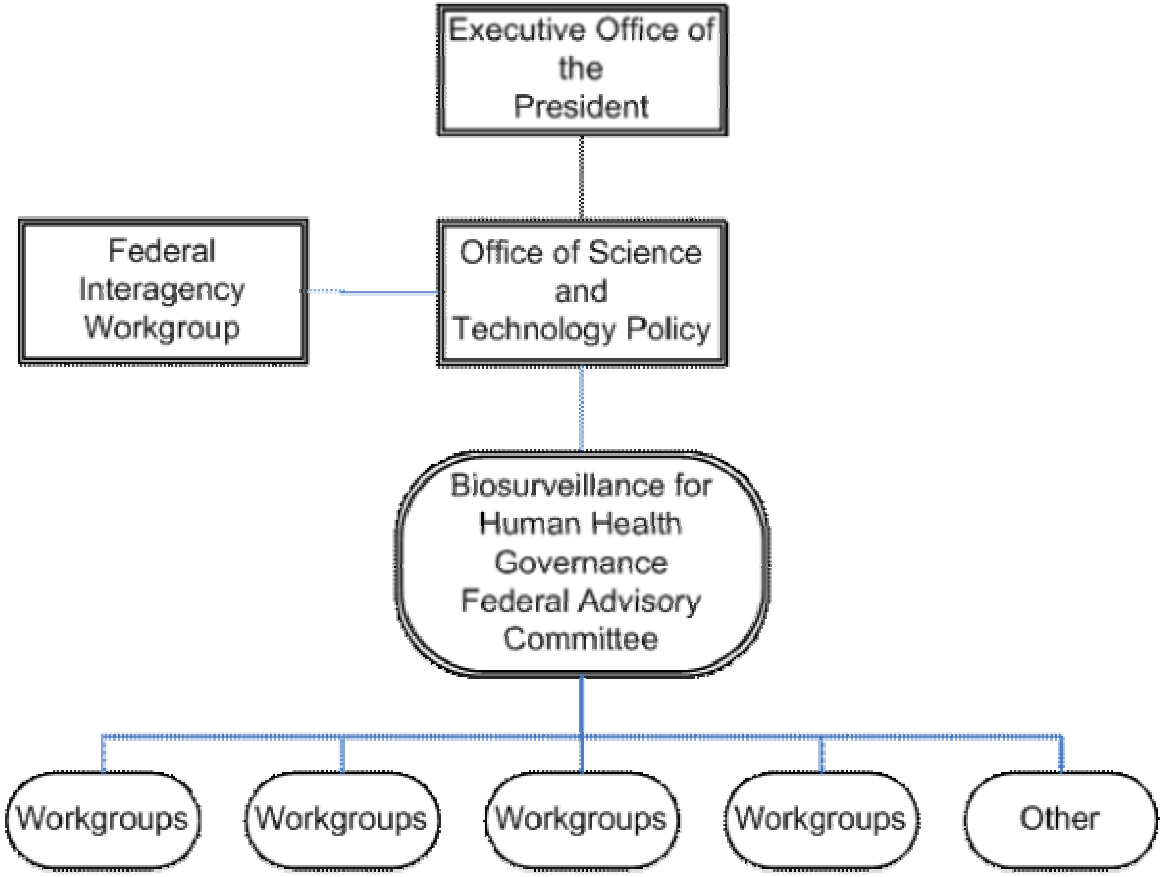
Figure 1. Interim Model for Biosurveillance Governance for Human Health



The interim model draws on the expertise of its members to provide advice and make recommendations to reach the goals defined in the *Strategy*. The model includes an Interim Biosurveillance Governance Federal Advisory Committee that operates under FACA.[5] The interim body would consist of approximately 30 members, broadly representing different levels of government and the private sector. The interim body would include work groups for each of the priority areas within the *Strategy*. The work groups would have a defined charge and individual charters that fall under the broader charter of the interim body. Each workgroup would develop recommendations within its priority area to be presented to the interim body. Work group efforts would be open to participation from experts in these areas. Participation and communication across work groups would be facilitated to coordinate efforts. It is envisioned that this interim governance approach would be maintained for no more than two years from the date of the initial meeting. After the first year, the Designated Federal Official would consult with the Chair and work groups to assess progress and to determine next steps, including the renewal of the charter if necessary.

The BPG Working Group envisions that an optimal governance model would be refined based on the experiences within the interim body. The optimal model, like the interim model, includes a federal advisory committee. Representatives of the State/Local/Tribal/Territorial workgroup from the former model will be members of the federal advisory committee in this model. The optimal model (Figure 2) also includes a federal interagency work group. In this optimal model, the FACA committee could report to the Office of Science and Technology Policy under the Executive Office of the President.

Figure 2. Optimal Model for Biosurveillance Governance for Human Health



The Federal Interagency Work Group would include federal representatives tasked with advising on funding and evaluation and making decisions in these areas that are outside the purview of the governance federal advisory committee. The Federal Interagency Work Group could receive administrative support from the BCU and would report to the Office of Science and Technology Policy (OSTP). The OSTP would also receive information from the Governance FACA committee for biosurveillance. At its discretion, OSTP would then report to the Executive Office of the President on the recommendations of the federal advisory committee and the Federal Interagency Work Group.

Implementation

The models proposed above are the result of thoughtful deliberation about the work that needs to be done in this national biosurveillance enterprise and the structures in which public health agencies and partners have to work. As a proposal, a number of decisions need to be made about the direction the governance effort will take and, if decided, how the interim and optimal models would be implemented. Examples of these decisions include: who will work with the administration to advocate the establishment of the permanent committee structure, and how will this individual or group of individuals proceed in this role. For the interim structure, the issue of

how OPDIVS of HHS will establish a FACA committee must be resolved: who will address the issue with HHS, who at HHS has the authority to approve the committee, and which HHS OPDIV will provide support for the committee once established. Once established, the work of the interim committee will be further refined, then approved and implemented as directed by HHS.

REGISTERING THE NATIONAL BIOSURVEILLANCE CAPABILITY FOR HUMAN HEALTH

A registry is proposed that will provide a picture of biosurveillance capacity in the United States by outlining what biosurveillance activities both 1) support the *Strategy* and 2) currently exist within Federal, State, local, Tribal, and Territorial governments and within multiple knowledge domains that impact human health (e.g., human, animal (domestic and wild), environment, and plant).

National Biosurveillance Registry for Human Health

The National Biosurveillance Registry for Human Health (the *Registry*) advances one of the foundational principles of the biosurveillance vision set forth in HSPD-21: the need to build on current capabilities. The *Strategy* provided a high-level assessment of current capabilities. *Strategy* stakeholders, including representatives from State, Tribal, Territorial, and local health departments, other federal agencies, advisory bodies, and CDC's scientists, further identified the need for a more comprehensive understanding of current capabilities, particularly related to the priorities of the *Strategy*.

The *Registry* will strengthen the understanding of how organizations collect, communicate, and use biosurveillance information. This insight will reveal opportunities for integration and collaboration as well as help determine overlaps, inefficiencies, and gaps in capabilities. The *Registry* should aid in the determination of how much funding is required to maintain existing systems and to gauge the impact of funding cuts. For example, public health practitioners may use the registry to identify influenza-like illness surveillance systems that exist across the country and analyze how they can be aggregated for a response. Others may use the *Registry* as a tool to determine possible areas where leveraging small investments in coordinating or combining two systems or efforts might result in large gains. Infrastructure planners may use it to ascertain opportunities to improve interoperability among similar systems in different jurisdictions or across levels of public health, to measure progress over time in achieving electronic exchange between systems, or to identify niche tools that provide specific capabilities, such as tools to standardize vocabulary or encrypt electronic messages.

As envisioned, the *Registry* would—

- Enable identification of opportunities for closer collaboration and improved interoperability within and across organizations.
- Capture data on surveillance activities and systems related to human health from all public health domains and levels of government.
- Serve as a single, trusted source for accurate data on biosurveillance for human health activities.
- Be updated by users annually to ensure that information about the registered activities is current.
- Provide a searchable platform to analyze the characteristics of, and report on surveillance systems.

- Cover all hazards, including biological, chemical, radiological, nuclear, and trauma agents.
- Contain elements including, but not limited to—
    - Focus of the activity (e.g., animal (domestic and wild), plant, human, food).
    - Geographic coverage (e.g., local, Tribal, Territorial, multistate).
    - Analytical and reporting capabilities.
- Support reporting federal entities including HHS (as well as CDC), the Government Accountability Office (GAO), and the Office of Management and Budget (OMB).
- Incorporate a phased approach to registering existing activities, beginning with CDC and then progressing to other federal agencies. Ongoing analysis will be conducted to determine completeness and usefulness of data before initiating work at other agencies. With value established, registration efforts will then include state and local health agencies, and end with interfacing with global and private sector partners that conduct human health-related surveillance.

The *Registry* will not include surveillance data. It will capture information on a range of efforts that support biosurveillance practice, including programs, collaboratives, information technology (IT) systems, and tools. For purposes of *the Registry*, a program is an activity undertaken by an organization which has inputs and outputs, processing, and structure. Programs may manage systems and support services. CDC's Emerging Infections Program (EIP) is one example. A collaborative exists when two or more organizations work together, share knowledge and expertise, and build consensus on how to meet common goals. The Integrated Consortium of Laboratory Networks (ICLN) is an example of a collaborative. A working group and an advisory committee are examples of collaboratives. In the context of the *Registry*, an IT system refers to application software for the end-user. These applications typically support one or more functions and have a frontend user interface, and a back-end component that supports data management, such as a database. These applications may also include other components specific to their function, such as data transformation and packaging to support data exchange. The Electronic Surveillance System for Early Notification of Community-Based Epidemics (ESSENCE) is an example of an IT-based surveillance system.

Within the *Registry*, a tool is considered a software application or service that supports a specific task, such as message transport, data transformation, communications, or identity management. A tool is an application that provides discrete targeted functionality that can be used independently or by a system, or by an entire organization. The Public Health Information Network Messaging System (PHIN MS) and the Early Aberration Reporting System (EARS) are examples of tools. Tools differ from systems mainly in terms of size, complexity, and the number of functions they support.

The *Registry* will include information about each of the registered programs, collaboratives, systems, and tools, including the name of the system and its acronym, contact information for persons primarily responsible for maintaining the system, the system's main purpose, and the diseases and conditions under surveillance.

Development of the National Biosurveillance Registry for Human Health

To facilitate the development of the *Registry*, a cross-discipline workgroup was formed to leverage a range of CDC staff expertise in epidemiology, biosurveillance, public health informatics, information technology, public health law, and laboratory information management. Through a series of meetings, the workgroup identified the potential purpose, goal, and scope of the *Registry*, and assessed the information needs of potential stakeholders. Requirements were captured and applied to iteratively refine the *Registry* questionnaire that will be used to populate the registry.

The workgroup conducted a review of similar registry efforts, as well as a thorough search for previously existing listings of biosurveillance activities. Several existing inventories were reviewed as part of this effort (Appendix B, Table 1). The review included a detailed specification of variables included in each list or registry, as well as an attempt to understand the scope and intent of the list. The review showed that many of the existing inventories or lists of biosurveillance systems were one-time efforts aimed at gathering information for a specific purpose, often with no plan to maintain or update the list. Although useful, such ad hoc efforts were not accurate or reliable in an environment in which systems are constantly being developed or changing. The use of ad hoc data collection processes to determine what surveillance systems exist often meant data calls were repeatedly made to programs and system owners. In addition, some ad hoc lists had a local or limited focus (i.e., focused on a particular discipline or type of system) and did not consider the potential for broader application across the biosurveillance enterprise.

After completing the review, the *Registry* workgroup refined the draft list of questions through a series of working meetings. The draft set of questions was then reviewed and refined by subject matter experts in surveillance science at CDC. Concurrent with the review, the questionnaire was pilot tested with the following: National Poison Data System, BioSense, BioPhusion, Public Health Laboratory Interoperability Project and USDA's Food Surveillance Inspection System—Public Health Information System (FSIS-PHIS). Feedback was integrated into the design of the questionnaire and helped define the basic information that the questionnaire will collect (Appendix A, Table 2).

Implementation Plan for the National Biosurveillance Registry for Human Health

Planning and development of the *National Biosurveillance Registry for Human Health* began in January 2009 and is proceeding in five phases:

- Phase I: Using survey software, the CDC staff is collecting a small but critical data set on activities at CDC. A draft list of systems, programs, tools, and collaboratives registered at CDC is provided in Appendix B, Table 3 and a sample report on a single system is provided in Appendix B, Table 4. Following revisions based on the initial data collection of a subset of critical activities at CDC, the remaining systems, programs, tools, and collaboratives at CDC will be registered. The registry will provide a wealth of information about our nation's biosurveillance-related capability and will provide much greater visibility and easier access to surveillance systems and programs across the federal sector, beginning with CDC. Initially access to the registry will be limited to those CDC systems, programs, tools, and collaboratives that are registered. This will allow

time for development of policies and procedures for sharing information more broadly. Eventually access will be available across the biosurveillance enterprise. Registering of CDC's surveillance systems, programs, collaboratives, and tools will begin in December 2009. An analysis will be conducted to determine the usefulness of the data collected before progressing to Phase II.

- Phase II: Upon establishing a useful tool covering CDC biosurveillance activities, the CDC staff working on the *Registry* will collect information on biosurveillance activities occurring in other federal agencies, but only for activities that pertain to human health.
- Phase III: The BCU will work with state, local, tribal, and territorial partners, their professional associations, and OMB to collect information in the *Registry* about biosurveillance activities that partners agree will enhance their ability to conduct epidemiologic investigation and will enable the federal government to support them better in those efforts.
- Phase IV*:* The *Registry* staff will collaborate with partners of the United States in the global surveillance network to register cross-border and other international biosurveillance activities that help the United States fulfill its responsibilities under the International Health Regulations (2005). A draft list of systems which may be registered is provided in Appendix B, Table 5.
- Phase V: The *Registry* staff will collaborate with private sector partners to register their activities that contribute human health surveillance information in support of the mission of public health.

HHS and CDC were assigned a leadership role for development of the *National Biosurveillance Strategy for Human Health* because many, though not all, of our country's human health-related activities reside in these agencies. A primary goal of the *Strategy* is to improve coordination among existing biosurveillance activities. Considerable success toward reaching this goal will begin when CDC's systems are completely registered. Even greater success will be realized when the full complement of biosurveillance systems can be easily accessed through the registry to provide planners and responders with essential information about our nation's biosurveillance capability.

ENABLING BIOSURVEILLANCE THROUGH COMMUNICATION AND POLICY DEVELOPMENT

Communication is central to enhancing collaboration among biosurveillance partners, soliciting input from stakeholders in the biosurveillance enterprise, building support for biosurveillance initiatives, and providing information about decisions by policy makers to the biosurveillance community and the general public. The registry and governance efforts, designed to achieve these purposes, will be enhanced through communication, as will the primary goal of better biosurveillance.

Developing Biosurveillance Messages

Public health partner organizations will work together to develop messages about biosurveillance for key stakeholders. The purpose of these messages is to educate partners and policy makers about the need for programs and policies that facilitate the development of an enhanced national biosurveillance capability and to raise awareness of existing systems, coordination, and efforts. Communications activities will strengthen the capabilities of Federal, State, Tribal, Territorial, and local governments and international health agencies in early warning, rapid characterization, and overall situation awareness of public health events of national concern. Communications activities include—

- Updating and disseminating the *National Biosurveillance Strategy for Human Health (Strategy).*
- Facilitating an understanding of the recommendations of the National Biosurveillance Advisory Subcommittee.
- Ensuring dialog among participants in the biosurveillance governance body.
- Disseminating the recommendations of the governance body.
- Identifying new partners in the biosurveillance enterprise and engaging them in the process of building the national capability.

These activities will be accomplished by engaging policy and communications personnel across stakeholder organizations and by identifying, developing, testing, and disseminating messages about biosurveillance.

Qualitative research methods will be used to determine appropriate messages, address feedback from intended audiences, draft and develop materials and planned activities, and evaluate the materials through pilot testing of the messages. Some possible themes that may be used in messages about biosurveillance are the importance of the link between biosurveillance and public health surveillance and infrastructure, the need to build upon and improve current biosurveillance infrastructure, and the roles and responsibilities for partners collaborating in the implementation of a national biosurveillance strategy.

Disseminating Biosurveillance Messages

Communications activities will focus on audiences such as state and local public health professionals, NBAS members, academic researchers, participants in the governance model, federal agencies engaged in human health-related biosurveillance, Congress, and nongovernmental organizations that support a priority area in the *Strategy*. Peer-reviewed publications, scientific presentations, educational teleconferences held in conjunction with partner organizations, and presentations of evaluation findings will be used to disseminate information to multiple scientific audiences. To reach policy makers, nonscientific professionals, and consumers of biosurveillance products, including the general public, various communications tools will be used, including targeted emails, press releases, editorials, information on the agency Intranet and Internet sites, question-and-answer documents, meetings, briefings, and talking points.

IMPLEMENTATION OF THE CONCEPT PLAN

To achieve implementation of the Homeland Security Presidential Directive 21 (HSPD-21), CDC has worked with a broad array of partners to carry out several major strategic planning activities. This *Concept Plan* outlines the next steps to be taken to move forward on the goals and priorities of both the *National Biosurveillance Strategy for Human Health* and the recommendations of the National Biosurveillance Advisory Subcommittee. Upcoming activities include development of a governance structure to formally enable collaboration and coordination across cabinet-level federal agencies and other stakeholder groups, developing an approach to identifying the biosurveillance systems that currently exist, and developing an approach to communicating about biosurveillance. These activities are intended to facilitate collaboration among federal agencies and other sectors in the creation of next-generation biosurveillance capabilities. In the near term, CDC will within its authorities coordinate the execution of this plan by carrying out the following:

- Seek the partnerships and approvals necessary to implement the proposed interim governance structure.
- Begin to register the more than 400 biosurveillance-related activities within CDC.
- Implement the initial stages of the communications plan described in this document.
- Begin to update the *National Biosurveillance Strategy for Human Health.*
- Provide support to the NBAS for follow-up on initial report and development of second report.

The leadership of the United States government in Congress and the White House have drawn attention to the critical importance of strengthening our nationwide biosurveillance capacity to protect human health. Important progress has been made in the past year to establish a national strategy and an exceptional NBAS to guide and inform the national effort. The urgency of our information needs demands that we move ahead quickly to address the priorities we have identified. This *Concept Plan* establishes critical steps toward the implementation of our strategy and is our commitment to a stronger nationwide biosurveillance capability.

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Appendix A

Tables

Table A-1. Inventories reviewed for the National Biosurveillance Registry for Human Health environmental scan

The United States Department of Agriculture's (USDA) U.S. Animal Health & Productivity Surveillance Inventory: USDA has created a user-friendly online inventory of surveillance and monitoring programs, epidemiologic studies, and other activities related to animal health in the United States (http://nsu.aphis.usda.gov/inventory/). The inventory includes summary-level data.
CDC's Enterprise Systems Catalog (ESC): ESC was developed to track the enterprise-wide use of IT systems at CDC. The web-based application captures various attributes about IT spending investments, but it focuses on capital planning rather than activities that support biosurveillance for human health. ESC is an in-production system that is updated and maintained.
**CDC's Event Response Information Supply Chain (eRISC): ** CDC began developing eRISC in 2007 to provide a central public health incident management resource for coordinating and supporting the staff, information, communications, and security issues associated with CDC's response to public health disasters, emergencies, disease outbreaks, and investigations. It was developed to fill gaps in the "information supply chain" for response activities. Although not currently in production, eRISC compiled a valuable database of biosurveillance resources that were reviewed during the the National Biosurveillance Registry for Human Health environmental scan.
CDC's Surveillance Science Advisory Group (SurvSAG): SurvSAG is an officially recognized workgroup of CDC scientists who have a vested interest in public health surveillance and, in addition to their regular duties, volunteer their time to advance the art and science of the field. To address the need to register the agency's surveillance systems, SurvSAG created a sub-committee to define terms pertinent to surveillance practice and identify data elements that could be used for a registry. The SurvSAG membership participated in the sub-committee's work by providing expert vetting on materials produced. The Biosurveillance Coordination Unit uses full-time, dedicated staff to continue the registry work begun by SurvSAG, with the intent to expand the registry beyond CDC and beyond traditional public health surveillance to include surveillance in animal, plant, and environmental domains that relate to human health.
The Department of Homeland Security National Biosurveillance Integration Center (NBIC) Listing of Systems: NBIC is the Management and Operations Center for the National Biosurveillance Integration System (NBIS). NBIC provides a biosurveillance common operating picture to senior leaders and decision makers regarding natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards. NBIC was chartered by Public Law in 2007. CDC provided NBIC with a preliminary list of CDC's surveillance systems. This list was reviewed by the NBRHHh Workgroup as a part of its planning work in developing the Registry..

Table A-2. Information to be captured by the National Biosurveillance Registry for Human Health

Information captured for all respondents:
• Name, title, degree designation, contact information
• Acronym or abbreviation used for the activity
• Name of the activity
• Point of contact for follow-up questions
• Name and ZIP code of the organization that is considered the primary owner of this activity
• If CDC activity—Division, Branch, Program that owns it
• One paragraph description or mission statement of this activity
• Surveillance system or an effort that supports biosurveillance practice, such as a program, collaborative, or tool
Information captured for tools:
• Current operational status and the year the tool became operational
• Primary purpose of the tool (e.g., geocoding, analysis visualization and reporting, data exchange, security, vocabulary)
• Internet information availability and URL
• Activity compliance with national standards
• Current fiscal year budget and nature of funding
Information captured for collaboratives:
• Current operational status and the year the collaborative it became operational
• Activity mapping to one or more of the priorities described in the National Biosurveillance Strategy for Human Health
• Domain and sub-domain main focus of the surveillance
• Main focus of the collaborative
• Internet information availability and URL
• Geographic areas covered
• Activity compliance with national standards
• Current fiscal year budget and nature of funding
• Official accountability for reporting status on any performance measures
Information captured for programs:
• Current operational status and the year the program became operational
• Use of information technology systems (e.g., ESSENCE, BioSense) or tools now owned by the activity
• Activity mapping to one or more of the priorities described in the National Biosurveillance Strategy for Human Health
• Description of type of surveillance system
• Domain and sub-domain main focus of the surveillance
• Disease, condition, or other public health issue being assessed
• Internet information availability and URL
• Geographic areas covered by activity, GIS capabilities
• Surveillance on unique or vulnerable populations
• Capabilities available through the electronic component of the surveillance system and

reports of analyzed data made available electronically
• Organizations that **provide** data to this surveillance system and whether the data is provided manually or electronically
• Organizations to which the data from the surveillance system is **sent** and whether the data is **sent** manually or electronically
• Ability to share data and timing
• Whether a public-use data set is regularly generated by using data from this surveillance system
• Whether a restricted-use data set is regularly generated by using data from this system
• Activity compliance with national standards
• Program utilization of or reliance on other services or tools
• Current fiscal year budget and nature of funding
• Official accountability for reporting status on any performance measures
Information captured for systems:
• Current operational status and the year the system came operational
• Activity mapping to one or more of the priorities described in the National Biosurveillance Strategy for Human Health
• Description of type of surveillance system
• Domain and sub-domain main focus of the surveillance
• Disease, condition, or other public health issue being assessed
• Internet information availability and URL
• Geographic areas covered by activity, level, Geographic Information System (GIS) capabilities
• Surveillance on unique or vulnerable populations
• Uniquely identified patient-level data for trace-back purposes to support an authorized public health investigation
• Capabilities available through the electronic component of this surveillance system and reports of analyzed data made available electronically
• Organizations that **provide** data to this surveillance system and whether the data is provided manually or electronically
• Organizations to which the data from the surveillance system is **sent** and whether the data is **sent** manually or electronically
• Formal assessment of the timeliness of the surveillance system data within the last 5 years, shareable results of the assessment, and when the assessment was conducted
• Ability to share data and timing
• Ability to respond to an urgent request for data from a public health partner
• Whether a public-use data set is regularly generated by using data from this surveillance system
• Whether a restricted-use data set is regularly generated by using data from this system
• Activity compliance with national standards
• Database platform used for system
• Operating System Software component of the surveillance system built by using one or more Commercial off the Shelf products (COTs) or custom built
• Program utilization of or reliance on other services or tools
• Current fiscal year budget and nature of funding
• Official accountability for reporting status on any performance measures

Table A-3. Sample list of biosurveillance systems, programs, and collaboratives maintained by CDC

CDC CIOs	Program/System/Tool/Collaborative Name
ATSDR	Hazardous Substance Release/Health Effects Database
OPHPR	National Select Agent Registry
NCCDPHP	Behavioral Risk Factor Surveillance System
NCCDPHP	National Breast/Cervical Cancer Early Detection
NCCDPHP	Youth Risk Behavior Surveillance System
NCCDPHP	National Oral Health Surveillance System
NCEH	Asthma Surveillance
NCEH	Childhood Blood-Lead Poisoning Surveillance System
NCEH	National Environmental Public Health Tracking Network
ATSDR	Hazardous Substances Emergency Events Surveillance
NCEH	Pesticide Sample Tracking, Analysis, & Reporting System
NCEH	Vessel Sanitation Program & Vessel Diarrheal Illness
NCHHSTP	National Tuberculosis Surveillance System
NCHHSTP	Sexually Transmitted Disease Surveillance Network
NCHHSTP	Viral Hepatitis Surveillance Program
NCHS	National Health and Nutrition Examination Survey
NCHS	National Immunization Survey
NCHS	National Vital Statistics System
NCHS	NHANES I Epidemiologic Follow-up Study
NCIRD	Active Bacterial Core Surveillance
NCZVED	National Antimicrobial Surveillance System
NCZVED	National Malaria Surveillance System
NCIPC	Web-based Injury Statistics Query and Reporting System
NCIPC	National Violent Death Reporting System
NCIRD	122 Cities Mortality Reporting System
NCIRD	National Respiratory and Enteric Virus Surveillance System
NCPDCID	Border Infectious Disease Surveillance Project
NCPDCID	eManifest
NCPDCID	National HealthCare Safety Network
NCPHI	BioSense
NCPHI	Epidemic Information Exchange
NCPHI	Health Alert Network (HAN)
NCPHI	Laboratory Response Network
NCPHI	Nationally Notifiable Disease Surveillance System
NCPHI	Public Health Information Network
NCPHI	Specimen Tracking and Results Reporting System
NCZVED	Electronic Foodborne Outbreak Reporting System
NCZVED	National West Nile Virus Surveillance System
NCIRD	CaliciNet

Table A-4. Sample of the National Biosurveillance Registry for Human Health Report

Profile Name:	PulseNet
Type of Activity:	Program
Owning Organization:	CDC/NCZVED
Mission:	• To conduct state of the art laboratory surveillance and consultation on the investigation of foodborne and diarrheal diseases occurring naturally or as a result of acts of bioterrorism. • To develop, evaluate and implement pathogen subtyping methods for cluster identification and for facilitating the identification of sources of foodborne and diarrheal disease • To establish and maintain libraries of DNA "fingerprints" of pathogens that cause foodborne and diarrheal diseases to facilitate early recognition and investigation of foodborne and diarrheal disease outbreaks in order to achieve goals 1 and 2.
Associated Programs, Surveillance Systems, Tools, etc.:	PulseNet National Database
Collaborators:	• state public health laboratories in all 50 states • city/county public health laboratories • state agricultural laboratories and laboratories • USDA • FDA • state agricultural labs
Domains:	• Animal • Environmental • Food • Human
Geographic Scope:	National
Budget Activity FY2009:	5 – 10 million

Table A-5. Sample list of biosurveillance systems, programs, tools, and collaboratives to be captured during future phases

Organization	Biosurveillance System Name	System Acronym
AAPCC	National Poison Data System	NPDS
AFENET	Africa Field Epidemiology Network	AFENET
Canada	Global Public Health Intelligence Network	GPHIN
DHS	Homeland Security Information Network	HSIN
DHS	National Biosurveillance Integration System	NBIS
DOD	Biological Threat Response Program	BTRP
DOD	Electronic Surveillance System for the Early Notification of Community-based Epidemics	ESSENCE
DOD	Global Emerging Infections Surveillance and Response System	GEIS
DOD	Pandemic Influenza Watchboard	
DOD	Secret Internet Protocol Router Network	SIPRNET
EU	European Influenza Surveillance Scheme	EISS
FDA	Adverse Event Reporting System	AERS
Georgetown U	Project Argus	Argus
FDA	National Antimicrobial Resistance Monitoring System	NARMS
HHS, USDA, DHS, DoD, DoS, ODN!	Biosurveillance Indications and Warning Analytic Community	BIWAC
HHS	Regional Emergency Coordinators	RECs
ISID	Program for Monitoring Emerging Diseases mail	ProMED
ITSM	GeoSentinel: Global Emerging Infections Sentinel Network	
NAHDO	National Association of Health Data Organizations	NAHDO
NALC	BioWatch/BioHazard Detection System	
NCI	Early Detection Research Network	EDRN
NPDPSC	Creutzfeldt-Jakob Disease Surveillance	
PATH	Rotavirus Vaccine Program	RVP
RSPH	Intensive Care Antimicrobial Resistance Epidemiology	ICARE
UK	QFLU	
U of Pittsburgh	National Retail Data Monitor	NRDM
U of Pittsburgh	Real Time Outbreak and Disease Surveillance System	RODS
USDA	Alaska Chronic Wasting Disease Surveillance Program	
USDA	Alaska Johne's Disease Monitoring Program	
USDA	ArboNET–Eastern Equine Encephalitis Surveillance	

USDA	ArboNET–West Nile Virus Surveillance Equine	
USDA	ArboNET–Western Equine Encephalitis Surveillance Equine	
USDA	Bovine Brucellosis Eradication Program	
USDA	Bovine Spongiform Encephalopathy Ongoing Surveillance Program	
USDA	Bulk Tank Somatic Cell Count (BTSCC) Surveillance Program	
USDA	Cervid Brucellosis Eradication Program	
USDA	Chronic Wasting Disease Surveillance	
USDA	Classical Swine Fever Surveillance Program	
USDA	Collaboration in Animal Health and Food Safety Epidemiology	CAHFSE
USDA	Exotic Newcastle Disease Surveillance	
USDA	Infectious Salmon Anemia Program	ISA
USDA	Iowa Chronic Wasting Disease Surveillance Program	
USDA	Johne's Disease Surveillance- Ovine / Caprine	
USDA	Microbiological Testing Program for Pasteurized Egg Products	
USDA	Microbiological Testing Program for Ready-to-Eat Meat and Poultry Products	
USDA	National Animal Health Laboratory Network	NAHLN
USDA	National Animal Health Reporting System	NAHRS
USDA	National Animal Health Reporting System	NAHRS
USDA	National Avian Influenza Surveillance System	NAISS
USDA	National Avian Influenza Surveillance: Wild Migratory Waterfowl	
USDA	National Bovine Tuberculosis Eradication Program	
USDA	National Cattle Fever Tick Eradication Program	
USDA	National Cervid Tuberculosis Surveillance	
USDA	National Johne's Disease Demonstration Herd Project	
USDA	National Poultry Improvement Plan	NPIP
USDA	National Scrapie Eradication Program	
USDA	National Veterinary Services Laboratory	NVSL
USDA	National Wild Fish Health Survey	
USDA	Offshore Pest Information System	OPIS
USDA	Pseudorabies Eradication Program	
USDA	Salmonella Testing of Raw Meat and Poultry	
USDA	Sentinel Feedlot Surveillance Program	
USDA	South Dakota Anthrax Surveillance Program	
USDA	South Dakota Chronic Wasting Disease Surveillance Identification Program	

USDA	South Dakota Trichomoniasis Surveillance Program	
USDA	Spring Viremia of Carp Surveillance Program	SVC
USDA	Swine Brucellosis Eradication Program	
USDA	Tennessee Chronic Wasting Disease Surveillance Program	
USDA	Trichinae Certification Program	
USDA	Vesicular Stomatitis Virus Surveillance	
USDA	Vesicular Stomatitis Virus Surveillance	
USDA	Veterinary Services Equine Infectious Anemia Surveillance	
USDA	Veterinary Services Foreign Animal Disease Surveillance	
USDA	Veterinary Services Import Program	
USDA	Voluntary Bovine Johne's Disease Control Program	VBJDCP
USDA/Canada	Bilateral Viral Hemorrhagic Surveillance Virus Initial Surveillance Plan	
USDA/CDFA	California Avian Health Program	
USDA/CDFA	California Bovine Trichomoniasis Control Program	
USDA/Michigan	Michigan Bovine Tuberculosis Eradication Project	
USPS	U.S. Post Office Hazard Sampling	
WHO	Epidemic and Pandemic Alert and Response	
WHO	Global Outbreak Alert and Response Network	GOARN
WHO	Integrated Disease Surveillance and Response	IDSR
WHO	International Food Safety Authorities Network	INFOSAN
WHO	Outbreak Alert and Verification System	
WHO	Rabnet	
WHO	WHO Global Influenza Surveillance Network	GISN

Appendix B

Workgroups Mission and Membership

Workgroups were developed taking into consideration individual recommendations from the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, and federal partners. The Biosurveillance Coordination Unit (BCU) opened all workgroups to individuals interested in participating without restriction. The workgroups are designed to provide individual input to the BCU and a forum for discussion on biosurveillance activities around the country. but not to provide consensus recommendations. Members are invited to participate in bi-weekly conference calls at which time the BCU provides an update on the work it is engaged in and often seeks individual recommendations on topics of interest to workgroup members.

HSPD-21 Biosurveillance Work Group

The mission of the federal HSPD-21 Biosurveillance Work Group is to represent the interests of federal departments and agencies in human health-related biosurveillance. Members represent the following organizations: the U.S. Department of Health and Human Service (HHS), Department of the Interior (DOI), Department of Defense (DOD), Department of Homeland Security (DHS), Department of Agriculture (USDA), Office of the Director of National Intelligence (ODNI), Indian Health Service (IHS), Environmental Protection Agency (EPA), National Institutes of Health (NIH), Veterans Administration (VA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and the U.S. Navy Postgraduate School. Additionally participating were members of NBAS.

State, Local, Tribal, Territorial Work Group

The mission of the State, Local, Tribal, Territorial Work Group is to provide input regarding the development of a national biosurveillance capability from the state and local public health and medical perspectives. This work group consists of both governmental public health and clinical medicine entities. Several members are employed by state or local government agencies. Others, although they do not officially represent their organizations, are employed by the following academic, private, and national professional institutions: the American Academy of Pediatrics; Association of Public Health Laboratories (APHL); Association of State and Territorial Health Officials (ASTHO); Attune, Inc; Boston University School of Public Health; Columbia University; Council of State and Territorial Epidemiologists (CSTE); Florida Department of Health; Georgetown University; Harvard University Medical School; Lawrence Livermore National Laboratory; LMI Research; MITRE Corporation; National Association of County and City Health Officials (NACCHO); National Plant Diagnostic Network; Northrop Grumman Corporation; Scientific Technologies Corporation; Siemens Healthcare; and Veratect Corporation.

CDC Stakeholder Groups

Within CDC, the BCU maintains three groups of stakeholders. The first is CDC leadership, which includes the CDC Director and Center and Coordinating Office Directors. This group has been holding weekly strategy meetings to discuss current and future biosurveillance efforts, gaps, and opportunities for success. The second group consists of policy and communications professionals from biosurveillance-related programs at CDC that provide input regarding policy issues, communications, and Congressional interest in biosurveillance. Policy and communications staff that participate in this group have met as a whole and, at times, in smaller, breakout groups to discuss the development of a national biosurveillance capability. The third group is the Biosurveillance Advisory Team, which consists of interested CDC scientific staff and program leads for biosurveillance efforts.

Appendix C

Acronym Glossary

A

ACD	Advisory Committee to the Director of CDC
AMIA	American Medical Informatics Association
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials

B

BGP	Biosurveillance Governance Partners

C

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

D

DHS	Department of Homeland Security

E

EARS	Early Aberration Reporting System
EIP	Emerging Infections Program
EOP	Executive Office of the President
ESSENCE	Electronic Surveillance System for Early Notification of Community-Based Epidemics

F

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

G

GAO	Government Accountability Office

H

HHS	Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
HSPD-21	Homeland Security Presidential Directive -21

I

IBGHH	Interim Biosurveillance Governance for Human Health

ICLN	Integrated Consortium of Laboratory Networks
ISDS	International Society for Disease Surveillance
IT	Information Technology

J
K
L
M

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

O

OMB	Office of Management and Budget
OPDIVS	Operating Divisions
OSTP	Office of Science and Technology Policy

P

PHIN MS	Public Health Information Network Messaging System
PHIS	Public Health Information System

Q

R

RECs	Regional Emergency Coordinators
RSPH	Rollins School for Public Health

S
T

U

USDA	United States Department of Agriculture

V
W
X
Y
Z