



NATIONAL STRATEGY FOR BIOSURVEILLANCE

JULY 2012





THE WHITE HOUSE

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There is no higher priority than the security and safety of the American people. As a Nation, we must be prepared for the full range of threats, including a terrorist attack involving a biological agent, the spread of infectious diseases, and food-borne illnesses. The effective dissemination of a lethal biological agent, for instance, could endanger the lives of hundreds of thousands of people and result in untold economic, societal, and political consequences.

In my *National Security Strategy*, I committed the United States to new approaches to counter biological threats. Specifically, I called for "obtaining timely and accurate insight on current and emerging risks." Such biosurveillance -- including early detection -- is one of our first lines of defense against these threats. As we saw during the H1N1 influenza pandemic of 2009, decisionmakers -- from the President to local officials -- need accurate and timely information in order to develop the effective responses that save lives. The sooner we can detect and understand a threat, the faster we can take action to protect the American people.

This first-ever *National Strategy for Biosurveillance* builds on the capabilities already in place and further institutionalizes our efforts to ensure that we are doing everything possible to identify and understand threats as early as possible. Its goal is to provide the critical information and ongoing situational awareness that enables better decisionmaking at all levels. It calls for a coordinated approach that brings together Federal, State, local, and tribal governments; the private sector; nongovernmental organizations; and international partners. It challenges us to take full advantage of the advanced technologies, new vaccines, the latest science, and social media that can help keep our citizens safe. It describes the core functions and critical capabilities we need to succeed.

As a next step, I am directing that a strategic implementation plan be completed within 120 days to lay out the specific actions that are required and the responsibilities of all partners in this mission. In the event of a biological outbreak or incident, the threat will move rapidly and transcend boundaries and borders. So must our response. Guided by this *Strategy*, I am confident that we can meet our shared responsibility and deepen the collaboration we need to keep our country safe and secure.

A handwritten signature in black ink, appearing to be the name 'Barack' followed by a stylized flourish.



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Introduction

A well-integrated, national biosurveillance enterprise is a national security imperative. Our ability to detect quickly and characterize a potential incident of national significance that affects human, animal, or plant health is of paramount importance. Rapid detection and enhanced situational awareness are critical to saving lives and improving incident outcomes, whether the result of a bioterror attack or other weapons of mass destruction (WMD) threat, an emerging infectious disease, pandemic, environmental disaster, or a food-borne illness. Beyond our need to protect domestic interests, and because health threats transcend national borders, the United States also plays a vital role within an international network of biosurveillance centers across the globe.

For years, there have been dedicated efforts to promote and strengthen biosurveillance capabilities. There exists a strong foundation of capacity arrayed in a tiered architecture of Federal, State, local, tribal, territorial, and private capabilities. We can strengthen the approach with focused attention on a few core functions and an increased integration of effort across the Nation. In these fiscally challenging times, we seek to leverage distributed capabilities and to add value to independent, individual efforts to protect the health and safety of the Nation through an effective national biosurveillance enterprise.

A key to improving all-hazards incident management is to focus efforts on collecting, analyzing, and disseminating information to facilitate timely decisionmaking, whether a health incident is a naturally occurring phenomenon, accidental, or deliberate in nature. From the individual, to primary care providers, to hospital practitioners, to state and local health officers, to Federal entities responsible for health emergency response, to the President of the United States, there exists an imperative to identify incidents early and to make decisions swiftly to save lives, even amidst great uncertainty. The goal is to achieve **a well-integrated national biosurveillance enterprise that saves lives by providing essential information for better decisionmaking at all levels.**

Our Strategy is to integrate and enhance national biosurveillance efforts to answer specific key questions that guide decisionmaking in times of crisis; enable more rapid detection and foster improved situational awareness by further extending a dynamic, distributed national network of expertise and capabilities; and put into practice new thinking to facilitate decisionmaking processes in conditions of significant ambiguity. This enhanced national biosurveillance capability will be applied broadly to identify and understand potential human, animal, or plant health impacts resulting from chemical, biological, radiological, and nuclear (CBRN) and environmental incidents, as well as influenza and other public health trends, all of which may also be leveraged in the service of global health efforts.

We must be resolved to strengthen life-saving biosurveillance capabilities within our existing resources. We can do this by leveraging more effectively our existing national network of expertise and capabilities, and through targeted enhancements that provide benefits across the enterprise. There are no higher priorities than the health, well being, and security of the American people.

Overview of the National Strategy for Biosurveillance

The *National Strategy for Biosurveillance* sets forth the United States Government approach to strengthen our national biosurveillance enterprise and describes a core set of functions critical to this Strategy's success. The approach builds on existing biosurveillance concepts and capabilities in seeking to enable more rapid detection, knowledge, and characterization of human, animal, or plant disease activity to enhance incident situational awareness. At the same time, this Strategy outlines an approach that is more selective and deliberate in its intent.

The Strategy defines biosurveillance as the process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and to enable better decisionmaking at all levels. This definition is consistent with that of Homeland Security Presidential Directive-21 and now emphasizes an all-hazards scope and informed decisionmaking.¹ This *National Biosurveillance Strategy* flows from the *National Security Strategy*, which highlights the importance of disease surveillance for public health threats, and is consistent with the *National Strategy for Countering Biological Threats*, which emphasizes information sharing among Federal departments and agencies to identify biological threats.

The Federal Government seeks to galvanize action across the Nation to further extend and integrate our distributed national biosurveillance enterprise. Where efforts since the tragic terrorist attacks of September 11, 2001, have focused largely on threats associated with the deliberate use of CBRN weapons, this Strategy embraces the need to engage in surveillance for WMD threats and a broader range of human, animal, and plant health challenges, including emerging infectious diseases, pandemics, agricultural threats, and food-borne illnesses. Therefore, we seek to strengthen biosurveillance capabilities to enhance all-hazards incident management by providing essential information for timely decisionmaking at all levels, whether an incident is deliberate, accidental, or naturally occurring.

Essential information is derived from a specific set of key questions that are common elements of any health emergency. These questions will be developed as part of a strategic implementation plan. This information is intended to help identify an incident, and to inform decisionmaking and time-sensitive actions at all levels to navigate health emergencies effectively. Identifying key questions and focusing our national enterprise on providing and sharing essential information is intended as a smarter, faster way to triage a health emergency and is a fundamental aspect of our Strategy.

1. Homeland Security Presidential Directive-21 remains in effect and defines biosurveillance as the process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity.

Structure of the Strategy. This Strategy articulates an overarching goal supported by core functions. It also includes guiding principles that provide a foundation for biosurveillance activities and specific enablers to achieve a well-integrated, national biosurveillance enterprise. Through a deliberate emphasis on the identified core functions and enabling focus areas, the aim is to enhance the Nation's ability to detect, track, investigate, and navigate incidents affecting human, animal, and plant health, thereby better protecting the safety, well being, and security of the American people.

The **Guiding Principles** serve as the Strategy foundation and inform biosurveillance efforts.

The **Core Functions** focus and prioritize our biosurveillance efforts.

The crosscutting **Enablers** are aimed at facilitating the successful implementation of our Strategy.

The Threat Environment

The deliberate use or accidental release of CBRN materials remains an enduring threat to the safety and security of the American people. One needs only to recall the terror and feelings of vulnerability caused by the anthrax letters of 2001. More recently, the Japan nuclear emergency resulting from an historic earthquake and tsunamis in 2011 reminded us of the social, economic, environmental, and health impacts of a radiological release incident.

Beyond CBRN-related concerns, the 2009-H1N1 influenza pandemic and the Severe Acute Respiratory Syndrome outbreak were clear demonstrations of the potential threat that pandemics and other emerging infectious diseases can pose to the American people. These incidents highlighted the challenges of ascertaining the course or impact of infectious diseases. Innovative developments mark the advent of threats of a new kind. Specifically, recent breakthroughs in synthetic biology offer the promise but also potentially the peril of technological progress, where the field is advancing at a staggering pace.

Our security and public health concerns are intertwined. Through science and technology developments, while it is increasingly possible to manufacture new and improved vaccines and therapeutics, it is equally possible to create genetically modified organisms that can evade our current countermeasures. In addition to various forms of biologic threats, intentional use of a chemical agent or radiologic device, along with the potential for chemical or radiologic industrial accidents, add to the spectrum of threats. Overall, the threat environment is dynamic and unpredictable. To address the challenge, this Strategy seeks to evolve our ability to detect rapidly and track incidents affecting human, animal, and plant health to save lives by informing decisionmaking at all levels.

Guiding Principles

Our national biosurveillance approach must address both near- and long-term information needs for a wide variety of decisionmakers and consider the context in which the overall enterprise is operating. The threat is dynamic and fiscal constraints are an everyday reality. As such, this Strategy focuses intentionally on existing, multipurpose capabilities. In addition, our biosurveillance approach emphasizes teamwork between and within Federal departments, across all layers of government, and with private sector partners.

This Strategy also aims to prompt action that will add value for individual contributors comprising our national biosurveillance enterprise. And where resources are constrained, we aim to leverage existing, distributed capabilities more fully. The Strategy intends to add value across our national enterprise and beyond, where global health security activities are an inextricably linked and necessary aspect of strengthening of our domestic biosurveillance approach.

Specific guiding principles form the foundation of our Strategy aimed at evolving and enhancing our national biosurveillance enterprise: (1) leverage existing capabilities; (2) embrace an all-of-Nation approach; (3) add value for all participants; and (4) maintain a global health perspective.

- 1. Leverage Existing Capabilities** – Taking full advantage of the resources we have, to include making key capabilities available more broadly across the enterprise, is a core principle. Extending electronic reporting of health information, including laboratory results, to public health serves as an example of rapidly communicating useful information. Another example is better integrating knowledge of human, animal, or plant health by leveraging social media and widely available tools to facilitate rapid information sharing domestically and globally. Routine, daily use of such capabilities may be leveraged to address critical requirements in the context of an emergency.
- 2. Embrace an All-of-Nation Approach** – A wide array of participants can enhance the Nation’s ability to detect, track, and navigate incidents affecting human, animal, and plant health. By consciously distributing biosurveillance activities, embracing novel community information sources, and prioritizing the development of a broader array of point-of-care diagnostics, as examples, we can expand exponentially the number of “sentinels” that may detect an incident of national significance. Establishing simple protocols and institutionalizing the sharing of discrete, essential information will enable us to achieve a meaningful integration of effort.
- 3. Add Value for All Participants** – With reduced resources a reality, a key tenet of our biosurveillance approach is to pursue deliberately a set of identified core functions and enablers across a distributed national architecture. This pursuit of core functions and focus areas should not radically alter current responsibilities or burden enterprise participants, and should provide a mutual benefit for participants. Even as we query others for information, or provide data ourselves, we can and should be mindful of how the exchange of information can enable efficiencies, to include leveraging the input of others to address local requirements. For example, providing information to the health care system can substantially benefit decisions regarding patient treatment, infection control measures, and hospital staffing. Maximizing the value of biosurveillance information at the community level will encourage greater participation and effectiveness across the national enterprise. There can be a value proposition for all with conscious attention.

4. **Maintain a Global Health Perspective** – Recent incidents have demonstrated consistently the global connections and our collective vulnerability to transnational health and security threats. In our interdependent world, where disease recognizes no borders, and where CBRN and other threats may emanate from abroad, our domestic biosurveillance approach must necessarily have an eye toward our shared participation in global health security. We should reinforce international connections with our national enterprise as the global biosurveillance network continues to grow. And we should encourage other countries to integrate their surveillance and situational awareness systems and make this information available to the global community, creating a network of information nodes enhancing global response to incidents.

Biosurveillance Goal and Core Functions

With the guiding principles as the foundation of our efforts, the *National Biosurveillance Strategy* articulates the overarching biosurveillance goal of the United States along with four core functions. Together, they promote deliberate focus and a common compass heading for our collective approach.

Our biosurveillance goal is to achieve **a well-integrated national biosurveillance enterprise that saves lives by providing essential information for better decisionmaking at all levels.**

Four core functions form the basis of the *National Biosurveillance Strategy*: (1) scan and discern the environment; (2) identify and integrate essential information; (3) inform and alert decisionmakers; and (4) forecast and advise potential impacts. These core functions are interrelated, multidimensional, and it is intended that they are pursued simultaneously, informing and influencing each other as part of a dynamic process. They are intended to increase incident understanding and to inform decisionmaking at all levels, even where significant ambiguity exists. Accomplishing these functions will help us to achieve the overall goal of biosurveillance.

1. **Scan and Discern the Environment** – This core function emphasizes attention to factors affecting the health and security of our citizens and the rapid evaluation of information to speed incident detection. Information from a range of sources, including those outside of human health or security disciplines – animal, plant, and environmental health sector information – may enhance the effectiveness of this function. The practice of actively scanning and discerning the environment involves efforts to confirm conditions and identify rapidly the emergence of new patterns or trends, while assessing their significance.
2. **Identify and Integrate Essential Information** – Our Strategy calls for the identification, sharing, and integration of essential information to expedite incident detection and assessment. Although all incidents have unique aspects, there are common elements of any national public health emergency. As with a health care provider and a new patient, there are certain key questions asked to identify symptoms and narrow probable causes to assist with patient treatment. Similarly, essential information can be derived from a discrete set of key questions to speed incident detection and awareness. Information sharing and integration will be easier to achieve and to institutionalize across the national biosurveillance enterprise by focusing on these key questions.

Beyond essential information to detect and characterize an incident of national significance affecting human, animal, or plant health, our Strategy emphasizes purposeful integration across disparate information sources, including data derived from intelligence, law enforcement, environmental, plant, animal, and other relevant areas. The intent is not to share all information with all participants in the national biosurveillance enterprise, but rather to seek opportunities to add value for others by thinking more broadly about what information may be useful to enterprise participants and to share this information and analysis proactively.

By identifying, sharing, and integrating diverse information sources and expert analysis, collectively we will be more likely to identify trends signaling an incident and better able to answer key questions. The initial priority is to detect the earliest signs of potential security and health threats, then focus biosurveillance activities on the characterization and validation of the identified threat, and finally, track the threat and provide ongoing situational awareness.

- 3. Alert and Inform Decisionmakers** – There exists an enduring requirement that our national biosurveillance enterprise be able to alert rapidly and inform decisionmakers of a potential incident of national significance, providing early warning and critical updates throughout any evolving incident. This function to alert and inform is iterative. And alerts do not necessarily mandate definitive action. A tension often exists between certainty and timelines for action, so it is necessary to find a balance among entities responsible for providing incident information and decisionmakers responsible for action regarding the information.
- 4. Forecast and Advise Impacts** – Decisions made during an incident require an accurate comprehension of the knowable facts of the current situation and benefit from a forecast of the probable trajectory, duration, and magnitude of that incident into the future. This forecasting capability can assist in addressing the need to act quickly to save lives and prevent negative economic consequences in certain situations, even amidst great uncertainty and ambiguity. This function involves identifying the most likely and probable impact and outcomes, and where applicable, the most dangerous and worst case scenarios. Forecasting is a cognitive process informed by facts and models, and honed with experience. Similar to economic forecasting, improvement in forecasting is not solely reliant on better modeling and simulation, but in cultivating skills derived through experience and professional development.

An efficient, effective, and well-integrated biosurveillance enterprise depends on all participants focusing their programs toward implementation of these functions. The core functions are the specific and priority areas of focus for enhancing the coordination and management of incidents of national significance affecting human, animal, and plant health, and serving as a key node in an emerging international network focused on global health. The deliberate pursuit of these carefully selected core functions is aimed at strengthening the national biosurveillance enterprise, adding value for all, and expediting decisionmaking at all levels.

Enablers for Strengthening Biosurveillance

Enabling capabilities are identified as part of our Strategy for a well-integrated national biosurveillance enterprise. Emphasis on empowering a distributed architecture and advances in relevant science and technology capabilities are a priority. These enabling capabilities are identified to facilitate the specified biosurveillance core functions. They represent ongoing focus areas to strengthen further the coordination and management of incidents of national significance affecting human, animal, and plant health.

- 1. Integrate Capabilities** – Seek out new and creative ways to integrate biosurveillance capabilities, such as regional information sharing arrangements combining human, animal, and plant health trends. Emphasize efforts to transcend regular boundaries and across traditional organizational lines. Consider social media as a force multiplier that can empower individuals and communities to provide early warning and global situational awareness.
- 2. Build Capacity** – Prioritize capacity building across our distributed national biosurveillance architecture, including development and use of point-of-care and multipathogen diagnostics, and the integration of fusion centers, law enforcement, intelligence, and other information collection and sharing activities. Develop a professional work force with multidisciplinary education, familiarization with information technology, and mentorship that emphasizes the four functions of biosurveillance, particularly forecasting.
- 3. Foster Innovation** – Identify science and technology capabilities that will facilitate biosurveillance activities, including new detection and health information exchange approaches. There is substantial opportunity with the evolution of information technology to create distributed networks and empower individuals to enhance the value of biosurveillance information. In addition, encourage new thinking and the development of revised methodologies aimed at forecasting likely CBRN incidents, food-borne illness, environmental disasters, and outbreak trajectories in the absence of definitive data. As with economic and weather forecasting, there are innovative ways to combine information and known facts to project what is likely to transpire.
- 4. Strengthen Partnerships** – Pursue biosurveillance activities that purposefully mix and match efforts and the sharing of information between and among Federal, State, local, tribal, territorial, private, nongovernmental, academic, and other national enterprise participants. Seek out an awareness of the interests of others and find ways to provide mutual benefit through existing and new partnerships and consideration of all aspects of the biosphere. Develop connections through collaborative international biosurveillance activities that will accelerate effective response to domestic and international incidents.

Way Forward

A strategic implementation plan shall be completed within 120 days of the issuance of this Biosurveillance Strategy, which will include specific actions and activity scope, designated roles and responsibilities, and a mechanism for evaluating progress. During the development of the implementation plan, we will delineate the key questions that identify biosurveillance essential information for decisionmaking. Current and planned activities and capabilities-based planning will complement the Presidential Policy Directive-8 – “*National Preparedness*” implementation process, where biosurveillance is identified as a key capability for national preparedness.

Conclusion

Protecting the health and safety of the American people through a well-integrated national biosurveillance enterprise is a top national security priority. It requires that we focus on core functions to make further progress. It also necessitates that we embrace an all-of-Nation approach and indeed a global health security intent, as the effects of any deliberate CBRN attack or accident, or emerging infectious disease, can transcend national borders. There exists an imperative that we expand our efforts to detect rapidly a potential incident of national significance affecting human, animal, or plant health, whether resulting from a bioterror attack or other CBRN threat, an emerging infectious disease, pandemic, or a food-borne illness. Rapid detection is critical to save lives and improve incident outcomes, and the United States serves as a key node as part of an international network of biosurveillance centers across the globe.

Our *National Strategy for Biosurveillance* seeks to leverage existing capabilities across the Nation yet emphasizes a discrete focus on specified core functions. It articulates that essential information can be derived from a specific set of questions to speed the detection of a deliberate or accidental CBRN incident or naturally occurring disease outbreak. This Strategy further articulates that when the collection and sharing of this essential information is prioritized, decisionmaking can be expedited at all levels of government and beyond. This is the essence of our approach. While other activities are integral to everyday local biosurveillance efforts that can and should continue, our Strategy calls for a national focus on fewer issues so that more can be achieved collectively. Our approach also seeks to inspire new thinking and revised methodologies to “forecast” that which we cannot yet prove, so that timely decisions can be made to save lives and reduce impacts during an emergency incident. This is our Strategy. It is our plan of action to protect the health, well being, and safety of the American people as part of the global community.

