EXECUTIVE SUMMARY

The United States Department of Health and Human Services (HHS) Secretary, through the Assistant Secretary for Preparedness and Response (ASPR), directs activities related to the nation’s public health and health preparedness, as well as assuring appropriate national response capability such as medical countermeasures. The National Biodefense Science Board (NBSB) was tasked with providing guidelines and recommendations for a coordinated strategy to assure the nation’s biosurveillance capacity as it contributes to situational awareness of issues potentially and actually impacting the public’s health.1

A “biosurveillance” system includes programs, policies, procedures, workforce, and technology related to biosurveillance for human health. Biosurveillance is an important component of public health and healthcare situational awareness2 but would not in itself include other components of situational awareness such as inventory and resource management. Biosurveillance is, however, connected to the public health and healthcare response component of situational awareness by ensuring the most optimal and informed decision making to thereby assure our national health security.

Effective and useful biosurveillance activities and systems already exist to fulfill the specific needs of the population and/or area for which they were developed. However, the NBSB recognizes that there are 1) duplication in biosurveillance activities across systems and agencies resulting in similar or identical analyses and consequently inefficient use of limited resources, 2) differing perspectives and analyses of the same “raw” information resulting in non-integrated and potentially confusing or even opposing situational perspectives, requiring better correlation and reconciliation across the US Government (USG) agencies, and 3) inadequate or lack of efficient and relevant information sharing at and across all levels and areas. In addition, the NBSB agrees that “…developing a robust, integrated, national biosurveillance capability could benefit from an effective national strategy and focal point with sufficient time, responsibility, authority, and resources to lead the effort.”3 Therefore, the NBSB in its report of April 3, 2013, recommended the establishment of a single centralized oversight authority, hereafter referred to as the Central Executive Strategic Group (CESG):

“The NBSB strongly emphasizes the need to designate an oversight authority to assure compatibility, consistency, continuity, coordination, and integration of all the disparate systems and data

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1 The 2013 HHS Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA) HR 307 Title II Sec 204, tasks the NBSB with providing expert advice, including recommendations, “regarding the measurable steps the Secretary [HHS] should take to modernize and enhance biosurveillance activities pursuant to the efforts of the HHS to ensure comprehensive, real-time, all-hazards biosurveillance capabilities.” P. 18
2 In their April 3rd report, the NBSB proposed that the scope of public health situational awareness encompasses: surveillance for existing and emerging public health threats (biological, chemical, radiological) domestically and abroad, whether through monitoring for changes in trends of current disease or signals of new diseases, and whether originating in human health or elsewhere (e.g. animal health); and real-time awareness of the capacity to provide routine as well as emergency public health interventions. The scope of healthcare situational awareness comprises real-time awareness of the capacity to provide routine as well as emergency healthcare, whether in regular practice or during a crisis. See http://www.phe.gov/Preparedness/legal/boards/nbsb/Documents/sa-evaluation.pdf
requirements. Therefore, the NBSB recommends that the Secretary of HHS designate a central situational awareness authority for coordinating all public health and healthcare situational awareness data that have already been collected, processed, and analyzed from respective agencies on a national level; the authority will also have the responsibility to recommend corrective actions to improve situational awareness, including, the standardization of common operating procedures. 

The NBSB specifically recommends that the HHS Secretary invite senior representatives from the multiple federal agencies involved in public health and healthcare biosurveillance to comprise this executive group to evaluate and coordinate biosurveillance activities across the federal agencies and its partners. The CESG’s role is to coordinate and develop national-level strategies for implementing an integrated nationwide biosurveillance system that provides continuous and accessible situational awareness to decision-makers at all levels.

In its April 3, 2013, report, the NBSB proposed a series of activities to be undertaken by the CESG. In addition to these activities, the NBSB recommends the following key activity:

To effectively and efficiently establish a comprehensive, real-time, and all-hazards biosurveillance system, the NBSB recommends that the CESG develop a detailed strategy for the design and implementation of an integrated analytical and interpretive capability that would be applicable across the existing public health and healthcare biosurveillance systems.

The strategy should include a formal assessment of human health biosurveillance system redundancies, overlapping activities, and biosurveillance information gaps. In this context, the CESG should consider the following:

- The newly developed HHS Centers for Disease Control and Prevention (CDC) National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC) mission is to provide recommendations related to both traditional and innovative sources of human health related information as well as the exchange of healthcare and public health information. Therefore, to ensure integration and consistency in advice and guidance regarding biosurveillance activities across USG agencies, NPHSBAC recommendations should be evaluated for inclusion into the integration strategy.
- The strategy should recognize that effective biosurveillance is necessarily broad in scope, monitoring all threats naturally occurring or intentionally introduced, and include animal, plant, and environmental monitoring to identify all potential threats to human health, domestically and abroad. Human skill and experience (e.g. epidemiologists and biostatisticians experienced in biosurveillance and public health investigations), as much as information collection and organization, are essential to provide appropriate context and interpretation for fully informed

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5 The NBSB recognizes the Department of Homeland Security National Biosurveillance Integration System’s (NBIS) current role as an interagency community providing national biosurveillance and situational awareness by acquiring, integrating, analyzing, and disseminating information, and recommends that the composition of the proposed CESG, in its main coordination role, utilize the NBIS’ interagency framework as a model for interagency engagement and collaboration.
decisions and recommendations. Both the specific information gleaned and derived from traditional surveillance as well as the potentially meaningful event indications from non-traditional methods of biosurveillance—e.g. syndromic surveillance and social media—could enhance current biosurveillance when leveraged appropriately; further investigation, however, is required to understand their usefulness for decision-making. Another non-traditional source of information to explore for potential additional and critical insights is national security information supplied by USG agencies, including federal law enforcement and intelligence agencies. Existing international agreements and codes of conduct (e.g. International Health Regulations), in addition to domestic laws, regulations, information-sharing, policies and agreements, must be accounted for and integrated into our biosurveillance efforts; our focus must expand beyond our own borders to include events that may impact our citizens at home and/or abroad.

- Finally, integration strategy initiatives should recommend ongoing transparency and communication efforts with relevant agency partners, the pursuit of standardization to achieve public health and healthcare information integration and situational awareness, and the ongoing conduct of program evaluations to ensure that the needs of an integrated biosurveillance network are continuously addressed across the relevant USG agencies.

To assure the implementation and management of the integration strategy, the NBSB in its April 3, 2013 report recommended the establishment of “a central portfolio management group, under the authority,” that would “help coordinate between all biosurveillance activities conducted by various agencies...” In the present report, the NBSB specifically recommends the establishment of a Strategic Integration Group (SIG) composed of appropriate program management representatives, including lead biosurveillance subject matter experts, from each of the involved federal agencies.

The SIG will work with the CESG to manage the implementation of the integration strategy and assure appropriate coordination among the agencies. The SIG will be responsible for the initial activities of the strategy, including the assessment of human health biosurveillance activity redundancies and gaps, and the development of critical information requirements and common standards for data collected to better facilitate the sustainability of systems and the alignment of activities across agencies. As the implementation of the strategy progresses and evolves, the CESG will assure appropriate coordination among the relevant agencies and, importantly, will assure that the eventual goal of integrated information and analysis, resulting in effective contributions to public health and healthcare situational awareness, is achieved. The intent of the NBSB recommendation is not to create yet another permanent agency or organization within the USG, but rather to fill a perceived need for coordination among all key players involved in public health and health care situational awareness activities, including biosurveillance. Through periodic evaluation of the CESG and SIG’s progress, the Secretary of HHS, at his/her discretion, will determine whether or not that need has been fulfilled.

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6 For example, information collected by the National Center for Medical Intelligence (NCMI)—NCMI defines medical intelligence as the category analysis and interpretation of foreign medical, bio-scientific, and environmental information that is of interest to national security and the Homeland; HHS is not involved in the gathering or dissemination of such medical intelligence. In addition, the Federal Bureau of Investigation (FBI) is involved in several biosurveillance activities in collaboration with other agencies. See pgs. 25-26 for further information.

INTRODUCTION

On April 3, 2013, the National Biodefense Science Board (NBSB) transmitted a report with recommendations to the Department of Health and Human Services (HHS) Secretary and Assistant Secretary for Preparedness and Response (ASPR), entitled, An Evaluation of Our Nation’s Public Health and Healthcare Situational Awareness, offering guidance and recommendations on the measurable steps to take to enhance the nation’s current public health and healthcare situational awareness capabilities. The NBSB has continued its work on this topic and offers this report with recommendations on the measurable steps the HHS Secretary should take to enhance our nation’s biosurveillance capabilities, in response to both the task from the ASPR and directives in the 2013 Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA).

The NBSB was asked by the ASPR to “… assess current biosurveillance activities, identify efficiencies, and make recommendations, in coordination with the applicable existing Centers for Disease Control and Prevention (CDC) advisory committees.” In addition, the 2013 PAHPRA directives (HR 307 Title II Sec 204) specifically asks the NBSB to identify the steps necessary to achieve a national biosurveillance system for human health with international connectivity; identify any duplicate surveillance programs under the HHS, or changes necessary to existing programs to enhance and modernize activities, minimize duplication, strengthen and streamline activities, and achieve real-time data for both human and zoonotic disease activity; and, to coordinate with applicable existing CDC advisory committees.

In coordination with CDC, the NBSB reconvened and augmented membership on the Situational Awareness (SA) Strategy and Implementation Plan (SIP) Working Group (WG) to obtain a range of stakeholder views. To thoroughly, thoughtfully, and effectively respond to the task and directives, the WG felt it was necessary to develop a strategic approach addressing the main key issues identified through their research, deliberation, and correspondence with several federal entities involved in public health and healthcare situational awareness and human health biosurveillance activities across the US Government (USG).

The NBSB held a public meeting via teleconference on October 31, 2013, to consider, deliberate, and vote on the recommendations presented by the SA SIP WG. Following discussion by the members and the public, the NBSB voted on, and approved the transmittal of the recommendations in this report to the Secretary of HHS and ASPR for consideration.

In response to the task from the ASPR and directives in the 2013 PAHPRA, the NBSB offers this report with recommendations regarding the measurable steps the HHS Secretary should take to modernize and

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9 See Appendix I for the task letter from the ASPR.
11 See Appendix II for revised SA SIP WG Roster
12 The WG held a series of teleconferences and webinars to gather further data, deliberate, and comment on this draft report, developed by the WG Chair, Dr. Sarah Park, and Co-Chair, Dr. Manohar Furtado.
enhance biosurveillance activities pursuant to the efforts of HHS to ensure comprehensive, real-time, all hazards biosurveillance capabilities.
RECOMMENDATIONS

The 2013 PAHPRA (HR 307 Title II Sec 204) tasked the NBSB with providing guidance, including recommendations, regarding the steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of HHS. The NBSB highlights that clarifying the numerous governmental and private sector entities’ roles and responsibilities for leading, partnering, or supporting biosurveillance activities could help ensure timely disease detection and public health/healthcare situational awareness across these multiple domains to enhance critical decision making, “Clarifying roles and responsibilities could also help identify gaps or duplications in biosurveillance coverage within and across domains and determine whether they should be addressed.” To help achieve a national biosurveillance system for human health with international connectivity, and ensure comprehensive, real-time, all-hazards biosurveillance capabilities, the NBSB re-emphasizes the need for the HHS Secretary to convene a HHS-led centralized public health and healthcare situational awareness oversight authority with invited federal partners to act as the central focal point to assure the compatibility, consistency, continuity, coordination, and integration of all disparate systems, and information requirements, hereafter, referred to as the Central Executive Strategic Group (CESG). A central task of the CESG is the development of a strategy to coordinate the effective integration of activities across the federal agencies (and partners) currently engaged in public health and healthcare situational awareness, including human health biosurveillance. The CESG’s role is to coordinate and develop national-level strategies for implementing an integrated nationwide biosurveillance system that provides continuous and accessible situational awareness to decision-makers at all levels.

The strategy should focus on alignment of key biosurveillance systems, processes, and protocols with the goal of ensuring that the necessary information is available to those who need it for decision making. In doing so, the strategy would identify any overlap of biosurveillance activities and objectives, any gaps in the current biosurveillance network and activities needed to fill those gaps, and develop critical information requirements and common standards for data collection. The strategy should eventually include specific recommendations for remediating any redundancies and gaps, should focus on the goal of integrating biosurveillance information and analytics, and include:

- A process for evaluating and selecting the optimal information collection and information reporting systems as well as the ideal combinations of such to provide direction to HHS agencies and recommendations to all USG departments involved in human health and healthcare-related biosurveillance activities, and hence fill in gaps in information requirements and avoid overlap, as appropriate;
- Periodic monitoring of information summaries provided by various agencies and sources relevant to public health and healthcare situational awareness (biosurveillance, public health, media, intelligence, etc.) to make recommendations regarding gaps in critical information, areas for improvement, and confirm that critical information requirements are being met; and

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Experts,

As the academia state, Secretary activities, coordination implementation another Integrated standing Specifics, especially on required/efficiencies. Committee recommendations strategically activities potential Stakeholders, biosurveillance practices (i.e., states and locals)—for example, Department of Defense (DoD) separately requesting the same or similar information from the same source as CDC.

As part of this effort, the NBSB also recommends the establishment of a Strategic Integration Group (SIG) composed of management representatives, including lead biosurveillance subject matter experts, from the relevant agencies. The SIG is specifically tasked with assuring the implementation of the CESG’s strategy with the goal of integrating and coordinating biosurveillance activities and analyses. The initial focus will necessarily be on the evaluation of existing biosurveillance redundancies and gaps. As the implementation of the strategy progresses and evolves, the SIG will assure appropriate coordination among the relevant agencies and, importantly, will assure that the eventual goal of integrated information and analysis, resulting in effective contributions to public health and healthcare situational awareness, is achieved. Under the guidance of the CESG’s strategy, the SIG will also ensure close collaboration and communication among the relevant federal partner agencies as well as across state, local, tribal, and territorial (SLTT) agencies, and including healthcare, private industry, and academia disciplines involved in biosurveillance activities. The work and accomplishments of the SIG should be regularly reviewed by the CESG. The intent of SIG, or even the CESG, is not to create yet another permanent agency or organization within the USG, but rather to fill a perceived need for coordination among all key players involved in public health and health care situational awareness activities, including biosurveillance. Through periodic evaluation of the CESG and SIG’s progress, the Secretary of HHS, at his/her discretion, will determine whether or not that need has been fulfilled by standing down one or both groups.

Specifically, the NBSB recommends that the CESG consider the following as it devises its strategy for implementation by the SIG:

Integrated Advice—Involve the National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC) with the CESG’s Activities

Assuming the formation of a CESG, the NPHSBAC should consider the CESG’s role when making recommendations for public health biosurveillance and situational awareness activities across the USG on a consistent and ongoing basis. Such recommendations should include not only CDC surveillance activities but, as needed, activities undertaken by other federal agencies to determine their usefulness, potential for coordination, as well as overlap/redundancy, and effort and resources required/efficiencies. Based on the recommendations from the NPHSBAC, the CESG will be able to strategically develop focused goals, determine a set of critical information needs among all stakeholders, integrate thinking, and recognize existing as well as cultivate new expertise and best practices with regard to limited resources to ensure a truly coordinated and integrated national biosurveillance system with international connectivity.
Within the scope of the NPHSBAC’s chartered duties, the NBSB proposes that the NPHSBAC thoughtfully consider and provide recommendations as it executes its charge by answering the following biosurveillance-centered questions in an effort to provide a foundation for the CESG’s strategy:

- Enabling State and local public health biosurveillance capabilities: What do the federal government and its state and local partners expect of “biosurveillance?” This requires specific articulation.
- Effectiveness of electronic health information exchange: Are the existing systems/methods adequate given this expectation and associated specific tasks?
- Innovative sources of biosurveillance information and its integration: Importantly, how can this be accomplished in the most efficient way, particularly with regard to integration of information and analysis?
- Gaps in biosurveillance and public health surveillance capabilities: Given the importance of integration, how should biosurveillance activities that occur across various government organizations (HHS, DOD, etc.) and are synchronized and centrally coordinated continue to identify and eliminate gaps in biosurveillance in a long-term sustainable manner?

**Additional Focus—Review and Define the Utility of Non-Traditional Information Sources to Traditional Ones**

With regard to the scope of biosurveillance that the CESG’s strategy must consider, the NBSB recommends the need to also focus on information from environmental, chemical, and radiological/nuclear surveillance which fall within the definition of biosurveillance as it relates to human health and safety. Additionally, a careful review of the added value of signals from these types of surveillance as well as non-traditional information sources, such as active surveillance of news and social media, should be evaluated as a complement to traditional specific, sensitive, real- or near real-time, all-hazards, and flexible capabilities. The utility of national security information to HHS can complement the full spectrum of biosurveillance from early warning by using non-traditional sources to enhance the traditional biosurveillance and response action that follows. Finally, agreements and information sharing processes with other countries should be improved and enhanced to ensure that critical biosurveillance data are accessible and available to recognize internationally emerging diseases of considerable national and global impact.

**Standardization of Strategies—Address the Same Baseline Needs for Consistency and Continuity**

To further the coordination of biosurveillance activities, integration initiatives should continue ongoing transparency and communication efforts with relevant agency partners, pursue standardization of data requirements to achieve public health and healthcare information integration and situational awareness, and routinely conduct program evaluation to ensure that the following needs are continuously addressed across the USG:

- Consideration of essential information needs and adequate performance of the systems that support them.
- Reduced and reasonable burden on SLTT partners.
• Broader, cost-effective, and more sophisticated use of information technology, including increased use of electronic health records (EHRs).
• An integrated approach to assuring information needs for all information-sharing partners are met while identifying opportunities for creating efficiencies.
• Consistent support for training and development of a capable, multidisciplinary biosurveillance workforce across the SLTT and federal system.

Ultimately, integration through the synchronization and coordination of biosurveillance efforts will enhance critical decision-making toward protecting our national health security.

Relationships and Responsibilities Outlined by Recommendations

HHS Secretary (Convening Authority)

Central Executive Strategic Group (CESG) (Reports to Secretary)

Composed of senior representatives from all relevant USG agencies involved in public health and healthcare situational awareness and biosurveillance. Responsible for better interagency communications and collaboration relevant to the monitoring of all public health and healthcare biosurveillance and situational awareness activities across agencies; in particular, the development of a strategy to coordinate the effective integration of such activities across federal agencies (and partners) currently engaged in public health and healthcare situational awareness, including human health biosurveillance.

Strategic Integrating Group (SIG) (Reports to CESG)

Composed of individuals with portfolio management expertise, including lead biosurveillance subject matter experts, from each of the USG departments and agencies involved in biosurveillance activities. Responsible for the implementation of the CESG’s strategy through evaluating and determining the optimal biosurveillance activities and systems, aligning disparate activities across multiple USG agencies by identifying and replicating best practices, recognizing programmatic overlaps, and making recommendations to maximize efficiencies.

National Biodefense Science Board (ASPR) Advisory Role

National Public Health Surveillance and Biosurveillance Advisory Committee (CDC Director) Advisory Role
KEY SUPPORTING INFORMATION - The following section presents elements that were considered in the development of the NBSB’s recommendations.

Definition and Scope of Biosurveillance

PAHPRA 2013 – “Biosurveillance means the process of gathering near real-time biological information that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing trafficking on health events, and overall situational awareness of disease activity.”

Optimal public health biosurveillance requires not only the collection and organization of information elements but, especially, skilled and experienced persons to appropriately validate/verify, analyze, and interpret these elements in the appropriate context. Information alone without the human element to verify its relevance would be meaningless. With this in mind, biosurveillance is the science and practice of managing and interpreting health-related information with the primary goal of timely and accurate public health and healthcare situational awareness for:

- Early detection of events
- Signal validation
- Event characterization
- Event monitoring
- Alert and notification of responsible governmental entities
- Public warning and protection
- Effective response to mitigate adverse health effects

The scope and function of public health biosurveillance:

- Encompasses all hazards: including biological, chemical, radiological, nuclear, and explosives such that animal health, plant/agricultural issues, microorganism characteristics, and environmental (artificial, man-made, and natural) factors impacting human health are monitored
- Is defined by urgency and potential for multi-jurisdictional interest
- Includes urgent notifiable conditions as well as non-specific and novel health events
- Includes ad hoc information gathering, analysis, and application of information
- Includes the following functions: case detection, event detection, signal validation, event characterization, projection of event impact, notification and communication, and quality control and improvement

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16 Ibid
17 The Council of State and Territorial Epidemiologists (CSTE) holds the responsibility for defining and recommending which diseases and conditions are reportable within states and which of these diseases and conditions will be voluntarily reported to CDC. A listing of currently nationally notifiable diseases can be found at http://www.cdc.gov/nndss/script/conditionlist.aspx?type=0&yr=2013.
Supports rapid and efficient discharge of responsibilities related to the International Health Regulations [IHR (2005)] and coordination with US National IHR Focal Point.

Efforts to Leverage Non-traditional Biosurveillance Capabilities to Traditional Ones

Different information sources can be utilized for biosurveillance. Ideally, monitoring and analysis of many disparate types of reports collected can allow government to identify potential threats with some advance interval to react with appropriate countermeasures or other public health actions as required; the potential utility of syndromic surveillance is exemplified in Figure 1 on page 12. However, some of this information must be categorized as preliminary and not verified when gathered and/or used, and “detection” could occur at any point based on the sensitivity, specificity, and positive predictive value of the information source, which could vary widely from one type to the other. Today, our nation’s biosurveillance capability rests primarily in our public health surveillance system. Traditional biosurveillance systems include the monitoring and gathering of information received from ambulatory care, hospital, laboratory, and epidemiological sources. Non-traditional biosurveillance capabilities include the regional and global monitoring and gathering of information with human health relevance for the emergence and spread of a pathogen that could enter the area of concern (e.g. the Homeland); this includes global syndromic surveillance—including national security information as well as active surveillance of news and social media. Such sources could contribute to establishing a baseline, in which context one might then assess events and identify changes that could potentially indicate an incident of public health importance. Further investigation of such a signal could determine whether a response is warranted and whether assets should be deployed. Figure 2 demonstrates the hypothetical timing of potentially useful information available from electronic sources in the evolution of a disease outbreak.

Caution must be taken when utilizing non-traditional information from international as well as domestic sources; the balance among finding new sources of information, strengthening the use of traditional biosurveillance information, and adapting to specific needs can vary from state to state and country to country. However, given the trend of emerging diseases with international origins, the global monitoring of “biological issues of national significance” should be prioritized for the surveillance of foreign disease events that could pose disastrous public health and non-public health effects on our nation’s infrastructure.

Previous Work to Develop Strategies/Recommendations to Improve Public Health and Healthcare Situational Awareness and Outline Ongoing Nationwide Biosurveillance Capability Efforts

Appendix III lists selected strategies and recommendations. In 2011, the National Biosurveillance Advisory Subcommittee (NBAS) submitted their second report entitled, Improving the Nation’s Ability to Detect and Respond to 21st Century Urgent Health Threats. The NBSB supports the recommendations offered by NBAS and fully agrees that the “achievement of comprehensive, effective domestic and international biosurveillance is compromised by jurisdictional complexity and inefficiencies.”

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Existence of Ongoing Integration Initiatives within Agencies and Departments Involved in Public Health and Healthcare Biosurveillance and Situational Awareness

An example of current efforts within an agency is CDC’s ongoing effort to develop and implement a draft CDC Surveillance Strategy. This effort involves working across CDC with leadership and programs to establish policy, procedures, and parameters to improve efficiencies and make data more readily available in order to enhance current and future surveillance/biosurveillance activities. A part of this effort is focused on reducing the burden of SLTT partners and enhancing their surveillance capabilities. This effort also includes the use of EHRs as a part of that strategy for public health surveillance. The goals of this initiative are to:

- Improve surveillance efficiency through a process of identifying areas where there are opportunities to standardize, consolidate, or eliminate duplication;
- Advance the use of EHR information; and
- Leverage new technologies that will enable shared infrastructure and services.

Development of a National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC) in the Fall of 2013

The CDC’s NPHSBAC will provide recommendations focused on ensuring the Federal Government is meeting the goal of enabling State and local government public health surveillance capabilities. Specifically, these include recommendations related to both traditional and innovative sources of human health related information as well as the exchange of public health and healthcare information. These recommendations will support CDC’s ongoing effort to evaluate public health and biosurveillance activities across CDC. Where feasible, these recommendations could also include activities outside CDC as they relate to usefulness, potential for coordination, overlap/redundancy, and effort and resources required/efficiencies. The NPHSBAC recommendations may be implemented in part or in their entirety by the CESG through the SIG as it works to ensure the integrated analysis and coordination of biosurveillance information and activities.

Existence of Multiple Coordinating Bodies Involved in Public Health and Healthcare Biosurveillance Activities toward National and International Situational Awareness

Biosurveillance activities to varying depths and success already exist at multiple levels, vertically (i.e., local, state, regional, national) and horizontally (e.g., across multiple agencies in the USG). Examples of some existing public health and healthcare situational awareness and biosurveillance coordinating entities at the national and international levels are provided in Appendix IV. Some agencies already work in concert with each other to varying degrees, while others are siloed, such that the full potential and dimension of the valuable information and analysis they might provide are not realized for lack of applying to a fuller context through sharing across relevant groups.

20 Also see Figure 3 on page 14 for a GAO diagram of USG agency biosurveillance roles and responsibilities
Figure 1. An example of the potential utility of syndromic surveillance through the demonstration of a progression of data sources as related to the underlying infection and associated behaviors.

Figure 2. Hypothetical timing of informal electronic sources available during a disease outbreak.

Figure 3. United States Government agency biosurveillance roles and responsibilities


APPENDIX I

Task Letter from ASPR to NBSB
Dear Dr. Parker and Members of the National Biodefense Science Board (NBSB):

The Department of Health and Human Services has begun activities to develop a Public Health and Healthcare Situational Awareness (SA) Strategy and Implementation Plan (SIP). The Public Health and Healthcare SA SIP aims to strengthen our overall national health security by serving as a comprehensive and national strategy and implementation plan, as called for in the current legislation to reauthorize the Pandemic and All Hazards Preparedness Act (PAHP). The Public Health and Healthcare SA SIP will provide a common approach to building SA capabilities, to ensure the early detection of incidents with potential adverse health impacts, as well as effective decision making and resource allocation during a response.

I would like the NBSB to review and evaluate the Public Health and Healthcare SA SIP during its development to offer guidance, including recommendations, on the measurable steps to take to enhance our current public health and healthcare situational awareness capabilities. Biosurveillance is one of the major components of situational awareness, therefore, I would also like the NBSB to assess current biosurveillance activities, identify efficiencies, and make recommendations, in coordination with the applicable existing Centers for Disease Control and Prevention (CDC) advisory committees. The Office of the Assistant Secretary for Preparedness and Response (ASPR) and the CDC will lead the SA SIP development process.

Given the NBSB’s demonstrated ability, experience, and expertise, your contributions towards the development of this strategy and implementation plan are yet another critical step taken towards ensuring the public health and healthcare preparedness of our nation.

In performing your deliberations, however, I encourage the NBSB to obtain stakeholder views on this topic using whatever means is deemed most appropriate. I look forward to discussing your initial thoughts on this topic at the June 26, 2012, NBSB public meeting. The timeline for completion will be consistent with the timeline established in the final reauthorization of the PAHP.

Thank you for your continued diligence in serving to strengthen our nation’s resilience.

Sincerely,

/s/ Nicole Lurie, MD

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
APPENDIX II

National Biodefense Science Board Situational Awareness Working Group Roster

Voting Members

Chair, Sarah Y. Park, MD, FAAP
State Epidemiologist and Chief
Disease Outbreak Control Division
Hawaii Department of Health
Honolulu, HI

Co-Chair, Manohar R. Furtado, PhD
Founder and President
Biology for Global Good LLC
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Georges C. Benjamin, MD, FACP, FACEP(E), FNAPA, Hon FRSPH
Executive Director
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Emilio A. Emini, Ph.D.
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John S. Parker, MD, Major General (Retired)
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Ex Officio Members

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Invited Federal Representatives

James B. Daniel, MPH
Public Health Coordinator, Office of Provider Adoption Support
Office of the National Coordinator for Health IT
US Department of Health and Human Services
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Director, Biosurveillance Coordination Activity
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Pam Evans, CEM  
Acting, Director, Secretary's Operation Center  
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Efrain E. Garcia, PhD  
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Division of International Health Security  
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Office of the Assistant Secretary for Preparedness and Response  
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Glenn Dowling, MD, MPH  
Director, Medical Preparedness Policy  
National Security Staff  
The White House  
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Taha A. Kass-Hout, MD, MS  
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FDA Chief Technology Officer (Acting)  
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Kathryn L Morici, MD, MPH  
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APPENDIX III

Selected Strategies, Recommendations, and International Agreements for Improving Situational Awareness:


- Informed and empowered individuals, communities
- National health security workforce
- Integrated, scalable health care delivery systems
- Situational awareness
- Timely and effective communications
- Effective counter measures enterprise
- Prevention/mitigation of environmental, other health threats
- Post-incident health recovery in planning and response
- Cross-border and global partnerships
- Science, evaluation, quality improvement


- Common national approach to public health and healthcare situational awareness for national health security
- Near real-time awareness of evolving incidents with potentially negative health consequences
- Near real-time awareness of availability and location of resources (both personnel and other) before and during incidents with potentially negative health consequences
- Effective coordination of health-related situational awareness, including scalability from local, national, and international levels, involving both private and public sectors


- Electronic Health Information Exchange
- Electronic Laboratory Information Exchange
- Unstructured Information
- Integrated Biosurveillance Information
- Global Disease Detection and Collaboration
- Biosurveillance Workforce of the Future

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Concept plan for Implementation of the National Biosurveillance Strategy for Human Health (January 2010):^24

- Governance model for enhancing collaboration between stakeholders
- Approach to assess existing biosurveillance activities that comprise our collective investment in national biosurveillance for human health
- Approach to communicating the efforts of this nationwide enterprise to a wider audience of policy makers and health professionals.

National Strategic Plan for Public Health Preparedness and Response (September 2011). (NSPPHPR):^25

- Prevent and/or mitigate threats to the public’s health
- Integrate public health, the healthcare system, and emergency management
- Promote resilient individuals and communities
- Advance surveillance, epidemiology, and laboratory science and service practice
- Increase the application of science to preparedness and response practice
- Strengthen public preparedness and response infrastructure
- Enhance stewardship of public health preparedness funds
- Improve the ability of the public health workforce to respond to health threats

National Strategy for Biosurveillance (July 2012) (NSB):^26

- Scan and Discern the Environment
- Identify and Integrate Essential Information
- Alert and Inform Decision Makers
- Forecast and Advise Impacts

National Security Council, National Strategy for Countering Biological Threats (November 2009), Objectives:^27

- Promote global health security
- Reinforce norms of safe and responsible conduct
- Obtain timely and accurate insight on current and emerging risks
- Take reasonable steps to reduce the potential for exploitation
- Expand our current capability to prevent, attribute, and apprehend
- Communicate effectively with all stakeholders
- Transform the international dialogue on biological threats

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National Biosurveillance Science and Technology Roadmap (June 2013)—identifies high-priority research and development objectives to be prioritized to enable the core functions of the NSB 2012.  

- Establish baseline levels of community and ecosystem risks, threats, and health;
- Identify causes of aberrations from normal at the ecosystem, organism, reservoir, vector, and host nexus;
- Identify indicators that are associated with potential outbreaks and develop models using these indicators to assist in better decision making at all levels;
- Enhance information integration, analysis, and sharing platforms for improved situational awareness of biosurveillance information at all levels, including with international partners, as appropriate;
- Further develop technological solutions that integrate and analyze electronic health information, while protecting private information, to better inform health decision making;
- Identify and evaluate the utility of novel sources of biosurveillance information, such as social media;
- Improve exposure assessment and diagnostic capability, especially at the point of care, to enable accurate and timely collection of information for early detection and situational awareness throughout an incident, and;
- Improve identification and characterization of known and unknown health threats.


- Privacy and Security: Facilitate electronic exchange, access, and use of electronic health information while protecting the privacy and security of patients’ health information
- Interoperability: Enable the movement of electronic health information to where and when it is needed to support individual health and care needs
- Adoption: Promote nationwide deployment of EHRs and personal health records that put information to use in support of health and care
- Collaborative Governance: Establish mechanisms for multi-stakeholder priority-setting and decision-making to guide development of the nation’s health IT infrastructure
- Privacy and Security: Advance privacy and security policies, principles, procedures, and protections for information access and use in population health
- Interoperability: Enable the mobility of health information to support population-oriented uses
- Adoption: Promote nationwide adoption of technologies and technical functions that will improve population and individual health
- Collaborative Governance: Establish coordinated organizational processes supporting information use for population health

Office of the National Coordinator for Health Information Technology Federal Health Information Technology Strategic Plan: 2011–2015 (September 2011). (ONC HIT—Performance measures available pg 49 Appendix A).

- Achieve Adoption and Information Exchange through Meaningful Use of Health IT
- Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT

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Improving the Nation’s Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee (April 2009). (NBAS 1).  

- Strong Executive Branch leadership in coordination of national biosurveillance
- Due consideration of global health threats
- Adequate funding for personnel for biosurveillance programs
- Investment in EHRs and lab information
- Strategic investments in new technologies


- Governance—establish policy oversight of the biosurveillance enterprise through the Executive Office of the President’s National Security Staff, with a lead advisory group established to provide ongoing input on biosurveillance events
- Information Exchange—need for an improved legal framework to better enable state-federal information sharing to be integrated into a system of biosurveillance for human health, in harmony with the International Health Regulations.
- Workforce—address widening gaps, key professions in public health need enhancement; modern workforces should cross-train and collaborate with clinicians and basic scientists in human and animal health.
- Research and Development—should focus on real-time information collection, easily deployable detection methods, and streamlined assay validation to better survey for pathogens and biomarkers of health and disease.

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An Evaluation of our Nation’s Public Health and Healthcare Situational Awareness: A Brief Report of the National Biodefense Science Board (April 2013)\(^\text{34}\)  

- Secretary of HHS designate a central situational awareness oversight authority for coordinating all public health and healthcare situational awareness information that have already been collected, processed, and analyzed from respective agencies on a national level.  
- Assurance of a common and unified strategy among all stakeholders involved in public health and healthcare situational awareness efforts, with the scopes of both public health and healthcare situational awareness to be explicitly defined.  
- Identification of the specific questions to be answered in support of both public health and healthcare situational awareness.  
- Recognition that the system for information coordination must integrate the expertise and experience from across all levels and sectors.  
- Bidirectional communication of government agencies with all stakeholders, public and private.  
- Caution in developing common technological systems for situational awareness and biosurveillance such that the valuable complexities of some existing systems are not reduced or lost.  
- Establishment of functional standards for information reporting to promote a common understanding of the target systems and capabilities.

World Health Organization (WHO) International Health Regulations (IHR) 2005 (Revised)\(^\text{35}\)  

- The formal IHR notification process has a 72-hour timeline and consists of many bidirectional informal and formal information sharing pathways leading up to, during, and after an IHR event notification to the WHO, which enhances the collaboration and coordination required during a public health event response.  
- Specifically, the IHR notification process contributes to biosurveillance activities by:  
  - Providing international critical information communication requirements and a standard decision matrix for use by all members of the WHO.  
  - Providing a functional national federal point of contact with direct responsibility for communicating and receiving information from internal and external stakeholders.  
  - Integrates IHR subject matter experts into domestic event information communication pathways to ensure that obligation under the IHR (2005) are maintained.  
  - Enables the establishment of formal/informal relationships that improve coordination and collaboration during emergencies.

Gorgas Memorial Institute (Panama) Cooperative Agreement  

- HHS-ASPR is partnered with the Gorgas Memorial Institute of Health Studies (GMI) to strengthen Panama’s laboratory diagnostic capacity to rapidly detect, communicate, and control the spread of select biological threat agents and pandemic influenza.  
- The project aims to support GMI to meet the standards for international membership and admission into the U.S. Laboratory Response Network (LRN) at HHS- CDC.  
- This project is part of an overall HHS effort to build capacity abroad with the ultimate intent of detecting, stopping or limiting the threat or spread of bio-terrorism agents and pandemics to the United States, thus enhancing the health security of the American population.

http://www.who.int/ihr/9789241596664/en/
ASPR Partnership with the Institute Pasteur and FUMEC (México)—specific regional partnerships

- ASPR’s Division of International Health Security (DIHS) supports global biosurveillance efforts by partnering with scientific, public health, and biomedical institutions through the provision of programmatic funding and expertise for certain countries (e.g. Mexico, Cambodia, Senegal, Cameroon, and the Central African Republic) to build, maintain, and enhance influenza and other respiratory infectious disease surveillance.
- Main biosurveillance activities include sentinel and laboratory surveillance for both influenza-like-illness and severe acute respiratory illnesses in African countries; human, animal, and environmental laboratory surveillance for H5N1 in Cambodia; and establishment of the Biosafety Level (BSL)-3 laboratory and training on bioterrorism agents as well as development of the AlertaMex system, an automated disease analysis and early warning system in Mexico.
APPENDIX IV

Examples of Federal Situational Awareness and Biosurveillance Coordinating Efforts:

CDC-Biosurveillance Coordination Activity (BCA): 36

BCA coordinates the development of strategies, initiatives, and actions to integrate human health information into a comprehensive national biosurveillance enterprise to improve the United States’ ability to respond to public health emergencies. The overarching goal is to provide decision makers with the essential information needed for the early detection, rapid response, management, and mitigation of these potentially catastrophic events. BCA collaborates across CDC with federal departments and other partners to strengthen the enterprise by working to integrate current activities and systems while leveraging new and promising technologies.

CDC—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) 37

NCEZID is composed of seven divisions that work with partners throughout the United States and around the world to prevent illness, disability, and death caused by a wide range of infectious diseases—from the rare but deadly, like anthrax and Ebola hemorrhagic fever, to the more common, like foodborne disease and healthcare-associated infections. NCEZID’s work overall directly reflects current CDC priorities to strengthen surveillance and epidemiology, enhance the agency’s ability to support state and local public health, provide leadership in global health, promote effective public health policy, and address the leading causes of death, illness, and disability.

CDC—Office of Public Health Preparedness and Response, Division of Emergency Operations (DEO), Emergency Operations Center 38

DEO is responsible for overall coordination of CDC’s preparedness, assessment, response, recovery, and evaluation prior to and during public health emergencies. DEO is also responsible for the CDC Emergency Operations Center, which maintains situational awareness of potential health threats 24 hours a day, 7 days a week, 365 days a year, and is the centralized location for event management when activated. The Situational Awareness Section in the EOC applies knowledge management and information technologies to define and collect relevant social-demographic, critical infrastructure, physical/environmental, and public health data to inform science and improve allocation and apportionment of critical resources during emergencies. Coordinating with incident management and scientific response staff, the section produces analytical products, reports, databases, and geo-spatial visualizations to support all-hazards situation awareness and enhance decisions and unity of effort.

DHS—National Network of Fusion Centers 39

Fusion Centers serve as primary focal points within the state and local environment for the receipt, analysis, gathering, and sharing of threat-related information among federal, SLTT partners. Fusion Centers effectively and efficiently utilize multiple internal and external information sources to conduct analysis for situational awareness, provide rapid decision support, and remain on the forefront of indicators and warnings of public

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36 Public Health Surveillance and Informatics Program Office. *Biosurveillance Coordination Activity- Coordinating Biosurveillance Efforts for CDC.* 2012 Atlanta: Centers for Disease Control and Prevention.  
37 *About the National Center for Emerging and Zoonotic Infectious Diseases, CDC.* June 9, 2011.  
http://www.cdc.gov/ncezid/about-ncezid.html  
38 Office of Public Health Preparedness and Response, N.D.  
http://www.cdc.gov/about/organization/ophpr.htm  
39 *National Network of Fusion Centers Fact Sheet.* N.D.  
http://www.dhs.gov/national-network-fusion-centers-fact-sheet
health emergencies. The Centers’ work provides decision-makers with the information necessary to be better prepared for public health emergencies, thereby leading to better rapid response and ultimately saving lives.

DHS—National Biosurveillance Integration Center (NBIC): 40

NBIC serves as the designated government entity to synthesize and analyze information collected from across the spectrum of various entities that are responsible for surveillance, analysis, and mitigation/remediation responses and typically report to national level authorities. Such information and activities serve to enhance the capability of the federal government to: rapidly identify, characterize, localize, and track a biological event of national concern; integrate and analyze information relating to human health, animal, plant, food, water, and environmental domains; disseminate alerts and pertinent information; and oversee development and operation of the National Biosurveillance Integration System (NBIS) interagency community.

DOD—Armed Forces Health Surveillance Center (AFHS): 41

The AFHSC aims to be the central epidemiological resource and a global health surveillance proponent for the U.S. Armed Forces. The AFHSC mission is to provide timely, relevant, actionable, and comprehensive health surveillance information to promote, maintain, and enhance the health of military and military-associated populations by: acquiring, analyzing/interpreting, and disseminating information and recommending evidence-based policy; developing, refining, and improving standardized surveillance methods; serving as a military focal point for sharing health surveillance products, expertise, and information; and coordinating a global program of militarily relevant infectious disease surveillance.

National Center for Medical Intelligence (NCMI): 42

The mission of the NCMI, a component of the DoD Defense Intelligence Agency, is to track and assess the full range of global health issues for the DoD, specifically monitoring and analyzing international health events that could negatively impact the health of U.S. military and civilian populations. The NCMI develops structured analytic approaches to disease occurrence of national significance (intentionally caused or naturally occurring) by leveraging disparate open-source information, intelligence derived from National Technical Means, epidemiologic expertise, and intelligence tradecraft (i.e., the methods to gather all disparate information and systematically synthesize it) to move the intelligence warning capability closer to the origins of an incident, thereby quickly identifying abnormal disease occurrences and behavior globally in the context of a well established baseline understanding of global disease occurrence.

Information Sharing and Access (ISA) Interagency Policy Committee (IPC): 43

The ISA IPC integrates the Information Sharing Council (ISC) and brings the work of ISC sub-committees under the auspices of the Executive Office of the President. This policy committee represents the national decision-making body for sharing high-level, cross-cutting policy matters with members from federal departments/agencies and is part of an ongoing federal effort to facilitate the development of definitions and key concepts in support of a common national approach to situational awareness.

Examples of the Department of Justice’s (DOJ) Involvement in Biosurveillance Issues

The Federal Bureau of Investigation (FBI) is involved in biosurveillance issues in several ways, including the following: the Senior Biological Programs Advisor of the FBI Forensic Response Unit, FBI Laboratory, serves on the National Science and Technology Council’s Subcommittee on Biological Defense Research and Development (including the Biosurveillance Science and Technology Working Group); the Science Response Unit represents the FBI Laboratory on interagency issues related to DHS BioWatch and works on issues related to the sentinel laboratories (LRN) and CDC; and the Weapons of Mass Destruction Division’s BioCountermeasures Unit also deals with biosurveillance issues.

## APPENDIX V

**List of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AFHS</td>
<td>Armed Forces Health Surveillance Center</td>
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<tr>
<td>ASPR</td>
<td>Assistant Secretary for Preparedness and Response</td>
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<td>BCA</td>
<td>Biosurveillance Coordination Activity</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CESG</td>
<td>Central Executive Strategic Group</td>
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<tr>
<td>CSTE</td>
<td>Council of State and Territorial Epidemiologists</td>
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<tr>
<td>DHS</td>
<td>Department of Homeland Security</td>
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<tr>
<td>DOD</td>
<td>Department of Defense</td>
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<tr>
<td>DOJ</td>
<td>Department of Justice</td>
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<tr>
<td>EOC</td>
<td>Emergency Operations Center</td>
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<td>EHRs</td>
<td>Electronic Health Records</td>
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<td>FBI</td>
<td>Federal Bureau of Investigation</td>
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<td>FUMEC</td>
<td>Fundación México-Estados Unidos para la Ciencia (US-Mexico Foundation for Science)</td>
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<tr>
<td>GMI</td>
<td>Gorgas Memorial Institute of Health Studies</td>
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<td>HHS</td>
<td>US Department of Health and Human Services</td>
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<td>IC</td>
<td>Intelligence Community</td>
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<td>IHR</td>
<td>International Health Regulations</td>
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<td>IPC</td>
<td>Interagency Policy Committee</td>
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<td>ISA</td>
<td>Information Sharing and Access</td>
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<td>ISC</td>
<td>Information Sharing Council</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>LRN</td>
<td>Laboratory Response Network</td>
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<td>NBAS</td>
<td>National Biosurveillance Advisory Subcommittee</td>
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<td>NBIC</td>
<td>National Biosurveillance Integration Center</td>
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<tr>
<td>NBIS</td>
<td>National Biosurveillance Integration System</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>NBSB</td>
<td>National Biodefense Science Board</td>
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<tr>
<td>NBSHH</td>
<td>National Biosurveillance Strategy for Human Health</td>
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<tr>
<td>NCEZID</td>
<td>National Center for Emerging and Zoonotic Infectious Diseases</td>
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<td>NCMI</td>
<td>National Center for Medical Intelligence</td>
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<td>NHSS</td>
<td>National Health Security Strategy</td>
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<td>NPHSBAC</td>
<td>National Public Health Surveillance and Biosurveillance Advisory Committee</td>
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<td>NSB</td>
<td>National Strategy for Biosurveillance</td>
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<td>NSPPHR</td>
<td>National Strategic Plan for Public Health Preparedness and Response</td>
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<td>NSS</td>
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<td>ONC HIT</td>
<td>Office of the National Coordinator for Health Information Technology</td>
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<td>PAHPR</td>
<td>Pandemic and All Hazards Preparedness Reauthorization Act</td>
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<td>SIG</td>
<td>Strategic Integration Group</td>
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<td>SLTT</td>
<td>State, Local, Tribal and Territorial</td>
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<td>USDA</td>
<td>United States Department of Agriculture</td>
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<td>USG</td>
<td>United States Government</td>
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<td>US GAO</td>
<td>United States Government Accountability Office</td>
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<tr>
<td>USPS</td>
<td>United States Postal Services</td>
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<td>WG</td>
<td>Working Group</td>
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<td>WHO</td>
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