

Advisory Committee to the Director Record of the Conference Call September 1, 2009

The Centers for Disease Control and Prevention (CDC) held a conference call of the Advisory Committee to the Director on September 1, 2009, to receive reports from the Chairs of the Biosurveillance, Health Disparities, and Ethics Subcommittees. The CDC Director gave an update on CDC's reorganization. The members of the Advisory Committee to the Director were also briefed on H1N1 activity and CDC budget matters were discussed.

Eduardo J. Sanchez, MD, MPH, FAAFP, Chair of the Advisory Committee to the Director, called the roll which included the required quorum of 12 members of the committee. Attachment #1 includes the names of Advisory Committee to the Director members and other participants. Dr. Sanchez requested a statement of any conflicts of interest by the members with none reported.

National Biosurveillance Advisory Subcommittee/First Report

During the March 2009 Advisory Committee to the Director conference call, the interim report from the Advisory Committee to the Director's National Biosurveillance Advisory Subcommittee (NBAS), "Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Threats" was presented and unanimously approved. Subsequent HHS review produced 14 comments, 12 of which were essentially grammatical and implemented. The other two were rejected by the Chair of the National Biosurveillance Advisory Subcommittee as inappropriately restricting the proper role of biosurveillance or the associated activity of federal agencies.

Dr. Sanchez thanked subcommittee chair Larry Brilliant, MD, MPH, Daniel M. Sosin, MD, MPH, FACP, Mr. Curtis Weaver, CDC staff, and the subcommittee members for their extraordinary work to accomplish this report so quickly. He also expressed his appreciation to Advisory Committee to the Director members who serve on this subcommittee (Mr. Sanford R. Climan, MBA, MS, Suzanne F. Delbanco, PhD, Jonathan T. Lord, MD, and Kenneth D. Mandl, MD, MPH). Contributing recommendations by the subcommittee's task forces, which addressed different aspects of biosurveillance, were particularly appreciated for their relevance to the anticipated H1N1 resurgence.

A motion was made to submit this first National Biosurveillance Advisory Subcommittee report to CDC Director Dr. Thomas Frieden, for forwarding to the HHS Secretary. The motion was seconded and, with no abstentions or nays, the **motion was unanimously approved.**

Health Disparities Subcommittee/2009–2010 Charge

The charge to the Health Disparities Subcommittee and a copy of presentation materials had been sent to the Advisory Committee to the Director members. Nisha D. Botchwey, PhD, Chair of the Health Disparities Subcommittee, outlined its mission, mandate, and the U.S. populations affected by health disparities (presentation details are in Attachment #2).

During 2006-2007, the subcommittee reviewed CDC's organizational structure, core values, operational framework, strategic imperatives, health protection goals and subgoals; assessed CDC's "Goals Implementation Roadmap," goal action plan template, and proposed approach to addressing health disparities; and participated in CDC's "Public Partner Engagement." Subcommittee recommendations addressed the criteria for CDC's starter objectives and the objectives' prioritization; address of health disparities in the goal action plans; expansion of the science and evidence base for risk predictors related to social context and social structure; and engagement of key organizations relevant to health disparities.

The reconstituted subcommittee membership remains at 3 for Advisory Committee to the Director members but increases non-Advisory Committee to the Director members to 11. The members' multiple areas of expertise were listed (Attachment 2). The proposed charge for the 2009-2010 Health Disparities Subcommittee is to (1) provide high-level counsel to the Advisory Committee to the Director on CDC's efforts to address health disparities and health equity; (2) support development of specific health disparity objectives, performance indicators, and agency priorities; (3) support CDC's work on health systems reform; (4) support CDC's activities to address health equity (includes collaboration with Health Equity Workgroup and the Advisory Committee to the Director Ethics Subcommittee); (5) advocate for action to prevent illness and death and achieve health equity; and (6) provide guidance on opportunities for CDC to work with other sectors.

Discussion included agreement to ensure the subcommittee's summary document aligned to that information presented in the slide set (summarized in Attachment 2). (Specifically, the document will indicate the Subcommittee's intent to support CDC's work to address health disparities and health equity, and provide guidance on opportunities for CDC to work with other sectors, including federal, state, tribal, and local health agencies, public and private health organizations and associations, and health advocacy organizations to achieve health equity.)

A motion was made to accept the proposed 2009 charge for the Health Disparities Subcommittee as presented by Dr. Botchwey. The motion was seconded and, with no abstentions or nays, **the motion unanimously passed.**

Ethics Subcommittee

Subcommittee Chair Robert Hood, PhD, identified five new subcommittee members and outlined subcommittee activities since October 2008: development of recommendations on use of travel restrictions and guidance on allocation of ventilator during a severe pandemic. Dr. Hood also provided an update on two subcommittee documents previously approved by the Advisory Committee to the Director (Ethical Guidance for Public Health Emergency Preparedness and Response, and Ethical Guidance for Pandemic Influenza). The former will be published in a special *Morbidity and Mortality Weekly Report* supplement either later this year or early next year and the latter was published in the August 11, 2009, *Journal of Disaster Medicine and Public Health Preparedness* (Kinlaw K, Barrett DH, Levine RJ. Ethical guidelines in pandemic influenza: Recommendations of the Ethics Subcommittee of the Advisory Committee of the Director, Centers for Disease Control and Prevention. *Disaster Medicine and Public Health Preparedness* 2009;3(Suppl 2):1-8).

Two documents were presented to the Advisory Committee to the Director for approval:

Document 1: Recommendation for Ethical Considerations Section for Inclusion in CDC Standard Operating Procedures regarding persons traveling with infectious illness.

A new tool, the Public Health Do Not Board List, enables CDC, in collaboration with the Department of Homeland Security, to request that persons with communicable diseases who pose a serious threat to the public's health be restricted from boarding commercial aircraft departing from or arriving in the United States. CDC has developed a standard operating procedure document that outlines the relevant authorities relating to use of travel restrictions, travel restriction tools, limitations of previously existing tools, criteria for requesting or removing travel restriction, notification procedures and suggested actions. CDC's guidance calls for action to be taken in an efficient, equitable, ethical, and judicious manner.

The Ethics Subcommittee developed a section on ethical considerations related to use of travel restrictions, to be inserted into a CDC document “Requesting Department of Homeland Security Assistance for Control of Communicable Diseases: Standard Operating Procedures.” These ethical considerations are (1) protecting community interests while respecting individual rights; (2) proportionality (using the appropriate and least intrusive means to reach public health goals); (3) social and distributive justice (fair treatment to avoid group stigmatization and equitably distributed risks/benefits of public health actions); (4) beneficence (weigh harms and benefits; minimize possible harms); (5) transparency (open, clear, efficient communication and actions to protect public health); (6) meeting CDC’s global responsibility/working with international partners; and (7) respecting individual privacy while protecting the community. Specific aspects of each recommendation were described by Dr. Hood.

Advisory Committee to the Director members offered no discussion of the document and recommendations.

A motion was made and seconded to approve the Ethics Subcommittee’s recommendation regarding inclusion of the ethical considerations section into the CDC document “Requesting Department of Homeland Security Assistance for Control of Communicable Diseases: Standard Operating Procedures.” With no abstentions or nays, **the motion was unanimously approved.**

Document 2: Response to report on compulsory use of travel restriction tools (Homeland Security Council Corrective Action #5)

In response to a report from the Homeland Security Council on use of travel restriction tools, CDC’s Division of Quarantine had requested ethical guidance as to whether certain diseases, posing imminent and extraordinary public health threats, should be subject to compulsory isolation/quarantine, or addition to the Do Not Board List, or other restrictive actions.

The subcommittee’s response was that compulsory use of travel restriction tools was inconsistent with CDC’s ethical obligations to use the least restrictive measures. CDC should consult subject matter experts to clarify such placement on a do not board list, as not all patients with infectious illness should be so listed or placed under other restrictions. The subcommittee also recommended further study to examine the effectiveness and consequences of travel restriction tools.

Advisory Committee to the Director members offered no discussion of the document and recommendations.

A motion was made and seconded to approve the Ethics Subcommittee’s response to the Homeland Security Council Corrective Action #5. With no discussion, abstentions or nays, **the motion was unanimously approved.**

Dr. Sanchez thanked Robert J. Levine, MD, Kathy Kinlaw, MDiv, and Clive M. Brown, MD, MS, MPH, experts who consulted with the subcommittee, for their contributions, and Drue Barrett, PhD, and her staff for their support to the subcommittee.

CDC Director Presentation

CDC Director Thomas R. Frieden, MD, MPH, joined the meeting remotely while traveling back to Atlanta from his meeting with President Obama in Washington, D.C. on the H1N1 pandemic. He thanked the Advisory Committee to the Director members for their work with CDC on behalf of public health and looks forward to future interactions and the Advisory Committee to the Director guidance. He provided a brief update on organization change at CDC. The current proposed structure will be shared as desired with Advisory Committee to the Director members

by the Health and Human Services Secretary and will be elaborated on in the future. CDC's focus will be to

1. Strengthen surveillance and epidemiology. A unit on surveillance and epidemiology will be created under a Deputy Director of CDC.
2. Strengthen support to state/local health departments. An Office of State and Local Support will be created under a Deputy Director.
3. Improve CDC's functioning in global health and global health development. The Office of Global Health will be upgraded to be a Center of Global Health, incorporating such global CDC programs as those addressing global AIDS, malaria, and parasitic diseases.
4. Increase CDC's effectiveness in influencing policies that affect health, including health care reform.
5. Address the leading causes of death and disability better.

We are in the process of making organizational improvements. We are in the process of receiving feedback from partners and employees. Changes thus far include the elimination of the coordinating centers. The new leadership structure will include five deputy directors including a principal deputy and four others who will address (a) surveillance and epidemiology, (b) state and local support, (c) infectious disease, and (d) non-communicable disease, injury, and environmental health. This approach will increase the autonomy/authority of the centers and ensure regular contact with the CDC Director. Dr. Sanchez thanked Dr. Frieden for his participation and anticipated his attendance at the October Advisory Committee to the Director meeting.

CDC Budget Challenges for Fiscal Year 2009 and Beyond

Debra R. Lappin, JD, expressed her enthusiasm for Dr. Frieden's described organizational changes, which align well with the Advisory Committee to the Director's review of CDC's budget structure and process. She hoped for further discussion of the relationship between the reorganization and the budget. The Advisory Committee to the Director members had received a document generated by Jonathan T. Lord, MD, and Debra R. Lappin, JD, on "Increasing the Efficiency, Productivity and Effectiveness of CDC," which presented an overview of CDC's budget challenges.

Ms. Lappin elaborated that CDC's 200 line item (categorical and restricted) appropriations and the current flat appropriations provided little flexibility to respond to emerging threats. Last October, the Advisory Committee to the Director discussed the idea of a comprehensive study of how, with greater coordination and flexibility, CDC could maximize and achieve accountable results through extramural funding of the public health infrastructure, facilitated by an adjusted approach to appropriations. Dr. Lord requested the Advisory Committee to the Director's support of this comprehensive reassessment of CDC's budgeting process in light of CDC's need for flexibility in the context of changing priorities regarding policy and disease burdens, to ensure that CDC is in the best condition to respond and protect the health of Americans and others. The review could mirror a National Institutes of Health budget review process that set that agency on a more flexible path in funding and discretionary use of funds.

With no discussion, **a motion was made** to approve sending this recommendation to Dr. Frieden, CDC Director. The motion was seconded and, with no abstentions or nays, **the motion was unanimously approved.**

Update on H1N1

Dan Jernigan, MD, MPH, Deputy Director, Influenza Division, National Center for Immunization and Respiratory Diseases, CDC, updated the Advisory Committee to the Director on H1N1 in the

United States. A framework developed by the White House national security staff supports CDC's response to H1N1 (details in Attachment #2).

Surveillance and situational awareness. Cases in the southern hemisphere have been moderate, and no genetic changes in the virus suggest increased severity or significant risk globally. Almost 100 percent of viruses respond to oseltamivir (Tamiflu®). The novel H1N1 is not resistant to zanamivir (Relenza®). In the few cases resistant to Tamiflu®, there has been transmission to others in contact with the patient in only a few instances.

Community measures. CDC's Division of Global Migration and Quarantine, National Center for Preparedness, Detection, and Control of Infectious Diseases, with the Department of Education, issued tool kits for K-12 and higher education and school guidance. School reentry is now allowed 24 hours after a fever subsides without taking anti-fever drugs. Additional guidance is pending for the childcare setting and for healthcare workers. Outreach is being done to at-risk populations in coordination with the White House, to improve understanding of H1N1 and promote use of vaccines.

CDC has distributed a quarter of the Strategic National Stockpile's antiviral drugs and more will be released shortly. CDC will publish antiviral guidance for the public. The focus will be on those with severe disease or high risk of flu complications and will advise use of antiviral drugs and early treatment. Advisory Committee on Immunization Practices' vaccination recommendations prioritize pregnant women, people living with or caring for children aged below 6 months, healthcare and emergency services personnel, individuals aged 6 months to 24 years, and those aged 25-64 years who are at high risk. Vaccine will be distributed through a public/private approach.

Public and further committee member comments

Dr. Sanchez asked for public comments or additional comments from the Advisory Committee to the Director members, and there were no responses. A **motion to adjourn** was seconded and passed unanimously. The next Advisory Committee to the Director meeting is scheduled for October 29, 2009.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the September 1, 2009, Advisory Committee to the Director, CDC, meeting are accurate and complete.

Date

Eduardo J. Sanchez, MD, MPH, FAAFP
Chair, Advisory Committee to the Director, CDC

Attachment #1: Attendance

Members of the Advisory Committee to the Director, CDC

Advisory Committee to the Director Chair:

Eduardo J. Sanchez, MD, MPH

Vice President and Chief Medical Officer
Blue Cross and Blue Shield of Texas

James Nicholson Baird, Jr., MD

Executive Director, Alliance to Make US Healthiest
President, Stillwater Solutions, LLC

Vivian Berryhill

President and Founder, National Coalition of Pastors' Spouses

Nisha D. Botchwey, PhD

Assistant Professor, Urban and Environmental Planning and
Public Health, School of Architecture, University of Virginia
Chair, Health Disparities Subcommittee, Advisory Committee
to the Director, CDC

Sanford R. Climan, MBA

President, Entertainment Media Ventures, Inc., and
Executive Producer, U23D

Mark A. Collar

Partner, Triathlon Medical Ventures

Suzanne F. Delbanco, PhD

President, Health Care Division, Arrowsight, Inc.

Debra R. Lappin, JD

Senior Vice President, B&D Consulting, LLC

Jonathan T. Lord, MD

President and Chief Executive Officer, Navigenics

Kenneth D. Mandl, MD, MPH

Associate Professor, Harvard Medical School, and
Director, Intelligent Health Laboratory, Children's Hospital
Informatics Program, Children's Hospital Boston

John R. Seffrin, PhD

Chief Executive Officer, American Cancer Society

The Honorable Louis W. Sullivan, MD

President Emeritus, Morehouse School of Medicine

M. Cass Wheeler

Strategic Consultant/Coach/Speaker
Former Chief Executive Officer, American Heart Association, Inc.

Advisors

Lawrence (Larry) Brilliant, MD, MPH

President, Skoll Urgent Threats Fund and Senior Advisor to Jeff Skoll
Chair, National Biosurveillance Advisory Subcommittee, Advisory Committee
to the Director, CDC

Robert L. Hood, PhD

Ethics and Human Research Protections Program
Assistant Director, Office of Public Health Research
Florida Department of Health
Chair, Ethics Subcommittee, Advisory Committee to the Director, CDC

Kathy Kinlaw, MDiv

Associate Director, Emory University Center for Ethics
Director, Center's Program in Health Sciences and Ethics
Former Member, Ethics Subcommittee, Advisory Committee to the
Director, CDC

Robert J. Levine, MD

Co-Director, Yale University Interdisciplinary Center for Bioethics
Director, Law, Policy and Ethics Core, Center for Interdisciplinary
Research on AIDS
Professor of Medicine and Lecturer in Pharmacology
Yale Center for Bioethics
Former Member, Ethics Subcommittee, Advisory Committee to the Director,
CDC

CDC Participants

Ileana Arias, PhD

Acting Deputy Director, CDC
Acting Administrator, Agency for Toxic Substances and Disease Registry (ASTDR)

Drue H. Barrett, PhD

Captain, U.S. Public Health Service, Public Health Ethics Coordinator
Office of the Chief Science Officer, CDC
Designated Federal Official, Ethics Subcommittee, Advisory Committee to the
Director, CDC

Byron Breedlove

Communications Specialist, Office of Strategy and Innovation, Office of the Director,
CDC

Clive M. Brown, MD, MPH, BS

Associate Director for Science
Division of Global Migration and Quarantine, National Center for Preparedness,
Detection, and Control of Infectious Diseases, CDC

Mark E. Byers

Contractor, Lockheed Martin, Enterprise Solutions and Services
Biosurveillance Coordination Unit, Coordinating Office for Terrorism
Preparedness and Emergency Response

Thomas R. Frieden, MD, MPH

Director, CDC
Administrator, ATSDR

Anne C. Haddix, PhD

Acting Chief, Office of Strategy and Innovation, Office of the Director, CDC
Designated Federal Official, Advisory Committee to the Director, CDC

Gayle J. Hickman

Governance Team, Office of the Associate Director for Management
Office of the Director, CDC

Daniel B. Jernigan, MD, MPH

Deputy Director, Influenza Division, National Center for Immunization and
Respiratory Diseases, CDC

Jennifer Meunier, MPH

Health Policy Analyst, Office of the Director, CDC

Priscilla A. Patin, BS

Program Analyst, Office of the Director, CDC

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Curtis Weaver, BS, MA

Senior Advisor to the Director, Biosurveillance Coordination Unit
Coordinating Office for Terrorism Preparedness and Emergency Response, CDC

Walter W. Williams, MD, MPH

Captain, U.S. Public Health Service, Associate Director for Minority Health,
Director, Office of Minority Health and Health Disparities
Designated Federal Official, Health Disparities Subcommittee, Advisory Committee to
the Director, CDC

General Public

Rebecca Berg
Donna Cary
Dolf Chianchiano
Charles Leocha
James Matthews
Jennifer Nuzzo
Ellen Rathfon
Michelle Sullivan

Attachment 2: Presentation Details

Health Disparities Subcommittee Report

The Health Disparities Subcommittee was formed to provide high-level counsel to the Advisory Committee to the Director on CDC's efforts to address health disparities in achieving CDC's health impact goals; to support development of specific health disparity objectives, performance indicators, and agency priorities; to advocate for action on health disparities; and to provide guidance on opportunities for CDC to work with other sectors. Its multiple areas of expertise represented by its 3 Advisory Committee to the Director members and 10 non-Advisory Committee to the Director members were outlined.

The subcommittee's mission is to help eliminate the United States' longstanding and pervasive health disparities related to race/ethnicity, socioeconomic status, and other important factors. Disparities are seen in status of insurance coverage; access to care; types of care (preventive, acute, chronic) available; and quality of care received, across multiple care settings (e.g., primary, dental, mental health, emergency, in-hospital, and nursing home care).

The racial and ethnic minority populations affected by dramatic and persistent health disparities include American Indians/Alaska Natives, Asian Americans, black or African Americans, Hispanics or Latinos, and Native Hawaiians or Other Pacific Islanders. Other populations have been affected by health disparities, by their socioeconomic status, geography (urban or rural), gender, age, disability status, and high-risk status related to sex and gender. Disparities are involved in the leading causes of illness and death.

Expertise represented on the Health Disparities Subcommittee: cancer disparities/research; community intervention; professional training; disability/physical activity; gay/lesbian health; Hispanic health disparities/diversity; policy analysis, strategic planning; professional training; public health practice/health disparities; rural and migrant worker health; sociology/health disparities research; cancer disparities/research, policy analysis, strategic planning, and professional training.

Criteria for Use of Public Health Do Not Board List

1. Likely contagious with a communicable disease that would constitute a serious public health threat should the person be permitted to board a flight;
2. Unaware of or likely to be nonadherent with public health recommendations, including treatment;
3. Likely will attempt to board a commercial aircraft.

H1N1 Update

Since the first cases emerged in April, more than 1,000 members of CDC's staff have participated in work with state/local health departments and professional societies, groups, and public health partners.

International surveillance with the ministers of health in Argentina, Chile, Brazil, Australia, and South Africa is monitoring illness in outpatient and inpatient settings and deaths. Southern hemisphere cases have been more moderate than seen in a severe flu season. Monitoring H1N1 through lab testing and use of reagents indicate no genetic changes that suggest increased severity or significant risk globally. In addition, characterization of the virus indicates that the vaccine will continue to be effective.

Almost 100% of viruses respond to Tamiflu®. As seen with regular flu virus, the few resistant cases were mostly among those on long-term therapy who have difficulty clearing the virus. The United States saw a significant spike in April and May that waned with school closings, but continued in settings where children congregate (e.g., camps). There is increasing flu in the

Southeast United States, mostly in ages 5–24, consistent with the earlier spring patterns. The weekly posting of hospitalizations and death surveillance will increase on CDC's Web site as the season proceeds.

Community measures. Outreach is being done to at risk populations in coordination with the White House, to promote vaccine use and improve understanding/promote use of vaccines. The CDC school guidance has been well used by schools starting up, especially in the Southeast. The guidance dropped the previous 7-day exclusion policy to allow school reentry 24 hours after a fever has stopped without the use of anti-fever medicines. Additional guidance is pending for the childcare setting and after the Institute of Medicine's September 3 recommendations on healthcare workers' wearing of N95 masks and other personal protective equipment for healthcare workers.

A quarter of the Strategic National Stockpile's antiviral drugs have been distributed and more will be released shortly. Antiviral guidance for the public will be publicized. The focus will continue on those with severe disease or high risk of flu complications, advising use of antiviral drugs and early treatment. Non-pharmacological measures are encouraged such as school closures as well as medical interventions such as testing and antiviral treatment.

Vaccine-associated issues. On July 29, 2009, the Advisory Committee on Immunization Practices recommended the novel H1N1 vaccine for pregnant women, people living with or caring for children aged <6 months, healthcare and emergency services personnel, individuals aged 6 months–24 years, and those aged 25–64 years who are at high risk. Those groups include ~150 million people in the United States. The government ordered 195 million vaccine doses that will be available in mid-October or earlier. It will be distributed through a public/private approach; the Vaccine for Children (VFC) program to those providers, and additional providers can sign up with VFC to get that vaccine. CDC is monitoring vaccine effectiveness and is closely monitoring for adverse events at a number of sites.

Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee

Report to the Advisory Committee to the Director, CDC

April 2009

April 30, 2009

Eduardo Sanchez, M.D., M.P.H., F.A.A.F.P.
Chairman
Advisory Committee to the Director, CDC
1600 Clifton Road NE
Atlanta, GA 30030

Dear Dr. Chairman,

On behalf of the National Biosurveillance Advisory Subcommittee (NBAS) and in keeping with our mandate to ensure that the federal government is enhancing state and local government public health surveillance capability, I am pleased to submit the report *Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats*. The report provides recommendations for action that describe how the United States could deploy people and technologies at all levels of government to improve the collection, flow and interpretation of data in a timely way as a means of preventing and mitigating threats to the health of communities.

In this report, NBAS identifies a matter of great importance to U.S. national security, namely, the ability to use *biosurveillance capabilities* to detect and respond effectively to public health emergencies of national significance. Effective biosurveillance is essential to the management of catastrophic health events; it is also essential to routine public health practice and disaster response.

This report is the culmination of quick work in fact-finding, consultation, and deliberation by the Committee. NBAS is grateful to the many individuals who shared their knowledge and perspective with us in the development of this report.

We appreciate the opportunity to address this important area and hope that our deliberations and recommendations will be helpful to you and the incoming leadership in the new administration.

Sincerely,

A handwritten signature in dark ink, appearing to read "Larry Brilliant". The signature is fluid and cursive, with a long horizontal stroke at the end.

Larry Brilliant, MD, MPH
Chair, National Biosurveillance Advisory Subcommittee

About the National Biosurveillance Advisory Subcommittee

The United States has a critical national security interest in preserving the health of its population, livestock, crops, and natural resources. Biosurveillance is the method used to detect, monitor and respond to the array of threats to our national security from natural, accidental, and intentional origins. On October 18, 2007, the White House released Homeland Security Presidential Directive 21 (HSPD-21) which mandates the development of a nationwide, robust, and integrated biosurveillance capability for human health, with connections to international disease surveillance systems, in order to provide early warning and ongoing characterization of disease outbreaks in near real-time. Additionally, HSPD-21 requires the establishment of a federal advisory committee, including representatives from state and local government public health authorities and appropriate private sector health care entities, in order to ensure that the federal government is enhancing state and local government public health surveillance capability.

In order to meet this mandate, Centers for Disease Control and Prevention (CDC) was designated the lead to develop the National Biosurveillance Strategy for Human Health and establish the National Biosurveillance Advisory Subcommittee (NBAS). NBAS is comprised of prominent public and private biosurveillance stakeholders and contributors and was created by the Advisory Committee to the Director (ACD), CDC on May 1, 2008. As a subcommittee to the ACD, the National Biosurveillance Advisory Subcommittee provides counsel to the ACD regarding the broad range of issues impacting the development and implementation of a nationwide biosurveillance strategy for human health. The membership of the NBAS ensures diverse perspectives important to the development of the strategy, including those from government, public health, health care delivery, academia and others, are reflected in the strategy's plans.

The NBAS provides leadership and guidance to the National Biosurveillance Strategy for Human Health. The NBAS has begun to advance recommendations to improve the nation's biosurveillance capability by developing innovative and practical solutions to challenges in the following areas:

- Attracting, developing and retaining a cross-trained and multi-talented workforce;
- Collaborating with global partners to strengthen local capabilities to rapidly identify and contain emerging health threats;
- Enhancing diagnostics and laboratory electronic information exchange;
- Improving exchange of information between public health and clinical medicine activities to improve accuracy and timeliness of diagnosis and reporting of health events;
- Examining the role of biosurveillance in addressing zoonotic and vector-borne diseases and food security;
- Integrating clinical and health information with environmental monitoring of air, toxin, microbiological disease threats, water quality, and infrastructure and geological disasters;
- Applying new technological advances in bioinformatics, data mining, aberration detection, digital scanning of open source information, analysis, and visualization methods while being mindful of important privacy concerns;
- Identifying solutions to cross-sector and intergovernmental collaborations for improving biosurveillance capability.

Subcommittee Roster

Chair

Larry Brilliant, MD, MPH
Chief Philanthropic Evangelist
Google
San Francisco, CA

Designated Federal Official

Daniel M. Sosin, MD, MPH, FACP
Acting Director
Coordinating Office for Terrorism Preparedness
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Centers for Disease Control and Prevention
Atlanta, GA

Members

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Dennis Coulombier, MD
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Former Director
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Nuclear Threat Initiative
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James Allen Heywood
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Jonathan Lord, MD
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Humana Inc.
Louisville, KY

Kenneth D Mandl, MD, MPH
Associate Professor, Harvard Medical School
Director, Intelligent Health Laboratory
Children's Hospital Informatics Program
Children's Hospital Boston
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Farzad Mostashari, MD, MSc
Assistant Commissioner
Primary Care Information Project
Health Care Access & Improvement
New York City Department of Health & Mental
Hygiene
New York, NY

David Heymann, MD
Assistant Director-General
Health Security and Environment
Representative of the Director-General for Polio
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World Health Organization
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Steven Hinrichs, MD
Director
Center for Biosecurity
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Paul Jarris, MD, MBA
Executive Director
Association of State and Territorial Health
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W. Ian Lipkin, MD
Director and John Snow Professor of
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Cecil Lynch, MD, MS
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Linda McCauley, PhD, RN, FAAN
Nightingale Professor of Nursing
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Tara O'Toole, MD, MPH
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John Russell, JD
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Michael Williams, PhD
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Gregory Poland, MD, MACP, FIDSA
Director, Mayo Vaccine Research Group and
Director
Translational Immunovirology and Biodefense
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Chris Ross, MBA
Chief Information Officer
MinuteClinic
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William Stephens, MS
Manager
Southwest Center for Advanced Public Health
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Tarrant County Public Health
Fort Worth, TX

Rajeev Venkayya, MD
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Executive Summary

The ability to use biosurveillance capabilities to detect and respond effectively to public health emergencies of national significance (e.g., smallpox, anthrax, foodborne disease) is a matter of great importance to U.S. national security. Effective biosurveillance is essential to the management of catastrophic health events; it is also essential to routine public health practice and disaster response.

Disease-related events that reach the level of national consequence and/or global significance are rare, episodic, and unpredictable. Because of these characteristics, it is difficult to maintain long-term public interest, funding and prioritization. In addition, prevention activities are often invisible to the public and go unnoticed. Finally, the responsibilities and authorities within the government to prevent and respond to these events of national consequence and/or global significance are dispersed, put into silos and not integrated. Because of this diversity and the episodic but horrific nature of these events, we must use a non-traditional approach to address the current gap in our nation's biosurveillance capability. The approach can not rely on public will or a single governmental agency for success, but must be built around on-going interagency collaboration and coordination.

Many federal agencies and offices have responsibilities and programs that pertain to the nation's overall biosurveillance mission. Moreover, much of the foundation of U.S. biosurveillance capacity depends on programs operated by state and local public health agencies. Efforts to coordinate and make sense of this broad array of biosurveillance efforts have encountered stern challenges

This report provides recommendations for action that describe how the United States could deploy people and technologies at all levels of government to improve the collection, flow and interpretation of data in a timely way as a means of preventing and mitigating threats to the health of communities.

These recommendations are offered by an esteemed group of experts from multiple disciplines comprising the National Biosurveillance Subcommittee (NBAS) which serves as a subcommittee of the Centers for Disease Control and Prevention (CDC) Director's Advisory Committee. The creation and mission of NBAS was mandated by Homeland Security Presidential Directive 21 (HSPD-21), issued in October 2007. This Presidential Directive addressed critical components of public health and medical preparedness and response to catastrophic health events, for example, a terrorist attack with a nuclear or biological weapon, an influenza pandemic, or a large-scale geological event. Any one of these scenarios could result in tens or even hundreds of thousands of casualties, and cause great societal and economic disruption and damage to U.S. national security.

The term biosurveillance is here intended to mean the organizational systems, people and technologies needed to ensure the nation's ability to detect a biological event or other hazards to health that are of national significance promptly; to sustain near-real time situational awareness of the evolution or consequences of such threats, and to provide decision-makers and the public

with accurate and timely information about how adverse impacts might be prevented, managed or mitigated. Early detection of potential threats is essential to forestalling larger scale impacts and may even allow interventions to eliminate some hazards before they become crises. Situational awareness during a crisis is critical to informed management decisions. Moreover, many biosurveillance systems contribute vital information about the baseline health of populations and the natural history of certain diseases.

The recommendations summarize the major actions that the NBAS has determined are necessary to build an adequate biosurveillance capacity for the nation.

- The Executive Branch must define the strategic goals and priorities of federal investments in biosurveillance activities and technologies, and implement a plan to achieve, fund and periodically assess progress toward these goals. To accomplish this, the White House should establish an Interagency Biosurveillance Coordination Committee (“the Committee”).
- The U.S. National Biosurveillance Enterprise must include global health threats in its purview and scope.
- The federal government must make a sustained commitment toward ensuring adequate funding to hire and retain highly competent personnel to run biosurveillance programs at all levels of government.
- Government investments in electronic health records and electronic laboratory data should be leveraged to improve how they serve biosurveillance and public health missions.
- The federal government must make strategic investments in new technologies (e.g., genomics, supply chain management, visualizations, display dashboards) to strengthen U.S. biosurveillance capabilities.

Biosurveillance is inevitably a mission that must be shared across multiple agencies. This characteristic has, in our view, led to chronic under-emphasis and under funding of biosurveillance programs. Lack of interagency investments, coordination and leadership has caused frequent delays in the execution of surveillance efforts. The complexity of federal-state collaboration and the challenges of sustaining funding for essential public health programs at the state and local level have further impeded efforts to improve the nation’s biosurveillance capabilities.

Introduction

The United States has a critical national security interest in preserving the health of its population, livestock, crops, and natural resources. Biosurveillance is the method used to confront the array of threats to our national security from natural, accidental, and intentional origins. On October 18, 2007, the White House released Homeland Security Presidential Directive 21 (HSPD-21) which mandates the development of a nationwide, robust, and integrated biosurveillance capability for human health with connections to international disease surveillance systems to provide early warning and ongoing characterization of disease outbreaks in near real-time. Additionally, HSPD-21 requires the establishment of a federal advisory committee, including representatives from state and local government public health authorities and appropriate private sector health care entities to ensure that the federal government is enhancing state and local government public health surveillance capability.

To meet this mandate, the Centers for Disease Control and Prevention (CDC) was designated the lead to develop the National Biosurveillance Strategy for Human Health and establish the National Biosurveillance Advisory Subcommittee (NBAS). NBAS is comprised of prominent public and private biosurveillance stakeholders and contributors and was created by the Advisory Committee to the Director (ACD), CDC on May 1, 2008. As a subcommittee to the ACD, the National Biosurveillance Advisory Subcommittee will provide counsel to the ACD regarding the broad range of issues impacting the development and implementation of a nationwide biosurveillance strategy for human health. The membership of the NBAS ensures diverse perspectives important to the development of the strategy, including those from government, public health, health care delivery, academia and others, are reflected in the strategy's plans.

The NBAS was formed and organized into Task Forces (see Appendix A) to research and make recommendations related to biosurveillance in the following initial priority areas:

- Animal, Food and Vectors
- Biosurveillance Workforce of the Future
- Cross-Sector Collaboration for Biosurveillance Strategies
- Diagnostics and Laboratory Exchange Information
- Environmental Monitoring
- Genomic Epidemiology and Digital Technologies
- Global Disease Detection and Collaboration
- Integrating Clinical and Public Health Reporting

Recommend actions from each of these Task Forces were put forward in December 2008, compiled and considered by the NBAS Steering Committee on January 8-9, 2009. The NBAS Steering Committee analysis of the recommendations from the eight priority areas identified a number of issues in common and much synergy. The Steering Committee then integrated these into five high-level and cross cutting areas. On Tuesday March 6, CDC's Advisory Committee to the Director (ACD) was asked to endorse an Interim Report and move to share the report with

members of the current Presidential Administration. By a unanimous vote, the ACD voted to endorse the Interim Report. This report serves as the final 2008 report of the NBAS.

Importance and Current Status of U.S. Biosurveillance Efforts

The federal government must build a National Biosurveillance Enterprise to deal with a wide range of potentially destabilizing, 21st century national security threats such as biological and nuclear terrorism, pandemic influenza, newly emerging infectious diseases, contamination of the food supply, and large-scale natural disasters. Without the capacity to recognize early signals of disease outbreaks or other population health hazards, we cannot hope to intervene successfully during public health emergencies and prevent additional deaths or social and economic disruption. Without accurate and timely information about the situation on the ground, decision-makers cannot make informed choices about how to mitigate or contain an emergency and forestall catastrophe.

Disease-related events that reach the level of national consequence and/or global significance are rare, episodic, and unpredictable. Because of these characteristics, it is difficult to maintain long-term public interest, funding and prioritization. In addition, prevention activities are often invisible to the public and go unnoticed. Finally, the responsibilities and authorities within the government to prevent and respond to these events of national consequence and/or global significance are dispersed, put into silos and not integrated. Because of this diversity and the episodic but horrific nature of these events, we must use a non-traditional approach to address the current gap in our nation's biosurveillance capability. The approach can not rely on public will or a single governmental agency for success, but must be built around on-going interagency collaboration and coordination.

Enhancing the nation's biosurveillance capabilities can also yield important peace-time benefits. A well-designed National Biosurveillance Enterprise could improve routine public health practice, lead to more prevention-focused and cost-effective health care, and mitigate economic losses associated with breaches in food safety that result in domestic recalls and barriers to export. Moreover, to meet its obligations under the revised International Health Regulations of 2005, the U.S. will have to participate in efforts to strengthen disease surveillance capacities at home and abroad.

Today, the U.S. does not have an integrated, national approach to biosurveillance that is capable of responding to catastrophic health threats or to more familiar problems such as the contamination of food supplies. There is no overarching strategy that establishes the objectives of a National Biosurveillance Enterprise or that lays out the implementation plan for such a system. Currently, multiple authorities in many federal agencies and all 50 states engage in biosurveillance activities. There are more than 300 separate biosurveillance efforts underway in various federal, state and local government agencies. These efforts are, for the most part, neither integrated nor interoperable, and propose to serve an array of purposes. The effectiveness of most of these systems remains untested and, in some cases, undefined. Some systems appear to have overlapping missions, while other important surveillance needs have not received sufficient attention. The National Biosurveillance Advisory Subcommittee (NBAS) has been unable to establish reliable estimates of the annual cost of U.S. biosurveillance programs—there is no

Office of Management and Budget (OMB) cross-cut that would assemble total federal spending—but it is at least several billions of dollars. Current appropriations do not appear to be sufficient for the tasks at hand, although additional cost-efficiencies are surely possible.

Additional problems with current U.S. biosurveillance efforts include constraints imposed by federal budget and contract management policies that make it difficult to build systems agile enough to adjust to changing threats and contexts, and that impede opportunities to take advantage of—and to catalyze—technological innovation. The existing government workforce dedicated to biosurveillance is inadequate and ageing, but there are currently no plans to develop a workforce of the future that has the skills and training needed to support effective biosurveillance programs.

Finally, the National Biosurveillance Enterprise must be founded on the basic, routinely-used surveillance systems and practices of local and state public health agencies. The U.S. Constitution established that States have authority over and responsibility for “public health,” a state of affairs that has taken on important national security implications in an age of catastrophic terrorism, asymmetric warfare and global interconnectedness. The quality, comprehensiveness, and sustainability of state and local public health surveillance programs that serve as the foundation of our national biosurveillance capacity, vary widely according to the skill and funding levels of state and local health agencies. Since 2002, states received approximately \$1B per year in federal funds for bioterrorism and pandemic flu preparedness; a significant proportion of these monies were spent on biosurveillance projects. Federal funding for biosurveillance has enabled states both to improve routine surveillance activities as well as be better positioned to respond to emergency conditions.

While initial investments in biosurveillance were an important first step, the level of federal and state funding for biosurveillance appropriated to date is not commensurate with the strategic importance of these systems. Moreover, initial gains in state biosurveillance capacities are now threatened by both a steady erosion of federal funding for public health emergency preparedness and significant state budget deficits due to the economic downturn. In effect, we are asking states to fund systems that are essential to U.S. national security, without establishing a coherent planning or funding strategy to sustain the keystones of the National Biosurveillance Enterprise.

The recommendations that follow are the result of an intense study of U.S. biosurveillance programs by the National Biosurveillance Advisory Subcommittee, whose collective membership represents extensive professional experience and knowledge of biosurveillance programs, applications and technologies. The Subcommittee’s assessment of current biosurveillance efforts revealed opportunities for improvement in five major categories: interagency coordination and strategy; workforce issues; opportunities to enhance biosurveillance through links to clinical electronic health records and electronic laboratory records; and new emphases on global health surveillance.

Recommendations

How We Can Better Recognize Public Health Hazards, Manage Crises, and Respond to Disasters

The Subcommittee recommends engaging the leadership of President Obama's Administration to embrace and establish a well-functioning and cost-efficient national biosurveillance capacity. The following high-level, cross-cutting recommendations should be considered by the newly appointed Cabinet officials. As part of the work of the NBAS in 2009, additional, more detailed recommendations will be generated and published for review by the appropriate agencies and parties.

- 1. The Executive Branch must define the strategic goals and priorities of federal investments in biosurveillance activities and technologies, implement a plan to achieve, fund and periodically assess progress toward these goals. To accomplish this, the White House should establish an Interagency Biosurveillance Coordination Committee (“the Committee”).**
 - The Committee should be established by the White House and chaired by a representative from the Executive Office of the President (EOP), perhaps from the National Security Council or the Office of Science and Technology, and should include representatives from all federal agencies with a substantive stake in biosurveillance issues. Among federal agencies and departments that should be represented are Health and Human Services/Assistant Secretary for Preparedness and Response (HHS/ASPR), National Institute for Allergies and Infectious Diseases (NIAID), Centers for Disease Control and Prevention (CDC), Food and Drug Agency (FDA), Department of Homeland Security (DHS), U.S. Department of Agriculture (USDA), Department of Defense (DOD), Department of Veterans Affairs (VA), Office of the Director of National Intelligence (DNI).
 - The Committee should define the strategic goals and priorities of the National Biosurveillance Enterprise, particularly in the context of detecting and responding to catastrophic health events, and, in collaboration with federal, state and local health officials, clearly delineate the specific biosurveillance responsibilities of particular federal and state agencies or parties.
 - The Committee should carefully consider the critical roles that state and local health agencies serve in contributing to the National Biosurveillance Enterprise and assess whether the current federal and state allocation of public health resources is adequate to sustain a viable Enterprise view of the national security threats the country confronts and how a more sustainable and coherent approach might be structured and funded.
 - The Committee should ensure that federally-funded biosurveillance programs are subject to objective performance assessments. The effectiveness of different biosurveillance

approaches should be examined in light of actual experiences, exercises and simulations. This information should be shared widely in government and the private sector.

- To assess the costs, approaches, and effectiveness of biosurveillance systems, the biosurveillance program itself must be well defined with clear criteria to evaluate activities core to achieving the program strategy, goals and objectives. To that end, the Committee should recommend that Congress assign a budget activity line for all federally-appropriated biosurveillance activities. Performance measurement and evaluation of biosurveillance appropriations could then be tracked and reported to the Office of Management and Budget (OMB). The Committee should recommend that OMB conduct a cross-agency budget analysis and review of biosurveillance programs to ensure that critical programs are adequately funded, to eliminate redundant activities and to ensure that top priorities are being met.
- The Committee should consider initiating and/or leading an interagency review of food safety biosurveillance that meaningfully engages the appropriate agencies and private sector actors. Food safety is exceedingly complex scientifically, organizationally and politically and involves issues of human, animal and plant health. The Subcommittee recognizes that food safety requires urgent review and improvement.

2. The U.S. National Biosurveillance Enterprise must include global health threats in its purview and scope

- In today's "flat" and richly interconnected world, the United States has compelling security, economic, development and humanitarian interests in global health security. Improving international biosurveillance capabilities should be a priority for U.S. national and homeland security and for U.S. foreign policy. Moreover, the revised International Health Regulations obligate the United States to participate in global disease surveillance activities.
- The EOP representative to the Interagency Biosurveillance Coordination Committee should lead coordination of U.S. government policy on global biosurveillance, along with a lead federal agency designated by the President. The designated lead agency would coordinate global biosurveillance policy and programs, and should improve communication across U.S. federal agencies and with key donor organizations.
- The EOP representative to the Interagency Biosurveillance Coordination Committee along with the lead agency on global health should craft, coordinate and implement multilateral initiatives that strengthen core capacities in global biosurveillance and respond to public health emergencies in order to support the effective and sustainable implementation of the International Health Regulations of 2005.

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

- Federal public health preparedness funding allocated to state and local health departments and schools of public health beginning in 2002 has greatly enhanced biosurveillance capacity for both emergencies and for important non-emergency public health conditions. A trained corps of epidemiologists and laboratory personnel has been created that is our current biosurveillance capacity. It is critical to maintain rather than allow further erosion of the public health preparedness funding that supports this added capacity since 2002 until the objectives and funding needs of a more integrated National Biosurveillance Enterprise have been defined.
- National leadership should undertake a sustained effort to recruit, hire and retain highly competent and properly trained personnel to plan, evaluate, design and execute biosurveillance programs at all levels of government. Consideration should be given to establishing tuition-for-service programs and to attracting technical experts to government with Intergovernmental Personnel Assignments (IPAs) and other mechanisms.
- To improve interagency cooperation and data sharing, and to enrich civil servants' understanding of the resources available across the government, agencies that are a part of the National Biosurveillance Information System (NBIS) should establish career tracks that ensure that appropriately skilled and senior civil servants perform interagency service and participation in NBIS. Individuals who rotate through the NBIS should see the assignment as a growth opportunity rather than as a diversion from their career path.

4. Government investments in electronic health records and electronic laboratory data should be leveraged to improve how they serve biosurveillance and public health missions.

- The President has initiated an intense effort to establish electronic health records (EHRs) nationwide as a key component of health reform and of economic recovery investments. The American Recovery and Reinvestment Act (H.R. 1) of 2009 has allocated \$2 billion for development of a nationwide health information technology infrastructure that improves health care quality and efficiency, but also "improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks." Priorities for State grants under this section should include the establishment of electronic laboratory reporting to public health agencies and nationwide electronic death surveillance. Establishing these surveillance capacities would greatly improve situational awareness during large-scale public health emergencies and routine public health practice.
- The Act also provides for an estimated \$29 Billion in Medicare and Medicaid incentives to providers who demonstrate "meaningful use" of qualified EHR systems. Clinical care data provide the highest quality, most specific inputs for biosurveillance of populations, but most commercial EHRs are not oriented toward data sharing between public health agencies and clinical care providers. The criteria for qualifying EHRs and meaningful use must include functionality and use that improves prevention by enabling bidirectional communication between clinicians and public health officials.

- Widespread use of increasingly electronic clinical data for public purposes (whether in research, quality measurement, or biosurveillance) will require a policy foundation and sound network architecture for information sharing that can earn and keep the public's trust. This framework would also help to define and facilitate data sharing among federal, state, and local officials. The federal government must lead an open and transparent process to develop these policies, or endorse an existing set of principles such as the Connecting for Health Common Framework.

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

- The National Biosurveillance Enterprise should support and encourage innovative ideas, technologies and applications. Next generation biosurveillance technologies, including genomics-based and digital innovations could transform the way we recognize, assess, communicate and respond to risks to individual and population health.
- Innovation in biosurveillance technologies and approaches would be furthered by continuous benchmarking of performance against specific objectives such as earliest possible detection of pathogen or disease events; rapid agent identification with potential to obtain forensic data; prediction and projections of temporal-spatial progression of disease outbreaks and bioterror attacks; producing actionable information; advancing situational awareness after an event, etc.
- Many issues related to data sharing, intellectual property and federal contracting and regulations have high impact on the likelihood, cost and ease of designing innovative technology platforms and approaches to biosurveillance. The Biosurveillance Coordinating Committee should be cognizant of potential barriers to innovation and suggest efforts to minimize or remove them.
- The federal government should make strategic investments in efforts to develop rapid, point-of-care clinical diagnostic tests that can be used quickly to identify ill persons and to help isolate contagious persons from those who are well. Clinical diagnostic tests could have important strategic value in managing an epidemic, particularly if there were shortages of vital medicines or supplies.

Conclusion and Future Year Plans

These recommendations are supported by information obtained through research and testimony to the Task Forces of the National Biosurveillance Advisory Subcommittee and discussion and deliberation with the National Biosurveillance Advisory Subcommittee.

Given the opportunity in time with the transition of leadership in most Federal agencies, the NBAS submits that this report provides initial high-level critical actions to be considered by the new Secretaries of the Department of Health and Human Services (DHHS), the Department of State (DoS), the Department of Defense (DoD), Department of Veterans Affairs (VA), the United States Department of Agriculture (USDA), the Department of Homeland Security (DHS) and the Office of Science and Technology Policy (OSTP). The NBAS has anticipated a four year tenure, therefore, the NBAS is continuing to develop additional specificity to these recommendations as well as address additional domain areas that are important to the overall biosurveillance enterprise. The extensive reviews carried out in each of the Task Force domains resulted in recommended actions and these will provide the basis of the 2009 work and the first full year report in March 2010.

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