Call to Action:
Include Scientific Investigations as an Integral Component of Disaster Planning and Response

A Report from the National Biodefense Science Board

April 2011

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I. Executive Summary

The environment associated with a disaster that presents a significant threat to public health presents many challenges to the conduct of scientific investigations,[1] including limited access to incident leadership, the need to prioritize critical response activities, difficulty engaging personnel in the mission, and the need for timely situational awareness of important health-related events during the response or recovery operation. The disaster environment is usually dynamic, often hazardous, and highly charged with conflicting scientific opinions, political pressures, and disparities in knowledge or capabilities among responders and the public. This National Biodefense Science Board (NBSB) report is a call to action for the U.S. Government to include scientific investigations as an integral component of emergency preparedness and response efforts.

Response and remediation workers at the World Trade Center, Pentagon, and Pennsylvania sites after the September 11, 2001, terrorist attacks faced countless hazards, not least of which was great uncertainty about the health risks posed by poorly characterized chemicals and particulate mixtures in debris and the air. Similarly, in the aftermath of the Deepwater Horizon oil spill of 2010, recovery workers and residents contended with poorly understood health risks from oil and oil dispersants. These and other examples of disasters that threaten public health demonstrate how the lack of pertinent and dependable scientific knowledge can complicate and impede an effective response to a disaster, place workers and the general public at unknown and potentially needless risks, and contribute to frustration and anger in an already stressed population.

Each disaster constitutes a critical opportunity in what may be a brief window of time to conduct scientific research that could lead to improved assistance to those affected by the event, and improve capabilities for responding to future disasters. The overall goal is to learn from experience to prevent being confronted with similar dilemmas and uncertainties again.

In recognition of the need for scientific investigations during a disaster, the Assistant Secretary for Preparedness and Response (ASPR) asked the NBSB to address the issue and provide recommendations. Scientific investigations, conducted in concert with a disaster response, can help ensure that scientifically valid data are available regarding public health risk, treatment modalities, and other factors needed to successfully manage incident response. The availability of such data would help to protect health and save money both during the immediate response and in future disasters. Effective scientific

[1] The term "scientific investigation" as used here is interpreted broadly and includes (1) public health investigations and those investigations that are primarily exploratory or preliminary in their approach, including those involved with exposure assessment, case reviews, pilot studies, and cluster investigations, (2) those that involve routine, standard, or baseline health monitoring, including collecting social-behavioral, and environmental data, and surveillance activities (including implementing rosters or registries), and (3) those that entail more rigorous or complex scientific methods to evaluate specific exposure-outcome relationships or other questions such as intervention effectiveness. This latter group of investigations could be of longer (even extended) duration.

investigations must include short-term elements to improve and focus immediate responses to an emergency, and long-term elements to understand and minimize the consequences of the present disaster or future emergencies. This will ensure that knowledge gaps that could create challenges in future disasters are fewer because they were addressed in prior, similar events. The Nation does not lack the technical resources to conduct these investigations rapidly and effectively. Rather, those resources have not been organized or readied for application in a disaster, in large part because the formal mechanisms necessary to deploy them are not in place. As such, scientific investigations have sometimes not been optimally conducted as part of a disaster response that is focused primarily on providing rapid assistance to those in urgent need.

Although the focus of this report is to incorporate health-related scientific investigations as an integral component of overall ASPR emergency preparedness and response activities, the NBSB recommends that scientific investigations be included in all aspects of disaster response whether the disasters threaten human health, animal or plant health, the food supply, or the environment.

The NBSB finds that during emergencies, scientific investigations and associated pre-planning for scientific work must be a fully integrated part of the framework of disaster planning and response. This will ensure that critical knowledge gaps are addressed in a timely way and will facilitate follow up to permit the identification of the long-term effects of the emergency on responders and the public. This NBSB report is a call to action for the U.S. Government to include scientific investigations as an integral component of emergency preparedness and response activities. The NBSB accordingly offers 10 recommendations to improve the Nation's ability to mount a comprehensive and rapid mobilization of its scientific resources in the investigative response to disasters that threaten public health.

1. **Immediately convene Strategic Science Planning Panels, made up of leading expert government and civilian scientists, to identify research questions and knowledge gaps likely to arise during a variety of incident types, including those foreseen in Federal Emergency Management Agency (FEMA) National Planning Scenarios.**
2. **Add a "Scientific Response Support Annex" to the National Response Framework (NRF), and amend the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) to include a scientific response.**
3. **Establish with leadership and staff from the Office of the ASPR an Interdepartmental Center for Scientific Investigations During Disaster Response (the Center); the Center will have a dedicated staff, and its primary mission will be to anticipate, plan for, coordinate, facilitate, and evaluate scientific investigations conducted before, during and after disasters.**

The new Center would have full-time staff and additional liaison staff appointed as needed, and would have primary responsibility for the successful implementation of Recommendations 4 thru 10 of this report (which are in no particular order of priority).

4. **Develop the concepts, doctrine, infrastructure, and personnel needed to begin scientific investigation and data collection rapidly in various types of incidents.**
5. **Integrate the Public Health Emergency Research Review Board (PHERRB) into standard operating procedures for review of research before, during, and after a disaster response.**
6. **Appoint a liaison within the Center to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to facilitate review of scientific protocols required by the Paperwork Reduction Act (PRA). There should also be an independent review of the benefit versus the net loss of the effect of the PRA on a timely, emergent, scientific response with consideration of possible approaches for remediation.**
7. **Establish funding mechanisms to support a rapid and robust scientific response to disasters.**
8. **Integrate individuals and communities affected *by* a disaster as full partners in scientific investigations related *to* the disaster.**
9. **Standardize approaches to data collection and sharing by Federal, State and local response organizations (and encourage the same among private and volunteer organizations), giving special attention to collection of baseline data.**
10. **Identify, acquire or develop, deploy, and maintain new information technology for collecting data in the field.**

II. Charge to the NBSB

In her letter of January 21, 2011, to the National Biodefense Science Board (NBSB),[2] United States Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Dr. Nicole Lurie noted that recent disaster responses, including the 2010 Deepwater Horizon oil spill, the 2010 Earthquake in Haiti, and the 2009 H1N1 influenza pandemic, had revealed a particular weakness in current disaster preparedness and response planning. "The United States (U.S.) and the U.S. Government have tremendous science research capabilities, but applying them for public health emergencies, especially using non-traditional public health science resources, has been challenging," she wrote.

Dr. Lurie therefore asked the NBSB to make recommendations for an "All Hazards Science Response." The goals of such a response would be to collect information to inform decision-making during and after the response, track the effects of the disaster on populations in the short and long terms, and devise strategies that would improve future responses. Although each incident is unique, Dr. Lurie noted that the types of scientific responses required share many characteristics, so that lessons learned from one type of response could usefully inform responses to other types of incidents.

Dr. Lurie asked the NBSB for a report that would answer three key questions:

- What are the various major components of an All Hazards Science Response?
- How would such a response be operationalized?
- What infrastructure and supporting pieces need to be put in place to ensure that an All Hazards Science Response is ready to be put into action when needed?

During the NBSB public meeting on January 25, 2011, the Board voted to form the All Hazards Science Response (AHSR) Working Group (WG) to gather information and prepare a report for consideration by the NBSB. The NBSB's AHSR WG convened a workshop in Bethesda, Maryland, on March 1 and 2, 2011.[3] Experts from within and outside the Federal Government[4] discussed issues pertaining to the scientific response to disasters, including obstacles (practical, logistical, and bureaucratic) that have impeded such efforts, and desirable elements of a scientific response that would most optimize future responses. The format of the workshop was informal, with speakers giving short presentations followed by extended question-and-answer sessions. Due to scheduling conflicts on March 1, Mr. Michael Fitzpatrick, Associate Administrator of the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA) and his staff met by teleconference with available workshop participants at a later date. Similarly, the AHSR WG met by teleconference with Dr. Richard Heron, Vice-President for Health and Chief Medical Officer for BP International Ltd; and subsequently the Chair of the AHSR WG met by teleconference with Dr. Mark Tedesco, RADM, US

[2] See Appendix 1, Letter from ASPR to NBSB

[3] See Appendix 2, AHSR Workshop Agenda

[4] See Appendix 3, AHSR Workshop WG Roster

Public Health Service, U.S. Coast Guard, Director of Health, Safety and Work-Life. The recommendations in this report are based on the information gathered at the workshop, augmented in some areas by further information obtained from relevant expert sources and advisers. The AHSR Working Group prepared draft recommendations that were reviewed by the NBSB during the public meeting on April 28, 2011, and further feedback was solicited from the public at that time. This report was prepared in final form following approval of the Board on April 28, 2011.

III. Background

Catastrophic events are rare and unique, yet the effectiveness of the U.S. Government's responses to these incidents may be compromised by insufficient scientific information. Each event constitutes a critical opportunity in what may be a brief window of time to conduct scientific research that could lead to improved assistance to those affected by the event, and improve capabilities for responding to future disasters. The overall goal is to learn from experience to prevent being confronted with similar dilemmas and uncertainties again.

The responses of the U.S. Government during public health emergencies have revealed crucial scientific knowledge gaps that require further research in the areas of toxicology, epidemiology, exposure assessment, as well as basic, translational, and clinical and social sciences. Key research questions, if asked and answered in a timely fashion, could enhance the effectiveness of responses to a current or future disaster, and provide new information about mitigating the long-term health effects of such events.

This NBSB report is a call to action for the U.S. Government to include scientific investigations as an integral component of emergency preparedness and response activities in an annex to the National Response Framework. The U.S. Government needs to develop a strategic approach or framework for incorporating health-related and other scientific investigations into the existing emergency preparedness and response paradigm, which generally focuses on acute situational management.

At the AHSR WG meeting held March 1 and 2, 2011, and during subsequent deliberations, a clear consensus emerged that scientific investigations during a disaster response must be fully integrated into national disaster response plans. Because mechanisms are not currently in place to initiate or conduct scientific investigations during a disaster, scientific responses to disasters have often been delayed and marked by imperfect coordination among the many Federal agencies and other organizations with relevant responsibilities and expertise. Mounting a more timely and effective response requires that scientific investigations be regarded as an integral component of overall emergency preparedness and response planning, and that a designated panel of subject-matter experts should decide whether to mount scientific investigations, what the priorities are, what to focus on first, and what protocols should be implemented. This decision-making authority should be given a clearly delineated organizational location within the U.S. Government (e.g., within the National Response Framework [NRF], the National Oil and Hazardous Substances Pollution Contingency Plan [NCP], and other

high-level federal disaster planning efforts). The new authority would need readily available funding and be able to identify, recruit, and support relevant scientific organizations and individual scientists.

The consensus reached at the AHSR WG meeting echoes recommendations made recently by a committee of the Institute of Medicine (IOM) in a report on research priorities for the Deepwater Horizon oil spill in the Gulf of Mexico.[5] The IOM committee also recommended that "priority be given to conducting research on the framework needed to deploy a rapid research response for future oil spills *and other potential disasters*" (emphasis added). In its recommendations below, the NBSB outlines a structure for this proposed framework.

Scientific Investigations During Disaster Responses

In the immediate aftermath of a disaster that presents a significant threat to public health, emergency responders—from high-level managers in an Incident Command System to first responders in the field—are primarily and appropriately focused on providing essential assistance to those in urgent need. The conduct of scientific investigations in the midst of a disaster has often been considered a distraction, and has been impaired by the lack of infrastructure and mechanisms for launching scientific studies in a timely and effective fashion.

Several past incidents clearly illustrate that scientific investigations are frequently needed for an optimal response to a disaster. Information about the occupational and environmental health risks to workers at the World Trade Center site was inadequate. During and after the subsequent anthrax attacks, there were uncertainties about how to diagnose and treat the disease, discern who might have been exposed, detect anthrax spores, and decontaminate buildings. The Deepwater Horizon oil spill of 2010 raised questions about the short- and long-term health consequences of exposure not only to oil but to the chemical dispersants used to clear the oil, as well as questions about a host of environmental, behavioral health, and food safety issues. In these cases and others, the lack of reliable and current scientific information presented real difficulties to those managing the emergency response or for determining the long-term impact of the incident on emergency workers and the community.

In the context of this report, "scientific investigation" is used in the broadest possible sense. It encompasses a rapid assessment of what is already known about a given problem, rapid compilation of data from the field to guide ongoing public health decisions, hypothesis-driven research needed to understand and cope effectively with the current incident, and developing and implementing improved approaches and responses to future incidents.[6]

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[5] Research Priorities for Assessing Health Effects from the Gulf of Mexico Oil Spill: A Letter Report. Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill; Institute of Medicine. 2010. Available at http://books.nap.edu/catalog/13036.html

[6] The term "scientific investigation" as used here is interpreted broadly and includes (1) public health investigations and those investigations that are primarily exploratory or preliminary in their approach,

Workshop participants noted that scientific investigations during a disaster response can be grouped according to whether the results are needed in the short term to guide immediate decision-making, or in the longer term to understand the important effects of the incident on populations or the environment. The problems presented by the types of investigations needed on these time scales are different, and may require different investigative solutions. Workshop members also noted that coordinated and timely research during incidents that pose a significant threat to public health is needed to improve the effectiveness of the response and ability to mitigate future disasters.

Uncertainties and associated scientific questions that need immediate answers are more likely to arise in unusual incidents (such as outbreaks of emerging infectious diseases or cases of chemical or radiological contamination) with which society has less experience than in more frequent and recurring disasters such as earthquakes, hurricanes, or floods. But scientific information is needed during both familiar and unfamiliar incidents to address basic issues such as accurately diagnosing diseases or other health problems, and distinguishing those who need urgent help from the "worried well." Guidance will often be needed about which treatments work best under what circumstances, and how emergency response personnel should advise people to protect their health. To manage an incident effectively, officials need a clear understanding of the current science, as well as the ability to identify scientific experts to help assess the situation and provide needed advice and expertise. Public health experts knowledgeable about the issues, in turn, need to make recommendations for the rapid collection of data, and conduct of investigations to answer critical questions.

The need for longer-term investigations concerning the health of individuals and communities arises as the immediate response to an incident transitions to the recovery phase. There are often unresolved questions about the short- and long-term health consequences of exposure to pathogens, toxins, contaminants, or other hazardous agents. Additionally, past experiences (e.g., 2009 H1N1 influenza pandemic, World Trade Center collapse, hurricanes, and the 2010 Gulf oil spill) have demonstrated that there is a real and increasing need to implement strategies to detect and treat health problems (including behavioral and mental health issues) that may appear long after the initial incident. Issues of concern and investigative approaches may differ significantly between the general population (which includes individuals with pre-existing medical conditions, children, the elderly, pregnant women, and other groups with increased vulnerability), and emergency workers, including first-responders, who might have experienced higher stress environments and greater exposure to dangerous agents. Questions also arise in determining how best to restore contaminated areas (i.e., "what is safe"), how well and

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including those involved with exposure assessment, case reviews, pilot studies, and cluster investigations; (2) those that involve routine, standard, or baseline health monitoring, including collecting social-behavioral, and environmental data, and surveillance activities (including implementing rosters or registries); and (3) those that entail more rigorous or complex scientific methods to evaluate specific exposure-outcome relationships or other questions such as intervention effectiveness. This latter group of investigations could be of longer (even extended) duration.

how rapidly natural processes will aid that restoration, and what health risks a contaminated area continues to pose to humans as restoration proceeds.

Effective planning for emergencies that could threaten public health includes pre-identification of subject-matter experts in a variety of scientific disciplines, pre-determination of data needs, and systems for obtaining the necessary data, (e.g., exposure assessments). Also, as the U.S. population changes over time (to include more immune-suppressed and elderly citizens, larger proportions of non-English speakers, etc.), new and unexpected challenges will emerge, requiring a continuing re-examination and evolution of responses and innovative solutions to meet these new needs.

A long-term study following a disaster can be costly and difficult to design; therefore, officials must carefully consider whether a proposed or requested study is likely to produce useful, reliable results and is a prudent investment of public health resources. Such concerns require a thoughtful assessment of the feasibility and likelihood of success throughout response efforts.

Many workshop participants stressed that a fundamental need in almost all health-related investigations, whether short-term or long-term, is to obtain a credible baseline of health, exposure, and demographic information, including biomarkers and DNA collection when appropriate, for affected populations and responders. It can be difficult or impossible to determine whether a health problem is occurring at an anomalously high rate unless that baseline rate of occurrence for the problem is known before or at the time the incident occurs. Obtaining such fundamental information without delay should occur in all incidents, even if the decision to conduct a study has not yet been made.

In general, different types of information might need to be gathered from response workers and the general public who might be exposed or are at risk. Depending on their roles during a disaster, emergency workers can experience greater exposure for longer periods of time than the general public. However, emergency workers often use personal protective equipment and operate within a regulatory framework that requires training, limits on exposure, health monitoring, and reporting of injuries and illnesses. For response and remediation workers, pre-event baseline data could be generated through pre-deployment health screening.

It also would be useful to catalog existing data sets so that those investigating an incident could determine quickly what baseline data are available or what biological or environmental samples might exist that would be of use in studying a particular event. For the population at large, analysis of existing databases could provide baseline information in some circumstances. Existing databases include the National Health and Nutrition Examination Survey (NHANES), the Behavioral Risk Factor Surveillance System (BRFSS) and Surveillance, Epidemiology and End Results (SEER) data for cancer incidence and prevalence rates, state-based infant blood spot repositories, and air pollution monitoring databases. (See Appendix 6 for more information about the advantages and short-comings of NHANES and BRFSS.)

For questions about potential long-term effects on public health following a disaster, such as the consequences of infection with a novel virus or other pathogen or exposure to hazardous chemicals, it is often not straightforward to decide which baseline data would be most relevant. Such difficulties point to a need for research programs to develop

protocols and best practices for collecting data in a focused and feasible manner in the midst of an emergency response.

One unarguable point is that data collection needs to begin as soon after the start of an incident as possible. Assembling a roster (a list of names and contact information for response and remediation workers, as well as affected members of the general public) is an important first step. In many cases, that roster might evolve into a registry containing more detailed information, such as health and exposure data. In some situations it may be prudent to identify the physical boundaries of the incident area by noting affected addresses, zip codes, GPS coordinates, geographic boundaries, or similar information.

Many protocols for data collection, including the specification of the data elements to be collected, can be formulated in advance of an event and categorized based upon the class of event. This work should be performed by panels of experts and should involve the specification of both initial data elements and those that should be repeated as necessary based upon the extent and degree of exposure.

The collection of environmental samples and data is crucial for conducting toxicology assessments, tracking the prevalence and migration of contaminants, characterizing and quantifying exposure, determining longitudinal health risks, and assessing environmental damage. The collection of clinical and other biological specimens, as well as biosurveillance and health monitoring data, also is crucial for identifying potentially hazardous situations and determining the causation of increased rates of injuries and illnesses. Understanding the effects of exposures of concern on the health of animals could provide early clues as to potential health effects on people. Attention must also be given to the improvement of the methodology of exposure measurement when dealing with biological, chemical, or radiological agents. The failure to obtain essential data or integrate basic scientific investigations into the management of an emergency response can compromise the ability to conduct meaningful scientific studies of the short- and long-term health impact of a disaster on human or animal populations, and the environment.

An example of a disaster data-gathering effort that has shown some success is the Disaster Medical Information Suite (DMIS), which has been created within the National Disaster Medical System (NDMS). DMIS has three main components, an electronic health record designed for use in the field and patient assessment, a patient-tracking tool designed to track injured or ill disaster victims, and a web-accessible Health Information Repository for real-time surveillance and analysis of documented injuries and illnesses. DMIS worked well in Haiti following the 2010 earthquake, speeding the collection of health data and transmission to headquarters, where it could be analyzed and acted on. Nevertheless, the inability to rapidly collect, analyze, and report detailed clinical data early in a disaster remains a key national disaster response vulnerability.

A proposed concept is the Operational Clinical Assessment Program (OCAP), also within NDMS, that would offer a more sophisticated data collection and analysis capability, utilizing DMIS to provide real-time critical information on emerging disease and/or emerging disaster-related public health threats. OCAP would rely on deployable Operational Clinical Assessment Teams (OCATs) that would have the expertise to gather

health data, determine needs, and identify relevant local resources that could assist in the response. OCAP is purposely designed to be part of a public health response with a robust and rapid analysis of the public health threat, not a long-term research activity; the data it would collect would be a valuable real-time resource in many types of investigations.

Several workshop participants emphasized the value of integrating the local community as a partner in scientific investigations conducted during disasters. "Community-based participatory research" encourages a cooperative process between investigators and community members in collecting important data. It also facilitates participation of a broader and more representative sample of community members as investigators conduct their inquiries. For example, such an approach could greatly enhance the creation of rosters and registries by engaging and working with a wide sector of the community, including local businesses, trade unions, and civic organizations, to inform the community of the potential benefits of participation for workers, other community members, and communities that might be affected by future disasters. As community members participate in this process, leaders within the community can be effective at articulating questions and concerns of the community, and also the benefits of the research. Messages delivered through respected local community figures are more likely to be trusted, and information obtained through active community participation is likely to be more complete and reliable.

Planning Is Essential

Although different kinds of disasters can occur, many important questions that arise in disasters can be anticipated. The scientific response to the 2009 H1N1 influenza pandemic was, to a considerable extent, built on preparedness activities occurring over several years prior to the pandemic. Nonetheless, the event highlighted several unanswered scientific questions. These included, for example, questions regarding the mode of transmission of influenza and associated protection measures, including whether the use of N95 respirators was indicated. By contrast, more unusual incidents, such as the anthrax attacks or the emergence of severe acute respiratory syndrome (SARS) presented situations with a generally less-developed scientific basis for an informed response.

Advanced planning is necessary to avoid bottlenecks that could impede a rapid and effective response. Barriers could include the lack of sufficient funding, the time needed to develop and conduct an ethical review of human subject protocols, inadequate information-technology (IT) infrastructure, and the lack of trained data-collection personnel who can operate in the field. A strategic approach to emergency preparedness planning entails analyzing a prioritized set of disaster scenarios to identify situations where scientific investigation would either be explicitly designed to fill pre-identified scientific gaps, occur as a natural follow-on to short-term investigations that address feasibility issues, or be nested within long-term post-event health surveillance efforts. Careful analysis in the planning stages by appropriate experts would enable the appropriate application of multidisciplinary expertise to identify scientific gaps,

formulate well-defined hypotheses, and design potential studies within the context of the life cycle of a disaster and the requisite phases of emergency management.

Emergency responses typically require a great deal of interagency and interdepartmental collaboration. Plans for scientific investigations will need to anticipate as much as possible the coordination that responses to various incidents will likely entail. Public health agencies should establish and communicate defined roles, responsibilities, and expectations regarding data collection and the conduct of scientific studies, in addition to identifying areas of collaboration. This will assist in avoiding redundancy, inefficiencies, and disagreements in the midst of an emergency. Collaboration should include the coordination of any investigations with local authorities and state and local public health departments.

At the time of an emergency, Federal Government officials would benefit from the advice and counsel of experts. Currently, there is no formalized mechanism to obtain this information quickly. Although concepts such as the maintenance of rosters of subject-matter experts, use of the Institute of Medicine, and the emergency convening of HHS advisory committees have been considered and in some cases utilized, there is no standardized approach to this issue. Each of these mechanisms presents specific issues that should be investigated by expert panels.

Research Involving Human Subjects

Many of the scientific investigations, but not all, that are part of a disaster response involve human subjects research, and are therefore closely regulated. Institutional Review Boards (IRB) are required by federal law to review many categories of proposed investigations that involve human subjects, in order to ensure that the work is ethical and in compliance with all regulations. Direct public health response called public health practice (e.g., surveillance for diseases and responding to outbreaks) does not require research oversight such as IRB approval. However, public health research, whether performed by a local state or federal authority, must have the same oversight as research done by other institutions.

National standards and expectations for the protection of human subjects must always be scrupulously respected, even under emergency or disaster circumstances. Thus, it is imperative to find ways to expedite review of research protocols under emergency conditions. With the concurrence of the Assistant Secretary for Health, and in collaboration with ASPR, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), the National Institutes of Health (NIH) is establishing a new, national IRB called the Public Health Emergency Research Review Board (PHERRB)[7] to advance critical research in the context of public health emergencies. In addition to carrying out IRB reviews, over time, the PHERRB might be able to take on other roles to facilitate research in the context of public health

[7] See Appendix 5, Public Health Emergency Research Review Board fact sheet

emergencies, such as advising on the design of studies or the formulation of protocols, and to assure public understanding of its role and mission (see Appendix 5.)

Public health emergencies demand a range of well-planned and coordinated investigations. Inquiry in the context of a public health emergency can entail:

- Gathering and analyzing individual and population data on health and illness
- Collecting clinical specimens from patients and healthy individuals
- Characterizing exposure via work site environmental sampling or biomonitoring
- Evaluating existing or novel pharmaceutical or non-pharmaceutical interventions in health care and community settings
- Using Treatment Investigational New Drug (IND) and Emergency IND protocols and Investigational Device Exemptions (IDE), or developing products to prevent, treat, mitigate and diagnose, including the use of medical countermeasures
- Collecting complementary data on products authorized for use during the emergency by FDA under its Emergency Use Authorization (EUA) authority, or products used during an emergency under other FDA regulatory mechanisms. The PHERRB has the potential to enhance the efficiency of IRB review of research conducted to support disaster response, while assuring protections for human subjects, and should be fully integrated into planning for scientific investigations involving human subjects that must occur during disasters.

Additionally, any data collected must in all cases have appropriate privacy protections and ethical safeguards for all participants. For example, the National Institute for Environmental Health Sciences GuLF Study acquired "Certificates of Confidentiality" to further ensure privacy and protection of study participants beyond the normal IRB approval process to further ease fears and facilitate participation in needed research efforts.

Certain provisions of the Health Insurance Portability and Accountability Act (HIPAA) require that protocols guard the privacy of personal health information. Data collection may require clearance by OMB under the Paperwork Reduction Act (PRA), which is designed "to reduce burdens on the public and improve the integrity, quality, and utility of information to all users within and outside the government."

These laws and regulations are not suspended during an emergency response, nor should they be. However, many workshop participants indicated that inefficiencies in the mechanisms designed to meet these requirements have slowed implementation of urgent disaster-related investigations. Regarding HIPAA compliance, there appears to be widespread confusion about what kind of data can be collected. For example, there is a "safe-harbor" provision in the act, so that data stripped of 18 key elements is deemed anonymous and therefore not subject to HIPAA oversight. Participants said that better education about when and how HIPAA comes into play might help avoid needless delays. Regarding the PRA, there was agreement on the need for better communication between the OMB Office of Information and Regulatory Affairs (OIRA), which reviews and acts upon collections of information subject to the PRA, and coordinates with agencies to determine when the act applies and how best to comply with it in an

emergency. The OIRA has developed four guidance documents pertinent to the preparation of data collection instruments pursuant to the requirements of PRA.[8]

IV. Recommendations

The NBSB has determined that scientific investigations must be an essential component of emergency preparedness and response planning, and should be initiated at the outset of an emergency that threatens public health. Scientific inquiry and methods need to become an integrated part of the framework of disaster response to ensure that critical knowledge gaps are addressed before, during, and after the "next" event.

The NBSB offers the following 10 recommendations to improve the Nation's ability to mount a comprehensive and rapid mobilization of its scientific resources in response to disasters.

1. **Immediately convene Strategic Science Planning Panels, made up of leading expert government and civilian scientists, to identify research questions and knowledge gaps likely to arise during a variety of incident types, including those foreseen in Federal Emergency Management Agency (FEMA) National Planning Scenarios.**

More effort needs to be devoted to anticipating and preparing for the kinds of scientific investigations that will be needed before, during, and after different types of disasters. The HHS Secretary can begin to address this problem by quickly convening multiple expert panels of top government, academic, and private-sector scientists to predict the kinds of scientific investigations that will be needed in various circumstances. This includes actions that should be taken during any incident to support scientific inquiry and public health responses. These teams should coordinate their activities to avoid redundancy and ensure a common approach.

The Federal Emergency Management Agency **(**FEMA) has developed a set of 15 representative National Planning Scenarios[9] to guide the development and testing of disaster response plans. Due to the diversity of these scenarios, the NBSB recommends that multiple panels be formed as indicated with the appropriate expertise. These expert panels should examine each of the FEMA and other relevant scenarios, and identify the knowledge gaps and the key questions that could arise and the scientific investigation and research that might be necessary to address the questions or concerns. The panels' findings would be forwarded to the new Center identified in Recommendation 3.

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[8] The four OIRA guidance documents are 1) "Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process," 2) "Paperwork Reduction Act-Generic Clearances," 3) "Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act," and 4) "Information Collection under the Paperwork Reduction Act (Primer)." All four are available on the OIRA section of the White House website at http://www.whitehouse.gov/omb/inforeg_infocoll.

[9] FEMA Fact Sheet: National Planning Scenarios. Available at http://www.fema.gov/pdf/media/factsheets/2009/npd_natl_plan_scenario.pdf Accessed 3/25/11.

These panels should also consider the pre-designation of experts in the various fields of concern to provide advice and council during specific types of events. This may involve the development of rosters of various government and non-government experts, the formalization of other mechanisms for convening such experts, and the timely utilization of existing HHS advisory groups. The panel should also consider how to formalize the relationship of these expert groups to other science agencies across the Federal Government.

2. Add a "Scientific Response Support Annex" to the National Response Framework (NRF), and amend the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) to include the scientific response.

A "scientific response" is a critical part of disaster response. The importance of science is not sufficiently integrated into the Nation's overall framework for disaster preparedness and response. To rectify this, the NBSB recommends amending both the NRF and the NCP to clearly delineate the important role that scientific knowledge and scientific investigation play in improving decision-making, risk communication, and overall management and understanding of incidents that threaten human health, animal or plant health, the food supply, or the environment.

The NRF, which is maintained by the U.S. Department of Homeland Security (DHS), provides a framework for how the Nation responds to all hazards (but not all events), from the smallest incident to the largest catastrophe. The NRF identifies the key response principles, as well as the roles and structures that organize the national response. Perhaps equally important, the NRF gives federal, state, tribal, local and nongovernmental responders a common frame of reference, and a common vocabulary, for the varied roles and responsibilities that responses to incidents might require. Several support annexes delineate how important support functions, such as financial management, private-sector coordination, and worker safety and health, will be handled. Overall, the NRF allows responders of all types and from different jurisdictions and disciplines to work together more effectively.

The NCP, which is maintained by the Environmental Protection Agency (EPA), guides the Federal Government's response to oil spills and hazardous substance releases. The document describes both a National Response Team (NRT) and Regional Response Teams; these teams lead NCP activities after a spill. The NRT, co-chaired by the EPA and the Coast Guard, was activated during the response to the Deepwater Horizon oil spill in the Gulf of Mexico in 2010 and provided the overall structure to the response; however, much of the work of FEMA, CDC, and other federal agencies in that response was shaped by the NRF, even though it was executed under the NCP.

HHS should work with DHS and other agencies to develop a "Scientific Response Support Annex" to be included in the NRF. This annex, like the other support annexes, should clearly delineate the various agencies' legislative authorities and programmatic capabilities that could support scientific inquiry during disasters, identify federal agencies' areas of responsibility, identify the lead agency for science for each type of disaster, and provide an overall concept of operations and basic components for the conduct of scientific investigations during disaster responses.

Similarly, HHS, EPA, and the Coast Guard must work together to incorporate language for science responses to be included as an essential part of the NCP and the NRT operating guidance and response structure.

Note that Recommendations 3 through 10 in this report should be embodied, as appropriate, in both the Scientific Research Support Annex to the NRF and recommended changes to the NCP.

3. Establish with leadership and staff from the Office of the ASPR an Interdepartmental Center for Scientific Investigations During Disaster Response (Center); the Center will have a dedicated staff, and its primary mission will be to anticipate, plan for, coordinate, facilitate, and evaluate scientific investigations conducted before, during and after disasters.

The primary responsibility for investigations concerning medical treatment and public health falls to HHS. However, many other federal departments and agencies also are expected to provide expertise and support for critical scientific investigations during disaster responses. These may include the EPA (e.g., specialized exposure assessments and evaluations of decontamination and remediation strategies following a chemical, biological or radiological incident), the Department of Agriculture (e.g., investigation of bioterrorism incidents affecting crops or livestock), and the Department of Justice (e.g., forensic investigation of chemical, biological, or radiological attacks).

A standing group and established organizational framework are essential to providing the rapid and highly technical responses and coordination necessary to support scientific inquiry during a disaster response. Therefore, the NBSB recommends that HHS establish the Center within the Office of the ASPR.

This Center would be permanent. It would have a dedicated staff, including a Public Affairs officer to handle communications with the public about scientific investigations in the context of disaster responses both before and during an incident response. The Center's primary mission would be to coordinate efforts across the Federal Government to plan and prepare for scientific investigations of all kinds during any type of incident. Additionally, the Center would be charged with ongoing evaluation of the scientific response to the incident, actions, and lessons learned to help improve future response efforts. Because some incidents are international in scope, the Center would represent the United States in the coordination of multinational scientific issues related to disaster response.

The concept of interdepartmental coordination and collaboration is demonstrated by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE[10] is an interagency effort coordinated by the Office of the ASPR that is responsible for ensuring that medical countermeasures are available to combat biological, chemical, and radiological incidents and more recently, emerging infectious diseases. To establish collaborations between PHEMCE and other Departments and agencies, HHS

[10] See https://www.medicalcountermeasures.gov/BARDA/PHEMCE/phemce.aspx

has memoranda of understanding (MOUs) with several partners, including the Department of Defense, DHS, and the Department of Veterans Affairs.

The new Center would have full-time staff and additional liaison staff appointed as needed, and would have primary responsibility for the successful implementation of Recommendations 4 thru 10 of this report (which are in no particular order of priority).

4. Develop the concepts, doctrine, infrastructure, and personnel needed to begin scientific investigation and data collection rapidly in various types of incidents.

The HHS Secretary should plan to deploy, support, and equip science teams to conduct necessary investigations during and following disaster response. First-responders are focused primarily on providing security, shelter, sustenance, and medical care during a disaster response. Although some scientific investigation teams already exist within HHS at the federal level (e.g., the CDC Epidemic Intelligence Service, and the Health Hazard Evaluation Program, a collaboration between CDC and the National Institute for Occupational Safety and Health [NIOSH]), additional capability is needed to carry out other types of specialty investigations, including teams that could begin long-term surveillance studies in a timely way and collect data for research into the mechanisms of action of infectious, chemical, or radiological agents. The concept of an Operational Clinical Assessment Program, operating within the NDMS and relying on deployable Operational Clinical Assessment Teams, should be explored to meet the need for valuable real-time data to inform decision-making on the scene.

People dedicated to conducting investigations and collecting data must be trained and deployed to work in concert with the first-responders and state and local health departments and officials during a disaster. The science teams must be given proper credentials, tools, and sufficient authority to carry out their work. Current plans, as reflected in the NRF and the NCP, do not identify where the science teams would fit into the overall response architecture; thus, these teams should be identified in the NRF Scientific Response Support Annex. The various agencies that will be responsible for conducting these investigations are not currently prepared to deploy the necessary personnel, with the proper support infrastructure to sustain them in the field. As part of developing the infrastructure and personnel to conduct scientific investigations, HHS agency roles should be clearly identified (e.g., NIOSH for occupational safety and health research and FDA for food safety), and specific agency representatives identified to staff the group of "scientific responders."

The U.S. Government supports extensive infrastructure and networks of academic institutions, hospitals, clinical and research laboratories, databases, surveillance networks and response teams to include personnel, equipment, supplies, and state-of-the-art technologies. Efforts must be made in advance of a disaster to identify what and how existing infrastructure components and resources can be leveraged to support scientific investigations during a response. Leveraging the Federal Government resources specific to particular agencies and departments as well as grantees and contractors, in coordination with non-government resources is key to the rapid collection, analysis, and dispersal of data on which to base decisions. Concepts and doctrines to guide the

engagements of these entities need to be developed and agreed to in advance of the event.

5. Integrate the Public Health Emergency Research Review Board (PHERRB) into standard operating procedures for review of research before, during, and after a disaster response.

National standards and expectations for the protection of human subjects must always be scrupulously respected, even under emergency or disaster circumstances. For the future, it is essential that processes intended to protect participants move forward rapidly, hand-in-hand with required response actions, so that critical data are available to assist decision-makers who are responsible for acute- and longer-term management of an incident. The PHERRB has the potential to enhance the efficiency of IRB review of research conducted to support disaster response, while assuring protections for human subjects, and should be fully integrated into disaster-related planning for scientific investigations involving human subjects (see Appendix 5). It may be appropriate to have a member of the NBSB be appointed as liaison to the PHERRB.

6. Appoint a liaison within the Center to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to facilitate review of scientific protocols required by the Paperwork Reduction Act (PRA). There should also be an independent review of the benefit versus the net loss of the effect of the PRA on a timely, emergent, scientific response with consideration of possible approaches for remediation.

The PRA was designed, among other things, to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal government." OIRA has statutory responsibility for the PRA. The PRA directs agencies to publish a 60-day notice in the *Federal Register* to solicit public comment on proposed data collections, as well as a second notice for a 30-day comment period. OIRA must review and act on data-collection instruments and supporting documentation before collection can commence. The review is designed to ensure that the study design is consistent with the intended use of the information, receives appropriate coordination across the Federal Government, and employs data-collection methods that are consistent with government-wide policy and practice.

Agencies can apply for "emergency" review from OIRA if data collection meets statutory criteria. Emergency review approval allows the process of data collection to proceed for a maximum of six months. The CDC, for example, obtained such emergency clearance twice during the response to the Deepwater Horizon oil spill, and twice when responding to the earthquake in Haiti. Guidance issued by OIRA on December 9, 2010, encourages early collaboration between agencies[11] and OIRA and suggests pre-review of some data-

[11] Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process, available at http://www.whitehouse.gov/omb/inforeg_infocoll.

collection instruments to streamline the approval process in actual incidents. Also of importance in accelerating approval during an emergency is alerting the OIRA desk officer that the agency plans to submit an emergency application, the timeline on which it will be submitted to OMB, and the time available for approval (hours, days, or weeks).

The NBSB recommends appointment of a liaison from the Center to OIRA. This liaison would be responsible for assisting agencies in understanding the requirements of PRA with regard to scientific investigations in disasters, and to facilitate investigations in disasters. The liaison would facilitate obtaining clearance for foreseeable data-collection efforts and communication between OIRA and those seeking PRA clearance during an emergency.

7. Establish funding mechanisms to support a rapid and robust scientific response to disasters.

Funding mechanisms should be considered and developed that will allow necessary scientific investigations to commence promptly after an incident begins, preferably within hours or days of the initial event.

Several approaches should be considered. One approach would be to put contract arrangements in place with qualified investigators who, perhaps after a streamlined application process, would implement plans already drawn up in anticipation of need. This could be done using an "indefinite delivery, indefinite quantity" (IDIQ) contracting vehicle, in which contracts are prepared and signed, but not executed until the agency places a "task order" to begin a specific project. Such contract mechanisms could also be put into place to provide qualified personnel to assist agency-lead research.

Another approach currently in use is to use the grant mechanism to fund research centers to work in the area of research needed, so the centers can act quickly to conduct specific projects when a disaster occurs. For example, the National Institute of Mental Health (NIMH) created the Disaster Mental Health Research Center (DMHR Center) in 2006. The DMHR Center developed infrastructure and research protocols needed to rapidly assess changes in behavioral health after a disaster; the protocols were reviewed in advance by relevant IRBs. The DMHR Center was able to put these plans into action when Hurricane Ike struck in September 2007. In another example, since 2001, a variety of research and training centers have been organized by CDC at academic institutions around the country, which could provide useful assets and resources for disaster-related scientific investigations. A third example of this approach is a network of Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases, created by the National Institute of Allergy and Infectious Diseases (NIAID). These Centers routinely conduct basic and clinical research related to the development of medical countermeasures, but can rapidly take on urgent research projects in response to a deliberate or naturally occurring infectious disease outbreak.

A third approach would be to create programs that can rapidly evaluate and fund new ideas for research projects from qualified researchers. The National Science Foundation, for example, has a "Rapid Research Response" funding mechanism under which

researchers can send brief proposals for rapid internal review; awards can be for up to $200,000 for up to one year.

8. Integrate individuals and communities affected *by* a disaster as full partners in scientific investigations related *to* the disaster.

Community-based participatory research should be the default model for the conduct of surveillance and other studies during and after disasters. A crucial principle of this model of investigation is transparency; investigators must work diligently to communicate clearly with the community about the purpose and methods of the study, and to share the data and results of the study with the community and individuals from whom data are collected. As part of this process, study coordinators must explain clearly whether the research will provide any direct benefit to individual community members and workers, whether the research is being conducted to further the science for future disasters, and how the findings will be shared.

To the extent possible, investigators should adopt a "community-based participatory research" model as they carry out investigations. In order for federally sponsored investigations—especially those requiring data collection from a large number of people—to go forward efficiently, it is imperative that potential participants understand the importance of the work, trust that it is being carried out for their benefit or society's benefit, and understand that the results will be shared with them when the data are collected and analyzed. Moreover, the population affected by the disaster can be an asset in many projects, supplying specific knowledge and skills, including appropriate languages and understanding of cultural sensitivities, which can strengthen data-collection efforts.

The integration with the community should extend to local, academic, medical, and public health communities with the intent of streamlining local and institutional review board (IRB) approval to scientific investigations when indicated.

9. Standardize approaches to data collection and sharing by federal, state, and local response organizations (and encourage the same among private and volunteer organizations), giving special attention to collection of baseline data.

To the extent possible, standardized processes and tools (e.g., lifestyle and psychosocial surveys, modular medical and symptom questionnaires, generic study protocols, and data entry forms), should be developed to expedite data collection from affected populations for scientific investigations during and following incidents. This would include procedures for collecting baseline health data (e.g., questionnaires, medical testing, and biological specimens), social-behavioral, and environmental samples (e.g., hazardous or threat agents, air, soil, water, and contaminated materials), identification of populations of concern, and the rapid creation of rosters or registries of individuals to be followed over time. Also needed are procedures to facilitate rapid sharing of data collected with various investigators and with affected populations, as appropriate, as well as with disaster responders. All data collected should be stored in interoperable databases, using consistent data-collection formats, to maximize efficient access by incident managers and

scientific investigators who would need it and have authorization to access it. Such data must be stored with proper safeguards to protect privacy rights.

Baseline data are a crucial component of studies to understand the effects of a disaster on a population, and the NBSB urges that efforts begin now to strengthen collections of baseline data. For example, in advance of an incident it would be wise to collect data on first-responders, under the assumption that these data will be representative of workers who respond immediately to a disaster. Moreover, in most incident responses, investigators should begin to collect a core set of baseline data such as rosters of exposed individuals and baseline health status information. The failure to begin collecting critical data as soon as possible can result in inefficiencies and loss of essential information, which can significantly compromise the ability to perform longitudinal research and the interpretation of any study findings. The sharing and storage of collected data must be done with proper privacy and ethical safeguards consistent with the human subject review process (see Recommendation 5).

10. Identify, develop, deploy, and maintain new information technology for collecting data in the field.

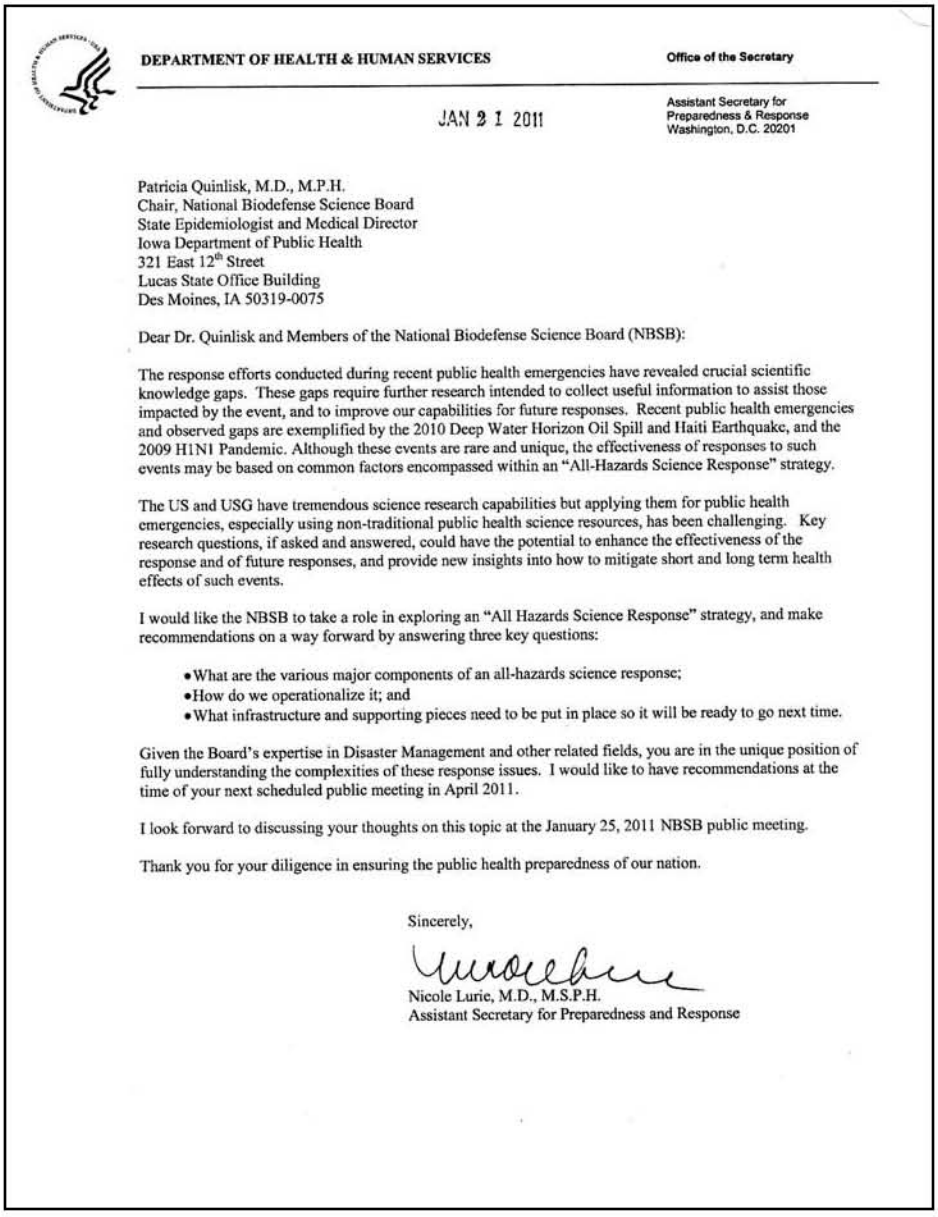
Powerful and inexpensive new information technologies have the potential to greatly enhance collection of data under adverse or chaotic conditions. Promising technologies that have become affordable include:

- "Smart" worker badges with sophisticated data-storage capabilities
- Broadband-enabled tablet computers with touch-screen capabilities
- Very small GPS tracking and storage devices
- Very small but sensitive chemical, radiological, or other sensors, and barcode readers and scanners
- Wearable devices that can measure an individual's environmental exposures as well as various human biological responses
- Utilization of web-based and social media technologies for data collection

These and other technologies could substantially improve upon our capabilities to make rosters and track individuals, establish rapid and representative surveillance of exposures and acute effects, and facilitate the rapid implementation of needed scientific investigations. These tools could also allow for the collection of a much richer dataset than has been possible in the past. For example, it could soon become feasible to equip cleanup workers with a "smart" identity badge that would not only contain detailed demographic and training data, but would transmit GPS and exposure data in real time to a central database. These and other technologies, if properly integrated into the standardized approaches to data-collection procedures referenced in Recommendation 9, could help manage an acute response operationally, and help provide detailed position and exposure data for future investigations.

V. Appendices

Appendix 1: Letter from ASPR to NBSB



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Preparedness & Response
Washington, D.C. 20201

JAN 21 2011

Patricia Quinlisk, M.D., M.P.H.
Chair, National Biodefense Science Board
State Epidemiologist and Medical Director
Iowa Department of Public Health
321 East 12th Street
Lucas State Office Building
Des Moines, IA 50319-0075

Dear Dr. Quinlisk and Members of the National Biodefense Science Board (NBSB):

The response efforts conducted during recent public health emergencies have revealed crucial scientific knowledge gaps. These gaps require further research intended to collect useful information to assist those impacted by the event, and to improve our capabilities for future responses. Recent public health emergencies and observed gaps are exemplified by the 2010 Deep Water Horizon Oil Spill and Haiti Earthquake, and the 2009 H1N1 Pandemic. Although these events are rare and unique, the effectiveness of responses to such events may be based on common factors encompassed within an "All-Hazards Science Response" strategy.

The US and USG have tremendous science research capabilities but applying them for public health emergencies, especially using non-traditional public health science resources, has been challenging. Key research questions, if asked and answered, could have the potential to enhance the effectiveness of the response and of future responses, and provide new insights into how to mitigate short and long term health effects of such events.

I would like the NBSB to take a role in exploring an "All Hazards Science Response" strategy, and make recommendations on a way forward by answering three key questions:

- What are the various major components of an all-hazards science response;
- How do we operationalize it; and
- What infrastructure and supporting pieces need to be put in place so it will be ready to go next time.

Given the Board's expertise in Disaster Management and other related fields, you are in the unique position of fully understanding the complexities of these response issues. I would like to have recommendations at the time of your next scheduled public meeting in April 2011.

I look forward to discussing your thoughts on this topic at the January 25, 2011 NBSB public meeting.

Thank you for your diligence in ensuring the public health preparedness of our nation.

Sincerely,

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response

Appendix 2: March 1-2, 2011 AHSR Workshop Agenda

DAY ONE – March 1 (8:00 am – 5:00 pm ET)

8:00 am – 8:05 am **Welcome and Introductions**
Leigh Sawyer, D.V.M., M.P.H., Executive Director, NBSB
CAPT, U.S. Public Health Service
U.S. Department of Health and Human Services (HHS)

8:05 am – 8:15 am **Overview of Agenda and Goals of Workshop**
Stephen V. Cantrill, M.D., Voting Member, NBSB
Chair, All Hazards Science Response (AHSR) Working Group (WG)

8:15 am – 10:15 am **Presentations**
10 minutes each, followed by up to 15 minutes of discussion each

Section 1 – Science in Past Crisis Events

Coordinating and Managing Science Before, During, and Following Large Scale Disasters
John Howard, M.D., NIOSH/CDC/HHS
Coordinating and Managing Science Following the Deepwater Horizon Oil Spill
CAPT Aubrey Miller, M.D., M.P.H., NIEHS/NIH/HHS
Coordinating and Managing Science During Pandemic H1N1
CDR Lewis Rubinson, M.D., Ph.D., FCCP, NDMS/OPEO/ASPR/HHS
Disaster Response and NSF Science Funding
Robert O'Connor, Ph.D., DRMS/NSF
Establishing H1N1 Data Systems in Response to a Mass Vaccination Campaign
Dan Salmon, Ph.D., M.P.H., NVPO/OASH/HHS

BREAK (10 minutes)

Section 2 – Regulatory Issues (Part 1)

10:30 am – 12:30 pm **Presentations (Continue)**
10 minutes each, followed by up to 15 minutes of discussion each
The Office of Management and Budget, the Paperwork Reduction Act (PRA), and the Impact of Post-event Data Collection: Issues? Solutions?
Michael A. Fitzpatrick, OIRA/OMB
The Public Health Emergency Research Review Board (PHERRB) and Institutional Review Boards (IRB)
Amy Patterson, M.D., OD/NIH/HHS
HHS Human Subject Protection Regulations
Jerry Menikoff, M.D., J.D., OHRP/OASH/HHS

CDC Perspective: OMB/PRA Issues and Distinguishing Public Health Research vs. Public Health Non-Research for Human Subjects
Ron A. Otten, Ph.D., OD/CDC/HHS

12:30 pm – 1:30 pm **LUNCH (1 hour)**

Continue – Regulatory Issues (Part 2)

1:30 pm – 3:30 pm **Presentations (Continue)**
Post Medical Countermeasure Administration Surveillance – Emergency Use Authorizations (EUAs), Pre EUAs, and Investigational New Drugs (INDs)
CDR Carmen Maher, OCET/FDA/HHS
Health Insurance Portability and Accountability Act (HIPAA) and Event-Related Data Gathering: Emergency Preparedness; Public Health, and Research
Christina Heide, J.D., HIPAA/OCR/HHS

BREAK (15 minutes)

Strategic Event-Related Research: A Non-Government View of the Legal Issues
Professor Michael Greenberger, J.D., University of Maryland

3:30 pm – 4:45 pm **Recap – Address Questions**
What are the various major components of an "All-Hazards Science Response? **–** *Group Discussion*

4:45 pm - 5:00 pm **Overview of Day 2 and Adjourn**

DAY TWO - March 2 (8:00 am – 4:00 pm ET)

8:00 am – 8:30 am **Recap – Components of All Hazards Science Response**
Group Discussion

8:30 am – 11:00 am **Presentations**
10 minutes each, followed by up to 15 minutes of discussion each

Section 3 – Operations - Data Gathering

Science Considerations

CDC Experience in Dealing with Registries vs. Rosters
Max Kiefer, M.S., C.I.H., NIOSH/CDC/HHS
Vikas Kapil, D.O., M.P.H., ATSDR/CDC/HHS
James Sapp, M.S., ATSDR/CDC/HHS

Science Considerations for Workers: First Responders, Remediation Workers, and Volunteers; Chronic Monitoring vs. Acute Data Gathering
John A. Decker, R.Ph., C.I.H., NIOSH/CDC/HHS

BREAK (15 minutes)

Integration of Science with Public Opinion
RADM James M. Galloway, M.D., FACC, FACP, RHA/OASH/HHS
Lessons from Community-Based Research and Inclusion in Science
Professor Lourdes Baezconde-Garbanati, Ph.D.
Keck School of Medicine, University of Southern California

11:00 am – 12:00 pm **LUNCH (1 hour)**

Section 4 – Operations - Response

12:00 pm – 2:30 pm **Presentations (Continue)**
The National Response Framework, the National Incident Management System, and an All Hazards Science Response
Donald Grant, NIC/FEMA/DHS
How Does HHS Mobilize the Commissioned Corps, and Do Officers have the Ability to be Engaged in a Science Response?
CAPT Dan Beck, M.D.,OFRD/OASH/HHS
Proposed Concept of Operations for NDMS Data Gathering During a Response
CDR Lewis Rubinson, M.D., Ph.D., FCCP, NDMS/OPEO/ASPR/HHS

BREAK (15 minutes)

Budget and Financial Preparedness for a Science Response
Liz DeVoss, ASFR/HHS
A Holistic Approach to All Hazards Events
S.J. Whidden, M.D., Ph.D., ABS Consulting
Lynette Stehr Ph.D., ABS Consulting

2:30 pm – 3:45 pm **Conclusions - Development of Straw List of Recommendations**
Group Discussion

- Recap of the major components of an "All Hazards Science Response."
- How do we operationalize this response?
- What infrastructure and supporting pieces need to be put in place before the next event?

3:45 pm - 4:00 pm **Next Steps and Adjourn**

Appendix 3: March 1-2, 2011 AHSR Working Group Roster

NBSB Voting Members

Chair, Stephen V. Cantrill, M.D.
Department of Emergency Medicine
Denver Health Medical Center
Denver, CO

Co-Chair, Jane Delgado, Ph.D., M.S.
President and CEO
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Co-Chair, John D. Grabenstein, R.Ph., Ph.D.
Senior Medical Director, Adult Vaccines
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Woburn, MA

John S. Parker, M.D., Major General (Retired)
Senior Vice President
Scientific Applications International Corporation
Alexandria, VA

Betty J. Pfefferbaum, M.D., J.D.
George Lynn Cross Research Professor
Paul and Ruth Jonas Chair
Professor and Chairman
Director, Terrorism and Disaster Center
Department of Psychiatry and Behavioral Sciences
University of Oklahoma Health Sciences Center
Oklahoma City, OK

Patricia Quinlisk, M.D., M.P.H.
State Epidemiologist and Medical Director
Iowa Department of Public Health
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Patrick J. Scannon, M.D., Ph.D.
Executive Vice President and Chief
Biotechnology Officer
XOMA, Ltd.
Berkeley, CA

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Commander
U.S. Army Medical Research Institute of Infectious Diseases
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U.S. Department of Health and Human Services

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Office of the Assistant Secretary for Preparedness and Response
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Deputy Director
Health Threats Resilience Division
Office of Health Affairs
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U.S. Department of Justice

Rosemary Hart, J.D.
Special Counsel
Office of Legal Counsel
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U.S. Department of Veterans Affairs

Victoria J. Davey, Ph.D., M.P.H.
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Appendix 5: Public Health Emergency Research Review Board fact sheet

Issue: With the concurrence of the Assistant Secretary for Health, and in collaboration with and on behalf of ASPR, CDC, and FDA, the NIH is establishing a national institutional review board (IRB), the Public Health Emergency Research Review Board (PHERRB), to advance critical research in the context of public health emergencies.

Background: Public health emergencies demand a range of well-planned and coordinated efforts, including the effort to facilitate the conduct of essential research—research ultimately aimed at the development of effective clinical and public health interventions. Such research is likely to be conducted at multiple sites and to engage multiple investigators and populations of potential human subjects. Research in the context of a public health emergency may, for example, entail:

- Gathering and analyzing individual and population data on health and illness;
- Collecting specimens from patients and healthy individuals;
- Evaluating existing or novel interventions in health care and community settings;
- Use of Treatment and Emergency Investigational New Drug Application (IND) and Investigational Device Exemptions (IDE) or development of products to prevent, treat, mitigate and diagnose, including medical countermeasures; or
- Complementary research on products authorized by FDA under the Emergency Use Authorization (EUA) Program, but being studied for conditions of use beyond those of the EUA.

Inefficiencies in the ethical review of studies involving human subjects that are carried out at multiple sites hamper the ability to initiate critically important research in the context of public health emergencies. Such research is essential to the development of novel or more effective interventions and to the collection and analysis of data essential to improvements in clinical care and public health. The timely conduct of such research depends upon an approach to the ethical review of proposed studies that is both streamlined and highly rigorous.

The PHERRB's authority to review protocols on behalf of multiple sites will be based on the use of reliance agreements between HHS and the respective research sites. (According to 45 CFR 46.103 and 114, an institution can rely on the review of another IRB by executing a reliance agreement with IRB's institution or organization.) With HHS-funded research, these agreements will be effected by making the use of PHERRB a term and condition of award. The feasibility of a second mechanism is under study—i.e., the Secretary's authority to waive part or all of the HHS regulations in accordance with 45 CFR 46.101(i). Specifically, a Secretarial waiver of institutional responsibility for 45 CFR 46.109, 118, and 119—provisions that require grantee institutions to ensure IRB review of HHS-funded research—would relieve institutions of their liability for the IRB review process, but not their responsibility for the ethical conduct of research and for the protection of human subjects.

Current Status: The PHERRB will be managed by one of the NIH Institutes with experience in IRB administration and composed of 15 voting members, nine of whom

will be Federal officials from CDC, FDA, and selected NIH ICs (NHLBI, NIAID, NICHD, NIEHS, NIMH, and NINDS) with current IRB experience. Further implementation steps, including the preparation of standard operating procedures, will be worked out through the trans-HHS working group that conceptualized the PHERRB (ASPR, CDC, FDA, NIH, and OHRP). Completion of the implementation steps is expected by early December. Once the PHERRB is operational, the working group will continue to be consulted on stewardship matters and to assess its effectiveness.

Point of Contact. Amy P. Patterson, M.D., Associate Director for Science Policy, NIH, 301-496-2122.

Appendix 6: National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS)

NHANES

NHANES provides information on environmental exposures based on measures of environmental chemicals or metabolites in blood or urine specimens. This biomonitoring program for environmental chemicals currently assesses approximately 200 chemicals. The primary objective of the NHANES biomonitoring program is to provide baseline reference data for environmental chemicals.

One potential application of NHANES would be to provide baseline references ranges when conducting biological monitoring research among workers and/or the general public. That is, the reference ranges from NHANES could be used as baseline data for comparison between the affected population and that of the U.S. general population.

A significant limitation of NHANES is the sample size. If the goal was to study an affected population in a particular area of the country, NHANES data for anyone area/region would likely be insufficient. Further, at the current time, NHANES can only provide national estimates, and for confidentiality reasons, cannot be used to examine exposure levels by locality, state, or region.

Additional limitations of NHANES biomonitoring data for use as baseline data in a disaster research initiative are as follows:

- NHANES does not test for every environmental chemical that might be of research interest due to factors such as cost, logistic or technical limitations. So, the chemical of interest in a disaster might not be evaluated by NHANES.
- The presence of an environmental chemical does not imply disease or other health effects, so interpreting the health impact of the chemical exposures in a disaster might be difficult.
- Having only blood and urine levels measures do not determine which exposure source or which route of exposure has occurred.

BRFSS

The BRFSS is a cross-sectional telephone survey conducted by state health departments with technical and methodological assistance provided by the CDC. Every year, states conduct monthly telephone surveillance using a standardized questionnaire to determine the distribution of risk behaviors and health practices among non-institutionalized adults. The states forward the responses to the CDC, where the monthly data are aggregated for each state. The data are returned to the states, then published on the BRFSS Web site. Although the BRFSS is funded largely by CDC, it is owned by the states. Therefore, CDC does not control the content of the survey. Instead, the participating states determine by vote what questions are included each year. Each year, new question proposals are submitted by CDC programs or states and are reviewed by the state BRFSS coordinators. State representatives typically consider proposed questions from the perspective of whether or not they meet the information needs of the state health departments.

Uses of BRFSS:

- Obtain representative population-based prevalence data for selected chronic diseases, health behaviors, and health risk factors for states, counties and metropolitan areas.
- Link to other data, by state, county or metropolitan area to do population comparisons or ecological analyses.
- States add their own questions to adverse health effect of a disaster; this was done after the September 11, 2001, terrorist attacks on the World Trade Center http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5135a2.htm
- Use the infrastructure to conduct a separate survey designed to monitor the mental and behavioral health status of a population affected by a national public health emergency (current example: Gulf States Population Survey). http://www.cdc.gov/OSELS/ph_surveillance/gsps.html
- On a few occasions, the CDC Director has compelled the inclusion of specific questions in the BRFSS core survey in instances of a national public health emergency.

Shortcoming of BRFSS:

- No individual identifiers; the data can't be linked with any other data by individual.
- Individuals are not repeatedly sampled – no information on progression of disease or condition.
- All information is self-reported, no confirmatory health examinations.
- No data is routinely collected about exposure to human-generated chemical, physical, or biological agents (there are some questions on exposure to oil and spill cleanup activities in Gulf State Population Survey).
- The lag time between design/proposal of BRFSS questions and available full-year data is typically 3-4 years; this might be reduced to approximately 2 years if the CDC Director adds questions after a national emergency.

Appendix 7: Acronyms

AHSR WG	All Hazards Science Response (AHSR) Working Group (WG)
ASPR	Assistant Secretary for Preparedness and Response
BRFSS	Behavioral Risk Factor Surveillance System
CDC	Centers for Disease Control and Prevention
HHS	U.S. Department of Health and Human Services
DHS	U.S. Department of Homeland Security
DMIS	Disaster Medical Information Suite
DMHR	Disaster Mental Health Research Center
EUA	Emergency Use Authorization
EPA	Environmental Protection Agency
FEMA	Federal Emergency Management Agency
FDA	Food and Drug Administration
GPS	Global Positioning System
HIPAA	Health Insurance Portability and Accountability Act
IDIQ	Indefinite Delivery, Indefinite Quantity
IT	Information Technology
IOM	Institute of Medicine
IRB	Institutional Review Board
IDE	Investigational Device Exemptions
IND	Investigational New Drug
MOU	Memorandum of Understanding
NBSB	National Biodefense Science Board
NDMS	National Disaster Medical System
NHANES	National Health and Nutrition Examination Survey
NIAID	National Institute of Allergy and Infectious Diseases
NIMH	National Institute of Mental Health
NIOSH	National Institute of Occupational Safety and Health
NIH	National Institutes of Health
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NRF	National Response Framework

NRT	National Response Team
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OCAP	Operational Clinical Assessment Program
OCAT	Operational Clinical Assessment Team
PRA	Paperwork Reduction Act
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHERRB	Public Health Emergency Research Review Board
SARS	Severe Acute Respiratory Syndrome
SEER	Surveillance, Epidemiology and End Results