

ASPR WORKSHOP: SCIENTIFIC PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH  
EMERGENCIES

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Natcher Auditorium, NIH

During a public health emergency there is a critical window of opportunity to conduct scientific research. Emergency-related research is crucial to inform public health responses to the ongoing event and future similar ones, and to advance our scientific understanding of crisis-associated health conditions. The need for such research has become acutely clear after a series of recent public health emergencies, including the SARS and H1N1 epidemics, the 9/11 attacks, Hurricane Katrina, the Deepwater Horizon oil spill, the 2010 Haiti Earthquake, and the Fukushima Dai-ichi nuclear reactor emergency in Japan. Public health responses during those incidents were hindered by incomplete knowledge of health risks to the affected populations and how best to manage them. At the same time, opportunities were lost to conduct research that could have addressed those knowledge gaps.

In most cases, there is no paucity of relevant expertise and technology available carry out crisis-related research. What is lacking is the infrastructure to rapidly mobilize those resources in the context of an emergency. As a result, research efforts during crises have been impeded by bureaucratic and logistical obstacles, including lack of ready funding mechanisms and institutional approvals, and lack of standard procedures for supporting research personnel at the crisis site. Although some important research efforts have been carried during past crises despite these obstacles, those efforts typically proceeded with suboptimal inter-agency coordination to establish research priorities and optimize use of available resources.

The goal of this workshop was to develop recommendations toward building an infrastructure for the conduct of scientific research during public health emergencies. Specifically, the workshop aimed to:

- To create a shared vision and definition of Scientific Preparedness and Response among departments and agencies with relevant activities or missions;
- To reiterate goals for Scientific Preparedness and Response among Departments and Agencies (D/As)
- To share information across D/As about relevant activities pertinent to conducting research during public health emergencies;
- Review the status of current activities and provide a blueprint for completing needed tasks in order to be fully prepared for all required integration activities;
- To promote strategic coordination by ASPR of science preparedness and response efforts to leverage existing efforts and inform future efforts;
- To speed the implementation and initiation of coordinated science preparedness and response efforts by carrying out the above in a cooperative, transparent, and interactive environment;
- Develop a roadmap for the process.

The workshop began with introductory talks and a keynote address to provide background and help frame the goals of the meeting. The rest of the day was devoted to breakout discussions and report-backs on the following topics: (1) Clinical Protocols and Data, (2) Surveys, Roster, and Medical Testing, (3) Specimens/Scientific Collections, (4) Funding Mechanisms, (5) Policy Processes, and (6) Science Responders. Participants were requested from across government with expertise in these specific areas, or who are mounting Science Preparedness and Response efforts for their agency more generally. This workshop report summarizes the plenary talks and the recommendations that emerged from the panel discussions.

## **Introduction**

*Dr. Nicole Lurie*

*Office of the Assistant Secretary for Preparedness and Response  
Department of Health and Human Services*

Dr. Lurie presented two examples of recent crises in which public health responses were seriously hindered by (1) major gaps in scientific knowledge, and (2) lack of infrastructure to carry out critical research. The first case was the Deepwater Horizon oil spill. At an Institute of Medicine workshop convened during that crisis, it became clear that we have virtually no understanding of the potential impact on human health of oil and oil dispersants. Although 30 significant oil spills have now occurred worldwide, during none of them was the necessary research done to answer this question.

In the second example, during the H1N1 pandemic, the National Heart, Lung and Blood Institute provided rapid funding to one of their clinical networks to study respiratory symptoms in critically ill patients, using a modified version of an ongoing clinical protocol. The data was collected and eventually yielded important findings. However, that information couldn't be put to effective use during the pandemic because Institutional Review Boards (IRBs) at some of the participating research organizations took so long (up to six months) to approve the modification to the data collection protocol. As a result, it wasn't learned until after the event that 40% of the children who died during the pandemic had methicillin-resistant *Staphylococcus aureus* (MRSA), which increased their vulnerability to H1N1 by eight-fold.

As these examples demonstrate, we are not organized to do science in the moment. We are organized to get disaster medical assistance teams out the door in under 12 hours. In contrast, it typically takes weeks or months to organize scientific research efforts and/or get access to the data generated by them, because the infrastructure to do so quickly is lacking. Thus, the goal of the meeting was to gather ideas about what basic building blocks of infrastructure we need to develop to ensure that in the future, when we face the same kind of crisis twice, we have more knowledge the second time.

## **Keynote Address**

*Dr. Harvey Fineberg*

*President, National Institute of Medicine  
National Academy of Sciences*

Dr. Fineberg cited instances of past flu epidemics (e.g., swine flu, H1N1) in which there were shortcomings in knowledge needed in real time to guide public health actions. He pointed out that every disaster is local, but that during disasters local communities are in special need of support, guidance and coordination from the national level. Particularly in view of current budgetary constraints, it is critical to establish a national infrastructure that can help local communities make more informed choices about emergency preparation and response, and enable more efficient and cost-effective handling of responses.

In developing and executing scientific research responses to different categories of events, it is important to consider not only the nature of the event but also its likely time course. Many crises can be divided into pre-, during, and post-event phases. The pre-event phase refers to the period when there is reason to believe a particular kind of emergency may be impending, as at the beginning of flu season or hurricane season. In the post-event phase, science response leaders can assess the public health consequences of the event and specific actions taken during the event, and derive lessons that could inform future responses. In addition to the “pre,” “during,” and “post” phases of an emergency, there is a fourth phase – the interval between emergencies. During that interval, response leaders can think broadly about commonalities underlying different categories of disasters, and what systems could be put into place to deal with the pre-, during, and post-event phases of specific emergencies.

Scientific research during the acute phase of a disaster is particularly important, and nearly impossible to accomplish if the groundwork for it has not been laid in advance. Without pre-preparation, response leaders and participating scientists are likely to encounter obstacles such as lack of IRB approvals and lack of funding to support emergency-related research studies. In addition, scientists who were in theory “ready reserves” to engage in research may turn out to be unavailable for the acute and/or long-term phases of the science research response.

Dr. Fineberg outlined eight areas in which preparation is needed to optimize the conduct of research during emergencies:

1. Identify, in advance, the core research questions that need to be answered, and prepare to answer them (e.g. understanding toxicities, effectiveness of health measures at baseline). Some of these questions will be specific to the nature of disaster, and others will be common to different kinds of disasters.
2. Determine if necessary legal authorities are in place to conduct research, and identify and resolve potential legal obstacles.
3. Clarify and ensure understanding of roles and responsibilities across different agencies and levels of the government, the private sector, local institutions and practitioners, and internationally for conducting research and disseminating the results.
4. Pre-position necessary institutional and governmental approvals – e.g., IRB approvals, clearance of survey instruments.

5. Ensure that research funding is accessible via mechanisms that can be rapidly activated.
6. Organize human resources to ensure a mobilizable ready reserve of personnel with the necessary expertise and sustained commitment to conduct and complete the research.
7. Establish organizational capacities to implement research, including pre-established lines of authority.
8. Think through model templates and research design questions for lab, field, and survey-based research and long-term epidemiological follow-up research.

Dr. Fineberg suggested that a first step would be to identify and codify what scientific resources (e.g., expertise, data collections) are already available, and what administrative infrastructure (e.g., lines of authority, institutional approvals) is currently prepositioned to conduct research during an emergency. We should identify critical knowledge gaps and research questions, and choose one to three priority actions that would position us better to address those questions. Dr. Fineberg also emphasized the need to reach out to and engage other federal agencies, state and local agencies, and the general public in planning for disasters and decision-making during them.

### **Plenary Talks**

#### **Creating a Coordinated Science Preparedness and Response Framework for Major Emergencies**

*Dr. Lewis Robinson  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health and Human Services*

Dr. Robinson identified several key areas of research that are critical to support and improve public health responses during emergencies:

- Basic research on underlying mechanisms of the disaster-associated diseases
- Clinical research to inform diagnosis and treatment
- Social science to understand impacts on behavior
- Operations research to improve responses
- Healthcare systems level research.

He emphasized that there is a wealth of scientific expertise and technology available that could in theory be leveraged to conduct emergency-related research. The central problem is how to adapt the modes in which research is normally conducted on a day-to-day basis (e.g., in academic laboratories) to the paradigm of disaster response. There are several specific challenges in this regard. First, data collection, analysis, and reporting all must be done within the short timeline of an emergency event. Second, crisis-related research often requires novel scientific collaborations and repurposing of scientific capabilities, as well as nimble cooperation between public health agencies that might not normally operate together. Finally, the sheer scale of an emergency event may overwhelm readily available research capabilities. Thus, we don't necessarily need to develop new scientific

capabilities for emergency-related research, but rather new mechanisms for coordinating and deploying them.

### **Science During Crisis: An Introduction to the Strategic Sciences Group**

*Dr. Gary Machlis*

*Senior Adviser to the Director, National Park Service*

*Department of the Interior*

Dr. Machlis offered an example of how another federal organization carried out science during a crisis by describing the experience of the Strategic Sciences Working Group (SSWG) during the Deepwater Horizon oil spill. The SSWG was an experimental group established by the Secretary of the Interior in response to the spill. The group's mission was to provide decision makers with rapid scientific assessments of the possible consequences of the spill on the ecology, economy, and people of the Gulf of Mexico.

The SSWG effort was guided by three major principles. First, they focused on mission, not process. Second, members of the team were recruited based on their expertise rather than their agency affiliation or seniority level, and team members were treated as equals during discussions and decision-making. Third, the team had direct access to crisis response leadership. The team was assembled at the site of the crisis (near the Mobile, Alabama, Incident Command), enabling them to communicate directly with decision makers. Dr. Machlis emphasized the importance of having scientific experts “on the ground” at the site of an emergency, so that they can interact face-to-face with another and with crisis leadership, and be aware of details at the scene that would be difficult or time-consuming to communicate by phone or email. He also pointed out the need for frank, clear, and concise communication with leadership. In addition, as there are occasions when key information must be conveyed in minutes or less, it is critical to be prepared in advance to do so.

Dr. Machlis also discussed the scenario-building approach the SWWG used to predict potential outcomes at different time points during the Deepwater Horizon crisis. The scenarios were not limited to individual physical, chemical, biological, economic, or sociocultural consequences, but included how those consequences would interact in impacting the overall system. A key insight that emerged from scenario-building for both Deepwater Horizon and Hurricane Katrina (and one that might well apply to public health emergencies) is that elements of the recovery response should be initiated concurrently with the acute emergency response.

A more detailed report of SWWG's scenario-building approach during Deepwater Horizon can be found in this article:

Machlis GE, McNutt MK. *Disasters. Scenario-building for the Deepwater Horizon oil spill*. Science. 2010 Aug 27;329(5995):1018-9.

## **Panel Sessions**

### **Clinical Standard Protocols and Datasets**

*Facilitator: Lewis Robinson*

#### **Overview**

During a public health emergency, there is a limited window of opportunity to capture critical clinical data, including markers of exposure to infectious or toxic agents, health symptoms in exposed populations, assessments of risk factors (e.g., age, pre-existing conditions, genetic risk factors), and efficacy of clinical interventions (including experimental interventions). These data are essential to inform treatment protocols and ensure clinical outreach to potentially vulnerable populations. Importantly, such data can also advance scientific knowledge about the biological mechanisms through which exposure to infectious or toxic agents leads to specific health conditions, and guide the development of new treatment approaches.

#### **Panel Discussion**

The panel discussion revolved around the questions of (1) how to establish priorities for what clinical data to collect during an emergency, and (2) possible mechanisms for collecting it. The panel agreed that there is a strong need for coordination of clinical research efforts during emergencies, and improved infrastructure to deploy and support those efforts. There was also considerable discussion about the difficulty of obtaining rapid IRB approvals, which many panelists viewed as the single biggest roadblock to carrying out clinical research during crises. IRB and other regulatory issues are addressed in detail in the Policy section.

#### **Recommendations**

##### *Prioritization of data collection efforts*

- To optimize the efficiency, utility, and cost-effectiveness of clinical data collection efforts, it is critical to define exactly what questions the data is intended to answer, and prioritize those questions with regard to their scientific and/or strategic importance.
- High priority should be given to collecting data that would inform public health strategy before, during, and after a crisis – for example, data that would help answer the following broad questions:
  - Is a public health crisis impending or currently unfolding?
  - What are the likely health impacts of the event?
  - Are treatment responses working?
  - How can we prepare better for future events?
- To the extent possible, we should identify in advance more specific clinical questions that are likely to arise during different categories of emergencies, and prepare in advance to answer them. In particular, we should undertake an inventory of:

- What data is already available to answer specific questions and what knowledge gaps still exist;
- What relevant clinical protocols and data collection mechanisms are already available to obtain critical data, and which ones need be put into place;
- What regulatory and administrative hurdles would challenge data collection efforts, and how they might be addressed in advance of an event.

A possible starting point for such an inventorying effort would be to pick three different kinds of emergencies (e.g., a flu outbreak, a bioterrorist attack, and a nuclear accident), and develop prioritized lists of clinical questions that would be important to answer in each kind of event. One could then design appropriate clinical protocols and develop federal, state, and local “playbooks” for implementing them.

- In prioritizing scientific questions to be addressed during a particular kind of crisis, the following information sources should be tapped:
  - *Records of past public health emergencies* should be analyzed retrospectively to determine what questions arose, what data was collected, how the data was used at the time to inform public health responses, what data could have been collected that wasn’t, and what barriers to data collection were faced.
  - *Clinicians and other scientists* should be engaged to determine what scientific in identifying and prioritizing research questions are most critical to address during specific kinds of events. Some questions are not clinical (e.g., in flu, should schools be closed?) and could be answered by non-academic experts.
  - *The general public*. Government and academic health experts are not always aware of real-life issues of greatest concern to communities and individuals affected during a crisis. During the Fukushima crisis, members of the public both in the US and Japan had very specific questions regarding their own clinical situations, and these were not necessarily the types of questions that public health officials had anticipated (e.g., “I received radiation treatment for breast cancer – are there any specific precautions I should take?”). Some of these questions could be answered using existing information, but mechanisms to elicit relevant concerns from the public are poorly developed at present. Crowd-sourcing (via social media or town meetings, for example) could be a useful method for gathering input from the general public about their own health concerns and other clinical questions.

#### *Mechanisms for data collection*

- Leverage ongoing clinical research efforts that could be repurposed to gather data during emergencies. For example:
  - *Individual investigators or clinical trials groups* could be recruited on a case-by-case basis to provide relevant scientific expertise and engage in data collection efforts.
  - *Clinical trials networks*. There are a large number of NIH-funded clinical trials networks currently in place with ongoing data collection protocols relevant to public health emergencies. The existing networks typically focus

on specific diseases or patient populations, but might be harnessed as groups to provide necessary expertise and protocols.

- *Clinical research organizations* on contract to the federal government can be leveraged to collect data.
- As a first step toward making use of these resources, develop an inventory of clinical trials groups and networks with ongoing protocols potentially relevant to emergency research.
- The panel discussed two possible approaches for organizing existing clinical trials networks for deployment during emergencies. First, a “network of networks” could be organized under the direction of a coordinating group. This approach has the advantage that the coordinating group could establish common data definitions and collection protocols, thereby enabling the compilation of more robust data sets. The disadvantage of this approach is that a formal “network of networks” might prove unwieldy and difficult to sustain over the long term, particularly if no data collection efforts were undertaken in the short term. Alternatively, clinical trials networks could be rostered according to expertise relevant to specific kinds of emergencies. Individual networks would operate under their own, pre-existing data standards and collection protocols if deployed. This alternative might prove more flexible and easier to sustain on the long term.
- Consider developing “master” protocols that could be used in a variety of different situations. For example, the National Cancer Institute has a standardized protocol for drug treatment studies that requires only insertion of the name of the specific drug to be studied. Such protocols would have to be designed with enough inherent flexibility to suit the requirements of the wide range of settings and circumstances under which clinical data collection takes place during emergencies.
- Similarly, the coordinating mechanisms and infrastructure for data collection during emergencies must be designed to be sufficiently flexible to accommodate the different logistical challenges faced during different kinds of emergencies (e.g., infectious versus chemical).
- Plans should be made in advance not only for data collection but also for data cleaning and analysis. Rapid data analysis is critical to inform public health decision making (e.g., by showing whether an antiviral drug is working, if there are unexpected side effects of standard treatments, etc.)
- Standardization of data definitions and protocols not only nationally but internationally would enhance data sharing as well as the robustness of datasets collected.

## **Surveys, Rosters, and Medical Testing**

*Facilitator: Chip Hughes and Dan Dodgen*

### Overview

We need to capture health and demographic information (both baseline and longitudinal) not only for individuals who are directly exposed during an emergency, but also for the larger cohort of impacted populations, including workers and community members, especially those who may be most susceptible to adverse affects (such as children, the elderly, pregnant women, and individuals with pre-existing conditions). Information on mental and behavioral health should be a part of that assessment. In addition to surveys, baseline and follow-up clinical evaluations (vital signs, pulmonary function, cardiovascular status, neurologic and cognitive function, etc.) should be rapidly performed for response workers in the field setting, for acutely ill individuals, and if possible, for high-risk segments of the community.

### Panel Discussion

Ideally, one would identify everyone whose health might be affected during an emergency, collect data on them at baseline, follow them over time, determine how they are affected, and which populations are most affected. Baseline health data are sometimes available for certain groups who are directly affected in an emergency. For example, detailed records of pre-event health status were available for the New York City firefighters who took part in rescue efforts after the World Trade Center attacks. In contrast, little or no baseline data was available for either rescue workers or civilians affected by Deepwater Horizon.

### Recommendations

- Identify and inventory pre-existing sources of baseline data available through local, state, and federal health agencies, and/or through open sources. These data may also include geographic identifiers.
- Consolidate and organize baseline data in a database for ready access and use during an event.
- Review existing survey tools to see whether they are collecting appropriate information – i.e., exactly what public health decisions and scientific analyses would be supported by the information being gathered? Are there unnecessary or redundant questions? Are there gaps that need to be filled? What kinds of questions would allow us to look not only at short- and long-term consequences of an event, but also make mid-course corrections in clinical treatments? In addition, survey tools should be flexible enough to enable addition of new questions as an event unfolds.
- A logical approach to developing survey tools would be to identify three different kinds of questions: (1) “core” questions that are shared by all events; (2) “common” questions, which are relevant to multiple kinds of events; and (3) “custom” questions, relevant to a specific event or category of event.

- To the extent possible, develop surveys in advance, and pre-establish relationships with OMB authorities whose approvals for new surveys or questions will be required. Also, clarify any issues that may exist with regard to local and state approvals.
- When possible, make use of pre-existing and site-appropriate technology for collecting data. For example, if workers in the field have cell phones that can use apps, develop surveys compatible with those apps.
- Create social media interfaces for capturing data.
- Pre-establish contract and grant funding mechanisms for both data collection and subsequent data analysis.

### **Specimens/scientific collections**

*Facilitator: Diane DiEuliis*

#### Overview

During certain kinds of disasters the acquisition of biological samples from exposed or affected populations may be crucial to understanding the health effects of exposures to potentially toxic agents (both infectious and non-infectious) and identifying risk factors for adverse health effects. Ideally, samples and associated clinical data would be collected not only post-exposure, but also longitudinally; exposure to certain chemical agents, infectious agents, radiation, etc., especially during early development, can have effects later in life. During crises involving potential environmental toxins (e.g., the World Trade Center attacks, Deepwater Horizon), it is also critical to collect samples of environmental material (water, air, dust, food) in order to compare levels of potentially toxic agents present in the environment before and after the crisis.

#### Panel Discussion

The panel emphasized the need for access to baseline samples of biological specimens from individuals (blood, urine, etc.) and environmental materials (dust, water, etc.) from populations and geographic regions comparable to those affected during an event. These baseline samples are critical for scientifically meaningful analyses of the health consequences of exposures to specific agents. Biological and/or environmental samples and data are collected on an ongoing basis by a number of federal agencies, including the National Health and Nutrition Examination Survey (NHANES), NIH, Agency for Toxic Substances and Disease Registry (ATSDR), EPA, DOI, and USGS. However, these are often of small and selected populations and may not pertain to an affected population. They may, however, be helpful in forming a comparison group. The CDC routinely collects specimens when responding to infectious disease outbreaks or toxic exposures. Environmental data are also collected in the private sector (e.g., at chemical and industrial plants), although that data may be proprietary in many cases. For example, during Deepwater Horizon, emergency responders were unable to access oil dispersant composition data from TransOcean, and so had to collect samples themselves during the crisis. Similarly, access to samples collected by public agencies may be hindered by

jurisdictional issues (e.g., samples collected during the anthrax attack were impounded by the FBI for forensic use).

### Recommendations

- Identify and inventory past and ongoing specimen and data collection efforts by governmental agencies (local, state, and federal) and within the private sector that could provide useful baseline samples and data. Establish partnerships with ongoing interagency and international efforts to catalog voucher data. Scientific Collections international (“SciColl”) and Global Biodiversity Information Facility (GBIF) already exist and would serve as good vehicles for international coordination and partnership.
- Identify the full range of not only biological but also other kinds of specimens (air, dust, water, building debris, oil dispersants, etc.) that might need to be sampled during different kinds of events.
- In thinking about what samples to collect, consider the following:
  - What kind of events do we expect and where might they occur?
  - What is the scientific purpose of collecting the sample – i.e., what specific question could the sample be used to answer?
  - Study previous events and after-actions, and think what kinds of samples could have helped answer questions that arose during those.
  - In collecting baseline specimens, be sure to include special populations that might be particularly at risk during an event, and for which sample collections are currently relatively sparse (e.g., young children and pregnant women).

The panel noted that specimen collections are expensive to maintain, and there is a danger of gathering huge collections that turn out to be worthless. Thus, it is important to develop clear scientific questions ahead of time to focus and prioritize specimen collection. At the same time, certain events may generate potentially toxic materials whose nature is impossible to predict ahead of time. (After the World Trade Center attacks, for example, physical materials were found at the site that no one would have expected.) In addition, health questions may arise that couldn’t have been anticipated, and new technologies may emerge to answer them. Thus, sufficient flexibility should be built into priorities for specimens to be collected and methods for collecting them to support scientific analyses that were not defined *a priori*.

The panelists suggested two sets of “low-hanging fruit” in terms of baseline samples that would be relatively straightforward to collect and of likely high usefulness:

- Any workers sent into an event should be sampled beforehand, and to the extent possible, sample devices for tracking exposures should be put into place.,<sup>a</sup>
- Biological samples should be collected from individuals who are at high risk for involvement in certain kinds of events (e.g. workers in chemical plants, civilians in Iraq who may be exposed to IEDs), and environmental samples from high-risk facilities (e.g. nuclear power plants).

- Establish standardized protocols for sample collection, cataloging and storage, so that samples collected by different groups can be directly compared. Develop “good stewardship” guidelines for repositories (e.g., sample storage and distribution logistics, monitoring and maintenance of storage equipment). Also, establish longevity standards for when different kinds of samples will begin degrade or otherwise lose their utility.
- Identify repositories where samples can be stored, and establish mechanisms for data management and sharing.
- Pre-plan for administrative, legal, and funding issues:
  - Pre-prepare consent language for specimen collection for inclusion in protocols for submission to the PHERRB or other IRB approval bodies, and frame it broadly enough to enable collection of any kind of sample that may prove relevant (e.g., blood, urine, etc.), and enables use of the samples for any purpose. To expedite IRB reviews, different sets of forms could be developed for more or less sensitive situations – e.g., invasive versus non-invasive samples, or vulnerable versus non-vulnerable populations. If possible, include permission to re-contact subjects for longer-term follow-up.
  - Establish an infrastructure (policy group or some type of incident command structure) to oversee distribution of samples and sharing of data (at local, state, and federal levels).
  - Pre-position contracts or other funding mechanisms for sample collection and storage that can be activated immediately during an emergency.

**Funding Mechanisms:**

*Facilitator: Chip Hughes*

Overview

In order to perform critical science beyond acute response and surveillance activities, we need mechanisms to rapidly provide funding to the broadly defined research community during emergency events. Previous response situations have been hampered by lack of pre-positioned or readily positionable funding, leaving agencies in the awkward position of using their program budgets to support response activities with no certainty of reimbursement. Additionally, even when funds are available, it may take up to several months for NIH or other HHS agencies to identify and fund relevant research projects or interest areas, and the ease of funding them depends on currently existing funding mechanisms, review criteria, and public notification, legal, and administrative processing requirements.

Panel Discussion

There was unanimous agreement that getting rapid funding to researchers ranks (together with getting rapid IRB approvals) as one of the top roadblocks to doing effective research during a response.

Much of the discussion revolved around alternative or novel mechanisms for rapid funding of emergency-related research. The following possibilities were identified, together with challenges associated with their use.

*Existing mechanisms that might be used to fund research in the context of public health emergencies:*

- *NIH* has the theoretical capability to rapidly approve allocation of supplements to existing NIH contracts, grants, or cooperative agreements. However, NIH cannot use the supplemental funding mechanism to fund research endeavors that lie significantly beyond the original, peer-reviewed aims of a currently funded project. In addition, NIH institute budgets are currently very strained, and there are administrative hurdles and time lags associated with transferring funds to NIH institutes from other sources via Interagency Agreements.
- *NSF* has a rapid research funding program, in which funding decisions can be made by program staff without peer review. This program can release funds within a week, but the grants are typically small (\$50-100K). However, they can provide a bridge to more sustainable funding.
- *NIMH*, through a Request for Applications, funded researchers to preposition themselves (i.e., to build a research team and infrastructure and do just-in-time training) for a potential emergency event), A concern was noted by panelists with regard to this approach: infrastructure established to support specific research projects is likely to degenerate within a year or two if not deployed.

*Private sector partnerships:* For example, British Petroleum funded research at Deepwater Horizon via transfer through NIH (although there was considerable delay in getting the funds released). In another example, the Weather Service partners with Weather Bug and the Weather Channel. The latter entities have developed road weather/condition apps that the Weather Service carries on emergency vehicles during responses, and during an emergency repackage weather data for use by emergency responders. It was noted that mechanisms to transfer money from private groups to Federal agencies exist (such as the NIH Foundation, for example).

### Recommendations

- Develop an inventory of clinical trials networks and other research projects currently funded by NIH whose expertise and resources could be deployed in science responses through supplements to their existing grants, contracts or cooperative agreements. It was noted that cooperative agreements are far more flexible than contracts or regular research grants with regard to funding of activities not specified in the originally peer-reviewed project proposals. Hence, it will be critical when developing this inventory to note the specific mechanisms through which the ongoing projects are

being funded. Also, note which projects already have relevant IRB approvals in place.

- Review past examples of research efforts that were successfully deployed in the context of emergency responses to identify best practices and innovative mechanisms for rapid funding.
- Explore the possibility of partnerships with private sector entities with whom Cooperative Research and Development Agreements (CRDAs) could be put into place and activated readily in the event of an emergency response (e.g. Google, to do data capture and crowd-sourcing).
- Identify private sector entities (e.g., pharmaceutical companies) that might welcome the opportunity to participate in and/or fund emergency response-related research.
- Inventory potential sources of funding for science response research.
- Pre-establish mechanisms for rapid transfer of funds between agencies to support emergency-related research.
- Identify or hire an “emergency research funding specialist” who would be responsible for keeping track of potential sources of funding for emergency research and the mechanisms, rules, and regulations necessary to mobilize them.
- Broaden discussions about the need for rapid funding mechanisms to include professional societies, the commercial sector, the general public, and relevant government authorities.
- Develop mechanisms for prioritizing allocation of funds for emergency-related research, both on the long term and during an actual event.

### **Policy processes**

*Facilitator: Diane DiEuliis*

#### Overview:

Preparing for and deploying emergency science responses will require coordination not only of research activities, but also associated policy and administrative issues. Institutional Review Board approvals, FDA approvals, and Privacy Act and Paperwork Reduction Act requirements have been established with the aim of protecting participants and ensuring ethical conduct of research. However, obtaining the approvals necessary to conduct human subjects research typically take weeks to months, and the inability to rapidly initiate research during a crisis results in missed opportunities to help people affected by either the ongoing crisis and future ones of a similar nature. The proposed NIH-based Public Health Emergency Research Review Board (PHERRB) and the existing FDA Emergency Use Authorization (EUA) and emergency IND (EIND) are among some of the approaches aimed at improving the speed of public health responses,

while ensuring that participant information will remain confidential (e.g., enhanced participant privacy for the Deepwater Horizon GuLF Study).

Additionally, there is a need to improve and coordinate involvement of non-Federal stakeholders (e.g., state health officials, impacted communities, unions) as well as relevant Federal agencies in the development, implementation, analysis, and communication of results of government-sponsored research to improve: 1) study designs, 2) acceptability of surveys and testing protocols, 3) participation levels, and 4) credibility and transparency of research findings.

### Panel Discussion

The first part of the discussion focused on the need for a group to coordinate scientific research efforts undertaken during emergencies, and exactly what roles such a coordinating group would assume. It was suggested that the oversight of emergency-related research might involve two distinct sets of activities:

1. *Coordination of scientific questions, research priorities, and data analysis.* Currently such coordination is lacking, and as a result there have been missed opportunities for scientific collaboration and sharing of scientific data, and potentially less-than-optimal use of research funds. During the Deepwater Horizon crisis, for example, 17 different federal agencies engaged in research activities, but there was little cross-agency awareness of what research projects were undertaken by each agency or what results were obtained by them.

2. *Coordination of infrastructure and operations* for initiating and supporting emergency-related research, including oversight of logistics of coordinating research efforts with other components of an emergency response. Problems encountered in the past have ranged from inability to obtain rapid IRB approvals for scientific research projects to the practical details of deploying researchers to crisis sites (e.g., near-collisions of science and emergency response team helicopters at Deepwater Horizon, researchers being sent to the wrong sites in Haiti).

In addition, it was pointed out that the office responsible for coordination of emergency-related research might not necessarily itself directly support or manage scientific research activities, but rather help coordinate other agencies with the appropriate expertise and resources to do so.

The second part of the discussion focused on administrative and policy challenges associated with the conduct emergency-related research. The number one challenge identified was in obtaining rapid IRB approvals, which typically these take four to six weeks to process. NIH is currently developing a PHERRB that might be called on in emergencies during which there is a need to get rapid approval for involvement of multiple sites. In addition, there are some private entities (e.g., RAND) that have experts on call who can review a protocol within 36 hours.

## Recommendations

### Science Response Coordination

Activities and information that should be coordinated during a science response would include:

#### *1. Scientific questions, research priorities, and data analysis*

- Coordination and prioritization of science questions to be asked during an event and research projects to be funded, based on input from relevant federal, state, and local agencies, academic experts, and the affected communities.
- Identification of academic partners who might conduct research or contribute scientific expertise.
- Identification of opportunities for capitalizing on the scientific value of clinical and other data being collected as part of public health responses to an event.
- Knowledge management to ensure that all parties funding and/or conducting research during an event are aware of each other's activities. This oversight would facilitate communication and synergism between groups with complementary research interests, ensure that multiple agencies aren't funding multiple groups to address the same question, and ensure rapid sharing of data and efficient sharing of scientific resources where appropriate.
- Ongoing oversight to determine whether research priorities should be modified as an event unfolds or new data comes in, and establishment of standards and a system for doing so.
- Harvesting and analysis of data collected on site that might inform public health responses during an event, and distribution of that data to relevant officials and agencies. There is a need to coordinate analysis of results coming from different agencies and decision-making based on those results.
- Situational awareness that continues after the event when research findings are put together, evaluated, and interpreted.(to ensure, for example, that two agencies don't publish incompatible reports).

#### *2. Infrastructure and operations*

- Infrastructure to deploy research teams to the site of an event, including mechanisms to travel, house, and feed them. It might be preferable to use systems already in place to deploy health teams and other emergency responders rather than creating a new infrastructure for deploying science responders.
- Logistical coordination and oversight to ensure public safety and that research operations don't strain the resources of the affected community (e.g., food and water supplies) or interfere with public health responses.
- Coordination of science and health responses with regard to specimen and data collection.
- Oversight to identify relevant authorities, jurisdictions, and legal issues and to ensure that individuals involved in science responses are aware of them.
- Administrative coordination to oversee project funding and associated paperwork, and to obtain necessary IRB, OMB, and other approvals.
- Coordination of communications between scientific researchers and the public.

### 3. *General recommendations about science response coordination*

- Choose a few examples of different kinds of events. For the “pre,” “during,” and “post” phases of each event, create lists of specific scientific activities that might be carried out, the infrastructure that would be needed to support them, what groups might be involved and what approvals would be necessary. Also, map out jurisdictions and authorities (realizing that these sometimes change as one moves from the “pre” to the “during” and “post” phases).
- Look at past events to see what issues and challenges arose, and what lessons were learned, and where there were gaps in information or capabilities needed to deploy science responses.
- Figure out what resources and capabilities we already have in place that might be used during a science research response, and which would have to be created *de novo*.
- Do as much work as possible ahead of time to establish resources, mechanisms, lines of authority, etc., to support and coordinate science research responses.

### Policy and administrative issues

- Identify alternatives to the PHERRB for rapid review of clinical protocols. Consider the possibility of establishing a central IRB with people on call. However, the use of central rather than institutional IRBs would make it necessary to develop agreements with institutions to buffer them from legal liability.
- Consider making it a term of funding a clinical network that the parent institution has to agree to review a protocol for emergency research within 48 hours.
- Establish best practices for rapid review for IRBs around the country. These would include communicating with PIs before they submit protocols to make sure they are clear on regulations, to cut down on lag time in review of incorrectly prepared protocols.
- Identify protocols and surveys for which IRB or OMB approvals could be obtained in advance, and develop and submit them ahead of time to reduce load on IRBs during an event.
- Improve communications with the public and with public officials about the importance of human research, and results that may emerge from them during an event.

## **Science Responders**

*Facilitator: Lewis Robinson*

### Overview

During large-scale emergencies, there are often many unknowns related to public health and safety. Many of these increasingly complex situations (e.g., WTC attack, anthrax attack, Hurricane Katrina, H1N1 pandemic, Deepwater Horizon oil spill) could have benefited by having independent multidisciplinary expertise available to assess the

current knowledge base and incoming data related to exposures, infections, injuries, or other health effects. Individuals focusing on “what we don’t know” and critically assessing existing data gaps, especially for susceptible and high-risk populations of concern, can help to ensure that important questions are addressed and that assumptions and public communications about risks and treatment guidelines are informed and accurate. Thus, the challenge is to create a new strategy to bring independent scientific expertise into the emergency response process to help assess the available information, inform the response, identify knowledge gaps, and make recommendations for needed research.

### Panel Discussion

“Science responders” were defined as (1) personnel carrying out research and (2) personnel overseeing and analyzing research results and providing expertise and advice to decision makers. The panel agreed about the importance of having some members of the second group available at the crisis site – not only to help inform decision-making but also to participate in communications with the public (e.g., press conferences, public meetings to disseminate information and to listen to community issues).

Key questions that emerged several times during the discussion were: what federal agencies are currently responsible for organizing and mobilizing clinical research efforts during emergencies? (I.e., in the case of a flu pandemic, would it be CDC, NIAID, FDA, or all of them?) Who is responsible for deciding what clinical information should be disseminated to the public and what treatment guidelines published for clinicians? And who is responsible, based on new incoming clinical data, for deciding if treatment guidelines should be changed? While the answers to these questions vary according to the type of emergency, currently there appears to be little cross-agency coordination with respect to these issues.

Most of the rest of the discussion focused on mechanisms for identifying and mobilizing science responders. The following recommendations were made in that regard.

### Recommendations

#### *Identifying science responders*

- It is important to develop ideas ahead of time about what scientific questions will be asked during an event, so that appropriate scientific experts can be identified and rostered.
- Develop communities of scientists at the local, state, and national levels with expertise relevant to specific categories of events; they can serve as a ‘pre-roster’ of individuals ready to respond, but can also function in non-event baseline activities such as the development of protocols in advance of events..
- The possibility should be considered of using “citizen scientists,” crowd-sourcing, and social media to identify key public health questions and collect scientific data.

#### *Mobilizing and coordinating science responders*

- It is critical not only to roster appropriate science responders, but also to develop an organizational structure for mobilizing them (where appropriate) to crisis sites, including traveling them, feeding and housing them, and ensuring that they don't impose a burden on the community they are supposed to be assisting.
- It is probably preferable not to build new systems from scratch to mobilize science responders, but rather to make use of mechanisms and infrastructure already available for health responses, and integrate the mobilization of emergency health responders and science responders. Thus, for each category of events, we should identify which agencies are currently involved in deploying emergency health responses and what mechanisms they use to do so.
- Once a plan has been established to mobilize scientific experts and research efforts during a particular kind of event, it should be practiced ahead of time to ensure that it operates smoothly and no false assumptions have been made. In the case of a viral outbreak, for example, federal authorities might assume that clinical data could be collected at local hospitals, but hospital administrators might opt to close down their facilities rather than risk contaminating them.
- Scientists mobilized to the actual scene of the crisis should be trained ahead of time or "just in time" about how to operate in an emergency response setting. Conversely, incident commanders and health responders should be educated ahead of time about the importance of the science response, and trained to participate in it.

### **General Recommendations**

During the course of the panel discussions, a number of overarching issues and themes emerged that cut across multiple topic areas, and similar recommendations were offered by different panels about how to address them. These common recommendations are summarized below.

- Inventory existing resources that could support science responses during crises, including:
  - .
  - Public health surveys and survey tools already in place, and data that has already been collected and/or is being collected by different local, state, and federal agencies on an ongoing basis.
  - Existing specimen collections and repositories, including repositories to which specimens gathered during a science response could be sent.
  - Sources of potential research funding and funding intermediaries, including federal agencies currently supporting relevant research projects that could be supplemented in the event of an emergency to carry out emergency-related research via transfer of funds from other agencies or the private sector.
  - Identify subject matter experts who do baseline research that could provide a "ready reserve" of science responders: networks of clinicians, scientists and research teams that could be pre-positioned, consulted and activated for public health emergencies.

- In developing strategies for future science responses, choose a few examples of past events and identify:
  - Scientific questions that arose or could have been addressed during those events.
  - Challenges (administrative, logistical, etc.) that hindered research efforts carried out during the events, or blocked the conduct of research projects that could have been carried out.
  - Best practices and innovative approaches that facilitated research during the events.
  - Develop and test playbooks for future science responses to similar events.
  
- Improve coordination and communication between federal, state, and local agencies previously involved in science responses, and agencies involved in emergency responses who might be called upon in the event of a science response (including identifying jurisdictional issues and lines of authority).
  
- Create coordinated networks throughout the federal government to coalesce disparate efforts on science preparedness research, to leverage and streamline to best advantage.
  
- Increase outreach to the general public, with regard to:
  - The importance of scientific research, and particularly human subjects research, during emergencies.
  - The potential use of crowd-sourcing to gather questions and concerns that could inform science responses, and to collect data during science responses.
  - Dissemination of health data and recommendations obtained during a science response.
  
- Improve federal/private partnerships with regard to potential private sector participation in and/or funding of science response efforts.
  
- Develop new mechanisms for rapid funding of and obtaining IRB and OMB approvals for research during science responses.
  
- Prepare as much as possible in advance of future events with regard to:
  - Identifying scientific questions to be asked.
  - Developing infrastructure to support necessary research.
  - Developing rapid IRB review mechanisms.
  - Developing approved, baseline surveys which can be tweaked for the specific event.
  - Establishing funding and administrative approvals to carry out research.
  - Developing liaisons and mechanisms for coordination of activities with potential public and private sector partners.
  - Building a coalition of scientists as “science responders”, and nurture the nascent research field that is “science research response”.