SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC MEETING
JANUARY 25, 2011

VOTING MEMBERS PRESENT

Patricia Quinlisk, M.D., M.P.H., *Chair*
Stephen V. Cantrill, M.D.
Jane Delgado, Ph.D., M.S.
David J. Ecker, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP
John D. Grabenstein, R.Ph., Ph.D.
Kevin A. Jarrell, Ph.D.
John S. Parker, M.D., Major General (Retired)
Betty J. Pfefferbaum, M.D., J.D.

VOTING MEMBERS NOT PRESENT

Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH
Ruth L. Berkelman, M.D. (*leave of absence*)
Thomas J. MacVittie, Ph.D.
Patrick J. Scannon, M.D., Ph.D.

RETIRING MEMBERS PRESENT

Albert J. Di Rienzo (via phone)
Kenneth L. Dretchen, Ph.D.
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.
Eric A. Rose, M.D.

EX OFFICIO MEMBERS PRESENT

Michael Amos, Ph.D., Biosciences Advisor, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of Public Health and Science, U.S. Department of Health and Human Services
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency (via phone)
Lawrence D. Kerr, Ph.D., Senior Bio Advisor, National Counterproliferation Center, Office of the Director of National Intelligence
Ali S. Khan, M.D., M.P.H., RADM, U.S. Public Health Service, Assistant Surgeon General and Director, Office of Public Health Preparedness & Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Randall L. Levings, D.V.M., Scientific Advisor, National Center for Animal Health, U.S. Department of Agriculture (via phone)
Vincent Michaud, M.D., M.P.H., COL, USAF Detailee, MC, CFS, Director, Medicine of Extreme Environments, Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration *(designated by Richard Williams, M.D.)*
Tracy Dewese Parker, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security *(designated by Sally Phillips, R.N. Ph.D.)*
Bonnie S. Richter, Ph.D., M.P.H., Director, Office of Illness and Injury Prevention Programs, Office of Health, Safety, and Security, U.S. Department of Energy *(designated by Patricia R. Worthington, Ph.D.)* (via phone)
John Skvorak, D.V.M., Ph.D., COL, Commander, U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD
Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S. Public Health Service, Executive Director
Jomana Musmar, M.S., Policy Analyst, Contractor
MacKenzie Robertson, Program Analyst
Brook Stone, M.F.S., LT, U.S. Public Health Service, Program Analyst

CALL TO ORDER, CONFLICT OF INTEREST RULES AND NBSB INTRODUCTIONS

Leigh Sawyer, D.V.M., M.P.H., CAPT USPHS
Executive Director, NBSB

CAPT Sawyer called the meeting to order at 1:15 p.m. EST.

She welcomed everyone to the first 2011 National Biodefense Science Board (NBSB) meeting. The purpose of this meeting is to:

- Welcome six new individuals to the NBSB.
- Congratulate and present certificates to members whose terms expired on December 2010.
- Discuss a new topic of interest: an All Hazards Science Response.

CAPT Sawyer briefly read the Federal Advisory Committee Act and reviewed conflict of interest rules. Members then introduced themselves along with their professional background.

WELCOME

Patricia Quinlisk, M.D., M.P.H.
Chair, National Biodefense Science Board

Dr. Quinlisk welcomed all participants. She thanked retiring members for their work and listed their contributions during the past year:

- Roberta Carlin, M.S., J.D., participated in three NBSB working groups as well as the subcommittee that focused on at-risk individuals and people with disabilities.

- Albert J. Di Rienzo, who focuses on science and technology acceleration, served on four NBSB working groups.

- Kenneth L. Dretchen, Ph.D., who has experience on pharmacological defense from biologic and chemical threats, helped guide many recommendations produced by five NBSB working groups.

- James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A., who has expertise in disaster medicine and public health preparedness, contributed to five NBSB working groups as well as a subcommittee.

- Eric A. Rose, M.D., whose expertise extends to both private industry and medicine, provided unique contributions to five NBSB working groups.

- Andrew T. Pavia, M.D., who has extensive experience in pediatrics and infectious diseases, contributed to the development of viral vaccine recommendations during the 2009 H1N1 pandemic. He also served on five NBSB working groups.

Dr. Quinlisk turned the meeting over to Nicole Lurie, M.D., M.S.P.H., the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services.

ASPR PRESENTATION TO NBSB MEMBERS
Nicole Lurie, M.D., M.S.P.H
Assistant Secretary for Preparedness and Response

Dr. Lurie welcomed everyone and thanked the former Disaster Mental Health Subcommittee for their contributions to the NBSB and the ASPR. The subcommittee's work over the past years has represented the highest spirit of public service. Largely because of this work, HHS has been able to do things very differently than in the past, particularly regarding some of its responses to the Deepwater Horizon Oil Spill and the H1N1 epidemic. The subcommittee's work also assisted in the current development of a behavioral health concept of operations (CONOPS).

The NBSB's work on the medical countermeasures enterprise has also been crucial. Partially due to NBSB's recommendations, the department has fundamentally changed how business is done in ASPR and BARDA – and has also impacted the way that FDA, CDC, DoD and other organizations work together. This was due in part to the careful analysis, thoughts and recommendations provided by the NBSB.

Dr. Lurie awarded certificates of appreciation to members rotating off the board. She then proceeded to swear in new members.

ALL HAZARDS SCIENCE RESPONSE
Nicole Lurie, M.D., M.S.P.H
Assistant Secretary for Preparedness and Response

Dr. Lurie remarked that NBSB members are among some of the preeminent scientific, public health and medical experts in the nation. They will be able to provide advice to help the country prepare and become more resilient to all hazards.

Dr. Lurie said than in three recent major emergencies (the Haiti earthquake response, H1N1 and the Deepwater Horizon Oil Spill) – as well as in other emergencies being planned for – there are several scientific gaps in knowledge about underlying threats, how people address them and what are the best things to do.

Some of these uncertainties were successfully confronted during the H1N1 epidemic. During the epidemic, the best available science and professional judgments were used to determine the vaccine's right dose, which was then subjected to rigorous testing, and a concerted scientific effort was undertaken to quickly develop the vaccine.

In retrospect, however, there are other scientific questions which could have been explored but weren't addressed in the heat of the moment. For example, in the Haiti earthquake response there was an urgent need for scientific and clinical information about how best to respond to many of the injuries, which wasn't yet available.

CONOPS, checklists and pre-scripted mission assignments already exist in case of an emergency. However, no CONOPS or pre-scripted mission assignments exist for carrying out an all hazards science response. This is important for several reasons, one of which is bringing the best available science to bear in an acute situation. Another reason is that it could be helpful in continuously managing the response.

The above mentioned gaps could be addressed, in part, by developing an all hazards science response strategy. The board could advise the department as to what such a response would look like and how it should be put together. In other words, what are the major components of an all hazards science response? How should it be operationalized within HHS? What infrastructure and supporting pieces need to be put in place so that one is ready to go? What would such a CONOPS look like? What would be the pre-scripted mission assignments?

Some of this work – such as developing rosters of scientists in key areas – has already begun as a result of the H1N1 response. There has also been thought on the development of a national IRB that could be used in case of an emergency. OMB has also recently issued new guidance documents on science and the OMB clearance process.

Overall, the idea is to determine what needs to be in place, so that when an emergency occurs that hasn't yet been confronted, the best available science can be harnessed to ensure that scientific opportunities to advance knowledge in important areas are not missed.

Q&A Session
Dr. Grabenstein asked if there are any specific categories of hazards that are in the greatest need of attention or categories that are already adequately covered.

Dr. Lurie answered that rather than tackling the issue on a "hazard by hazard" basis, it would be best to think of categories, such as exposure events of all kinds for both responders and the public. For each of these categories, there might be a set of generic issues that need to be addressed. An example of a generic issue could be a CONOPS to establish a team of scientists that would identify the priority scientific issues to be addressed and then develop recommendations which could be operationalized.

Dr. Quinlisk asked if perhaps the approach could be summarized into three types of science: pre-disaster, during the disaster and post-disaster. Pre-disaster science, for example, would aim to understand where the science might lie, who are the science experts and how one could get a hold of them. During the event one could develop a method to quickly answer key questions for that response. But also during a natural experiment of a disaster, one might identify things to be learned which might not necessarily be used during that specific disaster, but which could be used to better respond to future disasters.

Dr. Lurie agreed and explained that sometimes in an event there are some questions that can be answered in the acute period to manage the event, while others might take longer to be answered. The goal is to get out of the box quickly enough by asking the right questions and figuring out how to answer them. This requires a mechanism which would involve the right people, IRBs, budgets, data collection methods, considering different populations, etc. The board might want to think about what infrastructure is required for this and when such infrastructure should be mobilized – in other words, what unusual events would lead to this infrastructure being mobilized?

Dr. Delgado asked if – during an emergency – the OMB compliance rules for asking more than nine questions still apply?

Dr. Lurie responded that OMB has been very helpful in working with HHS to move things through the system quickly. She explained that collecting information from public health departments is different than collecting information from responders or the general population. The recent OMB science guidance documents contain suggestions for generic protocols that might be approved in advance and slightly modified in the future. This could really help shorten the process.

Dr. Jarrell asked if the focus of the science response was on the effects of human health.

Dr. Lurie responded that the focus is indeed on the effects of human health.

Dr. Parker asked about baselines. He said that when an agency studies a particularly environmental antigen it examines it one-on-one, while for this task one would need to

examine multiple effects on the human body as well as how antigens can accumulate in the body during a disaster. He asked how a baseline community health or human health could be developed.

Dr. Lurie agreed that this is a very important issue and that perhaps it could be addressed through the board's recommendations.

DISCUSSION
Patricia Quinlisk, M.D., M.P.H
Chair, National Biodefense Science Board

Dr. Quinlisk opened the meeting for board discussion on an all hazards science response.

Dr. Ecker asked how the board could coordinate efforts with other scientific organizations, such as the National Academy of Sciences and the National Science Foundation (NSF). He explained that the NSF has a rapid funding mechanism with a short turn around period. He suggested that consultations with other groups might also be appropriate.

Dr. Quinlisk agreed and said that it might be important for the board to better understand "which organization has been tasked to do what" and where the board might have the broadest impact.

Dr. Michaud suggested that one might want to also consider things that are not desired. In other words, impediments to a scientific response.

Dr. Quinlisk explained that when she worked at the epicenter of one the largest mumps breakout in the past 20 years, one of the challenges was the large number of requests received from various sources. There where requests from academicians, medical centers, and even economists as well as other researchers from a wide variety of backgrounds.

Another challenge, said Dr. Quinlisk, was the fact that there wasn't a lot of time to review or discuss research applications because the team was too busy trying to stop the breakout. Nonetheless, nearly ten studies were carried out during the epidemic. Some of the research was public health practice which didn't require formal IRB approval, while other types of research did require IRBs, such as those that involved drawing voluntary blood samples.

Dr. Cantrill concurred with Dr. Quinlisk and said that it might be important to separate responders from the individuals collecting the data.

Dr. Quinlisk agreed that it's important to separate responders from data collectors. She explained that while gathering data on individuals who were ill, they received a number of requests throughout the outbreak for additional questions to be asked. As a result, some individuals were asked all questions, while others were only asked some of the questions, thus creating an incomplete database.

Dr. Fagbuyi asked how one could approach the all hazards science response from a preemptive standpoint, given the fact that all hazards don't necessarily fit into "one box." Perhaps the board should examine various hazard categories (e.g. chemical, biological, etc) and begin by understanding what is known for some of these categories, what can be done, and then prioritizing. For example, one might prioritize for events are the most likely to happen or, alternatively, events that are uncommon but have high lethality.

Dr. John Parker said that while discussing infrastructure the board might also want to consider discussing virtual structures, as hiring large number of government employees will be unlikely. He added that during construction, contractors or developers need to file an environmental impact statement that goes to the EPA or the local government. This statement could be used in a risk assessment.

Dr. Delgado remarked that when discussing baselines one needs to understand the baseline of how things are currently operationalized within HHS, so the board can have a better understanding how things happen in an all hazards response. The board could also review additional response models, such as those developed by the DoD.

Dr. Quinlisk suggested that perhaps one of the places to start is to examine a science response from a recent event and determine if there are any things that could be built upon (e.g. best practices and recommendations).

Dr. Jarrell explained that during the Deepwater Horizon Oil Spill, his organization, which was part of a consortium, applied for a rapid NSF grant. It took two months from the day the NSF was contacted to the time the grant was awarded, which is incredibly fast. One of the things the board could discuss is how much time should pass before a response team goes into action.

Dr. Gellin remarked that one could examine existing networks that could be leveraged during a disaster. One needs to look at the spectrum of things that are already in place and brought into the fore.

Dr. Quinlisk indicated that they were various requests during the H1N1 epidemic for clinical information on the sickest patients as well as those who had died. But due to a lack of effective coordination, there were complaints from hospitals because there were different people asking for the same information. There might be a need for better coordination ahead of time to further reduce the burden on those trying to respond.

Dr. Fagbuyi said that, with regards to leveraging networks, a good point to start would be the NIH, which has "real time" grants. It would be helpful to have funding pre-positioned so that within 48 to 72 hours after an event occurs some of the researchers are in place and ready to go. Finding a list of various networks and including them in the working group's discussions could be also useful.

Dr. Quinlisk remarked that some research can be done with existing resources, because it's already part some people's current job (or individuals might be able to be delegated for a specific period of time without an immediate need for resources). However, there are other types of research which require additional resources before research can begin. Perhaps the board could discuss how these two types of research could be differentiated. This would ensure that researchers are available for things that can move forward without extra money.

Dr. Grabenstein said that an IRB often includes a provision for individuals to opt out, which could have both an up side and a down side. For example, some cleanup workers at ground zero during the World Trace Center disaster might have initially opted out but may have wished they didn't so they could have been included in a registry that could have helped them receive treatment sooner [for example, in the case of respiratory diseases]. He added that it would be a good idea to get an IRB started which would take such things – as well as public comment – into consideration, as there might not be enough time for public comment in the midst of an emergency.

Dr. Quinlisk said that when collecting data people are more likely to volunteer the closer they are to an actual event rather than, say, six months later. She added that some of the staff might also be doing double duty by both gathering information and disseminating information to help others better respond to the disaster.

Dr. Jarrell said that data collected from exposed populations would be more meaningful if there also were teams in place prepared to collect data on particular agents (e.g. chemical, biological, etc) and the distribution of particular materials involved in the incident.

Dr. Quinlisk explained that during the mumps epidemic, probably the hardest thing wasn't collecting data but entering it into a database. This was not only an amazing burden but also a bottleneck.

Dr. Cantrill moved that a working group be created to collect information and come to conclusions that could then be reported to the board. Dr. Delgado seconded the motion. A formal vote was taken by the NBSB. All nine voting members present (majority of voting members) unanimously approved the proposal to create an All Hazards Science Response Working Group.

Three volunteers agreed to co-chair the All Hazards Science Response Working Group: Dr. Cantrill, Dr. Delgado and Dr. Grabenstein. Dr. Cantrill agreed to be the working group's lead co-chair and main point of contact. The following individuals also volunteered to be part of the working group:

- Dr. Ecker
- Dr. Fagbuyi
- Dr. Jarrell
- Dr. Levings
- Ms. Maher

- Dr. Michaud
- Dr. Quinlisk
- Dr. John Parker
- Dr. Tracy Parker (as an alternate for Dr. Phillips)
- Dr. Pfefferbaum
- Dr. Skvorak

Dr. Khan said that the CDC could provide the working group with briefings on registry issues as well as research vs. non-research determinations. He also suggested that the group obtain a briefing from OMB to clarity which kind of research requires OMB clearance and which does not.

Dr. Kaplowitz indicated that there might be some individuals from ASPR who might be interested in addressing the working group. The input from the Office of Preparedness and Emergency Operations might also be important since they are directly involved in a response.

Another individual suggested that information from BARDA and their involvement in medical countermeasures might also be of interest to the working group.

Dr. Gellin said that the National Vaccine Program Office was involved during the H1N1 pandemic response and its efforts could also be of interest to the working group.

Dr. Hart said the Department of Justice would available should the working group have any questions.

Dr. Skvorak said that response teams across the Department of Defense could provide the working group with information on gaps in processes and procedures. CBRNE and post-traumatic stress are also an emphases for the Department of Defense.

Dr. Michaud explained that NASA has been involved in imaging for situational awareness and communications during disasters, and they could provide information on such expertise to the working group.

Dr. Amos said that as the scope develops, the working group should feel free to request any assistance from NIST.

CAPT Sawyer added that CDC's The National Institute for Occupational Safety and Health (NIOSH) would also be interested in assisting the working group.

PUBLIC COMMENT

Dr. Quinlisk opened the meeting for public comment.

Dr. John Decker from NIOSH said that the working group might want to consider the differences between two populations: the responder work force vs. the general

population. There are many differences between these two populations and the board might want to considered them separately. He added that NIOSH had sponsored an interagency workgroup, which included 49 government representatives, to discuss responder health monitoring and surveillance. The workgroup's resulting document, *The Emergency Responder Health Monitoring and Surveillance*, will be available for public comment during the first week of February. The document discusses baselines, including pre-deployment health screening for responders.

Dr. S.J. Whidden explained that he has been part of an effort to develop an all hazards risk assessment for DHS. The chemical infrastructure risk assessment is currently being completed. It's a holistic cradle-to-grave approach and examines approximately 17,000 chemical sites in the U.S. The assessment also models cleanup from a health impact perspective. The document, which also examines mitigation measures, is classified but an unclassified part also exists.

NEXT STEPS
Patricia Quinlisk, M.D., M.P.H.
Chair, National Biodefense Science Board

Dr. Quinlisk turned the meeting over to CAPT Sawyer who proposed that the working group's co-chairs consider the development of a timeline for the project.

Dr. Cantrill said the working group would have an extensive progress report, if not a final report, ready for the next NBSB public meeting. The next public meeting will be held on April 28-29, 2011 (for additional information on this meeting, please visit www.phe.gov/preparedness/legal/boards/nbsb/Pages/default.aspx).

Dr. Quinlisk proposed that other NBSB working groups go into "inactive" status, given the current project's short timeline. This would allow the All Hazards Science Response Working Group to focus on the task at hand. There was agreement on the matter by the board and the other working groups were deemed inactive.

Dr. Quinlisk thanked the staff of the NBSB for their work. CAPT Sawyer thanked all current and retiring members for their presence. She also thanked all members of the public for attending.

ADJOURN
The meeting was adjourned at 2:45 p.m.