

**SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD**

November 18–19, 2008

**Sheraton National Hotel
900 South Orme Street
Arlington, VA 22204**

VOTING MEMBERS PRESENT

Patricia Quinlisk, M.D., M.P.H., *Chair*
Ruth L. Berkelman, M.D.
Stephen V. Cantrill, M.D.
Roberta Carlin, M.S., J.D.
Albert J. Di Rienzo
Kenneth L. Dretchen, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.
John S. Parker, Major General (Retired), M.D.
Andrew T. Pavia, M.D.
Eric A. Rose, M.D.

VOTING MEMBERS NOT PRESENT

Thomas J. MacVittie, Ph.D.
Patrick J. Scannon, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee)

Diane Berry, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security
present December 19 (Dr. Terry Adirim, designee, by phone, November 18)
Richard E. Besser, M.D., Coordinating Office for Terrorism Preparedness and
Emergency Response, Centers for Disease Control and Prevention, U.S. Department
of Health and Human Services
Michelle M. Colby, D.V.M., M.S., Office of Science and Technology Policy, Executive
Office of the President (present November 18)
Lawrence Deyton, M.D., M.S.P.H., Chief Public Health and Environmental Hazards,
U.S. Department of Veterans Affairs (present November 18)
Bruce Gellin, M.D., M.P.H., National Vaccine Program Office, Office of the Secretary,
Office of Public Health and Science, U.S. Department of Health and Human Services
Rosemary Hart, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental
Protection Agency
Lawrence (Larry) D. Kerr, Ph.D., National Counterproliferation Center, Office of the
Director of National Intelligence

Carol D. Linden, Ph.D., Biomedical Advanced Research and Development Authority,
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of
Health and Human Services (present November 19)
Boris D. Lushniak, M.D., M.P.H., Rear Admiral/Assistant Surgeon General, Office of the
Commissioner, Food and Drug Administration, U.S. Department of Health and
Human Services (present November 18; Dr. Aubrey Miller, designee, November 19)
Dianne Poster, National Institute of Standards and Technology, U.S. Department of
Commerce (designated by Dr. Willie May)
Patricia R. Worthington, Ph.D., Office of Health and Safety, U.S. Department of Energy
(Dr. Bonnie Richter, designee)
John P. Skvorak, Colonel, D.V.M., Ph.D., U.S. Army Medical Research Institute for
Infectious Diseases, U.S. Department of Defense (present November 18)

EX OFFICIO MEMBERS NOT PRESENT

Joseph Anelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of
Agriculture
Hugh Auchincloss, M.D., National Institute of Allergy and Infectious Diseases, National
Institutes of Health, U.S. Department of Health and Human Services
Claudia A. McMurray, Ph.D., Environmental and Scientific Affairs, U.S. Department of
State
Carter Mecher, M.D., Homeland Security Council, Executive Office of the President
Patricia A. Milligan, R.Ph., C.H.P., U.S. Nuclear Regulatory Commission
Timothy R. Petty, Deputy Assistant Secretary for Water and Science, U.S. Department of
the Interior
Frank Scioli, Ph.D., Division of Social and Economic Sciences, National Science
Foundation
Richard S. Williams, M.D., Office of the Chief Health and Medical Officer, National
Aeronautics and Space Administration

DISASTER MENTAL HEALTH SUBCOMMITTEE MEMBERS PRESENT

Elizabeth Boyd, Ph.D., Disaster Mental Health Institute, Psychology Department
University of South Dakota
Lisa M. Brown, Ph.D., Department of Aging and Mental Health, Louis de la Parte Florida
Mental Health Institute, University of South Florida
RADM (Ret.) Brian Flynn, M.A., Ed.D., Assistant Surgeon General
Jack Herrmann, M.S.Ed., N.C.C., L.M.H.C., National Association of County and City
Health Officials
Stevan E. Hobfoll, M.A., Ph.D., Department of Behavioral Sciences, Rush University
Medical Center
Gerard A. Jacobs, Ph.D., Disaster Mental Health Institute, University of South Dakota
Russell Thomas Jones, Ph.D., Department of Psychology, Virginia Polytechnic Institute
and State University
Ann E. Norwood, M.D., University of Pittsburgh Medical Center—Center for Biosecurity

Josef Ruzek, Ph.D., Acting Director, Dissemination and Training Division, National Center for PTSD, Veterans Affairs Palo Alto Health Care System (by phone)
David Schonfeld, M.D., F.A.A.P., Division of Developmental and Behavioral Pediatrics, National Center for School Crisis and Bereavement, Cincinnati Children's Hospital Medical Center
Robert Ursano, M.D., Department of Psychiatry, Uniformed Services University of the Health Sciences

DMH EX OFFICIO REPRESENTATIVES PRESENT (or designee)

Peter R. Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental Protection Agency
CAPT Dori Reissman, M.D., M.P.H., U.S. Public Health Service, National Institute of Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (designated by Dr. Richard Besser)
LT COL Lisa Sayegh, M.S.W., Ph.D., U.S. Air Force, BSC, NORAD-USNORTHCOM/SG, Office of the Command Surgeon, U.S. Department of Defense (designated by Dr. John Skvorak)
Marc Shepanek, Ph.D., Lead, Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (designated by Dr. Richard S. Williams)
Farris Tuma, Sc.D., M.H.S., Division of Adult Translational Research and Treatment Development, National Institute of Mental Health, National Institutes of Health, U.S. Department of Health and Human Services (by phone, November 19; designated by Dr. Hugh Auchincloss)

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director
Erin Fults, Scientific/Technical Writer
Rayshawn Holmes, Junior Analyst
Donald Malinowski, M.S., Program Analyst
David Noll, Ph.D., Science Policy Fellow
Amanda Richardson, Ph.D., M.S., Science Policy Fellow
Andrew Rickles, M.P.H., Policy Analyst
MacKenzie Robertson, Program Analyst
Carolyn Stevens, Executive Assistant
Brook Stone, M.F.S., LTJG, U.S.P.H.S., Program Analyst

WELCOME AND INTRODUCTION

CAPT Leigh Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board (NBSB)

CAPT Sawyer welcomed the Board members and introduced RADM William C. Vanderwagen, M.D., Assistant Secretary for Preparedness and Response. Following RADM Vanderwagen's remarks, CAPT Sawyer reviewed the guidelines for Federal advisory boards. She then outlined the agenda and welcomed the public to weigh in during the designated public comment periods.

OPENING REMARKS: PAST, PRESENT, AND FUTURE

RADM William C. Vanderwagen, M.D., Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services (HHS)

RADM Vanderwagen thanked the Board members for their work over the past 11 months. He described some of the challenges the Office of the Assistant Secretary for Preparedness and Response (ASPR) faces, including the need to work with partners around the world, across specialties, to create an infrastructure that meets global preparedness needs. He anticipated that the next Secretary of HHS will need the expert input of the Board, and he felt confident that the next administration would continue to support the Board's efforts.

RADM Vanderwagen noted that the Federal Education and Training Interagency Group (FETIG), required under the Pandemic and All-Hazards Preparedness Act (PAHPA), will hold its first meeting in December. He thanked the NBSB's Disaster Medicine Working Group for their input into the FETIG charter. The same working group led a review of the National Disaster Medicine System, with advice from a panel of national experts. Their recommendations were reviewed and approved by the Board as a whole and sent to the Secretary; the recommendations will assist HHS in making significant improvements to the system, said RADM Vanderwagen. He added that the group took a comprehensive approach to providing public health and medical support to communities and identified how HHS can build on existing local, State, and Federal resources to create a national response plan.

RADM Vanderwagen thanked the Personal Preparedness Working Group for articulating important concerns of the Board about home stockpiling of antibiotics. The working group will continue to evaluate the scientific and policy ramifications of personal preparedness. RADM Vanderwagen hoped the Disaster Mental Health (DMH) Subcommittee would also weigh in on personal preparedness as a means to increase community resilience.

The Pandemic Influenza Working Group will address a number of policy and scientific questions that could have an impact not just on influenza but also on other vaccine-preventable diseases. The Working Group on Medical Countermeasure Research and Development Processes for Chemical, Biological, Radiological, and Nuclear (CBRN) Agents has made progress evaluating the assets of various Federal agencies, specifically aligning the development assets of the Department of Defense (DoD) and HHS. The Markets and Sustainability Working Group is tackling the difficult question of how to develop a sustainable market for products, especially during a global financial crisis. RADM Vanderwagen said the United States has opportunities to align its research efforts with those of its European counterparts, and he appreciated having input from the Board on such issues.

RADM Vanderwagen said the Federal hurricane response in 2008 demonstrated that the U.S. government can meet the requirements of communities through preparedness efforts

and coordinated responses. Following Hurricane Gustav, ASPR hosted a three-day meeting to identify areas for improvement, noting opportunities to look more closely at the needs of special populations and mental health issues. The National Health Security Strategy, now in development, will help ASPR clarify its efforts for the next four years and serve as the basis for a long-term strategy. RADM Vanderwagen said security means more than preventing terrorists from using weaponized pathogens; it means ensuring the health and well-being, resiliency, and mental health of the population as well as protecting the structure of the health system. Expanding telehealth capacity could also create opportunities to improve preparedness and response.

RADM Vanderwagen thanked the DMH Subcommittee for producing critically important recommendations in such a short timeframe. He called for better understanding of what allows a community to survive a disaster and recover. He read aloud a letter of thanks from the Secretary to the DMH Subcommittee members, which stated that, by offering their expertise to the Board, they provided a public service that may lessen the impact of future events on untold numbers of people. RADM Vanderwagen presented each member of the DMH Subcommittee with a copy of the Secretary's letter and a commemorative coin bearing the HHS and ASPR logos.

Finally, RADM Vanderwagen thanked Margaret Giannini, M.D., Director of the HHS Office on Disability, for her constant support, energy, and leadership. He said Dr. Giannini, a pediatric oncologist, helped him to think more holistically, and he applauded her tireless efforts.

RADM Vanderwagen indicated he would continue to work with the Board in some respect regardless of whether he is reappointed as Assistant Secretary in the new administration. He noted that ASPR is an organization of committed people who believe in continued communication and cooperation. Patricia Quinlisk, M.D., M.P.H., Chair of the Board, expressed thanks to RADM Vanderwagen on behalf of the Board, the DMH Subcommittee, and the ex officios for his support.

RECOMMENDATIONS REPORT OF THE DISASTER MENTAL HEALTH SUBCOMMITTEE

Patricia Quinlisk, M.D., M.P.H., Chair, DMH Subcommittee

Daniel Dodgen, Ph.D., Executive Director, DMH Subcommittee; Director, Office of At Risk Individuals, Behavioral Health, and Human Services Coordination, ASPR, HHS

Dr. Quinlisk said the DMH Subcommittee had done an amazing amount of work that, she felt, would make a real difference. Dr. Dodgen gave a brief overview of the DMH Subcommittee, explaining its charter and development. With the recommendations report presented to the Board at this meeting, the DMH Subcommittee addressed its mission to provide advice and guidance on “protecting, preserving, and restoring individual and community mental health in catastrophic health event settings.” The DMH Subcommittee divided its task into three content areas—intervention, education and training, and communication and messaging—and assigned members to writing groups to address each area. Dr. Dodgen presented the cross-cutting principles that the

DMH Subcommittee agreed to all of the recommendations, summarized as follows:

- The definition of disaster mental and behavioral health should be comprehensive.
- Interventions should be practical, flexible, empowering, compassionate, and respectful.
- Interventions should be sensitive to cultural diversity.
- Vulnerable and at-risk populations should be addressed in all facets of disaster planning and response.
- Recommendations should not create burdens or impose unfunded mandates.
- Collaboration should take place at all levels and include two-way communication.

Representatives from each writing group presented their recommendations and gave a brief rationale for each.

Intervention Writing Group

CAPT Dori Reissman, M.D., M.P.H., Co-Chair

CAPT Reissman explained that “intervention” cuts across all the topics the DMH Subcommittee discussed and incorporates everything that does not clearly fall into the other two content areas. The success of emergency response strategies and public health directives depends on integration of mental and behavioral health, said CAPT Reissman.

Recommendation 1

Integrate mental and behavioral health into all public health and medical preparedness and response activities.

(1a) At the Federal level, coordinate mental and behavioral health service efforts through a unified concept of operations (CONOPS) that addresses pre-, intra-, and post-event phases of disaster and that includes:

- near real-time reach-back capacity to allow for mental and behavioral health expert input and consultation;
- representation of mental and behavioral health functions, including consultative and clinical roles, within operational frameworks across local, State, and national levels aligned with the National Incident Management System; and
- standard mental and behavioral health triage of at-risk individuals and populations that is linked with needs-assessment activities and surveillance of emerging health effects and behavioral risk factors.

Without a CONOPS, CAPT Reissman said, response will always be fragmented, and responders will not be able to put communication efforts into place or target areas in need. Input from behavioral health experts ensures that evidence and real-world experience inform practice. A pool of experts from around the country could be identified in advance to provide real-time input during an incident.

As many as 40 percent of people directly affected by a disaster can develop mental health problems that can lead to chronic dysfunction, said CAPT Reissman. Successful intervention requires adherence to public health directives—a tall order, CAPT Reissman conceded. Applying lessons learned from behavioral science may improve adherence. Further, leaders must be psychologically prepared for disasters so that they don't make poor decisions at times of crisis.

(1b) At the national level, facilitate State-based disaster mental and behavioral health planning and operations through the following:

- Include language on mental health, substance abuse, and behavioral health in all appropriate legislation, regulations, and grants (for example, in the Pandemic and All Hazards Preparedness Act (PAHPA)).
- Integrate disaster mental and behavioral health planning and exercising into performance benchmarks of new or existing Federally-funded emergency management programs or grants.

CAPT Reissman called for building a common language throughout legislation and across disciplines. Grant language should be consistent, especially in terms of outcomes evaluation, because “What you measure is what you do,” said CAPT Reissman. Further, responders must have an opportunity to practice disaster mental health response in realistic exercises.

Recommendation 2

Enhance the research agenda for disaster mental and behavioral health.

One step toward enhancing the research agenda and improving understanding may be to convene a DMH Subcommittee working group to review the research portfolios of Federal research funders (including the appropriate agencies within the Departments of Health and Human Services, Veterans Affairs, Homeland Security, and Defense) to identify gaps in knowledge, areas of recent progress, and priorities for research in disaster mental and behavioral health program evaluation, early intervention, treatment for disaster-related problems, and dissemination of training in disaster mental and behavioral health interventions. The findings could be used to set a national agenda that is supported by the funding Federal agencies. CAPT Reissman emphasized the need for a coordinated effort to build an evidence base for successful interventions in various settings.

Recommendation 3

Enhance assessment of mental and behavioral health needs during emergencies.

A better understanding of what is happening on the ground will help responders provide the appropriate resources during an emergency. Epidemiological strategies could be used to capture information for public policy and resource allocation. Federal and State governments have the capacity to obtain real-time data from households and could use existing health surveillance systems to rapidly assess and track mental and behavioral health needs and recovery processes in affected populations. Some examples are CDC's

Behavioral Risk Factor Surveillance System, Youth Behavioral Risk Surveillance System, National Hospital Discharge Survey, and National Health Interview Survey; the Substance Abuse and Mental Health Services Administration's National Household Drug Utilization Survey; the American Red Cross Mental Health Triage information; and the Los Angeles County Rapid Mental Health Triage System.

Education and Training Writing Group

Gerard A. Jacobs, Ph.D., Co-Chair

Dr. Jacobs noted that those directly affected by disaster as well as those responsible for providing disaster relief need psychological support. For example, it's important to understand that the effects of trauma can manifest well after the event and in subclinical ways. Traumatic stress also affects decision-making, which can harm disaster-relief efforts.

Recommendation 4

Enhance disaster mental and behavioral health training for professionals and paraprofessionals.

Dr. Jacobs called for training in psychological first aid (PFA), which promotes psychological resilience. Like cardiopulmonary resuscitation training, PFA training can encompass basic "grassroots" psychological support provided for family, friends, neighbors, and colleagues by members of the general population and more advanced training to professionals in the field. By comparison, training in disaster mental health services prepares mental health professionals to respond during the emergency phase of a disaster operation and relies on knowledge from the broad field of study.

Implementing Recommendation 4 involves working with licensing and accrediting bodies to improve disaster-related training for behavioral health professionals. It also entails working with other organizations to promote PFA training to improve self-care and psychological support for colleagues and clients. At the community level, community leaders and local emergency responders should be trained both in the importance of disaster mental health in emergencies and in providing PFA so they can be more effective in their decision-making during a disaster and better support community recovery efforts. Dr. Jacobs hoped FETIG would address mental health education and training.

Recommendation 5

Promote the population's psychological resilience.

After the attacks of September 11, 2001, the Institute of Medicine determined that the current disaster mental health model would not work for disasters larger than the September 11 attacks and proposed a national public health model for psychological support. Dr. Jacobs envisioned a national PFA program that would be low-cost, easy to sustain, community-specific, and culturally responsive because it involves communities getting together to identify their psychological support needs. Individuals, families, and communities would have community-based training in basic tenets of providing

psychological support and would not have to wait for mental health professionals to respond during a disaster.

Recommendation 6

Ensure that the needs of at-risk individuals and issues of cultural responsiveness are being addressed in all efforts of the NBSB.

Dr. Jacobs said disaster response tends to focus on the mainstream. He gave an example of unique cultural and religious beliefs that may conflict with common ways that mental health providers and emergency responders talk about and address crises. Dr. Jacobs suggested the National Response Framework be updated to better document the needs of at-risk and vulnerable populations and to ensure that technical assistance is available to those who provide aid to diverse populations.

Messaging Writing Group

Ann E. Norwood, M.D., Chair

Dr. Norwood emphasized that effective communication requires dialogue. One-way communication that delivers a single key message in a unified voice fails to take into account the unique responses of individuals. Furthermore, accurate, timely, and credible information increases the likelihood that people will choose appropriate actions. In other words, successful communication promotes self-efficacy. Finally, people feel better when they are active participants in a response—when they see themselves as survivors, not victims, said Dr. Norwood.

Recommendation 7

Develop a disaster mental and behavioral health communication strategy.

Dr. Norwood outlined the actions to support this recommendation:

- Develop mass communication messages that deliver psychological education, information on sources of help, and other mental and behavioral health topics related to specific hazards/threats and disaster phases.
- Develop education and training regarding the integration of mental and behavioral health/social science principles and emergency risk communication.
- Develop a process to identify, educate, and train a cadre of mental and behavioral health experts to serve as consultants, interviewees for Federal television/Internet broadcasts, and resources to the media.
- Establish and enforce a policy, with respect to all disaster and emergency health issues, that requires that:
 - prior to soliciting/undertaking new Federally-funded communication initiatives, a review of similar and/or related activities of other Federal components will be performed and documented to ensure integration and prevent duplication and
 - all communication activities (directly operated or supported through grants, contracts, or cooperative agreements) document and ensure that

they are informed by current evidence-based psychosocial factors.

Emergency responders need more education on mental and behavioral health and social science principles to better understand how people interpret and respond to the information they receive, said Dr. Norwood. She suggested evaluating, consolidating, and building on the many existing products and mechanisms to deliver key mental health messages. Furthermore, messages should be tested in all the scenarios spelled out by the National Response Framework.

Recommendation 8

Develop an Internet-based communication toolkit.

At present, no single Federal source consolidates communication/messaging research and products developed for events such as pandemic influenza, terrorism, and environmental contamination from chemical stockpile/industrial accidents, said Dr. Norwood. An Internet-based toolkit would provide access to all the available materials. Keeping up with new technology will further enhance communication, Dr. Norwood added, noting that online social networking allows communities to gather and spread information quickly. It's important to acknowledge that people get information from multiple sources and in different styles, she concluded.

DISCUSSION

Dr. Quinlisk asked the Board to consider the recommendations of the DMH Subcommittee. John Parker, M.D., suggested expanding the definition of "disaster" to cover such areas as the global financial crisis. DMH Subcommittee member Robert Ursano, M.D., referred to the concept of "slow-evolving" disasters, noting that victims of Hurricane Katrina suffered mental health problems as long as 18 months after the event. DMH Subcommittee member Russell Thomas Jones, Ph.D., pointed out that broadening the definition could help expand access to resources for victims, as most intervention efforts end shortly after the disaster. Dr. Jacobs responded that educating more people in PFA would help them cope before, during, and after disasters.

Stephen Cantrill, M.D., suggested that all those involved in risk communication should take mental health considerations into account, regardless of the population. He also asked that the term "environmental scan" be defined in the DMH Subcommittee's report.

Kenneth Dretchen, Ph.D., suggested that in communications efforts, the DMH Subcommittee take into account multiple audiences with different education levels, language proficiency levels, and relationships with the community. It should also consider who should deliver the message in a given community and by what mechanisms.

Richard Besser, M.D., said CDC is developing educational guidance on cooperative agreements with States in the area of public health. He stressed the importance of prioritizing the DMH Subcommittee's recommendations in light of the shrinking budget to support such initiatives. Dr. Besser said a CDC white paper determined that involving communities in emergency planning and promoting individual preparedness help to build

community resilience. He called for broadening the recommendation about PFA to include community engagement across all aspects of disaster mental health response. Dr. Jacobs clarified that PFA involves working with communities to help them prepare for disasters by implementing PFA in a manner that is consistent with community resources and values.

DMH Subcommittee member Stevan Hobfoll, Ph.D., said the discussion so far had focused on issues of concern to social and behavioral scientists. However, he sees advancements in neuroscience pushing the fields of psychology and psychiatry away from addressing social systems by overemphasizing the role of neurobiology in mental health. Dr. Hobfoll also emphasized the importance of creating a team of experts who could provide advice in real-time to communities experiencing disasters.

James James, M.D., asked the DMH Subcommittee to consider how to equip trained disaster response professionals in the field to do upfront assessment and research. He added that the concept of resiliency should be incorporated into education and training, and that education and training should be built around a set of core competencies taught in school settings.

John Grabenstein, Ph.D., suggested that the DMH Subcommittee not only prioritize the recommendations but also develop a work plan that details the sequence of events needed to implement the recommendations.

Peter Jutro, Ph.D., called for more attention to long-term recovery efforts, particularly to communicating with individuals about long-term or lingering risks (e.g., environmental contamination).

Albert Di Rienzo said communication is interrelated with education and training. To improve both communication and education efforts, he suggested the DMH Subcommittee look for mechanisms for feedback after events and consider the efforts and products of other fields and industries (e.g., how do marketing and training industries promote their message?). He said the military can provide examples of communicating with a broad range of audiences.

Roberta Carlin, J.D., said the recommendations recognize and imply that communications should meet Federal accessibility guidelines, but that point should be emphasized. She said the disability community can provide some models on communication about preparedness, response, and recovery. She noted that implementation efforts often must be paired with funding to be effective.

Eric Rose, M.D., asked whether the recommendations take into account the need to scale up for large disasters. Dr. Hobfoll felt the current scale is reasonable, but the nimbleness of response must be improved to better address crises as they happen. He added that having information from the ground is key to effective response. For example, during evacuation for Hurricane Katrina, no attention was paid to how victims would reclaim their property later on. Their concerns were justified, said Dr. Hobfoll, when speculators

took over and sold their property. LT COL Lisa Sayegh, Ph.D., agreed that better information from the field will inform scalability of the response.

Ruth Berkelman, M.D., asked whether communities or populations had the capability of measuring their resiliency. Dr. Ursano responded that community efficacy—that is, the belief among community members that the community has the tools and capacity to respond to crisis—can be measured and addressed. Brian William Flynn, Ed.D., said the mental health community has a wealth of well-grounded knowledge and guidance it can apply to ensure two-way communication and improve mental and behavioral health preparedness and planning. He emphasized that the recommendations represent the DMH Subcommittee's belief that resources exist, but the public health community needs to work together to develop and communicate an integrated plan.

In response to a question from the audience about where to find education on PFA, Dr. Jacobs noted that the term is broadly applied to a variety of situations. The DMH Subcommittee has recommended developing a national program or model of PFA training at the community level.

Dr. Hobfoll reiterated his concern that mental and behavioral health considerations are declining in priority as the NIH and academic institutions shift their focus to the biological bases of mental disorders. Dr. Rose asked the DMH Subcommittee to consider whether the recommendations for research should emphasize the need to address larger social systems with less emphasis on the biological components of mental health.

PUBLIC COMMENT

Susan Chu, Executive Director of the ReadyMoms Alliance, called for expanding awareness about the mental health effects of disaster. She felt bereavement, specifically for the loss of a child, was not addressed in the recommendations. In a public health disaster involving children, PFA will not be effective, she said. DMH Subcommittee member David Schonfeld, M.D., noted that bereavement is acknowledged in the recommendations regarding research.

COL Paula Underwood, Office of the Army Surgeon General, asked how to reach out to the disenfranchised, such as illegal immigrants who avoid seeking care after a disaster. DMH Subcommittee member Elizabeth Boyd, Ph.D., responded that one advantage of PFA is that it enables mental health providers to work within the community to find people who may not be represented by community leaders or have a voice in community governance. DMH Subcommittee member Jack Herrmann, M.S.Ed., echoed Dr. Boyd, saying that addressing planning and preparedness within a community can bring all the stakeholders together, which can help address the needs of the disenfranchised.

COL (Ret) S.J. Whidden, M.D., Ph.D, from Tetra Tech, Inc., said his institution has developed a Public Health Vulnerability Assessment tool to identify vulnerable populations, map their locations and concentrations at the county level, and determine whether State and local response organizations are addressing issues such as preparedness, mitigation, and resilience.

DISCUSSION

Dr. Rose moved to approve the recommendations of the DMH Subcommittee, and Dr. James seconded the motion. Ms. Carlin offered a friendly amendment that the word “accessible” be added to Recommendation 8. Dr. Dodgen clarified that the DMH Subcommittee would develop a two-year implementation plan for the recommendations that would include periodic reporting to the Board for input and progress updates. The implementation plan would include sequencing of the action steps. He asked for more feedback from the Board members on prioritization and sequencing.

Dr. Quinlisk asked Board members to communicate their feelings about prioritization of the recommendations directly to Dr. Dodgen. She also asked that, once the DMH Subcommittee identifies the order of prioritization, it should seek further input from the Board.

RECOMMENDATION

The DMH Subcommittee’s report and recommendations will be sent to the Secretary of HHS as the recommendations from the NBSB, with one change: the word “accessible” will be added to Recommendation 8 so that it will read “accessible Internet-based communication toolkit.” The definition of the term “environmental scan”¹ will also be added.

WORKING GROUP UPDATE—U.S. GOVERNMENT MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PROCESSES FOR CBRN AGENTS

**John Parker, M.D. (for Patrick J. Scannon, M.D., Ph.D.
Chair, Medical Countermeasure Research and Development Processes)**

Dr. Parker reiterated the charge to the working group, which sought to evaluate effective interagency collaborations toward medical countermeasure research for CBRN agents and identify gaps and redundancies in the Federal research portfolio. Biodefense issues cut across many agencies, primarily DoD and HHS, and while the specific goals of the two agencies may differ, both contribute to national security. The working group interviewed representatives across the Federal government and found many successful efforts to integrate activities in medical countermeasure research across agencies. The group found that the White House and its Homeland Security Council, DoD, and HHS have identified their common goals as well as requirements specific to each entity and are using taxpayer dollars for research efficiently. Dr. Parker emphasized the flow of communication among the agencies and praised the recognition that integration does not

¹ *An environmental scan is a broader search than a traditional literature review of professional and scientific journals. In addition to scholarly work, an environmental scan includes Web-based materials (as well as published pieces) written by Federal and State government sources, national associations, and research institutions. Environmental scans allow researchers to glean information on nontraditional resources and current work appearing outside the usual academic channels.*

mean dilution of the mission. Existing efforts to reduce redundancy in the research portfolio are not perfect but are improving continuously, said Dr. Parker.

Dr. Parker concluded that in recognition of the ongoing efforts across the Federal government to ensure communication across agencies and minimize redundancy in the research portfolio, the working group should stand down.

Discussion

Dr. Quinlisk pointed out that the working group could be reconvened at any time, and no formal vote is needed to stand the group down. She asked that the members of the working group stay abreast of developments in medical countermeasure research and let the Board know whether further attention is warranted.

ACTION ITEM

The Working Group on U.S. Government Medical Countermeasure Research and Development Processes for CBRN Agents will stand down as of this meeting. It will reconvene in the future if needed.

WORKING GROUP UPDATE—MARKETS AND SUSTAINABILITY

John Parker, M.D., Chair, Markets and Sustainability Working Group, NBSB

Dr. Parker presented the charge to the working group, which seeks to identify the barriers that industries face to developing medical countermeasures, identify incentives for participation, and inform recommendations to enhance market sustainability. He described the process of product development from the initial assessment of need through testing, licensure, delivery, and follow up. Agencies across the Federal government play roles throughout the process. For example, the NIH's National Institute of Allergy and Infectious Diseases plays a significant role in basic research; the Biomedical Advanced Research and Development Authority (BARDA) is heavily involved in preclinical development and phase-1 trials; and CDC, Project BioShield, and the U.S. Food and Drug Administration (FDA) take on production and storage.

The working group has identified many of the obstacles to greater industry participation but has been unable to identify effective incentives to encourage more participation. Reliable funding and a predictable return on investment are key concerns for industry. The working group considered alternative models for product development but found none that meet current development and acquisition regulations.

The working group's initial findings are as follows:

- Advanced product development requires dedicated funding. Without increased or at least sustained levels of funding, the underpinning of medical countermeasure development is in jeopardy. While funding for Project BioShield appears to be secure, BARDA needs funding for basic research and advanced product development.

- Multiyear funding signals a commitment from Federal government and enhances the likelihood of longer-term market stability.
- Sustained funding commitments may alleviate industry concerns about making a product for one-time government purchase.

The working group will continue to assess the situation. Dr. Parker said the new administration may be open to revising Federal acquisition regulations in a way that encourages more industry participation. In the future, the working group hopes to discuss with the Board whether HHS or other agencies should educate the public about how development of medical countermeasures differs from other product development and therefore requires a different approach. The group is also considering holding a symposium to gather input from industry representatives on alternative product development models.

Discussion

Andrew Pavia, M.D., asked whether input from industry representatives was gathered at the recent PHEMCE meeting. Dr. Parker responded that the working group should have set up a formal mechanism for gathering input at that meeting but thought of it too late. Dr. Rose pointed out that finding funding for early-stage development has become even more challenging with the recent economic deterioration, and raising money through venture capital firms is almost out of the question.

NATIONAL HEALTH SECURITY STRATEGY

Brian Kamoie, J.D., M.P.H., Director, Office of Policy and Strategic Planning and Communications; Deputy Assistant Secretary for Preparedness and Response, HHS

Mr. Kamoie explained that PAHPA requires HHS to present Congress with a comprehensive National Health Security Strategy every four years that evaluates the challenges to health security and offers a plan to address them. The National Health Security Strategy is required to further the following preparedness goals: integration, public health and medical infrastructure, at-risk individuals, coordination, and continuity of operations. The strategy will address health security at all levels: Federal, State, local, and tribal; the private sector; and individuals and families. Mr. Kamoie said the first strategy will be presented to Congress at the end of 2009 and every four years thereafter.

The guiding principles are a strategy that is transparent; involves collaboration; incorporates lessons learned; and is executable, flexible, balanced, measurable, and realistic. The strategy must include developing benchmarks, standards, and timelines, although Mr. Kamoie noted that measuring preparedness is difficult. The strategy also must include continuous assessments and periodic reviews to evaluate trends and fill gaps. It must be consistent with the existing doctrine of the National Response Framework, the National Incident Management System, and the National Preparedness Goal. In addition, the strategy must include a plan for international collaboration, reflect an all-hazards approach, address all aspects of health, and be comprehensive and coordinated.

To date, HHS has convened a Department-wide working group, with representation from all divisions, that is co-chaired by a CDC representative. It has drafted a framework to guide strategy development. The RAND Corporation will support HHS in this effort. The working group has defined the following terms:

- “Health security” is the protection of the public from health threats having potential large-scale economic or national security implications. Health security is achieved through the application of public health preparedness and medical preparedness.
- “Public health preparedness” is defined as the capability of the public health system, communities, and individuals, to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those whose scale, timing, or unpredictability threatens to overwhelm routine capabilities.
- “Medical preparedness” is defined as the capability of the health care system to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those whose scale, timing, or unpredictability threatens to overwhelm routine capabilities.

Next steps include more extensive outreach and a formal community engagement process to get input on the strategy. Mr. Kamoie hoped to update the Board periodically to solicit feedback on the strategy.

Discussion

Dr. Pavia asked whether HHS would evaluate the capacity for detecting, assessing, and projecting the possible spread of emerging infections. Mr. Kamoie responded that HHS is working with the intelligence community to learn more about mechanisms for risk identification and threat analysis. He said DoD’s material threat determinations provide some guidance, but HHS is seeking input from others as well. The BARDA Strategic Plan will be incorporated into the strategy, and BARDA representatives are evaluating the capacity to assess emerging infections.

Dr. Parker asked how the National Health Security Strategy would remain distinct from any new health plan that might be enacted by the new administration. Dr. Kamoie responded that his office will talk with the new Secretary about the foundation for the strategy and incorporate the new Secretary’s goals. To be executable, the final strategy must be consistent with whatever changes are proposed to the health care system.

Dr. Rose asked whether DoD material threat determinations include economic analyses. Lawrence Deyton, M.D., confirmed that they do include economic consequences.

Mr. Kamoie said that, as with all the requirements put forth in PAHPA, the vision for the strategy is far-reaching and puts public health, medical preparedness, and health security on par with other national strategic initiatives.

DISASTER MEDICINE WORKING GROUP: TELEHEALTH CONSIDERATIONS FOR PUBLIC HEALTH EMERGENCIES AND MEDICAL

DISASTERS

Matthew Minson, M.D.

Dr. Minson, Senior Medical Officer for Strategic Initiatives in ASPR explained that telehealth mechanisms offer an opportunity to marry current technology and tactics to better serve the population in a disaster. PAHPA requires ASPR to develop a telehealth inventory. Dr. Minson posed two fundamental questions to Board:

- Would an inventory or registry of telehealth initiatives and networks that can provide resources for use in preparing for and responding to a public health emergency or disaster be valuable?
- Should the NBSB maintain an ongoing working group or committee to address the greater strategic advisory considerations that would contribute to a national strategy for telehealth?

Assuming that an inventory would have value, Dr. Minson asked that the NBSB's Disaster Medicine Working Group consider the following questions over the long term:

- What is the optimal role of the Federal government in developing and/or housing a telehealth inventory?
- Should the telehealth inventory reside within a Federal agency or program, a public-private partnership, a private organization, or some other entity?
- If the telehealth inventory resides outside the Federal government, should the Federal government have an administrative, oversight, programmatic, or other role in its ongoing maintenance?

Dr. Minson added that victims of disasters such as Hurricane Katrina could have benefited if existing technology had been configured, for example, to establish and identify evacuees in the system sooner; track them individually; link them to resources for consultation, follow up, and definitive health care; and facilitate epidemiological investigation.

Federal Health Architecture (FHA) Program

Craig Miller, FHA Program Advisor, described the creation of the Office of the National Coordinator for Health Information Technology, HHS, and its relationship with the American Health Information Community, the Health Information Technology Standards Panel (HITSP), the Certification Commission for Health Information Technology, and the Nationwide Health Information Network (NHIN). He explained the role each plays in identifying priorities in health information technology (HIT), developing use cases (i.e., test scenarios), harmonizing HIT standards, certifying HIT products, and creating a framework that links all the products together.

Mr. Miller likened the HIT development process to building a railroad system: while one body identified the technical standards and specifications, another was needed to link together the tracks. NHIN is the latter—a mechanism for linking together HIT systems to create a national network of networks that enable health information exchange.

Mr. Miller outlined progress on several HIT issues related to emergency care and telehealth, including use cases, HITSP interoperability specifications, and NHIN service functions. Among the NHIN services finalized are the ability to discover (identify) patients from across multiple health settings and exchange health information using a pseudonym to protect a patient's identity.

Access to more patient information during a disaster or emergency would enable providers to improve the overall quality, efficacy, and safety of patient care. An efficient health information exchange system also would pave the way for better continuity of care. It would improve situational awareness, enabling public health personnel to monitor population health and alert providers about concerns. Better situational awareness would improve planning and management.

NHIN would serve as the common language that supports effective health information exchange. It would be a network of networks, knitting existing networks together so that they can transfer information reliably and securely via the Internet. Mr. Miller described NHIN as analogous to our phone system: individuals have different service providers, but nothing prevents a Verizon customer from calling an AT&T customer. NHIN would provide the same fundamental framework to link together existing HIT systems.

Federal agencies face unique challenges linking their HIT systems to non-government systems, and the FHA program is coordinating Federal participation in NHIN. Four opportunities to advance the use of telehealth mechanisms in emergency response situations have been identified within the Federal government:

1. The National Disaster Medical System, for example, allows users to create local computer networks on site during a disaster and to create electronic health records for patients as they treat them. NHIN would offer an opportunity for the clinicians providing patient care on site to get patient information from hospitals, pharmacies, etc., at the point of care and to send the information about a patient's on-site treatment to the hospital, long-term care facility, or other facility where the patient is transferred.
2. Through NHIN, links could be established that allow public health systems to identify possible public health concerns and notify providers. For example, when clinical information from a patient's electronic health record, such as symptoms, corresponds with a public health alert, the provider would be notified immediately. The FHA program has already initiated discussion with CDC on this potential use.
3. CDC's BioSense system collects patient information in a confidential manner from public health organizations that allow public health authorities to evaluate population health trends. With NHIN, BioSense could connect to laboratories, hospitals, pharmacies, and clinics to gather more granular data on routine care that would improve situational awareness.

4. NHIN could improve planning and response by helping users better understand what resources are available (e.g., open beds), where those resources are positioned, etc., with information that is updated as conditions evolve.

To achieve these goals, Mr. Miller said, a telehealth inventory is needed to get a more thorough understanding of the people, systems, and resources available to support disaster response. It would serve as a basis for the network of networks. Over time, Mr. Miller suggested, the registry could evolve into a more granular database or registry.

Mr. Miller summarized the keys to success in health information exchange as follows:

- Focus on implementing basic emergency capabilities, such as identifying and tracking patients across different settings and providing critical, relevant data, such as patient allergies.
- Leverage existing HIT to enhance biodefense.
- Recognize that many challenges to health information exchange are not technical but legal and political, such as sharing information across States and patient concerns about confidentiality.
- Ensure collaboration among government entities and the private sector, recognizing that much of the information needed to improve HIT resides in the private sector.

DISCUSSION

Dr. Cantrill pointed out the lack of good research studies demonstrating the benefits of telehealth mechanisms. He raised concerns about clinicians being overwhelmed with information if it cannot be presented in a succinct fashion. Dr. Minson countered that in disaster situations, the health care provider or researcher generally has an incomplete picture of the event and the patient's history and course throughout the system, and technical advances could allow the provider to identify and track that patient and their history and outcome as he or she moves on through definitive care to discharge and disposition. Dr. James said he would prefer having too much information over having too little, especially if a system allowed more rapid exchange of key data, such as medications a patient is taking.

Dr. Rose added that larger patient privacy concerns have yet to be fully resolved. Dr. Minson noted that during Hurricane Katrina, there were required exemptions from the Health Insurance Portability and Accountability Act (HIPAA). He added that patient privacy is an issue NBSB could deliberate on in the context of telehealth strategy, and he recommended that ethics be a primary consideration. Additionally he recommended Nancy Kass, Sc.D., of Johns Hopkins Bloomberg School of Public Health, as someone familiar with such disaster medical considerations.

American Telemedicine Association

Jonathan Linkous, Chief Executive Officer of the American Telemedicine Association (ATA), explained that "telemedicine" can be defined liberally to include a wide range of methods for providing medical services over a distance. Radiologists, for example, use

telemedicine to read and interpret images off-site. Telemedicine may also be referred to as use of devices, such as pacemakers, that are monitored remotely, often by a private company. The Department of Veterans Affairs has prioritized the use of home telehealth devices to monitor vital signs among patients with chronic disease and transmit the data to nurses.

Mr. Linkous said the fields of public health and medicine have been estranged, but telemedicine can be the link that brings them together, with HIT acting as the backbone to facilitate the link. The biggest barrier to using telemedicine is the lack of knowledge about existing telemedicine mechanisms. His organization has discussed increasing the role of telemedicine with CDC, among others, and has support from the Federal Communications Commission, which is seeking to establish broadband networks in rural areas. Through a four-State demonstration, the Southern Governors' Association determined the biggest hurdle to overcome was linking existing networks.

Mr. Linkous pointed out that using telemedicine effectively requires that emergency responders at the local level know what tools are available in advance of an emergency. ATA has begun developing an inventory of telehealth networks, but a national network is needed to facilitate exchange not just of patient health information but also of available medical services. The Medical Disaster Resources Network (<http://www.mdrn.us>) is a refinement of the ATA's inventory.

DISCUSSION

Mr. Linkous noted that during disasters, most States suspend their interstate licensure requirements, which facilitates resource sharing. In his experience, companies with proprietary resources have been willing to get involved to assist in disaster response, as long as Federal entities are willing to work with the private companies to do so. Dr. Minson added that the Emergency System for Advance Registration of Volunteer Health Professionals carries provisions for funding within the Hospital Preparedness Program grant to facilitate emergency credentialing of health care providers. He added that existing mechanisms should be incorporated into telehealth strategies to eliminate confusion or duplication.

The level of granularity of a proposed telehealth inventory remains open to interpretation. Dr. Minson stressed that ASPR seeks advice on such issues, including how to constrain the inventory to mechanisms used for disaster response. Efforts are underway in the private and academic sectors, but a common infrastructure is needed to link all the efforts together.

Dr. Minson clarified that the format and length of the proposed inventory remains undetermined, and the inventory would form the basis for a broad national strategy for use of telehealth. He hoped that the NBSB would 1) confirm the need for a telehealth inventory and 2) agree to advise ASPR in developing a strategy by bringing together the relevant experts and stakeholders. Dr. Minson added that several groups have taken on the task of creating an inventory; he did not want to prescribe to the NBSB how to address the issue but said evaluating the concept of using telehealth networks during a

disaster, as mentioned by Dr. Parker, would be a reasonable place to start. It is important that the inventory be constructed with an understanding of how it would be used as part of a larger strategy.

Under PAHPA, ASPR was charged with reporting a telehealth inventory, Dr. Minson said, and initial efforts revealed that various Federal agencies had conducted their own telehealth initiatives and evaluations. With rapidly changing technology, any inventory would quickly become obsolete unless it was to be updated periodically. A telehealth strategy would determine how the inventory would be maintained and updated. The complex challenges of creating an inventory have prevented ASPR from completing a thorough Federal assessment.

Dr. Berkelman suggested including the networks developed by academic health centers in the inventory, noting that they are often tied to State entities. Mr. Linkous agreed but cautioned against trying to create a comprehensive inventory because of the rapid pace of change. For its inventory, ATA is focusing on gathering a few key points of information that will facilitate connection. Dr. Pavia noted that the term “inventory” represents an outdated concept; in reality, ASPR is seeking a dynamic database. He added that many of the so-called networks are not really functional, and he felt Mr. Miller’s description of the existing level of interoperability overstated the case. Dr. Pavia urged ASPR to seek advice from people working on the cutting edge of informatics.

Dr. Rose supported the concept of a telehealth strategy. He posited whether standards could be developed to enable users to query other networks openly in times of disaster. On the other hand, he said, privacy concerns must be addressed. A system should allow connectivity and rapid access but also protect privacy outside of an emergency.

Dr. Berkelman raised concerns that developing an inventory would require a heavy investment but provide little direct benefit, and would likely be outdated before completion. Mr. Linkous said ATA is struggling with questions of an inventory’s capabilities, cost-effectiveness, and privacy protections.

Dr. Parker felt that the NBSB should not take inventory of existing tools nor tell local providers how to use their tools during a disaster. He argued against centralizing control of telehealth and said a universal electronic medical record format that could be accessible in an emergency would be a better use of time and resources. Dr. Linkous reiterated the need to help local responders identify medical resources, providers, and capabilities available to them in times of emergency, which may lie outside their local region. Dr. Parker countered that local responders already know how to reach beyond their immediate resource base to access additional services.

Mr. Linkous pointed out that, in the case of mass evacuation, as during Hurricane Katrina, local responders are not able to identify resources far beyond their local, State, and regional scope. Dr. Quinlisk said the Board seeks to have the biggest possible impact on disasters occurring across the United States. She asked whether the inventory and

strategy would focus only on events like Hurricane Katrina at the expense of more common types of disaster.

Dr. Minson noted that a recent Institute of Medicine workgroup considered the use of telehealth mechanisms to assist in supporting point-of-delivery systems (PODS). The ability to conduct more screening and consultation remotely could magnify the capacity of the PODS in some situations.

Mr. Linkous described two real events in which better situational awareness would have helped providers identify and share needed information more quickly. Dr. Quinlisk pointed out that good communication remains a challenge during any disaster, despite sophisticated communications technology. She felt a telehealth inventory would not necessarily improve communication. To the contrary, Mr. Di Rienzo stated that an inventory would be a logical first step in enabling public health professionals, health care providers, and others to capture data, incorporate it into response efforts, and use it to improve future efforts. He also added that of equal importance to telehealth/telemedicine back-end system capabilities is the ability to accurately capture and track the patient, the patient's environment, attending front-line resources (e.g., emergency medical technician, clinician, pharmacist), and support resources (e.g., devices, supplies, medications) from the first point of contact until discharge. Much of this tracking can be accomplished via bar code imagers or other data-capture technologies.

Dr. Grabenstein offered his perception of the minimum capabilities that a telehealth inventory function should provide:

- Access to resources needed when providing care for displaced people (e.g., access to vaccination records for children who evacuated to Texas from Louisiana during Hurricane Katrina)
- A mechanism for identifying health care providers or facilities outside the affected area that can provide assistance
- The ability to exchange and integrate information among health care providers, emergency responders, and public health officials to better understand the disaster

Dr. Minson said these three capabilities could and actually do constitute the basis of a strategy.

Dr. Dretchen noted that tracking patients and exchanging information differs significantly from remote consultation. Dr. Minson said he sees those capabilities as interrelated.

Dr. Cantrill said he is skeptical about the promise of telehealth because of the lack of evidence but felt that NBSB could look at potential solutions and identify areas where more research is needed. Dr. Pavia supported the idea that NBSB identify the questions that need to be addressed about telehealth, gather opinions from experts in the field, and advise ASPR on whether to pursue a telehealth inventory and strategy. Dr. Minson asked the Board to set aside the debate regarding the necessity of a telehealth inventory

(because PAHPA mandates that ASPR address one, regardless) and focus on whether it will advise ASPR on crafting a national telehealth strategy.

Dr. James asserted that the issues under discussion are of sufficient importance that the NBSB should assign the topic to the Disaster Medicine Working Group for further evaluation. Board members agreed unanimously on the following:

ACTION ITEM

The Board will charge the Disaster Medicine Working Group with convening a task force to advise the Board in the development of a strategy for the use of telehealth and its applications to enhance the care provided in a public health emergency and medical disaster setting.

Dr. Cantrill noted that the Disaster Medicine Working Group is already conducting a literature search on telehealth, which will aid in identifying subject matter experts who should be consulted. Dr. Quinlisk proposed and the Board agreed to the following:

ACTION ITEM

The Disaster Medicine Working Group will identify strategic telehealth issues for consideration by the Board, create a broad outline for addressing the issues, and identify experts who should be consulted and engaged. All Board members are welcome to take part in the Disaster Medicine Working Group discussions.

The below public comment was submitted to the NBSB after the public meeting:

Captain Leigh Sawyer, D.V.M., M.P.H.
Executive Director, National Biodefense Science Board
U. S. Department of Health and Human Services

Patricia Quinlisk, M.D. M.P.H.
Chair, National Biodefense Science Board
U. S. Department of Health and Human Services

Public Comment re: Telehealth

Dear Captain Sawyer, Dr. Quinlisk, and Members of the Board,

I appreciate this opportunity to comment on the “Telehealth Considerations for Public Health Emergencies and Medical Disasters” (Telehealth) presentation at the meeting of the NBSB board Tuesday, November 18, 2008.

My initial reaction to the Telehealth presentation is one of caution. On its face, having access to medical information that can be updated and follow a patient during a disaster seems like a good idea. My concerns derive from considering the some of the possible unintended consequences of such a policy. Although Telehealth may have an important

role, I would submit that these unintended consequences must be considered and addressed before implementing such a system.

My main concern is that such a system would increase the chasm between the “haves” and the “have nots” in the U.S. Specifically, Telehealth could negatively impact the poor and the working poor because these individuals would be less likely to be covered by the Telehealth network and would therefore be disadvantaged in an emergency. At the same time, anecdotal evidence of the evacuations after the hurricanes in 2005 suggests that this is exactly the population who would be most in need of evacuation and on-scene medical assistance in a disaster.

In addition, some people might be hesitant to participate in such a system. Undocumented workers are one group that comes to mind, but other groups might also be resistant to the idea of a Telehealth network. Consider that the well-known Tuskegee Syphilis Experiment (1932-1972) has had implications for the ways that African Americans perceive health care in the U. S. since the details of the “experiment” became public. In the “right to die” debate that took place after Dr. Jack Kevorkian became a household name, African American groups expressed reluctance to support legalizing assisted suicide, an act that on its face seems like a completely private decision, for fear that physicians would apply more than one set of standards in approving the decision to terminate a patient’s life. Given this background, some historically disadvantaged segments of U.S. population might consider the Telehealth network as a way of stratifying who to help first in a disaster.

Perceptions among members of the general public are also important. Concerns about whether information is made available to other organizations, e.g., to insurance companies, have resulted in some individuals being hesitant to be tested for diseases such as HIV/AIDS. I would therefore submit that it would be important to ensure that all segments of the population feel comfortable in providing access to their health data if Telehealth networks are adopted.

Lifesaving information is critical in responding to disaster situations. It is important, however, that that information does not privilege one group over another. The social challenges of such a system must be addressed early in the process.

I genuinely appreciate the opportunity to express my concerns to the board.

Sincerely,

Janis E. Johnston

ENHANCING NATIONWIDE BIOSURVEILLANCE FOR HUMAN HEALTH
CAPT Daniel M. Sosin, M.D., M.P.H., FACP, Director, Biosurveillance
Coordination Unit, Coordinating Office for Terrorism Preparedness and
Emergency Response, CDC, HHS

Dr. Quinlisk prefaced CAPT Sosin's comments by saying that the Board had organized a working group to address biosurveillance, but that group has deferred to the CDC's biosurveillance efforts. CAPT Sosin explained that Homeland Security Presidential Directive (HSPD) 21 called for creating a group to lead interagency efforts to establish a national biosurveillance system for human health. He referred to the latest draft of the National Biosurveillance Strategy for Human Health and the efforts of the Biosurveillance Coordination Unit to integrate the strategy into the Department of Homeland Security's larger biosurveillance efforts.

CAPT Sosin noted that the strategy will include all-source, relevant, accurate, and timely information that will help governments, health care providers, businesses, and individuals make decisions about health emergencies. It will improve horizontal and vertical information sharing, enhance capability through shared responsibility, integrate related initiatives, and set priorities for limited resources. The scope of biosurveillance is defined in HSPD-21 and encompasses the science and practice of managing health-related data and information so that effective action can be taken to mitigate adverse health effects from urgent threats.

The strategy is required to address case and cluster detection, signal validation, event characterization, notification and communication, and quality control/improvement. It is intended to address gaps in access to digital information to inform situational awareness, skilled workforce capacity, effective information-sharing mechanisms, and health intelligence. All levels of government will be asked to contribute to filling these gaps.

The guiding principles for planning are as follows:

- Build on current capabilities and relationships
- Respect multi-organizational and multidisciplinary perspectives
- Ensure value for stakeholders
- Ensure protection of rights and authorities

The Biosurveillance Coordination Unit is undertaking three activities: development of the national strategy, establishment of a National Biosurveillance Advisory Subcommittee (NBAS), and development with CDC of biosurveillance priorities and an operational plan. The group will also coordinate input from stakeholders across government, although it has yet to determine how it will engage the private sector. A final draft for public consideration will be available on December 15.

CAPT Sosin anticipated that the strategy would enable stakeholders (i.e., contributors to and users of national biosurveillance) to see their roles clearly and to understand how they can contribute to fill gaps. He presented six priority areas addressed by the draft strategy and asked for input from the Board members:

Electronic Health Information Exchange

- Create nationwide capability for health information exchange
- Strengthen surveillance processes and notifiable disease reporting mechanisms
- Strengthen biosurveillance communications in health care
- Address health information privacy, security, and use considerations
- Establish a governance body to guide electronic health information exchange

Electronic Laboratory Information Exchange

- Ensure the electronic management and exchange of laboratory test orders, specimens, and results information
- Ensure usable laboratory information is electronically combined with clinical and epidemiological data
- Create a governance structure for electronic laboratory information exchange
- Ensure interoperability and collaboration across human-health-relevant laboratory domains

Unstructured Data

- Define and evaluate options for the use and management of unstructured data
- Develop the capacity to collect and utilize unstructured data for biosurveillance purposes
- Promote implementation and use of information products and technologies that utilize unstructured data most effectively

Integrated Biosurveillance Information

- Define requirements for multi-level situation awareness monitoring and reporting
- Establish a nationwide capability for integrated biosurveillance information management and exchange
- Create a collaborative environment for the sharing of situation awareness information and health intelligence
- Provide technical assistance and support State and local health departments to integrate biosurveillance information products and processes

Global Disease Detection and Collaboration

- Strengthen partnerships and leverage resources of U.S. government and non-government partners
- Adopt a risk-based approach to focus efforts in areas of greatest vulnerability, need, and impact
- Build in-country public health facilities and expertise in support of

International Health Regulations 2005

- Support efforts to connect the worldwide “network of networks” to foster more rapid information sharing and earlier detection

Biosurveillance Workforce of the Future

- Assess current biosurveillance workforce capability, identify gaps, and articulate needs
- Ensure a competent biosurveillance workforce
- Develop competitive strategies to recruit and retain an effective biosurveillance workforce
- Establish a governance body for biosurveillance workforce

CAPT Sosin said that the purpose of the NBAS is to provide biosurveillance advice to the Federal government and guide the development of the National Biosurveillance Strategy for Human Health. It is comprised of 33 prominent public and private biosurveillance stakeholders and contributors who have already established eight task forces and identified subject matter experts to address specific areas of concern. Each task force will develop recommendations by December 15, which will subsequently be consolidated by a steering committee, and a final report with recommendations will be produced by March 15, 2009. NBAS is an opportunity to bring together national and international leaders in surveillance.

The CDC has identified the following short-term goals:

- Extend outreach about the National Biosurveillance Strategy for Human Health and update the strategy annually.
- Address annual assessments and recommendations of the independent Federal advisory committee.
- Operationalize the National Biosurveillance Strategy:
 - Map global efforts to the strategy and track progress
 - Establish governance
 - Support full stakeholder contributions

Discussion

Dr. Parker asked whether the strategy faces political as well as scientific hurdles to implementation. CAPT Sosin responded that the strategy would involve significant new dollars and resources, but if biosurveillance is truly a national priority, then investment is needed. CAPT Sosin added that the need for biosurveillance has been recognized and the strategy serves as a map that addresses areas of interest to the next administration. However, the effort requires a champion to cement its place as a significant national priority and identify resources. CAPT Sosin added that investment is significant, because at the local level, dollars are shrinking.

Dr. Pavia asked whether the strategy will address diminishing laboratory capacity, noting that both the number of microbiology laboratories and the number of specimens

submitted to laboratories are decreasing. CAPT Sosin said the issue falls within the scope of NBAS but none of the existing task forces have subject matter experts who can address the broad question of laboratory capacity. Dr. Berkelman added that at a recent meeting of the Infectious Diseases Society of America, participants debated whether microbiology laboratories were needed, given the poor quality of the laboratories. She suggested Centers for Medicare and Medicaid Services reevaluate how it reimburses for the public health and biodefense community for accurate and rapid clinical diagnosis of serious illness caused by infectious diseases.

CAPT Sosin said the challenge to NBAS is setting manageable boundaries, as the entire health care system could fall within its scope. It is attempting to identify other entities and existing recommendations that fit into the National Biosurveillance Strategy and are critical to effective biosurveillance.

Dr. Rose pointed out that the Google search engine was used to track the number of people who used the Internet to find information about influenza. He asked whether NBAS has considered repurposing existing tools for biosurveillance. CAPT Sosin responded that the group needs to consider new technologies and data resources. He said the Google Foundation has indicated an interest in addressing infectious disease globally and suggested the private sector may be able to evaluate information search patterns to identify early indicators of patient behavior.

Dr. Parker asked whether the Board could provide input on privacy issues. He said hospitals are willing to engage in data collection and integration efforts if they do not have to pay for the technology to support it. He asked what States and health care organizations receive in return for cooperating with national biosurveillance efforts. CAPT Sosin said existing systems are effective at gathering raw data but not in sharing the information effectively. He said a system is needed that addresses sovereignty and privacy issues, facilitates information exchange, and supports the ability to conduct analysis at the local level. The quid pro quo, said CAPT Sosin, is that local organizations will receive useful information on which they can base their actions. Hospitals are among those feeling the economic pinch, he said, and he agreed with Dr. Parker that an approach is needed that does not overburden the hospitals.

WORKING GROUP UPDATE—PANDEMIC INFLUENZA

Andrew T. Pavia, M.D., Chair, Pandemic Influenza Working Group, NBSB

Dr. Pavia noted that the working group had met earlier in the morning, so the slides were not completely up to date. He reiterated the mission of the group and said any Board member is welcome to join at any time. In recent meetings, the group has learned about strategic planning processes within and between agencies and the role of advisory bodies. In determining what the working group can do to assist HHS and ASPR, the group has focused on exploring critical issues around prepandemic vaccination. The key questions are whether the United States should sponsor research on prepandemic influenza vaccination and whether the current strategy for stockpiling pandemic influenza vaccine should be revised given the increased capacity to manufacture vaccine (especially for H5N1 virus).

Dr. Pavia explained that a prepandemic vaccine would protect against viruses with the potential to cause pandemic influenza. It could be produced during gaps in annual vaccine production now and year-round in the future and stored in bulk for maximum shelf-life and flexibility of formulation. How well a prepandemic vaccine would match the pandemic strain—and the efficacy of the vaccine—are not yet known. It is not clear when prepandemic vaccine would be used, although one approach would be to use it once a pandemic is declared to have begun.

By comparison, a pandemic vaccine is intended to protect against the specific, identified pandemic virus but can only be produced once the pandemic occurs and the strain is identified. The production lag time, product certification, and potency assays are issues of concern.

Dr. Pavia pointed out that the landscape has changed dramatically. The first generation of H5N1 virus vaccines were narrowly focused, type-specific, and provided homologous immunity. However, the use of new oil-in-water adjuvants boosts the immunogenicity of H5N1 virus vaccine. Recent data suggest that two or three doses of vaccine-plus-adjuvant may induce heterologous immunity so the vaccine can respond to an evolving virus strain. Priming the body with an adjuvant, Dr. Pavia said, appears to facilitate a booster response such that individuals can be primed with a less specific vaccine.

Dr. Pavia said the traditional plan for pandemic vaccination begins with identification of the pandemic, followed by production of the vaccine, followed by administration of two doses of vaccine. Other strategies involve vaccinating identified subgroups with two doses of a vaccine that can provide partial cross-protection followed by a third dose during the pandemic.

To date, BARDA has contracts with manufacturers to produce vaccines of different clades. The stockpile of influenza vaccine is growing, and the number of doses depends on whether it is given alone or with adjuvants. By the end of 2008, the stockpile will have enough vaccine to cover 21.5 million people with a two-dose course or potentially up to 250 million people with vaccine-plus-adjuvant.

A number of policy questions must be addressed, and the Board could catalyze the dialogue by bringing in people with the necessary expertise. For example, should some of the existing H5N1 virus vaccine in the stockpile be used to vaccinate some populations in advance, and, if so, who should the target population(s) be? Among the many scientific questions to be addressed is the safety of prepandemic vaccination for an unknown threat.

Dr. Pavia asked for the Board's approval to develop a working group focused on prepandemic vaccination that includes experts on adjuvants and influenza vaccine, those with experience in threat modeling, ethicists, lawyers, safety experts, and people who have addressed similar situations (e.g., individuals involved in swine influenza vaccination). The new group would hold a workshop to identify the specific questions to

be addressed and exchange the latest data. It would identify the decision points for expanding or contracting prepandemic vaccination and determine how decision making can evolve as the situation changes.

Discussion

Bonnie Richter said she has already been involved on an advisory board for prepandemic vaccination. She said the Department of Energy has received a pandemic planning checklist from the White House asking whether the Department has identified which employees would get prepandemic vaccination and whether the Department has purchased prepandemic vaccine. The White House document exposes a disconnect between the expectations of planners and the uncertainty in the field about prepandemic vaccine. Dr. Pavia responded that he did not think there was a prepandemic vaccine to purchase at present. However, he did suggest that the Department of Energy consider asking whether its employees would participate as research subjects to evaluate the safety of prepandemic vaccine and that the Department consider who might need to get prepandemic vaccine.

Bruce Gellin, M.D., pointed out that focus has been on identifying who should receive the prepandemic vaccine, not how to administer it. He confirmed that no such vaccine is available for purchase. He said the more pressing question is when to administer prepandemic vaccine.

Mr. Di Rienzo asked how the efforts of the various existing working groups could be captured to inform questions about prepandemic influenza and where issues such as screening, diagnosis, and surveillance fit in. Dr. Pavia said BARDA is working on diagnostic tools for H5N1 virus and other sera types. Another concern is the lack of new antiviral drugs in pipeline, he added. Dr. Pavia said that the Board must decide which issues to tackle while still staying aware of all the concerns. He said no other group appears ready to address the question of prepandemic vaccine, and the Board offers a forum that allows for important public input.

Dr. Rose raised concerns about the lack of models to predict how prepandemic vaccine would work, especially given limited safety data. Dr. Pavia said such questions would be the focus of the new working group. Dr. Rose reiterated the importance of having individuals with experience modeling threats on the working group.

ACTION ITEM

The Board agreed unanimously that the Pandemic Influenza Working Group may develop a subgroup that includes invited experts to address science and policy questions surrounding prepandemic vaccine.

WORKING GROUP UPDATE—PERSONAL PREPAREDNESS

Ruth L. Berkelman, M.D., Co-Chair, Personal Preparedness Working Group

Dr. Berkelman said the working group was established in June 2008 as a result of heated discussion when the Board learned that HHS was exploring a plan to give information to

the public and health care providers on maintaining antibiotics at home. The group has expanded its focus to consider not only home stockpiling of prescription antibiotics but also MedKits. In addition, the Working Group is discussing other issues that it may want to focus upon: These include public communication, education, and outreach; professional outreach; operational research; existing personal preparedness efforts in the United States and abroad; and long-term approaches to personal preparedness. The working group includes all of the voting members of the Board.

In August, the group provided input into a second letter from the Board to the Secretary on home stockpiling. In October, it presented the Board with three recommendations on collecting operational research from programs that involve pre-positioning antibiotic countermeasures in homes. Via conference calls with HHS and DHS representatives, the group has learned that although the Strategic National Stockpile contains medical countermeasures for a biological attack, current mechanisms for distributing them may be too slow, resulting in the need for Federal agencies and others to evaluate alternatives such as home stockpiling and rapid distribution through the U.S. Postal Service.

The working group is currently reviewing an HHS question-and-answer document on home storage of antibiotics. It plans to consider the issues surrounding pre-positioning of antibiotics or providing MedKits for first responders. It also hopes to assist HHS with implementing personal preparedness programs and policies, particularly by identifying where the government can help communities close gaps in preparedness. Dr. Berkelman emphasized that public engagement on preparedness issues is very helpful to HHS and others.

Dr. Pavia added that the recommendations of the DMH Subcommittee resonated with the Personal Preparedness Working Group. Their report reminded the group to consider what other elements of preparedness should be strengthened to ensure community resiliency and efficacy.

WRAP-UP AND FUTURE ACTIVITIES OF THE BOARD

Dr. Quinlisk noted that the new administration will provide the Board with new challenges and opportunities. She summarized the work of the Board during this meeting, reiterating the action items and decisions (see below). Dr. Quinlisk said she would prepare a letter on behalf of the Board thanking HHS Secretary Michael Leavitt for his support and compose another letter offering the Board's service to the incoming Secretary.

Dr. Cantrill added special thanks to CAPT Sawyer and the entire NBSB staff for their support, which has enabled the Board and its working groups and DMH Subcommittee to achieve so much in its first year, and Dr. Quinlisk echoed his statement. CAPT Sawyer, in turn, thanked the NBSB staff for their tireless efforts. She also thanked all of the Board members for their hard work and the guest speakers and invited experts who contributed to the Board's deliberations. CAPT Sawyer reminded the audience that the Board welcomes and encourages participation from the general public. She added that the next Board meeting is scheduled for April 22–23, 2009. Dr. Quinlisk concluded the

meeting by saying she felt the Board's work is already having an effect and will make a real difference to the public's health.

SUMMARY OF RECOMMENDATIONS AND ACTION ITEMS OF THE NBSB, NOVEMBER 18–19, 2008

RECOMMENDATION

The DMH Subcommittee’s report and recommendations will be sent to the Secretary of HHS as the recommendations from the NBSB, with one change: the word “accessible” will be added to Recommendation 8 so that it will read “accessible Internet-based communication toolkit.” The definition of the term “environmental scan²” will also be added.

Action Items

The Working Group on U.S. Government Medical Countermeasure Research and Development Processes for CBRN Agents will stand down as of this meeting.

The Board will charge the Disaster Medicine Working Group with convening a task force to advise the Board in the development of a strategy for the use of telehealth and its applications to enhance the care provided in a public health emergency and medical disaster setting.

The Disaster Medicine Working Group will identify strategic telehealth issues for consideration by the Board, create a broad outline for addressing the issues, and identify experts who should be consulted and engaged. All Board members are welcome to take part in the Disaster Medicine Working Group discussions.

The Board agreed unanimously that the Pandemic Influenza Working Group may develop a subgroup that includes invited experts to address science and policy questions surrounding prepandemic vaccine.

² *An environmental scan is a broader search than a traditional literature review of professional and scientific journals. In addition to scholarly work, an environmental scan includes Web-based materials (as well as published pieces) written by Federal and State government sources, national associations, and research institutions. Environmental scans allow researchers to glean information on nontraditional resources and current work appearing outside the usual academic channels.*