

SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
CLOSED SESSION
June 25, 2012
10 a.m. to 1 p.m.

VOTING MEMBERS PRESENT

John S. Parker, Major General (Retired), M.D., *Chair*
Georges C. Benjamin, M.D., FACP, FACEP(E), FNAPA, Hon FRSPH (by phone)
Nelson J. Chao, M.D., M.B.A.
Jane Delgado, Ph.D., M.S.
David J. Ecker, Ph.D.
Emilio A. Emini, Ph.D.
Daniel B. Fagbuyi, M.D., FAAP, Major (by phone)
Manohar R. Furtado, Ph.D.
Kevin A. Jarrell, Ph.D.
Steven E. Krug, M.D.
Sarah Y. Park, M.D., FAAP
Betty J. Pfefferbaum, M.D., J.D. (by phone)

EX OFFICIO MEMBERS PRESENT

Kay Marano Briggs, Ph.D., Lead for Genetics and Microbiology, Ecosystems Mission Area, U.S. Department of the Interior (*designated by Lori Caramanian*) (by phone)
Bernard L. DeKoning, M.D., FAAFP, COL, Commander, U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense (by phone)
Heather Evans, Ph.D., Policy Analyst, Program and Planning Office, Director's Office, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce (*designated by Dianne Poster, Ph.D.*)
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (by phone)
Sam Groseclose, D.V.M., M.P.H., DACVPM, Associate Director for Science, Office of Science and Public Health Practice, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice (by phone)
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency (by phone)
George W. Korch Jr., Ph.D., Senior Science Advisor, Office of the Principal Deputy, Office of the Assistant Secretary for Preparedness and Response, 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 (by phone)

Richard A. Martinello, M.D., Acting Senior Medical Advisor, Veterans Health Administration, Office of Public Health and Environmental Hazards, U.S. Department of Veterans Affairs (*designated by Victoria J. Davey, Ph.D., M.P.H.*)
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.*) (by phone)
Marc Shepanek, Ph.D., Deputy Chief, Medicine of Extreme Environments, National Aeronautics and Space Administration (*designated by Richard Williams, M.D.*) (by phone)
Amber Story, Ph.D., Deputy Division Director, Division of Behavioral and Cognitive Sciences, National Science Foundation (by phone)
Gwen Tobert, Office of International Health and Biodefense, Bureau of Oceans, Environment, and Science, U.S. Department of State (*designated by Kerri-Ann Jones, Ph.D.*)

OTHER PARTICIPANTS

Susan Gorman, CDC
David R. Howell, ASPR/OPP
Robert Huebner, ASPR/BARDA (by phone)
Lisa Kaplowitz, ASPR/OPP
Michael Kurilla, NIH/NIAID
Bert Maidment, NIH/NIAID (by phone)
Michael Mair, FDA
Scott Nystrom, ASPR/OPP (by phone)
Joanna M. Prasher, ASPR/OPP (by phone)

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD

CAPT Charlotte D. Spires, D.V.M., M.P.H., Diplomate ACVPM, NBSB Executive Director
Jomana Musmar, M.S., Senior Management Analyst
Anissa Addison, Executive Assistant

CALL TO ORDER, ROLL CALL, AND CONFLICT OF INTEREST RULES **Charlotte Spires, D.V.M., M.P.H., Dipl ACVPM, Executive Director, National Biodefense Science Board (NBSB), CAPT, U.S. Public Health Service**

CAPT Spires called to order the closed session of the NBSB meeting and reviewed the conflict of interest guidelines. She explained that the documents under discussion for the meeting are pre-decisional; therefore, the Board cannot provide formal recommendations on them to the Assistant Secretary for Preparedness and Response (ASPR) or the Secretary of the U.S. Department of Health and Human Services (HHS).

WELCOME AND INTRODUCTION

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker welcomed the Board members and Ex Officios and thanked them for their participation. He noted that the NBSB shortened its meeting from three days to two (June 25–26) to ensure a quorum for the duration of the meeting.

PHEMCE PRIORITIZATION FRAMEWORK AND IMPLEMENTATION PLAN: STATUS UPDATE

George Korch Jr., Ph.D., Senior Science Adviser, ASPR, HHS

Dr. Korch explained that the implementation plan will describe how to achieve the goals and objectives of the strategic plan. Input from members of the Board into the strategic plan has been tremendously helpful in crafting the strategy. The process of developing a prioritization framework is evolving, and the goal is to publish the PHEMCE Strategy this summer and Implementation plan in the fall. Dr. Korch explained how the Office of the ASPR and the PHEMCE will select prioritization tools; the implementation plan will include the priorities themselves.

A central tenet that has complicated development of the PHEMCE SIP from the beginning has been the lack of a clear end-state—that is, what does preparedness look like? What constitutes appropriate preparedness has not been well-defined for any specific threat or hazard. However, the Federal partners have been meeting in small and large groups to articulate what near- (less than three years), mid- (three to five years), and long-range (more than five years) actions are necessary to improve preparedness and response capabilities across identified threats. Because the PHEMCE must address not only identified threats but also emerging threats, it is moving from a threat-based assessment to a capability-based assessment—that is, determining what capabilities are needed to respond to a variety of threats as they arise. All of the HHS partners are then expected to align their programs with the PHEMCE SIP strategies, in coordination with non-HHS Federal partners. Dr. Korch said that progress towards these goals will be evaluated frequently. The actions and plans for developing and delivering medical countermeasures (MCMs) will be evaluated against the criteria derived by the PHEMCE senior leadership.

Similar to the 2007 PHEMCE SIP, the PHEMCE activities will be centered around “commodity domains,” especially in the later development stages, e.g., anthrax vaccine, smallpox antivirals, and radiological/nuclear therapeutics. Earlier in the development pipeline, partners may focus on multifunctional MCMs.

Unlike in 2007, the 2012 SIP will call out activities needed across the PHEMCE, from requirement setting through delivery, concept of operations, and clinical benefit guidelines, particularly to support the high-priority commodity domains. Dr. Korch noted that the focus on commodity domains does not conflict with the criterion to explore multifunctionality, e.g., the development of vaccine platforms that could be used for multiple conditions. In creating the implementation plan, the PHEMCE will identify the preparedness gaps that affect the commodities, discuss how the PHEMCE should

prioritize among commodities, and determine the programs and activities that HHS should pursue over the next three to five years.

In discussing the decision support tool results, it was pointed out that existing programs and activities reflect priorities previously identified. Therefore, efforts are underway to catalogue all of the existing programs and activities in the context of the implementation plan. The ASPR will review the results and identify gaps across programs.

It was determined that the originally proposed prioritization framework discussed with the Board identified some areas of consensus but ultimately was too unwieldy and difficult to implement, said Dr. Korch. Instead, each PHEMCE partner will describe the priorities of its programs and how they were selected, in light of the six prioritization criteria. The SIP Steering Committee will review the input and determine the most effective mechanism for prioritization. That committee plans to reach consensus by mid-August and present the draft implementation plan for review by NBSB members and the Enterprise Executive Committee. Then, the draft will be reviewed by the Enterprise Senior Council and, ideally, cleared by the HHS Executive Secretariat for dissemination to the public in early fall.

DISCUSSION

Dr. Korch assured members that the PHEMCE leadership is engaged with the security and intelligence communities, which are reassessing threats and identifying any emerging issues. Recognizing that threats are changing, the PHEMCE strategy aims to build in adaptability to respond to whatever arises. Dr. Korch also expressed confidence that the PHEMCE SIP is headed in the right direction to meet national security demands.

Dr. Korch pointed out that the priorities of the 2007 PHEMCE SIP remain relevant and that HHS is not asking all of its partners to start fresh in light of a new SIP. The current SIP will focus on ensuring that the PHEMCE has an end-to-end plan. Efforts are underway to determine how well current programs address the important elements of the new PHEMCE SIP and how to address gaps. The PHEMCE is looking at what exists and how to update it to meet the new challenges.

Dr. Emini, noted that refining existing programs is somewhat useful but would be more so in the context of clearly defined endpoints, which are lacking. Also, adding specificity to the implementation plan would contribute to success. Finally, Dr. Emini asked who would evaluate the overall PHEMCE to ensure that programs are integrated and moving the enterprise toward its objectives. Dr. Korch responded that the senior managers will have to reach consensus about the effectiveness of programs and their alignment. He recognized that the process is important in developing a high-quality product.

PHEMCE STRATEGY: STATUS UPDATE

David R. Howell, Ph.D., Executive Director, PHEMCE SIP Steering Committee, Office of Policy and Planning, ASPR, HHS

Dr. Howell reiterated that the 2012 PHEMCE SIP is both an update and an expansion of the 2007 version. The final 2012 strategy portion is now available to the public. As outlined by Dr. Korch, the PHEMCE aims to release the draft implementation plan later this summer. Dr. Howell offered a visual depiction of the SIP that illustrates how each piece feeds into the PHEMCE vision. He summarized the key inputs into the PHEMCE SIP:

- PHEMCE leadership and NBSB member perspectives
- PHEMCE principle players and their priorities
- Changes to the PHEMCE landscape since 2007 (including real-world emergency responses, and new guidance)
- Existing strategies, implementation plans, and other documents (about 17 documents, yielding about 200 elements with strategic relevance)

Dr. Howell highlighted some of the ways the PHEMCE strategy reflects input from the NBSB members, which fell into four categories:

- **Communication and clarity:** Emphasized the validity and importance of threats, simplified language, emphasized the importance of communication across all levels during a response, and expanded list of accomplishments since 2007 in an appendix.
- **Partnerships:** Included importance of addressing first-responder needs, emphasized integration with State and local entities, and noted the importance of user feedback in developing new products.
- **Defining the PHEMCE:** Added plain-language description in summary, added visual depiction of agency roles, and incorporated description of governance structure.
- **Shift emphasis:** Emphasized that innovative solutions must also be efficient and effective.

The PHEMCE strategy includes a list of high-priority threats to national security that may merit investment in MCM development, but Dr. Howell noted that not all threats are equal, and resources can be moved to address shifting priorities. The strategy also describes all of the components that make up the PHEMCE mission. A wheel chart shows how each component aligns with a lead agency(s), non-HHS agencies, and other stakeholders. The strategy describes the PHEMCE governance structure and roles at each level.

The strategy gives a high-level overview of the prioritization framework described by Dr. Korch. The goal is to develop an integrated prioritization framework for PHEMCE investments based on a common vision across PHEMCE mission components. The core principles of the framework are MCMs that limit the adverse health impact of a threat

and contribute to an enduring capability. Priorities are judged primarily by the three major criteria (threat, multifunctionality, and operational capacity).

In conclusion, Dr. Howell described the four goals of the 2012 PHEMCE strategy¹.

DISCUSSION

Dr. Korch explained that HHS and the Department of Defense (DoD) work together via the Portfolio Advisory Committee to align efforts around MCM development where threats overlap in terms of public health and national security. As a result, research and development and manufacturing efforts look better now than they did in the past, said Dr. Korch. The Department of Energy (DoE) focuses more on basic research than product development, but HHS is aware of DoE programs and collaborates with DoE on requirement setting, he continued. The PHEMCE Enterprise Executive Committee includes representatives from numerous cabinet departments and the executive branch.

Dr. Ecker asked whether the PHEMCE could evaluate the current investment in programs and activities that focus either on a specific threat or on multifunctionality and use the findings as the basis for future planning. Dr. Korch responded that following the 2010 MCM enterprise review, the PHEMCE partners are working on five-year budget plans, which provide more detail about investment. As a result, Dr. Korch said, it is clear that the portfolio of the Biomedical Advanced Research and Development Authority (BARDA) is very threat-specific (and reflects more mature products). The National Institute of Allergy and Infectious Diseases (NIAID) has a mixed portfolio, but investment in multifunctionality is increasing. There has been an effort over the past few years to smooth the transition from NIAID research efforts to BARDA needs, and the situation has improved, said Dr. Korch. He projected that investments will likely move toward multifunctionality.

The Strategic Investor approach (similar to a venture capital firm, proposed by HHS and under consideration by Congress) would further affect investment in products that have both commercial and defense or public health applications, said Dr. Korch. Also, HHS is working with academia and manufacturers to develop centers of excellence for flexibility in manufacturing.

Dr. Michael Kurilla pointed out that multifunctionality of products has been a part of NIAID's biodefense research focus since 2007, but now it will be part of the analysis that feeds into decision-making about investments. By way of example, he noted that even within the narrow domain of anthrax vaccine, NIAID researchers have developed temperature stabilizing technologies that could be used with other applications.

Dr. Korch said multifunctionality encompasses the application of a product in other species to reduce the risk of threat (e.g., pandemic influenza). He also said efforts are underway to address multi-drug resistance with novel compounds or by repurposing

¹ For access to the PHEMCE Strategy, please visit <http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Strategy.pdf>

existing products. In addition, said Dr. Korch, there is real promise for development of a universal influenza vaccine as well as increasing capability to manufacture large quantities of influenza vaccine rapidly in the event of a pandemic.

Dr. Delgado said she appreciated the shift from threat-based to capability-based assessment. She raised concerns about communication, particularly in the event of multiple, small, diverse events occurring simultaneously. Dr. Korch said the ASPR oversees the Office of Preparedness and Emergency Operations, which tracks regular events (e.g., hurricanes). The PHEMCE plans for large events but also evaluates smaller events and conducts detailed exercises. Dr. Korch said the PHEMCE relies on partners at the local level to facilitate communication.

Dr. Krug noted that threat assessment is a ‘thorny’ issue; stakeholders and consumers can only assume that the PHEMCE will identify priorities on the basis of ongoing assessment of risk and capabilities. Without knowing the real risk, it is possible that key players may not adequately support needed activities to ensure capability. As pointed out earlier, desired outcomes or endpoints have not been defined. Dr. Krug added that the wheel chart presented by Dr. Howell describing the mission and roles of partners seems complex. In such a complicated structure, everyone involved needs a clear picture of the priorities and the endpoints, or the goals will not be reached, Dr. Krug concluded.

Dr. Korch acknowledged that coordinating efforts across agencies is complicated, but all of the partners want to ensure that efforts underway are relevant and aimed at preparedness. Much progress has been made, but difficulties remain at the transition zones or handoffs between agencies, he said. Also, HHS was not organized to produce, acquire, or disseminate products in the way that DoD and other agencies were. The agency has evolved over the past 10 years, and independent divisions are now working together more closely. Dr. Korch reiterated that the PHEMCE is an enterprise with many moving parts, and he believes it is moving steadily forward, aided by the governance structure and the opportunities for discussion. Dr. Lisa Kaplowitz added that the PHEMCE process works well, and the discussions at the Enterprise Executive Committee are quite substantive.

NEXT STEPS

John S. Parker, Major General (Retired), M.D., NBSB Chair

Dr. Parker asked members to consider how a Board working group should go about critiquing the PHEMCE strategic plan in light of the fact that members have already given substantial input and the implementation plan is not yet available. Dr. Emini said it would be difficult to evaluate the strategic plan without seeing the implementation plan, which likely will flesh out some of the gaps in the strategic plan, and several members agreed. Dr. Krug added that how the PHEMCE intends to assess performance also affects the likelihood that the strategic plan will be realized.

Dr. Parker said that despite the move to create five-year budget plans, funding is provided yearly, and future Federal funding is not guaranteed. The strategic plan does not spell out whether its goals should be accomplished within five years (or along any specific

timeline). Dr. Parker also said the PHEMCE should describe (at least internally) how it will enforce the strategy among the partners.

Dr. Howell noted that NBSB members will have an opportunity to give input on the draft implementation plan. He also noted that goals are categorized as near-, mid-, and long-term, as defined in Dr. Korch's presentation. The draft legislation for the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization includes similar timeframes.

Dr. Howell noted that it is the intention that the implementation plan would have the same level of granularity in terms of specific examples as the 2007 report does. He added that even if the published report does not clearly identify how progress is monitored, the PHEMCE tracks progress with such efforts as the MCM enterprise review and by incorporating Government Accountability Office report recommendations. Dr. Emini suggested the PHEMCE identify how the governance structure will operate to execute the implementation plan. In addition, the SIP should spell out what success looks like and then establish metrics to track progress. Metrics can be qualitative or quantitative, said Dr. Emini; they not only provide guidance but also can be used to evaluate progress in the context of annual budgeting.

ADJOURNMENT

Dr. Parker thanked the participants and adjourned the meeting at 12:50 p.m.