

Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events: Current Initiatives

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ABSTRACT

It is only possible to achieve a resilient community and an integrated, comprehensive, and resilient health system that can respond effectively to a public health emergency through active collaboration, coordination, and shared responsibility among a broad group of public and private stakeholders and the community itself. The Institute of Medicine established the Forum on Medical and Public Health Preparedness for Catastrophic Events in 2007 to provide a neutral venue for dialogue and collaboration among stakeholders in the preparedness field. In the Forum's first year, the members began to address topics such as medical countermeasures dispensing, crisis standards of care, and medical surge capacity. In the past 9 months, the Forum members have expanded their areas of interest in response to current events and national areas of focus. Current topics include individual, family, and community preparedness and resiliency; medical countermeasures from development through dispensing; and the response to the 2009 H1N1 influenza pandemic. Across all of the initiatives undertaken by the Forum, the common element is that they tackle problems, gaps, and future opportunities that can only be successfully addressed if multiple stakeholders work together.

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The vision of a nation that is prepared for and resilient in the face of a large-scale public health threat is built upon the engagement of all segments of society in this endeavor, from government, to private sector, to communities, families, and individuals. It is only possible to achieve a resilient community and an integrated, comprehensive, and resilient health system that can respond effectively to a public health emergency through active collaboration, coordination, and shared responsibility among a broad group of public and private stakeholders and the community itself.

The Institute of Medicine (IOM) established the Forum on Medical and Public Health Preparedness for Catastrophic Events in 2007 to provide a neutral venue for dialogue and collaboration among stakeholders in the preparedness field.¹ The Forum regularly brings together representatives and leaders from local, state, tribal, and federal governments; leaders of professional and business associations; and other stakeholders and key decision makers to address obstacles to the nation's medical and public health preparedness and to explore strategies and solutions that require engagement across sectors, agencies, and organizations. Recognizing the importance of bringing to the table stakeholders who do not traditionally take part in preparedness planning, the Forum has placed special emphasis on including representatives from the private sector and community- and faith-based organizations in its activities.

In the Forum's first year, the members began to address topics such as medical countermeasures dispensing, crisis standards of care, and medical surge capacity.^{2,3} The topic of crisis standards of care was also addressed in a subsequent Institute of Medicine consensus committee report.⁴ In the past 9 months, Forum members have expanded their areas of interest in response to current events and national areas of focus. Current topics include individual, family, and community preparedness and resiliency; medical countermeasures from development through dispensing; and the response to the 2009 H1N1 influenza pandemic. These activities are discussed below. Across all of the initiatives undertaken by the Forum, the common element is that they tackle problems, gaps, and future opportunities that can be successfully addressed only if multiple stakeholders work together.

INDIVIDUAL, FAMILY, AND COMMUNITY PREPAREDNESS AND RESILIENCY

One of the long-term priorities set by the membership of the Forum is enabling a culture shift toward individual, family, and community preparedness and resiliency. This was a major focus of the Forum's workshop on the National Health Security Strategy (NHSS), described in more detail below, and is also a theme integrated throughout the Forum's activities. The other long-term priorities of the Forum are developing a framework of medical and health emergency management, developing a research agenda to improve the evidence base for prepared-

ness and response, and examining information technology for public health emergencies and disaster medical response.

Developing Implementation Strategies for the NHSS

The first NHSS, a congressionally mandated quadrennial strategy for public health emergency preparedness and response, is intended to galvanize efforts to minimize the health consequences associated with significant health incidents.⁵ The vision laid out in the NHSS emphasizes that achieving health security is a responsibility that is broadly shared across society.

In response to a request from the US Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), the Forum convened a workshop in which stakeholders proposed and discussed innovative ideas and strategies for implementing the priorities identified by the NHSS. The workshop was intended to provide input into the Interim Implementation Guide, which was released alongside the NHSS in December 2009, and also the Implementation Plan, which will be released in September 2010.⁶

A central theme in the NHSS is that national health security is built on a foundation of community resilience. It was, therefore, critically important that any conversation about implementing the NHSS include participants from community groups, organizations, and populations not traditionally included in preparedness efforts. Among the workshop panelists were representatives from a nonprofit organization serving families of children and youth with special medical needs; the Evangelical Lutheran Church in America; AARP; the American Academy of Pediatrics; the National Hispanic Health Foundation; and the Tuskegee Area Health Education Center, whose mission is to improve health care in rural and underserved communities in central Alabama.

Workshop participants highlighted the importance of reaching people where they live and tapping into existing social and community networks. For example, communications should be designed using sources that families already use to obtain their information, such as newspapers, television, movies, and other families. Likewise, it is critical to engage individuals and other families in places such as football games, schools, grocery stores, health centers, economic services centers, pharmacies, workplaces, and religious centers. Participants also emphasized the importance of customizing the message and being sensitive to culture, beliefs, language, literacy, socioeconomic level, and special needs. Several participants emphasized that it is important to listen, meet people's needs, and address their concerns first or they will not be focused on what the planner is attempting to convey.

Another idea that resonated among participants was the importance of finding an "honest broker" or "catalyst" who would convene stakeholders in a neutral venue and facilitate the process of improving preparedness in the community. The catalyst may be a prominent and trusted community leader or a dedi-

cated and knowledgeable individual or group from an organization that is deeply trusted by the community.

MEDICAL COUNTERMEASURE DEVELOPMENT AND DISPENSING

Enhancing Medical Countermeasures Products From Discovery Through Approval

With limited commercial markets for most bioterrorism-related medical countermeasures, the government must create incentives to encourage large pharmaceutical and small biotechnology companies to develop the products that are essential to ensure the health of the nation. The medical countermeasures research and development enterprise seeks to create collaborative relationships among government and industry to maximize their respective strengths and capabilities through synergistic relationships that meet national demands while respecting private, governmental, and community needs and goals.

In December 2009, the Secretary of HHS asked ASPR to lead a review of the entire public health emergency medical countermeasures enterprise. In turn, ASPR asked the Forum to host a workshop focused on identifying and discussing innovative strategies to enhance products from discovery through approval. This workshop was cohosted by the IOM's Forum on Drug Discovery, Development, and Translation. The workshop brought together representatives from federal agencies including ASPR, the Department of Defense, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health; state public health officials; participants from private enterprise including large pharmaceutical and small biotechnology companies; and those with expertise in the finances and risks associated with drug and countermeasures development. A summary of the workshop was published in April 2010.⁷

Workshop participants emphasized the immense progress in countermeasures development since the anthrax bioterrorism mailings in 2001, including the creation of the Biomedical Advanced Research and Development Authority (BARDA) within HHS. Many spoke highly of the progress that BARDA has achieved despite its limited resources; however, participants encouraged better alignment between the Food and Drug Administration (FDA) and BARDA, emphasized the need for a clear regulatory pathway for medical countermeasures, called for an increased science base and the development of more sophisticated regulatory science at FDA, highlighted the pressing need for additional resources at FDA, and discussed how to achieve better alignment between basic research funded by and conducted at the National Institute of Allergy and Infectious Diseases and national priorities for medical countermeasures. Several participants also recommended a shift to a multi-use focus in which the private sector develops platforms and products that have a commercial market, but which the government can also use for countermeasures development.

Participants discussed structural mechanisms that could enhance management of the enterprise, improve collaboration with

the private sector, and more effectively harness the capabilities of the different stakeholders. Several participants proposed that management of the enterprise be outsourced to a central entity, for example, a public–private partnership or other nonprofit organization. Participants also discussed the establishment of centers with high levels of technical expertise and state-of-the-art manufacturing technology and other mechanisms to advance the integration of skills of private groups to create essential products for the public good. Many of the private sector participants stressed the need to make it easier to navigate the process, for example, using a consortium that facilitates interactions with the agencies to work on particular issues. Private sector participants also said that increased data protection or patent terms can be effective incentives.

As plans are made to enhance the medical countermeasures enterprise, it is critical to remain cognizant of the end goal: ensuring the health of the people. Several participants emphasized that the needs of the end user should be integrated from the beginning so that the people who will distribute and dispense the countermeasures are able to do so. For example, although this is the way many new drug efforts start, the extensive variety of formulations and indications for the H1N1 vaccine severely complicated the effort to administer vaccine to the targeted groups. Throughout the workshop, participants said that it is also important to remember that the fundamental needs and goals of the public and private sectors are unlikely to change. The government agencies are likely to always perceive constraints that stem from inadequate resources, complex contracting procedures, ongoing programmatic activities, budget cycles, overlapping goals, and existing federal regulations and departmental policies. The private and public sectors may wish to advance innovation at different speeds. A number of participants said that during urgent situations, however, both the public and private sectors may need to adapt their usual practices if the potential benefits to first responders, at-risk groups, and the public outweigh the risk involved. Several participants noted that the development of a public–private partnership methodology that meets the needs and goals of both public and private sectors will help ensure the public's health.

Emergency Use Authorization

In November 2009, the Forum hosted a workshop on Emergency Use Authorizations (EUA), which can be issued by the FDA to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during an emergency. Participants emphasized that EUAs are valuable mechanisms in the preparedness toolbox but also expressed frustration that EUAs cannot be preauthorized so that the conditions under which the product may be used are not known in advance.

A number of participants had been involved in the pilot program of the US Postal Service Delivery of Medical Countermeasures, implemented in Minneapolis/St Paul, Minnesota. Participants described how postal workers and their union came to feel comfortable enough to volunteer for the program, in-

cluding assurances regarding security, fit testing of masks, and prepositioning medical kits in their homes. Since the workshop, President Barack Obama has issued an executive order requiring the establishment of a national Postal Service medical countermeasures dispensing model for cities to respond to a large-scale biological attack.⁸

THE RESPONSE TO H1N1

Assessing the Severity of Influenza-Like Illnesses: Clinical Algorithms to Inform and Empower Health Care Professionals and the Public

Faced with the looming prospect of an overwhelming H1N1 pandemic, in early September 2009 the Forum hosted a meeting on clinical algorithms that could be used by members of the public and by practitioners to assess the severity of influenza-like illnesses and the risk for progression to severe or life-threatening disease. An effective decision-support process would reduce overcrowding and long waits in primary care clinics and emergency departments, allow health professionals to focus their attention on the most seriously ill people, protect those individuals who have minor influenza-like illnesses from unnecessary visits to health care facilities, and simultaneously decrease the risks to others associated with exposure to the H1N1 virus in medical settings. Based upon meeting discussions, CDC and other entities posted a revised adult algorithm on their Web sites. This activity demonstrates that the Forum can also serve as a resource to the preparedness and response community during a public health emergency.

Private–Public Integration in the Response to H1N1

The private sector played an important role in the response to H1N1, and a number of important partnerships and initiatives were established that advanced the level of private–public integration in the preparedness and response arena. In January 2010 the Forum hosted a meeting with private sector stakeholders, including large pharmacy chains, distribution and supply-chain management companies, health insurance companies, representatives from critical infrastructure sectors, and other companies engaged in the H1N1 response. Participants discussed 2 examples of innovative projects in which the public and private sectors partnered to significantly enhance the response: the extensive use of pharmacies to administer vaccine and the CDC Division of Strategic National Stockpile's Supply Chain Dashboard. These projects are discussed below.

Recognizing the unique ability of pharmacies to reach large numbers of people in a convenient and accessible location with extended hours of operation, the Association of State and Territorial Health Officials convened a meeting of representatives from large chain pharmacies, pharmacy associations, health insurers, and relevant government entities in the summer of 2009. They sought to address key concerns such as how pharmacies would be integrated into the distribution mechanism while achieving mutually acceptable standards for documentation, liability, and compensation.⁹ Participants at the Forum meeting discussed how to maintain this momentum built during the re-

sponse to H1N1 and engage the private sector in other preparedness activities.

The second innovative project discussed at the Forum meeting was CDC's Supply Chain Dashboard. The Dashboard provides public health leaders with the national-level aggregate data describing the quantities of antiviral drugs and respiratory protective devices reported throughout the commercial supply chain and within state and federal stockpiles. The data provided by the Dashboard is intended to assist state and federal officials in making decisions regarding the management and release of these resources. Participants at the Forum meeting noted that the Dashboard project had achieved unprecedented success due to the willingness of private sector manufacturers, distributors, and retailers who voluntarily submitted precise, up-to-date information about on-hand quantities of supply chain resources.

H1N1 Vaccination Campaigns

In spring 2010, the Forum hosted a series of regional meetings to examine the H1N1 vaccination campaigns and identify strategies to improve future emergency vaccination programs and other medical countermeasure dispensing campaigns. Workshop participants represented many aspects of the vaccination system, including federal, tribal, state, and local public health officials; national provider associations and health care providers, including pediatricians, family physicians, obstetrician/gynecologists, nurses, pharmacists, and emergency medical services providers; community organizations; health care administrators; and health insurers. Participants presented and discussed innovative efforts to distribute and administer vaccine, such as the use of a centralized distribution system, expanded involvement of health care facilities and their providers in the administration of vaccine, and extensive use of administration strategies like school-based and drive-through vaccination clinics. Participants also discussed and analyzed communications strategies and the collection and use of data during the vaccination campaign. Across all areas of discussion, participants identified challenges and discussed strategies to address these challenges and enhance future efforts.

SUMMARY

The Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events acts as a convening body for those with a stake in the success of preparedness and response, including the private sector, community groups, organizations, and populations who have not always been included in preparedness efforts. Although the Forum and its workshops do not make consensus recommendations, the regular meetings and workshops serve as a venue for thoughtful, provocative, and open discussions about complex problems that require a multipartner approach. The Forum can also serve as a resource for the preparedness and response community during public health emergencies. Through its efforts, the Forum hopes to continue to contribute to the vision of a healthy nation that can respond effectively to public health threats while manifesting the resilience necessary to recover from them.

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