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HHS PUBLIC HEALTH EMERGENCY
MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE)
stakeholders Workshop 2009 and BARDA Industry
Day
December 2 – 4, 2009

Executive Summary

“So as you meet today, I would like to challenge you to think about what has gone well that we have to be sure to maintain and where do we need to go into the future, and most importantly, how does our enterprise need to be modernized. And I’d like for you to think about this from the very beginning scientific underpinnings, how we do that early science to get the best ideas out into the marketplace, how we take those best ideas and pull them through to countermeasures that can be licensed and used for the American people, how we not only get those products made in the lab, but get to be able to make them quickly and rapidly, that large scale manufacturing capacity for the American public, and frankly, often for the world, and how we align all of the scientific, financial, regulatory and policy incentives to get to where it is that we need to go.”

HHS Assistant Secretary for Preparedness and Response,
Rear Admiral Nicole Lurie
2009 PHEMCE Stakeholders Workshop
December 2, 2009

Overview

The annual PHEMCE Stakeholders Workshop is an effective venue for agencies to evaluate their roles and relationships in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). The very nature of this conference draws professionals from across the spectrum of federal government, pharmaceutical development, health care, public health, emergency preparedness, public safety and science, showing both the breadth of the field and the reach and productivity of the partnerships.

The 2009 conference was a joint session of the PHEMCE Stakeholders Workshop and BARDA Industry Day, sponsored by The Department of Health & Human Services (HHS), and The Third National Congress on Health System Readiness, sponsored by The American Medical Association (AMA). This joint venture afforded a rare opportunity to delve into issues at the interface of public health and emergency medicine.

The 2009 PHEMCE Stakeholders Workshop took place in the wake of the H1N1 influenza pandemic and against the backdrop of a recent request from the HHS Secretary for an evaluation of the medical countermeasure enterprise and mission. Questions considered at the conference included: What are the areas of knowledge that are lacking? What are the medical countermeasures (MCMs) that need to be developed? Are we better prepared? Did we set a roadmap that was fair to us and our partners in industry about the products that we are looking for?
The PHEMCE mission rotates along major axes of partnership:

- coordination among government agencies at the federal level
- coordination of the federal government with state and local planning and operations
- coordination among local public health and emergency response agencies
- partnership with the pharmaceutical industry

Conceptualized as a continuum of capabilities in a preparedness and response timeline, the preparedness and response mission is optimal when federal agencies coordinated through the PHEMCE - and engaged with commercial supply chain and markets for medical countermeasure product development - collaborate effectively with a coordinated emergency response infrastructure at the local level. The mission also requires coordination across disciplines, such as between clinicians who practice public health one patient at a time and public health officials whose practices affect thousands or millions of people.

**ATTENDEES**

More than 650 participants attended the three-day PHEMCE event, while hundreds more viewed the live webcast. The joint AMA/PHEMCE sessions were attended by over 1,000 stakeholders. Attendees included federal, state, and local government representatives; academicians; first responders and emergency personnel; professional association and non-profit staff; and pharmaceutical and biotech industry representatives. The 2009 events included plenary talks from federal government, AMA, and state/local speakers, as well as 7 breakout sessions on various topics related to the PHEMCE mission.

The following chart shows the distribution among categories of registered attendees:
PROGRAM OVERVIEW

OPENING ADDRESS

BARDA Director Dr. Robin Robinson opened the 2009 PHEMCE Stakeholders Workshop and BARDA Industry Day joint session with the AMA with an address that emphasized the importance of reexamining the status of the PHEMCE. Dr. Robinson introduced Assistant Secretary for Preparedness & Response (ASPR), Rear Admiral Dr. Nicole Lurie, who, through a taped message, addressed the importance of cataloging lessons learned during the national response to H1N1. Dr. Lurie also unveiled HHS Secretary Sebelius’s initiative to provide a comprehensive stem-to-ster姆 evaluation of the medical countermeasure mission to identify the strengths worth sustaining as well as opportunities for modernization in the areas of innovative partnerships and alignments of scientific, regulatory, and policy incentives. Extending beyond medical countermeasure development, the evaluation is expected to span the gamut of capabilities from the bench (early research) to the bloodstream (dispensing and utilization).

ALL PREPAREDNESS IS LOCAL

Determining the needs for medical countermeasure products and distribution strategies requires understanding the various ways state and local jurisdictions plan to use medical countermeasures (Monique Mansoura, Director, Medical Countermeasure Policy, Planning, & Requirements Division, Biomedical Advanced Research & Development Authority). In building a regular communication pathway between local, state, and federal agencies, expectations can be aligned. PHEMCE agency partners continue to broaden engagement with local stakeholders, as illustrated by the CBRN Medical Countermeasure End-User Roundtable in Denver November 2-3, a productive dialogue with first responders, emergency room physicians, hospital directors, and state and local emergency planners hosted by The Policy, Planning, & Requirements (PP&R) division of BARDA. The insights produced by this dialogue are expected to support PP&R’s efforts in medical countermeasure design and requirements setting (Mansoura).

LATERAL COMMUNICATION AT THE OPERATIONAL LEVEL

A common awareness of roles and responsibilities across the mission space is conducive to preparedness. More specifically, a common understanding of roles and responsibilities within the emergency response system is integral to a rapidly adaptable, coordinated response. Critical information requirements vary widely across roles and responsibilities, and these requirements need to be articulated and shared. The creation of system-savvy professionals through community response curriculum promotes the ability to visualize how personnel outside their disciplines pull together in crisis situations. This principle benefits horizontal and vertical relationships equally. For example, DHS Assistant Secretary of Health Affairs and Chief Medical Officer Alexander Garza reports benefiting from an ability to understand the view from the street.

The confluence of clinical and public health professional models is a theme headlined by the joint nature of this year’s session (i.e. Health & Human Services and The American Medical Association) with one keynote speaker explicitly calling for a more formalized and structured relationship between the health care workforce authority and the Department of Public Health.
Fostering this [the social and implicit relationships between public health and the clinical workforce authorities] at the time of a pandemic is too late, much too late.” – Frederick M. Burkle, Jr., M.D., Senior Public Policy Scholar, Woodrow Wilson International Center for Scholars

SHORING UP THE PUBLIC HEALTH INFRASTRUCTURE WITH SURVEILLANCE AND DETECTION CAPABILITIES

Since the implementation of a health response is ultimately local, preparedness hinges on supporting the public health infrastructure by pushing capacity and capability out to the level where the events occur. This is exemplified by the coordination of biosurveillance data and diagnostics services from federal agencies to help decision makers in public health management and in the field build common concepts of the unfolding crisis. The Centers for Disease Control and Prevention’s (CDC’s) Laboratory Response Network (LRN) geographically distributes biosurveillance and testing resources across a tiered network of laboratories, with an articulated system for the referral of suspicious specimens from hospital, commercial, and private labs to the nearest state, military, veterinary, or food lab with the capability to test definitively for a bioterrorism threat agent not typically seen in clinical practice (Peter Shult, Director, Communicable Disease Division and Emergency Laboratory Response, Wisconsin State Laboratory of Hygiene). During the H1N1 crisis the LRN was free to redirect its resources to advanced testing while the National Institutes of Health (NIH) expanded the high throughput diagnostics capacity of its emerging disease centers to provide rapid evaluation and triage assistance directly to state and local health departments. The CDC also supported the effort to characterize the nature and magnitude of threats to communities through a $700M funding program to provide 62 project areas with public health advisors and epidemiologists.

DHS also administers part of a layered early detection system (i.e. BioWatch), a series of pathogen detectors that collect airborne particles onto filters for transport to laboratories for analysis, potentially alerting authorities of a pathogen release before exposed persons show symptoms. This BioWatch system works in partnership with federal, state, and local entities, financed and managed at a senior level by DHS but operated on a daily basis by the state and local jurisdictions (Robert Hooks, Deputy Assistant Secretary for Weapons of Mass Destruction and Biodefense, Office of Health Affairs, U.S. Department of Homeland Security). BioWatch is a collaboration between: DHS, which administers the program; the EPA, which maintains the sensors that collect the airborne particles; CDC, which coordinates analysis and laboratory testing of samples; the FBI, which coordinates law enforcement response upon detection of a bioterrorism agent; and local jurisdictions responsible for the public health response. BioWatch complements disease and syndromic surveillance and DHS works with state and local communities on criteria and procedures for transitioning from detection of an agent on an assay to declaration of an actionable event. BioWatch is being reviewed in an effort to expand a next-generation technology into additional cities and shorten the cycle of detection, transport, and analysis from the present 10-34 hours to 4-6 hours. The new system will implement the National Academies of Science Institute of Medicine study recommendation to move beyond notification, integrate disparate pieces of information from animal surveillance, and determine an appropriate federal communications interface (Hooks, DHS). In conjunction with
the FBI, EPA, CDC, and ASPR, DHS has embarked on testing of Generation 3, leading up to pilot deployment in Chicago to test buy-in of a local community.

Headlined by the CDC’s evolving Biosurveillance registry, PHEMCE partners are working toward a system of sharing environmental monitoring data both within the PHEMCE and with state and local decision makers.

While these remain works in progress, the networks are already in place, as evidenced by the various ways in which the work of PHEMCE partners is intertwined. Many of the assays and reagents used currently in the LRN were developed by the CDC in conjunction with DoD. The FBI and USDA assisted the CDC in its development of the Select Agents Program, standard operating procedures that regulate the possession, use, transfer, and testing of all biological agents and toxins. The FBI also assisted the LRN in chain of custody procedures and policies to protect the integrity of sample evidence for criminal investigations.

An effective response requires integration and analysis across a number of disparate systems. With information from surveillance systems at CDC, ASPR, USDA and the FDA, the DHS National Biosurveillance Integration System creates a common operating picture for the federal government, monitoring the nation’s health security as a normal operating procedure rather than a re-invention in times of crisis. NBIS is designed to examine the broader societal impact of events across 18 critical infrastructure sectors including the workforce, population, schools, and economic sectors. DHS involvement in the Enterprise underscores the intersection of health security and national security, advising the Secretary, FEMA Administrator, state emergency managers, and private sector leads on threats to agriculture, livestock, and plants that can damage industries economically and threaten the workforce, including those security personnel (e.g. border control, military) who supply the homeland security posture.

Digitization of health information provides an opportunity to improve the timeliness, quality, and completeness of the health information of populations by pushing for earlier markers and indications to investigate and respond sooner (Sosin, CDC). The collection and use of unstructured data such as Google Flu trends can tap into changes in human behavior to identify unusual patterns of disease in populations a week before the health care system would otherwise be aware of spiraling up activity of flu-like illness. The electronic health information system would have built in flexibility to account for fluctuations in information needs across the event timeline with confirmed threats precipitating escalating levels of focused surveillance as well as increases in the frequency, breadth, and depth of analysis. Electronic medical records also protect clinical data from damage.

OPERATIONAL PLANNING AT THE LOCAL LEVEL: CASE STUDIES

Presentations from State and Local response planners provided insight into the diverse forms operational planning can take across local jurisdictions in a federalized nation. As a home rule state, Texas is required to defer to decisions made at the local level. During the H1N1 pandemic flu response, the Texas Department of State Health Services (DSHS) adjusted its plan to meet the challenges on the ground related to the dispensing of anti-viral medicines.

“...our original plan related to the national stockpile, actually we had exercised it and actually had done very well, had scored 100 percent in the last two exercises.
However, it didn’t meet the challenges that we saw on the ground related to this H1N1 event... So we basically threw out that plan and redesigned a plan that met the need for a state level medical event. Instead of being a dispensing plan, a distribution plan...” – David Lakey, Commissioner, Texas Department of State Health Services

Texas attributes its successful responses to Hurricanes Rita and Ike to partnerships with the private sector and created positions for private sector representatives (e.g. Shell) in its State Operations Center (SOC). The SOC collaborated with the private sector for power restoration priorities for hospitals and other mental health related facilities, delivery of fuel (i.e., Exxon, Shell, Valero), priority prescription needs (i.e. The Blue Ribbon Committee for Pharmacies) and commodities such as water and ice (HEB, Brookshire Brothers).

Over several years, Texas developed a state stockpile of 2.4 million courses of Relenza and Tamiflu. However, H1N1 compelled Texas to redesign an emergency operations plan built for hurricanes to meet the distribution and dispensing challenges of a state-level medical event, specifically the challenge of ensuring any Texan in need of an anti-viral would receive it regardless of geographical location (rural etc) or ability to pay.

By leveraging the distribution capabilities of pharmacies, the redesigned Texas plan allows for: (a) monitoring of the supply chain; (b) use of the general healthcare system to obtain medication (i.e. physician prescription to pharmacy); (c) timely dispensing; and (d) relief of the Local Health Department to focus on other aspects of response. The complexity of the contracting and reporting process, the cost of compounding, the need for additional product in the supply chain, the specific issues in rural areas, and the need for a physician prescription in a state in which 25 percent of the population is uninsured were cited as challenges.

The Texas plan is communicated via Texasflu.org (where the flu vaccine locator identifies all participating pharmacies by county), conference calls for situational awareness updates to stakeholders, and partnership with a 2-1-1 call center, a source of information for healthcare providers and the general public.

Dana Cary, Strategic National Stockpile Coordinator for the Yolo County (California) Health Department, characterized an emergency preparedness program that consists of online training modules\(^1\) to train approximately 2,367 volunteers to operate 11 PODS in support of the county's mass prophylaxis response capability. The online modules transmit test scores and other useful demographic information (e.g. previous volunteer experience) that assisted in the selection of 125 new volunteers. One training module trains individuals to perform medical screenings at their POD for multiple biological agents using such off-the-shelf technology as iPhones and iPods. The system performed well across a range of exercises including an annual mass vaccination clinic, first responder activation for mass dispensing, and a vaccination of 2,300 individuals for seasonal influenza.

Linda Scott, Bioterrorism Hospital Preparedness Program Coordinator for the Michigan Department of Community Health, presented their statewide all-hazards rapid chemical event response program (The Michigan Emergency Drug Delivery & Resource Utilization Network [MEDDRUN]) designed by a multidisciplinary

\(^{1}\) www.yolobusinesspartners.org
committee representing EMS services, regional SNS technical advisors, medical biodefense leadership, state pharmacists, state police emergency management, and state and national veterans affairs. The program uses EMS ground and air transport services and an intimate knowledge of the state’s diverse geography, to design area-specific capabilities to deliver medical countermeasures to 90% of the state within one hour. For example, the state entered into a cost-effective partnership with the 61,000-volunteer Civil Air Patrol to deliver resources to areas with no level 1 trauma centers. The MEDPACK is a forward-deployed component of the Michigan MEDDRUN program that provides the capability to deploy a sustainable cache of antidotes to chemical and biological attacks within 10 minutes of activating the MEDDRUN phone communication system 2. The trained recipients of these emergency calls leverage sophisticated tools and adhere to information gathering procedures through which they determine (a) the type of resources based on location and incident type and (b) the appropriate number of MEDPACKs to balance medical and air transport weight requirements. Following rapid deployment, the primary communication agency puts a secondary communication agency on backup and notifies the state emergency operations center which, in turn, notifies emergency medical and public health officials within the affected jurisdiction. The Michigan Department of Community Health Office of Public Preparedness recently harmonized the MEDDRUN and federal CHEMPACK programs so that they use the same communication agencies and deployment schemes.

**INTEGRATING THE CLINICIAN COMMUNITY INTO PREPAREDNESS & DISASTER RESPONSE**

The AMA Center for Public Health Preparedness and Disaster Response has called for education and training to support the role of physicians in community response planning. The national disaster life support course administered by the AMA’s National Disaster Life Support Program Office teaches physicians and other health care professionals about the medical and public health implications of natural disasters, terrorist attacks, and infectious disease outbreaks. The program office also lobbies health professional schools to allocate more of their curriculum to emergency preparedness and mitigation and promotes workshops to share best practices and lessons (Cecil Wilson, President-Elect, American Medical Association).

The AMA’s Center for Public Health Preparedness and Disaster Response and The AMA’s Public Health Readiness Office coordinated assistance across the public and private sectors to provide (a) adequate resources and supplies for medical and public health responders, (b) a comprehensive strategy for creating surge capacity in a mass casualty event, (c) a system for notifying health care professionals and the public about a terrorist attack or other major event, (d) a state-based registry for physician volunteers, (e) research programs to ensure AMA preparedness initiatives are comprehensive, evidence-based, and contemporary, and (f) a new CPT code 3 to streamline reporting and reimbursement for physicians (Wilson, AMA).

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2 by a public health or emergency medical services professional (e.g. incident commander, hospital emergency department, local public health)

3 CPT (Current Procedural Terminology) codes are numbers assigned to every task and service a medical practitioner may provide to a patient including medical, surgical and diagnostic services. CPT codes are used by insurers to determine the amount of reimbursement that a practitioner will receive by an insurer.
In response to Hurricane Katrina, the AMA coordinated the overwhelming physician response to the crisis and helped states verify physician licenses to register over 33,000 professionals and relief personnel. The AMA Foundation created a health care recovery fund to provide grant assistance to affected physicians as they rebuild their practices and lives. The AMA web site, developed with the assistance of the Office of Health Information Technology, HHS, Medicaid, retail pharmacy chains, and benefit managers in Louisiana and Mississippi, helped patients displaced by Katrina and their physicians access prescription drug records.

AMA periodicals and web sites also serve as vehicles for coordinating response operations. The online edition of the Journal of Disaster Management and Public Health Preparedness offers guidance for physicians and other health professionals on dealing with H1N1. The AMA’s AMAH1N1info.org website includes clinical guidance, vaccination information, patient information, and the latest H1N1 news. As the focal point for quality of care initiatives linking patients, physicians, and other caregivers, AMAfluhelp.org, a joint venture of the AMA, CDC, and the National Vaccine Summit, serves as the nation’s first comprehensive web-based flu assessment program and clinical decision-making support system. The site provides tools to help patients determine severity of flu symptoms and help physicians monitor patient symptoms, facilitate care and treatment decisions, and manage patient flow through a practice. The AMA is planning to collaborate with a broad-based coalition comprising such flagship companies as Microsoft, Blue Cross, CVS, and Merck (i.e., Flu Information and Care System) to expand its portal to support patient-physician communication, minimize redundant testing, and support continuous monitoring of patients with complex health conditions.

**Empowering the End User**

Plenary session presenters cite two principal reasons for increasing the role of individual end users in emergency planning: (1) the majority of victims in pandemics (60% SARS; 84% H1N1) having been cared for by capable non-expert caregivers (Burkle, Woodrow Wilson International Center for Scholars); and (2) the need to protect the health care system in a resource-constrained environment (Hooks, DHS; Carol Linden, Principal Deputy Director, Biomedical Advanced Research & Development Authority). Communication science and health messaging are terms used by interagency partners for efforts to bring information to individual end users that will help them make good health decisions for their families and manage risks to overall public health. Information about FDA quality control standards stems erosion of public confidence in lifesaving products, while information about the threat prevents panic-stricken individuals from overloading emergency departments and hospital wards. Initiatives like the PHEMCE Personal Preparedness Initiative and the AMA Current Citizen Ready Intervention presuppose a shift in attitudes toward citizens from dependent consumers of health care to essential partners. CDC research illustrates that passing mitigation strategies along to communities (e.g. shelter-in-place at home, respiratory etiquette, hand-washing) can flatten the epidemic curve – a visual representation of an outbreak's magnitude over a specific time period.
FEDERAL INTERAGENCY COLLABORATION – COORDINATION AND FLEXIBILITY

Serving as the primary conduit for communication among entities involved in medical countermeasure development, the PHEMC Enterprise coordinates movement through the phases of the bench-to-bloodstream preparedness and response continuum, conceptualized as research and development (NIH), advanced development (BARDA), acquisition (BARDA and CDC), storage and maintenance (CDC), biosurveillance and detection (CDC and DHS), and deployment and utilization (CDC and OPEO). The PHEMCE integrates and coordinates across the full spectrum of public health emergency preparedness activities for all intentional and naturally occurring CBRN threats, including research, early- and late-stage product development, and procurement activities addressing the medical countermeasure requirements. Evidence of this collaboration can be found in all phases of the medical countermeasure mission (see sections that follow), most notably in the flexibility to rapidly adapt to changing conditions and support decision-making with incomplete information. A consistent theme throughout the workshop, flexibility was often cited as quintessential to the PHEMCE mission:

“The spring [H1N1] response, and I would argue the current response as well, is heavily dependent on very hard working people and public health and health care across the spectrum and across disciplines...the special needs of a situation are hard to anticipate...flexibility within our systems...is really critical.” – Daniel Sosin, Acting Director, Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention

“From a health standpoint, decisions have to be made with incomplete information. We’re not going to know if this is a drug resistant bug. We’re not going to know a lot of information about the threat.” – Alex Garza, Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security

“...and this is one of the other things that we learned. We have to be flexible. Our mission capability has to be changeable to meet the demands of the particular time. It has already been said that this pandemic did not evolve as we expected. We expected that we would push out all of our material over the course of a few weeks and that we would be pretty much out of business for a while. Didn’t work that way. One of the things that we learned early on is that we had to know more about the commercial supply chain.” – Greg Burel, Director, Division of Strategic National Stockpile, Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention.

Public health and emergency response professionals across the mission space will need to provide a coordinated response to (a) covert attacks (b) with no discernible crime scene (c) using any of a number of unidentified biological agents (d) that were likely released 12-36 hours prior to being detected and (e) may be drug resistant and (f) have been reloaded for attacks in other cities (Garza, DHS). This
flexibility must be reflected in procedures, structured relationships (Burkle, Woodrow Wilson International Center for Scholars), collection and analysis of unstructured data (Sosin, CDC), and technologies (e.g. new diagnostics technology to identify a zebra in a room full of horses [Carole Heilman, Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health]). Such flexibility must afford us the ability to operate during shifts in strategic guidance such as during changes in administrations (Boris Lushniak, Assistant Commissioner, Counterterrorism Policy, Office of Counterterrorism and Emerging Threats, Food and Drug Administration).

The uncertainty and volatility endemic to the field of public health consequence mitigation compels the PHEMCE to seek a balance between fixed and flexible defenses and to think more broad-spectrum, as illustrated by the NIH approach to targeting common metabolic pathways in various bacteria (Heilman, NIH).

**SETTING REQUIREMENTS & PRIORITIES FOR MEDICAL COUNTERMEASURE DEVELOPMENT & ACQUISITION**

Operational plans, utilization constraints, and a host of other local realities are considered when BARDA’s Medical Countermeasure Policy, Planning, and Requirements division (PP&R) works with the interagency in determining PHEMCE medical countermeasure requirements (Monique K. Mansoura, BARDA). In order to meet national needs, medical countermeasures should be able to be used within a medically relevant and operationally feasible time frame following exposure to the public health threat for which it was designed. Requirements also provide critical information for industry partners as to the size and scope of the marketplace and desirable product specifications.

PP&R also leads the interagency in conducting preparedness assessments to identify the weakest links in a complex chain of capabilities that begins with early science and development (i.e., biochemical effects of agent, analysis of plausible and high consequence bioagent deployment scenarios, NIH clinical trials) and culminates in the act of putting pills in the palms of the people who need them and monitoring follow-up care. PP&R revisits the issue of what it means to be prepared and to respond effectively by collaborating with interagency partners, thought leaders, and local stakeholders to revise the PHEMCE Strategy & Implementation Plan. The 2007 HHS PHEMCE Implementation Plan for CBRN Threats prioritized near-term (FY07-08), mid-term (FY09-13) and long-term (FY14-23) goals for research, development, and acquisition of CBRN medical countermeasures that is consistent with the guiding principles and priority setting criteria defined in the HHS PHEMCE Strategy for CBRN Threats.

**THE RESEARCH & DEVELOPMENT PATHWAY**

Gaps in the research and development pathway are being addressed by increased coordination among PHEMCE agencies (e.g., BARDA and NIH). The NIH contributes to the development of a medical countermeasure product pipeline through its application of new technologies (e.g., genomics, proteomics) into models of basic research, its increasing understanding of pathogenesis through which specific monoclonal antibodies can be identified, its translation of knowledge into products through clinical research, its pre-clinical animal model development, its innovative methods of expanding research capabilities, and its understanding of animal model requirements in an effort to apply off-patent antibiotics in novel ways.
“... We’re also thinking about ways, for example, and, again, this will require a lot of interactions with the FDA, where you can really develop platform technologies which will allow some re-certification, some common manufacturing, and then simply allow you to drop things in, expedite the kinds of requirements we have with respect to vaccines” – Carole Heilman, Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health

The NIH in collaboration with the DoD also recently established Four Centers of Excellence to increase and enhance the chemical threats pipeline.

The Pandemic and All- Hazards Preparedness Act (2006) established BARDA as a bridge for products as they evolve between the early phase discovery and pre-clinical development supported by NIH to late stage development and procurement (i.e., products within 8 years of licensure) funded by Project BioShield (Gerald Kovacs, Director, CBRN Countermeasures, Biomedical Advanced Research and Development Authority). NIH funds programs at the National Institute of Allergy and Infectious Diseases to pull them through the pipeline, having to date successfully transferred to BARDA one advanced development contract^4 (Kovacs, CBRN).

In collaboration with BARDA, NIH redressed a second gap in the countermeasure pipeline between pre-clinical and Phase I clinical trials associated with the challenges in developing and validating animal models (Robin Robinson, Director, Biomedical Advanced Research & Development Authority).

The FDA provides regulatory guidance to companies, helping them correctly carry out the statutes, regulations, and policies to make available products that are safe and efficacious. The FDA also provides technical assistance to commercial developers at various stages of MCM development (Lushniak, FDA). As one of the major points-of-entry into the Enterprise^5, the FDA steers inquiring developers to the appropriate agencies. The FDA makes itself available for pre-meetings with companies to limit surprises as products enter the regulatory pathway. FDA-articulated review processes and decision models for weighing the risks and benefits support both a pathway with fast track mechanisms to facilitate availability and also offer options for using not-yet licensed products that may be the best available at the time of an emergency (e.g. Emergency Use Authorization [EUA]).

**DISTRIBUTION & DISPENSING**

The H1N1 Pandemic^6 provided an opportunity to evaluate the nation’s distribution and dispensing capabilities in an experiential setting^7 as well as the capabilities to rapidly adapt to unforeseen emergencies (e.g. communications, partnerships). During the distribution of H1N1 vaccine, DHS provided the intelligence to monitor threats to the supply chain. The Division of the Strategic National Stockpile (DSNS) staff, a division of the CDC, provided state health officials with the information

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^4 PharmAthene recombinant Protective Antigen (anthrax vaccine)
^5 Along with the Medicalcountermeasures.gov website
^6 Declared by The World Health Organization June 11, 2009
^7 Exercises operated by the CDC have been the standard method of testing the timely delivery of medical countermeasures from the stockpile to point of care.
they needed to determine when to release vaccine from state stockpiles and when to request more product from the federal government. An Interagency Meeting on the IV Antiviral Drug Initiative (October 1, 2009) was convened for a comparative analysis of potential models of distributing antiviral that weighed the pros and cons of inventories managed by users (e.g. hospitals) and vendors with respect to supply chain visibility, product ownership/oversight, speed of delivery, and integrity of product during transport. One of the most remarkable advances has been the voluntary partnership through which manufacturers, distributors, and retailers agreed to share information of a proprietary and sensitive nature so that federal agencies had a common operating picture of the supply chain, which for example helped anticipate a shortfall in the production of pediatric suspension and an advanced distribution of additional supplies in the SNS to minimize the impact (Sosin, CDC).

**Response Operations**

Layering plans for managing the transfer and triage of patients is critical, with discipline-directed plans needing to be integrated into broader, system-wide management schemes. Surge capacity in a resource constrained system can be created through provisions for transferring a measure of critical care capability to traditionally non-critical care settings when intensive care units - identified as a major limiting factor - are taxed to the limit. Keynote speaker Frederick M. Burkle, Senior Public Policy Scholar for the Woodrow Wilson International Center for Scholars, advocated for robust crisis-specific health hotlines with clear operational requirements similar to those implemented in New Zealand.

The attention paid to community-level operations by strategic level authorities was the subject of debate. Enterprise leaders and stakeholders processed the thesis that states are inconsistent and fragmented in surveillance capacity and many local jurisdictional pandemic plans lack adequate provisions for operational level tasking and decision making. Strategic approaches geared toward harnessing and deploying available resources have overlooked weaknesses in operational responsibility at the local level. Plenary session presenters diverged on the merits of the concern that the United States has not adjusted to the SARS lessons learned to ensure delivery of timely and accurate data to WHO in accordance with international health regulations. The progenitor of the thesis, Frederick Burkle, advocated for a concerted effort to bolster operational research opportunities at local levels and deplored the lack of influence on policy of published research and opinion in this area.

State emergency management offices would benefit from having a clearly designated agency or organization to collect the names of in-state and out-of-state volunteer positions as well as the authority to assign volunteers within affected areas. The AMA encourages physicians and other health professionals to join formal response entities such as the Medical Reserve Corp to avoid the problems associated with their volunteer service out of state. A system of keeping track of physicians is also necessary in the event they are dislocated by disaster from their patients and community. County medical societies should maintain a directory of all cell phone numbers of their members as a backup to jammed landlines and other destructions in local communication networks.

Local jurisdictional incident command systems would benefit from decision-making tools (i.e. triage protocols, algorithms, and ethical issues) developed in health emergency operations (center-like organizations) by intensivists and critical care experts responding to SARS and H1N1.
ANTHRAX CASE STUDY

Mr. Tom MacKay, Senior Program Analyst responsible for training and exercises for the Office of Preparedness and Emergency Operations in ASPR, provided background information for a video presentation of a case study that used factual knowledge of real world assets to frame and formulate an anthrax attack on a fictitious U.S. city and the likely national response. The case study was an interactive decision-making tool designed to (a) stimulate workshop participants to think and talk through how they would respond at various stages of an evolving crisis and (b) demonstrate the confluence of federal, state, and local entities in response to such an event. Video case study updates along the time line of the fictitious event were presented between afternoon panel sessions. Attendees answered questions following each installment of the case study. Sixty-three worksheets were returned at least partly completed.

Attendees were asked if they would wait to begin city-wide post-exposure prophylaxis in the targeted MSA until the exposed population is better identified and 84% opted not to wait for this clarification. Eighty-one percent also opted not to wait out an assessment of the commercial supply chain before recommending release of material from the Strategic National Stockpile (SNS). Seventy-eight percent of attendees reported that as SNS Coordinators, they would not prevent people from leaving the MSA. Sixty percent of attendees opted to limit risk of further exposure by shielding individuals from sources of infection (i.e. shelter-in-place, personal protective equipment, closing windows, limiting air conditioning, close schools / businesses around filters), while 34% emphasized cleaning and decontamination (i.e. removal of clothes, showering, street washing, cleaning filters and exposure sources, vacuum and dusting of homes, and decontamination of vehicles and all surfaces in public buildings). Eighteen percent recommended limiting social contact through quarantine, school closings, or shutting down public transportation. However, only 5% of attendees were favorably disposed to shutting down public transportation, with an additional 9% willing to shut down subway systems confirmed as sites of aerosolized release or willing to shut down upon assurance of access to PODs.

When asked what medical countermeasures, in addition to oral antibiotics, they would release as SNS Coordinator for the MSA, the most popular responses included antitoxins (39%), vaccine (33%), and personal protective equipment (22%). Other countermeasures making the list include provisions for special population (e.g. oral suspension for children; allergic reaction treatment), ancillaries (e.g. ventilators and syringes), strategies (e.g. citizen mitigation; quarantine; dispersion and cleanup), and information (e.g. communication to surrounding community). Seventy-eight percent of attendees endorsed the strategy to offer prophylaxis to first responders and medical personnel before the general public. When asked how they would allocate a limited quantity of oral suspension antibiotics for pediatric dosing, attendees indicated they would prioritize based on age (priority to youngest children, 22%) and proximity to epicenter of release (22%). Other considerations included pediatric proportion of population, risk factors, symptom presentation or confirmed diagnosis of infection, income (priority to low income), medical cost/benefit, requirements analysis, and the inability to take oral or crushed oral tablets. When asked how they would get Patient Information Sheets to millions of people in their MSA who will be receiving PEP antibiotics, attendee responses included a mix of both locations and communications modalities. Communications strategies included the Internet (44%), television (30%), snail mail (24%), telephone / text messages (15%), email (13%), radio (13%), newspaper (11%),
and locations included major retailers (e.g., grocery stores, box stores, and gas stations, 24%), PODs (20%), elementary schools (20%), hospitals, clinics, and physician offices (13%), pharmacies (9%), public buildings (e.g. post offices, fire stations, police stations, libraries, local government, 7%), and employers (4%).

As Oak City POD administrators, 83% of attendees preferred to open the POD immediately and take 48 hours to dispense PEP antibiotics rather than wait until a full staff was available to begin dispensing the following day for a period of 24 hours.

Attendees were asked to select a cohort of vulnerable (i.e. functionally disadvantaged) individuals for which to modify or adapt POD operations. Transportation-challenged individuals - individuals with no personal vehicle and POD not on bus route - drew priority status from a plurality of attendees (46%). The vast majority of solutions involved a method of bringing the POD to the person, as through home delivery by way of U.S. postal service, first responders, qualified nurses, volunteers, and senior citizen transportation companies, or by establishing mini-PODs in nursing homes, shopping centers, or voting centers. Medically-challenged individuals (e.g. people for whom ciprofloxacin and doxycycline are contraindicated) were the priority for 26% of attendees. These attendees proposed alternative therapies including additional PEP, amoxicillin, levofloxacin, linezolid, IV monoclonal antibodies as well as instructions for clinical monitoring.

Communications-challenged (e.g. people who are visually impaired) and non-independent (e.g., children who can not authorize treatment) individuals each drew the priority status from 13% of attendees. Only one attendee assigned priority status individuals requiring supervision (e.g. people unable to comply with daily oral dosing of PEP) over all other cohorts.

Attendees asked to recommend a location for PODs responded both conceptually and concretely, i.e. with algorithms (e.g. “places familiar to preponderance of population”) and facilities (e.g. “schools”). Fifty-two percent of attendees recommended schools, with hospitals (16%) garnering the second greatest number of recommendations. Other sites preferred by at least 10% of attendees include pharmacies, public transportation routes, first responder sites, shopping centers, and churches. Conceptually, attendees recommended the following criteria: (a) accessible to high density population centers, (b) familiar to population, (c) able to be protected, (d) non-disruptive to emergency services, (e) proximity to biofilters, (f) readily accessible by transportation to isolated areas and low income households, and (g) easy to fund.

As the primary public health official for the MSA, attendees were asked to propose alternative plans for dispensing PEP. Thirty-six percent favored dispensing from the post office, 14% from local pharmacy, and 14% through mobile field delivery units / hospitals operated by the military.

Attendees were also asked to formulate a strategy for handling an unprecedented surge consisting of (a) patients with influenza-like illness who require immediate ventilator support, (b) anxious, asymptomatic patients convinced they have been exposed and demanding immediate treatment for anthrax, and (c) people who dropped by to claim their 10-day supply of PEP antibiotics not knowing which POD to go to.

\[8\] Whose need status can be communicated or verified through a hotline
Seventy-six percent of attendees recommended triage, with 36% emphasizing the need to separate patients into the above three groups, 27% emphasizing set-up of a mini POD outside the ER for dispensing of 10-day PEP supply, and 16% noting the importance of additional security and staff to maintain control of the triage system. Twenty-six percent want to limit antitoxin for the severely ill while providing PEP antibiotics to all, while 18% want to re-direct all asymptomatic persons to the nearest POD. Other recommendations include memoranda of agreement to request additional personnel and supplies from other hospitals or the SNS, volunteer-manned telephone lines, and recruitment of outside staff (e.g., health clinics, school/college health services, National Guard).

Attendees were asked how as MSA Public Information Officers they would explain to the media the need to administer 50 additional days of PEP antibiotics to healthy people with no symptoms of anthrax. Forty percent emphasized the long incubation period, explaining the pathology of the exposure and that anthrax can be in the body for variable time before symptoms become apparent/appreciable. Twenty-five percent emphasized the risk of death from residual environmental contamination, explaining how anthrax spores sustain in the environment with the potential to germinate some time after exposure. Other rationales include risk-benefit (i.e., better to be safe than sorry), symptom masking/suppression by PEP antibiotics, science as authoritative source (i.e., animal studies established that antibiotics make the difference between life and death), consequence-of-noncompliance (i.e., deaths have been attributed to early termination of course of PEP antibiotics), and sheer uncertainty (i.e., development of symptoms varies by dose as well as individual differences in immune systems and routes of infection).

**BARDA INDUSTRY DAY**

Several BARDA Industry Day sessions provided an opportunity for selected industry stakeholders to present information on their products and activities for public awareness and consideration in oral or poster presentations. Topics included pandemic influenza countermeasures; pandemic influenza vaccines; anthrax therapeutics; vaccine innovations; therapeutics; platform technologies; diagnostics, biodosimetry, and bioassay; and therapeutics for chemical, radiological, and nuclear threats.

The 2009 BARDA Industry Day was the largest ever, with the highest submission of abstracts ever received resulting in 35 posters and 20 exhibitors joining over 40 simultaneous session talks in highlighting cutting edge medical countermeasure research.