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Editor's Notes

By James D. Hessman, Editorial Remarks

Military geniuses, mess cooks, and master sergeants all know the old saying that "an Army travels on its stomach." If the rations are not there – in sufficient quantity and on a regular basis – even the best trained and most highly motivated military forces start to slow down, and soon thereafter come to a screeching halt. Well, a nation also travels on its stomach. The long-running famine in Ethiopia helps illustrate this heart-rending truth.

However, in the United States – i.e., "the land of plenty" (and of the obese) – the nation's most dangerous "food problem" is not lack of food, but rather ensuring that the millions of tons of food in the nation's food supply chain at any given time are pure, untainted, and free from harmful toxins in general. That is a daunting and almost impossible task, particularly considering that there are millions of food "outlets" – e.g., supermarkets, restaurants, school cafeterias, private homes – in which huge quantities of food are prepared, cooked, served, sold, and/or otherwise distributed to more than 300 million citizens each and every day of the year.

Not too surprisingly, there are a number of cases of unintentional food poisoning that occur each and every year as well. That number last year was not quite 50 million cases, according to the U.S. Centers for Disease Prevention and Control. There have also been cases of deliberate food poisoning (e.g., the salad bars in Oregon), but the number of intentional cases of food poisoning has been considerably lower. That situation might well change, massively, in the near future, if – "when" might be the more accurate word – terrorists decide to take aim at the huge and complex U.S. food supply chain. The 14 authors in this month's printable issue of DomPrep Journal point out possible problems as well as solutions for protecting the food supply and protecting the population against biological agents.

Scott McCallum, a former Wisconsin governor now serving as CEO of a major food-distribution organization, sets the stage with an authoritative summary of the basic building blocks of the U.S. food-supply system and its importance not only to the United States itself but to many other nations throughout the world. R. Douglas Meckes follows up with an analysis of the difficulties involved in protecting the nation's food – and, therefore, the nation's citizens – from infectious diseases (and/or deliberate poisoning). Kimberley Wetherille and Evan Henke team up on a report on CIFOR (Council to Improve Foodborne Outbreak Response) programs to train food handlers and others in detecting/preventing and coping with foodborne diseases. And Joseph Cahill discusses an operational-level "Food Fight" problem – i.e., bioterrorism – as it affects, and sometimes infects, emergency medical technicians and other first responders.

Christina Spoons focuses on a closely related topic – bioterrorism in general – and how to keep responders uphill, upstream, upwind, and properly protected from biological agents. Earl Stoddard points out that one of the nation's most generically effective tools in this area is scientific research – but warns that such research can be a double-bladed (or dual-use) tool, and weapon, that in certain circumstances and situations can be used for the benefit of or against a country and its allies. Catherine Feinman follows up with a timely situation report on the latest publish-or-perish chapter of a pending article on the H5N1 avian influenza virus.

Elsewhere in the issue: Andrew Roszak reports on recent-year funding cuts, balanced to some extent by the growth of healthcare coalitions. Dennis Schrader and John Morton discuss the recent-year and future growth in state and local preparedness capabilities. Raphael Barishansky and Audrey Mazurek emphasize the growing need for training and preparedness drills and exercises at all levels of government – state, local, and national. And Loren Thompson resurrects a timely pre-WWII warning on the mortal consequences of NOT being prepared in times of imminent peril.

About the Cover: A field of golden wheat – the eternal and almost global symbol of nutrition, a plentiful food supply, and the health of both a person and a nation (iStock photo). Take it away, and the person might starve. Burn it, or poison it, and the nation might die – a possibility certainly worth discussing, today more than ever before.

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Hi-Tech Food Banks & The Safety of Food Supply Chains

By Scott McCallum, Viewpoint

"Food security is closely connected with economic growth and social progress as well as with political stability and peace." – G8 Summit (July, 2009)

According to the September 2011 U.S. Department of Agriculture's Report on "Household Food Security in the United States in 2010," nearly 49 million Americans are "food insecure" – meaning that they struggle with the problems caused by not having a sufficient amount of food on a daily basis. Hunger relief organizations across the United States provided 3.3 billion pounds of food last year to all 50 states, the District of Columbia, and Puerto Rico, according to the 2011 Annual Report of Feeding America, the largest U.S. food banking network.

Organizers of food banks continually struggle to secure and protect the very large quantities of food required to fulfill the demand. Some food is donated or purchased at local food agencies, but most of the food distributed comes through a sophisticated network of providers – also known as a supply chain – of growers, food processors, government agencies, and other organizations. An ongoing challenge for a supply chain is keeping the food safe as it crosses between various groups. This task is especially difficult because, according to the Feeding America report, an estimated 78 percent of charitable food is considered "nutritious" – a term that often means short expiration dates and specific handling requirements.

Food contamination could pose an even higher risk for populations that are already nutritionally weakened – and often either uninsured or underinsured. Because of hospitalization and other medical costs associated with food contamination, any health-related issues can be extremely detrimental to any local community, large or small, throughout the entire country. Fortunately, food banks across the nation have been pioneering a number of new hi-tech approaches to address both current and future food-safety problems.

A For-Profit Model in a Non-Profit World

Feeding America itself provides an excellent example of how the "best practices" used in the for-profit world can be modified and applied directly to the nonprofit world of hunger relief and food protection. In 2001, Feeding America started to automate its operations in the same way the business world does. By employing highly efficient SCM (supply-chain management) software, suppliers, food banks, and relief agencies are now digitally connected with one another.

More than a decade ago, this type of strategic information technology (IT) investment by a nonprofit was almost unheard of – at least in part because nonprofits usually do not have budgets large enough for multi-year IT investments.

By adopting the technology of the for-profit world, food banking networks can better integrate and share data with the IT systems of major food processors. However, the increased volume of food now being delivered across the country also means there is an increased risk of more individual citizens becoming ill, or worse, if a shipment of food is found to be contaminated (and/or has been recalled by the food processor for other health reasons). To minimize such risks, thorough planning – combined with the creation of an infrastructure that supports rapid communication throughout the supply chain – can help identify and locate contaminated "batches" of food and thereby minimize the overall impact.

Better Tracking Translates Into Better Prevention

Additional technological advances are already expected as bar-coding and RFID (radio-frequency identification) technologies are tested and adopted by hunger-relief supply chains. These new technologies will provide even greater accuracy in identifying the location of a specific food item at the unit level. In addition to enhancing the ease of receiving and distributing items, these solutions will further reduce the cost of tracking shipments that are transferred from one region to another by: (a) eliminating or at least reducing various shelf-life issues; and (b) simplifying the sometimes complicated communications and logistics problems associated with food recalls.

The collective goal of the numerous agencies and organizations involved is to create a highly efficient hunger-relief supply chain that can deliver foods that are as safe as possible. In the process, these systems can also help protect vulnerable populations from the additional illnesses sometimes caused by recalled or contaminated food products. Although Feeding America has pioneered much of the work carried out in this area, other hunger and disaster relief nonprofits may not have either the staffs or the budgetary resources needed to adopt the same technologies. For that reason alone, public-private partnerships provide an attractive option for financially funding the startup investment costs required to adopt those technologies and thereby improve food safety.

The importance of food safety within the hunger-relief supply chain is a concern that touches every community – from

cities to suburbs to rural America – and it is one that food banks and technology providers continue to address and improve upon every day. For that reason, among others, it is important for communities across the nation to work more closely together, both now and for the foreseeable future, to help protect the safety of the entire food supply chain.

For additional information on:
USDA's "Household Food Security in the United States in 2010" Report, visit http://www.ers.usda.gov/Publications/ERR125/ERR125.pdf

Feeding America's 2011 Annual Report, visit http://annualreport.feedingamerica.org/misc/FeedingAmerica_2011_Annual_Report.pdf

Case study on Feeding America, visit http://www.aidmatrix.org/relief-programs/Feeding%20America%20Case%20Study.pdf

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Former Wisconsin Governor Scott McCallum has more than 30 years of executive experience leading organizations in the private, nonprofit, and government sectors. He was elected four times as Lieutenant Governor before becoming one of the youngest State Senators in Wisconsin history. He also has taught at the University of Wisconsin-Milwaukee, Northwestern University, Sun Yat-Sen University, and Hunan University in China, and is presently an Adjunct Professor in the School of Health and Medicine at the University of Wisconsin-Madison. He also serves as President and CEO of The Aidmatrix Foundation, a nonprofit organization that annually has mobilized and distributed more than $1.5 billion in aid worldwide. With operations on six continents and more than 40,000 user organizations, Aidmatrix provides humanitarian-relief supply chain technology and internet information systems to connect private sector businesses, government agencies, and nonprofit organizations with one another to achieve their individual and collective missions more efficiently.


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Protecting the U.S. Agriculture and Food Sector

By R. Douglas Meckes, Standards

The cultivation of crops and livestock remains a vital component of the nation's economy. According to the U.S. Department of Agriculture, the United States exported $137 billion in agricultural products in 2011, and the sector is one of the few to record an annual trade surplus. Recognizing the importance of U.S. agriculture and food systems – and their vulnerabilities – President George W. Bush signed Homeland Security Presidential Directive 9 (HSPD-9), "Defense of United States Agriculture and Food," on 30 January 2004; that directive called specifically for the Food and Agriculture Sector's protection as a matter of national security.

U.S. agriculture and food systems are open, complex, and interconnected by nature, and thus provide ample targets for terrorists seeking to harm the public and/or disrupt Americans' way of life. A large-scale attack could cause catastrophic health and economic consequences and could require a long and/or complicated recovery.

To answer the threat, HSPD-9 established national policies to protect the nation's agriculture and food systems against terrorist attacks, major disasters, and other emergencies. The directive defines the roles and responsibilities in this area for the U.S. Department of Homeland Security (DHS) and acknowledges the vulnerabilities of the nation's agriculture and food systems to diseases, pests, and toxic agents – whether naturally occurring, accidentally introduced, or deliberately released. To meet the requirements spelled out in the directive, DHS has taken a number of constructive steps and coordinated extensively with its federal partners on other actions.

The U.S. Department of Homeland Security is working with other federal agencies to ensure the safety of the food distribution industry within the United States. Many changes already have been made in response to Homeland Security Presidential Directive 9, and many more are yet to come.

Roles and Responsibilities

HSPD-9 directs the various federal agencies involved to: (a) identify and prioritize sector-critical infrastructure and key resources; (b) develop the improved awareness and early-warning capabilities needed to recognize threats; (c) mitigate vulnerabilities at critical production and processing facilities; (d) enhance screening procedures for domestic and imported products; and (e) bolster preparedness to ensure effective response and recovery operations. The directive focuses special attention on 18 key requirements in six distinct areas of responsibility: Awareness and Warning; Vulnerability Assessments; Mitigation Strategies; Response Planning and Recovery; Outreach and Professional Development; and Research and Development.

HSPD-9 also designates the Secretary of Homeland Security to serve as: (1) the lead or co-lead, in coordination with partner departments and agencies, to implement the specific tasks assigned; and (2) coordinator of the efforts of all federal departments and agencies, state and local governments, and the private sector to protect critical infrastructure and key resources.

Additional roles and responsibilities are assigned, consistent with their mission areas, to other agency leaders – which include, but are not necessarily limited to: the Secretary of the Department of Agriculture; the Secretary of the Department of Health and Human Services; the Secretary of the Department of Interior; the U.S. Attorney General; the Director of the Central Intelligence Agency; and the Administrator of the Environmental Protection Agency.

Duties & Requirements, Summaries & Specifics

Following are brief summaries, under the "areas of responsibility" indicated, of other roles, duties, and requirements directed by HSPD 9.

Awareness and Warning: Under "Awareness and Warning," DHS and other agencies are charged with developing a

biological threat awareness capability – currently being undertaken through the National Biosurveillance Integration Center, which is managed by DHS. The center's specific goal is to ensure that human, plant, animal, and environmental biosurveillance information is shared and promulgated throughout the federal government to facilitate early warning and situational awareness of biological events determined to be "of national concern."

Mitigation Strategies: DHS contributes as a co-lead on a number of related mitigation efforts. For example, the DHS Customs and Border Protection (CBP) agency, USDA, and HHS have forged closer working relationships – most notably at the National Targeting Center and the Commercial Targeting and Analysis Center – to more effectively screen and inspect agricultural and food products entering the United States from other nations. CBP's 2,400 highly trained agriculture specialists also work on the front lines at U.S. ports of entry to prevent the introduction of harmful pests, plants and plant diseases, animal products and diseases, and other biological threats. Most if not quite all of these threats are destructive, diverse, and often invisible to the untrained eye.

Response Planning and Recovery: DHS and its partner agencies coordinate on several fronts to ensure that combined federal, state, and local capabilities are adequate both to respond to and to quickly and effectively recover from incidents impacting the nation's agriculture and food infrastructure. Within DHS itself, the Federal Emergency Management Agency (FEMA) has marshaled its programs and resources to support sector-specific response and recovery operations. In addition, FEMA's National Preparedness Directorate has both funded and managed stakeholder training and education – made available primarily through universities, community colleges, and the agency's own Center for Domestic Preparedness. Similarly, FEMA's Grant Programs Directorate has funded numerous state and local government initiatives to enhance preparedness and upgrade the ability of the public at large to prevent, protect against, respond to, and recover from all hazards, including those involving agriculture and food systems.

DHS's National Protection and Programs Directorate has already carried out vulnerability assessments of the beef industry in Texas and the dairy industry in

California. These assessments are being combined with regional analyses of the surrounding infrastructure with the goal of reducing vulnerabilities to all-hazard threats. In addition, DHS developed a food emergency response plan template in 2006, working in coordination with the National Association of State Departments of Agriculture (NASDA), the Food Safety Inspection Service of the U.S. Department of Agriculture (USDA), and the Food and Drug Administration. The template helps protect the agricultural and food infrastructure through increased and improved prevention, detection, response, and recovery planning. (Last year, the DHS's Office of Health Affairs and NASDA released a revised template to reflect new and more stringent federal guidelines.)

Outreach and Professional Development: The DHS Secretary is coordinating with a number of private-sector agencies and organizations to establish a more effective information-sharing and analysis mechanism for food and agriculture stakeholders. Such partnerships are key to continued progress in this area, particularly in light of the fact that the private sector owns and operates roughly 85 percent of the nation's food and agriculture critical infrastructure. Here it should be noted, though, that: (a) threat information-sharing by the federal government is typically restricted to other public agencies; and (b) each sector already has in place various security programs, research and development activities, and other resources that may be more effective if shared with and discussed among partners.

Research and Development: The DHS Secretary has already consulted with a number of partner agencies to establish several university-based "centers of excellence" in the areas of food and agriculture security. The centers of excellence – which are managed by the DHS Science and Technology Directorate (S&T) – that have a specific food or agriculture nexus include: the National Center for Food Protection and Defense at the University of Minnesota; the National Center for Foreign Animal and Zoonotic Animal Disease Defense at Texas A&M University; and the National Center of Excellence for Emerging and Zoonotic Animal Diseases at Kansas State University. These centers already have trained hundreds of scholars and fellows and have pioneered several new technologies and both upgraded and expanded the mass of "critical knowledge" available consistent with the DHS mission.

In addition, DHS has already announced plans to build a new state-of-the-art biocontainment facility in Manhattan, Kansas, for the study of foreign animal diseases that threaten animal agriculture and public health. The proposed new National Bio and Agro-Defense Facility, currently in the design stage, will strengthen the nation's capabilities to conduct research, develop vaccines and other countermeasures, and train veterinarians in preparedness and response against livestock diseases – specifically including emerging and zoonotic diseases – that are not endemic to the United States. The new facility will replace the Plum Island (New York) Animal Disease Center, which has served the nation for the past 50 years as the primary facility conducting such research and is today the only U.S. facility that specifically studies the live Foot and Mouth Disease (FMD) virus – the spread of which could be devastating to the U.S. cattle industry.

Additional DHS Efforts

The DHS S&T Chemical Biological Defense Division's Agriculture Defense Branch develops new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases. DHS S&T and the USDA's Animal and Plant Inspection Service and Agriculture Research Service have developed the first new technology for the manufacture of a Foot and Mouth Disease (FMD) Virus vaccine in 50 years: an adenovector FMD virus vaccine (AdA24). More importantly, because the replication functions of the FMD virus have been removed, the FMD vaccine – which has already completed five safety studies (on cattle) – can be manufactured on the U.S. mainland.

In addition, DHS S&T provided funding and sought permission for Transboundary Animal Biologics Inc. to import FMD and Classical Swine Fever vaccines into the United States. Agreements have been established with Biogenesis-Bago in Argentina to facilitate the rapid import of a ready-made quadravalent FMD vaccine for use in the event of an outbreak of the disease; this would give USDA a new capability in an area important to the health of farm and ranch animals.

Although much remains to be done, the efforts already undertaken by DHS and its partner agencies in the implementation of HSPD-9 already have resulted in a more secure food and agriculture sector of the U.S. economy. Ensuring the safety, security, and resiliency of the nation's food and agriculture infrastructure will undoubtedly remain a top federal priority for many years to come.

Douglas Meckes, D.V.M., is the Chief of the Food, Agriculture and Veterinary (FAVD) Branch of the Department of Homeland Security's Office of Health Affairs (OHA). FAVD provides DHS leadership with comprehensive, relevant, science-based information related to food, agriculture, animal health and veterinary public health. The division also provides oversight and management of DHS's implementation of the Defense of United States Agriculture and Food (Homeland Security Presidential Directive-9), integrating the efforts of DHS components, and coordinating with other federal, state and local governments, and the private sector.

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Aligning Priorities with Healthcare Coalitions

By Andrew R. Roszak, Health Systems

Federal preparedness funding for the healthcare sector of the nation has traditionally come from two sources, both of which are agencies of the U.S. Department of Health & Human Services (HHS): (a) the Hospital Preparedness Program (HPP) of HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR); and (b) the Public Health Emergency Preparedness (PHEP) Program of the Department's Centers for Disease Control and Prevention (CDC). Both programs have an overall mission to improve U.S. healthcare preparedness in general, but the two agencies have historically operated with disparate goals and objectives.

Through the HPP program, ASPR provides funding to states, territories, and eligible municipalities to improve surge capacity and enhance both community and hospital preparedness to deal with public health emergencies. In most jurisdictions, HPP funding flows through the state to local hospitals and is used to increase surge capacity across the nation, enhance system planning and response capabilities, and improve the healthcare infrastructure. In contrast, the CDC administers the PHEP cooperative agreement, which provides funding to public health departments and is used primarily to improve the ability of health departments to respond to public health threats.

Both programs have identified the specific capabilities that serve as national health preparedness standards and largely determine how program dollars are spent. Recognizing that both programs enhance preparedness, ASPR and CDC have recently been working in close cooperation to more closely align the sometimes varying goals and priorities of both programs. The newly aligned cooperative agreement between ASPR's HPP and CDC's PHEP is scheduled to take effect this summer – i.e., in July 2012.

The Coming Consolidation & Coordination of Coalitions

Under the new agreement, ASPR and CDC have aligned the HPP and PHEP capabilities to assist healthcare systems, coalitions, and organizations in their preparedness, planning, and response activities. This new model, which will be consistent with the Department's 2009 National Health Security Strategy, will be used to promote community resilience and response capabilities by establishing and leveraging coalitions that are charged with fully integrating the public health, public safety, emergency management, and healthcare sectors of the entire nation.

Providing support and funding to coalitions represents a shift from facility-level preparedness to a more community-centric model. As stated in ASPR's January 2012 *National Guidance for Healthcare System Preparedness*, "strong and resilient healthcare coalitions are the key to an effective state and local ESF #8 [Emergency Support Function #8 – Public Health and Medical Services] response to an event-driven medical surge." Going forward, the development, sustainment, and effective use of these coalitions will be central to achieving the goal of improving community resilience and community-wide planning efforts.

Although a few regions of the country currently have well-functioning healthcare coalitions already in place, most regions do not, and that lack creates the challenge of designing, developing, and implementing strategies designed to push competitors closer together in a timely fashion. The new guidelines will quite likely, therefore, challenge even the most forward-thinking localities to expand the depth, breadth, and utilization of existing coalitions. Establishing new coalitions, and expanding the scope of existing ones, will undoubtedly require considerable hard work on the part of dedicated staff experienced both in healthcare and in coalition building.

Healthcare Coalitions: Defining the Term

At the most basic level, a healthcare coalition is a single organizational unit that coordinates and interfaces with other healthcare facilities and assets, community organizations, and a broad spectrum of various public and private sectors. Its strength usually is measured by the breadth and diversity of its membership. However, an ideal coalition should be representative of the majority of healthcare assets, both public and private, within the same political jurisdiction and/or geographic area, and therefore should receive at least some degree of financial support from its members.

Membership in the coalition should include, but not necessarily be limited to, representatives of hospitals, public health agencies, skilled nursing facilities, long-term care facilities, ambulatory care centers, emergency medical services agencies, public safety agencies, dialysis centers, poison control centers, and other local healthcare facilities and organizations.

Understandably, competition between and among the providers within a given community may hinder development efforts to at least some degree. However, forming coalitions even in those communities is not an impossible task, as has been amply proved by the example of several national models described in ASPR's May 2011 report *From Hospitals to Healthcare Coalitions*.

Not a One-Size-Fits-All Endeavor

Under the new alignment, and consistent with the May 2009 ASPR handbook – "Medical Surge Capacity and Capability: The Healthcare Coalition in Emergency Response and Recovery" – the new coalitions are expected to provide support to the healthcare sector on a daily basis. Although they are particularly useful in times of sudden disaster, the true value of a coalition is demonstrated daily through improved coordination, management, and communications within the community's overall healthcare system. For one thing, as a neutral third party, the coalition can focus more objectively on community-wide preparedness, planning, response, and recovery efforts and initiatives.

The framework for the coalition also provides a helpful forum where providers can come together not as competitors but as members of the same community to address a myriad of issues – e.g., the reallocation of personnel, equipment, resources, and supplies during large-scale incidents. Planning and discussing these and other issues at the coalition level can and should lead to the complete visibility of a jurisdiction's overall healthcare resources and capabilities.

As coalitions are established throughout the country, they will undoubtedly possess certain attributes that reflect the local landscape. However, although recognizing that a one-size-fits-all approach may not be entirely appropriate, there are a number of common features and functions that should define a true healthcare coalition – specifically including the following:

1. It should be an active daily partner in the healthcare system, not a working group that meets solely to allocate HPP or PHEP dollars, whether for individual facilities or to build core caches of equipment or supplies;

2. Although ASPR guidance dictates that it should be response-oriented, it is not active only during disasters, but instead provides daily support and value to the community it represents; and

3. Its success and long-term sustainability depends in large part upon its ability to be fiscally self-sustaining.

A Shift in Both Thinking and Planning

As all U.S. political jurisdictions are well aware, ASPR and CDC funding for preparedness has decreased significantly over the past 10 years. Moreover, in the current fiscal and political climate, it is very likely that funding for healthcare preparedness will continue to decline. It is also likely that federal funding streams will continue to be consolidated – as demonstrated by the planned consolidation of the Department of Homeland Security's preparedness grants in fiscal year 2013.

It seems almost certain, therefore, that healthcare coalition leaders cannot rely on government funding to pay for any significant share of their future operations. Instead, they must develop fiscal strategies that are well defined and reflect the local landscape – including extensive plans and outreach capabilities to ensure that senior executives of member organizations understand the value-added services that the coalition provides.

Viewed in that context, the alignment of ASPR and CDC capabilities represents a major shift in preparedness thinking and planning. Although facility-level preparedness continues to be important, history has shown that community-level planning and engagement are even more important for response and resiliency operations. Coalitions are thus in a unique position to greatly increase and improve coordination, collaboration, and communication between and among public health, public safety, emergency management, and overall healthcare system operations. Acting as on-the-scene facilitators, these coalitions should also help to ensure that communities are both better prepared and more resilient in the future. Achievement of that goal also will lead to better coordination and planning in both day-to-day activities and during future disaster planning and preparedness operations.

Andrew Roszak, JD, MPA, EMT-P, serves as Senior Preparedness Advisor at MESH (formerly Managed Emergency Surge for Healthcare), which is a non-profit, public-private coalition enabling healthcare providers to respond effectively to emergency events, and remain viable through recovery. Previously, he served as a Senior Advisor in the Office of the Administrator in the HHS's Health Resources and Services Administration (HRSA), and as the Senior Public Health Policy Advisor for the Department's Emergency Care Coordination Center (an ASPR agency). During the 110th and 111th Congresses, Roszak served as a Winston Health Policy Fellow, working on healthcare reform, in the U.S. Senate. Prior to shifting into federal service, he worked for eight years as a firefighter/paramedic in the Chicago area, and for two years in the Illinois Department of Public Health.

Food Fight – Bioterrorism & Emergency Response Capabilities

By Joseph Cahill, EMS

Many anti-U.S. socio-political goals can be attained by launching a biological attack on the nation's food supply. One distressing example of how that could be done occurred in 1984 when a small commune in Oregon launched a food-based attack in an attempt to control local land-use policy positions – by, of all things, contaminating the restaurant salad bars in the area with salmonella poisoning. In other cases, even the *rumor* of infected beef, vegetables, and/or other foods has led to moratoriums on both imports and exports being imposed at the national/international level – and/or resulted in consumer boycotts at local distribution sites.

In many states, kitchen and wait staff are required to attend food handling classes such as ServeSafe – a program that was created by the National Restaurant Association to train employees in the rules required to avoid accidentally tainting products. Bartenders and other staff go through similar training such as Health Communications Inc.'s TIPS (Training for Intervention ProcedureS) program – to learn the rules of safely serving alcohol to prevent or at least reduce intoxication, drunk driving, and underage drinking. In all of these classes, the addition of a module on bioterrorism – the signs to look for and, more importantly, information on who to contact if an attack is suspected – would put extra eyes on the ground.

However, although there are historical precedents for responding to large-scale biological attacks, the early detection of such attacks at any scale is of paramount importance. Many major cities and regions have already put in place the systems needed for syndromic surveillance – i.e., the monitoring of acute illness. This type of surveillance can be effective because bioterror attacks generally follow a limited number of common pathways at the onset of symptoms – respiratory symptoms, usually, and/or severe gastrointestinal distress. Many of the systems already created track indicators of the volume of such cases, usually to spot a statistical rise in their incidence prior to announcement of an attack by terrorists – an outcome that is usually contrary to the goals of the terrorists. Some of the more robust syndromic surveillance systems integrate the large volume of data received from hospital emergency rooms, EMS (Emergency Medical Services) systems, death certificates, school nurses, veterinarians, and pharmacies.

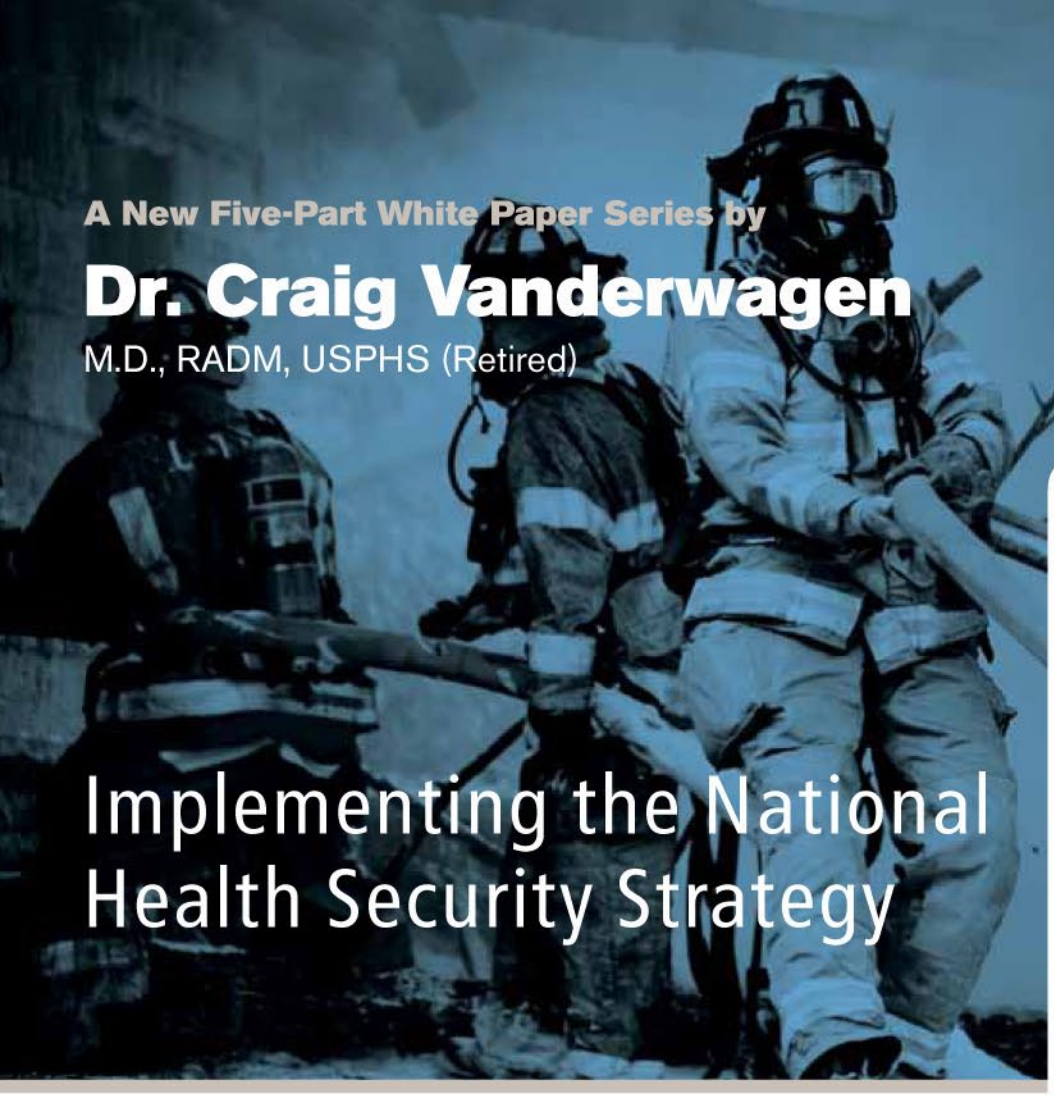
Close Monitoring, Accurate Diagnoses & "Just in Case" Check-Ins

In at least some states in which the monitoring of EMS cases is not yet required, legislation is being considered to make such monitoring mandatory throughout the state. In addition, many infectious diseases must be reported to the U.S. Centers for Disease Control and Prevention (CDC) and/or to state and local public health officials. In most instances, it is not practical to make EMS personnel mandatory reporters of individual cases, if only because most EMS units do not have the laboratory resources needed to make a specific diagnosis. In addition, the vast majority of "significant" cases of such diseases will usually end up in hospital emergency rooms, where they can and will more easily be reported.

Information packets about specific bioterror agents and the illnesses they cause also should be made available for distribution to the response community, particularly to the EMS community. Briefing sheets are already available from the CDC as well as from many state public health agencies. The briefing sheets would serve as a scientific/medical basis for the packets, which must also address such other important issues as: (a) the personal protective equipment (PPE) available to responders; (b) reminders of the appropriate treatment for infectious disease cases; and (c) emergency plans – including the names and locations of specific hospitals or wards that may be set aside for suspected bioterror victims.

Additional information also should be made available to the general public, obviously, so that everyday citizens also will be better prepared and informed about what they can do to protect themselves. As with all similar threats, the EMS and public health community share a number of common goals for the most important aspects of effective response: (a) early recognition; (b) the effective use of available resources; and, above all (c) full and frequent communications to the medical staff and to the public. In short, providing additional information, as quickly as possible, on bioterror agents and their warning effects will help medical systems reduce the risk of being overwhelmed by the "worried well" who, although not personally displaying any of the symptoms accompanying a particular disease, may still decide to check themselves into the nearest hospital on a "just in case" basis.

Joseph Cahill is a medicolegal investigator for the Massachusetts Office of the Chief Medical Examiner. He previously served as exercise and training coordinator for the Massachusetts Department of Public Health and as emergency planner in the Westchester County (N.Y.) Office of Emergency Management. He also served for five years as the citywide advanced life support (ALS) coordinator for the FDNY – Bureau of EMS. Prior to that, he was the department's Division 6 ALS coordinator, covering the South Bronx and Harlem. He also served on the faculty of the Westchester County Community College's Paramedic Program and has been a frequent guest lecturer for the U.S. Secret Service, the FDNY EMS Academy, and Montefiore Hospital.



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Foodborne Outbreaks in Minnesota: Training and Performance

By Kimberley Wetherille & Evan Henke, State Homeland News

Foodborne disease outbreaks requiring public health emergency responses occur regularly across the nation. The U.S. Centers for Disease Control and Prevention (CDC) estimated in 2011 that foodborne illnesses are responsible for an average of 47.8 million illnesses of various types, more than 125,000 hospitalizations, and over 3,000 deaths per year in the United States. Unlike other disaster-response scenarios, training for this type of response is continuous – and usually acquired on the job. To provide a better and more structured framework for training and evaluation, several improved guidelines were developed by the Council to Improve Foodborne Outbreak Response (CIFOR) – which is co-chaired by the National Association of County and City Health Officials (NACCHO) and the Council of State and Territorial Epidemiologists (CSTE), and is supported by both the CDC and the U.S. Food and Drug Administration (FDA).

A grant from the CDC also is being used to support the University of Minnesota's U-SEEE (Simulations, Exercises, and Effectiveness in Education) program to carry out a "Retrospective Cohort Study of Responders Training and System Performance." U-SEEE investigators are using the CIFOR guidelines as the metrics needed to evaluate training, communications, and the foodborne outbreak response system in Minnesota itself. This approach addresses the top-priority research areas for public health preparedness as identified in the National Academy Institute of Medicine's 22 January 2008 report on *Research Priorities in Emergency Preparedness and Response for Public Health Systems*.

These research areas focus primarily on, but are not necessarily limited to, the following: (a) enhancing the usefulness of training; (b) improving the availability and use of timely emergency communications; (c) creating and maintaining sustainable response systems; and (d) generating effectiveness criteria and metrics.

Suggested Models & Flexible Guidelines – But Uncertain Compliance

The CIFOR guidelines identify the following suggested models for conducting investigations of foodborne outbreaks:

1. Local- and state-level public health department activities focused on outbreak detection and response – from disease surveillance carried out by public health laboratories and/or healthcare professionals, as well as from complaint-based surveillance information received from the general population;

2. The preparation and planning used for outbreak investigations, including defining the roles of specific agencies, standardizing processes, and the training of investigative teams;

3. Suggested procedures for investigating clusters and outbreaks – while also maintaining flexibility; and

4. The reduction of further exposure to the public, and – after a source for the initial outbreak has been established – the prevention of additional future outbreaks.

These models are not meant to be followed rigidly, but can be adapted, for the use of each individual agency and municipality participating, in ways that are considered to be the most useful and expedient to the needs of a particular area and/or outbreak investigation.

Although the CIFOR guidelines were intended to be flexible, the level of compliance to these model practices at local- and state-level public health departments in Minnesota was somewhat uncertain. To learn more about the overall implementation of these model practices, the U-SEEE research team surveyed a number of public health departments throughout the state. The survey results compared the use of model practices in state- and local-level foodborne outbreak investigations. In the model practices described, there appeared to be, at both state and local levels, a bimodal pattern of usage. Model practices appeared to be either commonly used (75 percent of the time or more) or infrequently used (25 percent of the time or less); a few fell somewhere between these upper and lower extremes. The same pattern was observed regardless of whether the investigation was initiated as a result of a public complaint or as follow-on to lab reporting.

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The Framework Needed for "New and Better Methods"

Future research will enable the comparison of model practice use patterns in multiple states, with different systems for organizing outbreak responses. Currently, a second survey is underway investigating the practices used in the CDC's FoodCORE (Foodborne Diseases Centers for Outbreak Response Enhancement) sites, which, as described by CDC itself, "work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases." The principal goal of this second survey is to establish a framework to relate the use of the model practices, training, staffing, resources, and agency roles to the ability of the system to detect and respond to foodborne outbreaks.

For states with limited resources, it may be necessary to prioritize which practices to implement and in what situations. These decisions should be based on successes that the health department can maintain to identify how investigations could be improved. Determining where there are shortcomings in the process – in surveillance, preparation and planning, defining agency roles, standardizing processes, training, staffing, or resources – can lead to more precisely targeted improvements.

Those improvements, it is hoped, will be obvious not only in Minnesota, but throughout the entire country. By using standard practices and including measures focused on thorough data collection and timely responses, all of the nation's health departments will be better able to predict the outcomes of outbreak investigations, in a more timely, more complete, and more effective way.

For additional information on:
CIFOR Guidelines, visit http://www.cifor.us/documents/CIFORGuidelinesforFoodborneDiseaseOutbreakResponse.pdf

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Kimberley Wetherille (pictured) MPH, is a PhD candidate in Environmental Health Sciences at the University of Minnesota's School of Public Health. Her research examines the relationship between disaster responses and training for emergencies in the state of Minnesota during situations ranging from flooding and foodborne outbreaks to structural collapses.

Evan Henke, MPH, is a PhD candidate in Environmental Health Sciences at the University of Minnesota's School of Public Health. His research is focused on the evaluation and continuous improvement, for rapid outbreak detection and investigation, of foodborne disease surveillance systems.

Enterprising Solutions

Buying/Building New State & Local Preparedness Capabilities

By Dennis R. Schrader & John F. Morton, CIP-R

Following the 9/11 terrorist attacks in 2001, the United States started to build new capabilities that would pull state and local governments, as well as the private sector, into the national security enterprise in what would be an unprecedented effort to better protect the U.S. homeland. The federal government also started to push new policies and "voluntary" requirements to the individual states in the hope that grant funding would result in a rapid infusion of sustainable capabilities into the system.

Operational leaders in state/local governments and the private sector have struggled to keep pace with the federal government's effort to build the new capabilities required to support what the 2010 Quadrennial Homeland Security Review (QHSR) called the "Homeland Security Enterprise" (HSE). However, these leaders still lack the acquisition infrastructure needed to take full advantage of the resources that already have been poured into the collective federal/state/local effort. For one thing, it is difficult for them to justify the overhead costs required to establish the competencies necessary to carry out rigorous requirements analyses and to oversee the program management capabilities needed to upgrade public safety and security. (Previous articles published in *DomPrep Journal* have advocated the direct resourcing of planning and systems engineering capabilities to state and local jurisdictions. However, that idea has not yet gained traction.)

Compounding the problem are the numerous cultures and business models of the companies that rushed into the homeland security marketplace in an attempt to "follow the money." For example, defense contractors are accustomed to focus on multi-billion-dollar programs that have relatively long life cycles – often with a generous built-in overhead. In addition, many companies already in the U.S. Defense Industrial Base (DIB) attempted to focus on the emerging and rapidly evolving homeland security market in an effort that was largely fueled not only by the billions of grant dollars suddenly available but also by establishment of the new U.S. Department of Homeland Security (DHS).

Needed: More Effective Planning & Continuing Effort

The initial allure of state and local work – and its limited cost structure, small-scale budgets, and indemnification requirements – has proved over time to be financially unattractive to at least some defense contractors. When resources continue to diminish, as now seems likely, it will be critical that these acquisition issues are much better understood if state and local jurisdictions are asked to invest scarce resources more effectively in the continuing effort to build a truly national, and effective, Homeland Security Enterprise. Otherwise, it will be almost impossible for them, and their private-sector partners, to participate in a meaningful partnership with the federal government.

In a July 2010 *Government Security News* (GSN) article by Jacob Goodwin, Mark Sloman of the Homeland Security Research Corporation (HSRC) suggested that the process just described had already presented some "serious challenges" for businesses trying to "penetrate" the decentralized state and local marketplaces. In that context, it should be remembered that companies already

operating in the DIB are focused on a centralized, single-agency market controlled by the Pentagon – which thereby controls the cost and behavior of all of the sellers in the market, thus providing: (a) not only the standard processes adhered to by all of the companies in the market; but also (b) a considerable degree of predictability. Nonetheless, given the smaller but still very large size of the Homeland-Security market, meeting the serious challenges just mentioned seems likely to be worth the extra effort involved.

After a decade, though, it has become clear that the Homeland Security Industrial Base (HSIB) may in several important ways be related to, but in certain other respects be considerably different from, the traditional DIB. A September 2011 article by Eric Beidel in the National Defense Industrial Association's *National Defense* magazine not only corroborates this view but also acknowledges that the two markets "are driven by different factors."

There is an ongoing struggle to adapt the National Defense Acquisition Model to the National Homeland Security Enterprise. Bridging the gap between federal, state, and local market spaces requires strong and continuing efforts on the parts of all those involved.

Differences in Scale – But Still a Very Large "Middle Market"

The 2010 QHSR mentioned earlier advocated, among other recommendations, an accelerated maturation of the Homeland Security Enterprise. Developing an improved understanding of the HSIB and how it relates to state and local governments, and to the private sector, would be an important step forward in that maturation. For example, the threats that face the nation domestically include sectors such as food and agriculture, healthcare, and life-line sectors such as power, communications, and transportation.

The HSRC report cited in Goodwin's July 2010 GSN article suggests that, at that time, there was an HSE market, estimated at about $53-62 billion and largely financed by state and local governments, and supplemented (by an estimated $3-4 billion) in federal grants. It should be remembered, though, that that very large market is spread throughout all 50 states (and the District of Columbia) and 30,000 counties, cities, and towns throughout the nation.

Industry needs to recognize that a different business model is required to work the two elements of the Homeland Security Market. The scale of both elements is much smaller than the Pentagon market – $428 billion in 2010, according to a July 2011 Center for Strategic and International Studies (CSIS) study (*DHS Contract Spending and the Supporting Industrial Base*) led by David J. Berteau, Senior Advisor and Director of the CSIS Defense-Industrial Initiatives Group. In fact, the U.S. Defense Department's 2010 research and development budget (approximately $41 billion) alone was larger than the entire DHS budget that same year. For that reason, among others, industry would be well advised to evaluate the needs of HSIB leaders in state and local governments – and the private-sector markets as well. All of these potential customers have needs that are different in numerous ways from the needs of the program managers of large federal/national defense programs.

Industry also should focus greater attention on the "middle market" of somewhat lower-cost consultants that can bridge the federal, state, and local market spaces. For their part, state, local, and private-sector customers should look to the small- and medium-sized businesses – which are already very active in the homeland security market – as a potential source of the innovation and flexibility required to develop and sustain the capabilities needed, but at a lower cost, to build out the HSIB and the Homeland Security Enterprise in general.

Dennis R. Schrader (pictured) is President of DRS International, LLC, and former deputy administrator of the Federal Emergency Management Agency's National Preparedness Directorate. Prior to assuming his NPD post he served as the State of Maryland's first director of homeland security, and before that served for 16 years in various leadership posts at the University of Maryland Medical System Corporation.

John F. Morton is the Strategic Advisor for DomPrep. He is also the Homeland Security Team Lead for the Project on National Security Reform (PNSR). A member of the DomPrep team since its founding, he has served as managing editor for writer assignments and interviewer for scores of DomPrep audio interviews.

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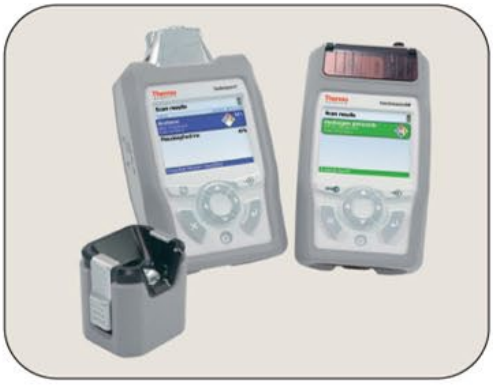

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"The Bomber Will Always Get Through" – 80 Years Later, A Prophecy

By Loren B. Thompson, Viewpoint

The following article is reprinted with permission of Lexington Institute. The opinions expressed herein do not necessarily represent the views of DomesticPreparedness.com, but are considered to be of interest to DomPrep readers.

This November marks the 80th anniversary of one of the most disturbing military assessments ever uttered by a western leader. On 10 November 1932, Britain's de facto prime minister Stanley Baldwin said the following in a parliamentary debate about military policy:

> *I think it is well also for the man in the street to realise that there is no power on earth that can protect him from being bombed. Whatever people may tell him, the bomber will always get through. The only defence is an offence, which means that you have to kill more women and children more quickly than the enemy if you want to save yourselves.*

On the eve of Armistice Day, and just before the latest futile European disarmament conference, Baldwin's remarks created quite a stir. They captured the widespread fear of how the emerging air weapon might be used in future wars – a fear that led thousands of people to evacuate Paris and other continental cities during the Czech crisis in 1938.

As it turned out, Baldwin was only half right. The invention of radar in the late 1930s greatly reduced the danger of not knowing the direction from which an air attack might originate. But the advent of ballistic missiles and nuclear weapons at the end of World War II, and since then, has restored the power of Baldwin's prophecy, because even with radar it is not possible today for any nation to prevent a well-armed adversary from causing untold damage. Western societies spent the second half of the 20th century protected against nuclear attack mainly by the threat of retaliation.

There is not much discussion today about Baldwin's bleak vision, even though mankind continues to live with the threat of nuclear attack. But, as time goes by, more of the security threats the nation faces seem to have the same character of inevitability that the British leader attributed to strategic bombing. For example, in Iraq, costly U.S. military vehicles were destroyed by inexpensive IEDs (improvised explosive devices). The Pentagon then had to spend billions of dollars fielding trucks that could withstand the danger.

There are many other arenas in which disruptive technologies and tactics are now posing an inexorable challenge to U.S. security. It did not take much time and money for Osama bin Laden's ragtag band to mount the 9/11 attacks in 2001 that cost the United States thousands of lives and, in the years that have passed since then, trillions of dollars. Much additional money will be spent over the next decade trying to defend U.S. computer networks against increasingly ubiquitous cyber threats that cost very little to launch but could turn off the lights across the country, or shut down the nation's financial system, or cause any number of other perhaps unsolvable problems. And when a major biological attack is launched against the U.S. homeland, the nation will find out how well it will cope with a real, rather than metaphorical, virus that has been engineered to evade containment and treatment.

Will Americans Be Strong Enough?

The current U.S. military, healthcare, and homeland-security establishments are not much better equipped for dealing with these kinds of emerging threats than the Royal Air Force was in 1932, when Baldwin made his tragically accurate prediction, at coping with German bombers. It is not that defenses against emerging threats are unimaginable but, rather, that those defenses are so expensive, relative to the effort made by attackers, that in the end it may bankrupt the nation trying to keep up.

It is not just money that will be lost trying to keep these latter-day "bombers" from reaching domestic shores. Many cherished rights may also have to be forfeited. Most, if not all, Americans are today unprepared to make that sacrifice – because the consequences of what disciplined and innovative adversaries can accomplish through the use of emerging technologies is yet to be seen. When that day arrives, the question that must be asked is this: "Will Americans struggle with the same despair Britons felt as war clouds gathered in the 1930s, or will they be strong enough to make sacrifices in defense of the nation's homeland, and its values?"

Loren B. Thompson, Ph.D., is the Chief Operating Officer of the non-profit Lexington Institute and Chief Executive Officer of Source Associates. Prior to assuming those posts, he was Deputy Director of the Security Studies Program at Georgetown University and taught graduate-level courses in strategy, technology and media affairs at Georgetown. Disclosure: The Lexington Institute receives funding from many of the nation's leading defense contractors.

Protecting First Responders from Biological Agents

By Christina Spoons, Fire/HazMat

Biological weapons pose a significant threat not only to public health, but also to emergency responders who are trying to assist those directly affected. The use of bio-weapons offers terrorists a low-cost way to carry out an attack against the United States. Such attacks were in fact launched through the U.S. mail system both in 2001 (the anthrax letters that followed the 9/11 attacks against the World Trade Center and the Pentagon) and in 2003-2004 (the ricin-infected letters sent to a number of government offices).

Whether an unexpected incident or event seems to be intentional or unintentional, the early detection and surveillance of possible biological agents that might be present is important for quickly and accurately identifying the disease process and beginning the necessary response procedures.

In addition to widespread fear and the illnesses that would probably follow a biological attack, evidence of the biological agents themselves may not surface immediately. The symptoms in persons exposed to the agents may not be visible for hours, in fact, or even days. In addition, after the symptoms do surface, they are often mistaken for influenza. Moreover, the long delay between release of a toxic substance and detection/identification of the agent would provide terrorists additional time to plan and execute their own escape. Another factor to consider is that a major biological attack is likely to overwhelm local medical facilities and could also deplete the stocks of medication and vaccines immediately available and/or quickly replaceable.

Recognizing the possibility of a future bio-terror attack is the first step needed in protecting first responders. The next step is determining the right combination from the multiple: (a) categories of bio-agents involved; (b) routes of transmission possible; and (c) levels of protection required.

Categories of Biological Agents & Various Routes of Transmission

The U.S. Centers for Disease Control and Prevention (CDC) has categorized biological agents – viruses, bacteria, and bacterial-derived toxins – into three main groups: (a) Category A agents – e.g., anthrax, botulism, plague, which pose the highest risk because they can be easily disseminated and quickly spread from one person to another. The result would be high mortality rates and a major impact on public health. (b) Category B agents – e.g., ricin toxin and/or food/water threats such as salmonella and cholera, which also are relatively easy to disseminate. The result here would be a medium risk of illnesses and in most cases a somewhat lower death rate. (c) Category C agents – e.g., emerging pathogens, which in the future may be engineered for mass dissemination and are the most destructive because of their availability, ease of production, and immense potential for widespread illness and death.

Simply being in the vicinity of a biological agent does not necessarily ensure that a person will become ill. In order to affect an individual human being, the agent must actually enter that person's body. The three principal routes of transmission are: (a) the physical contact of a person with a substance or microorganism; (b) the inhalation of vapors, droplets, or aerosols (particles up to five microns in size may be made into an aerosol and, with the right conditions, can travel distances up to 12 miles and harm anyone in its path); and (c) ingestion of the substance – usually by the consumption of contaminated food or water.

Physical contact, either directly or indirectly, is the most frequent mode of transmission. Direct-contact transmission takes place when a microorganism is transferred directly from an infected person to another person through touch. Indirect contact transmission is when the transfer occurs through use of an intermediary object such as a contaminated needle. Contact also may occur when a microorganism is transmitted by a broad spectrum of "living vectors" such as mosquitoes, flies, or rats.

Some diseases, of course, are capable of being transmitted in more than one way, with each route of

transmission creating different symptoms. Anthrax and plague are just two examples of agents that, depending on the mode of transmission used, develop into different forms of the same disease.

Four Levels of Protection And the Three-Ups Rule

When deliberately used as a biological weapon, an infectious disease can affect a greater number of people in a short amount of time. Obviously, therefore, additional safety precautions are needed to protect first responders themselves from becoming victims of secondary contamination. Fortunately, the Occupational Safety and Health Administration (OSHA) has already defined four levels of protection recommended for the personal protective equipment (PPE) used by responders (and/or other persons likely to be present at the scene of a biological incident or event).

Following, as defined by OSHA, are the PPE specifics: (a) Level A – a fully encapsulated suit fitted with an internal self-contained breathing apparatus (SCBA) – provides maximum protection against most vapor and liquid materials; (b) Level B – a chemical-resistant suit fitted with an external SCBA – offers a high level of protection against oxygen-deficient atmospheres, but a lower level of skin protection; (c) Level C – a chemical suit accompanied by an air-purifying respirator (APR) – can help protect against known hazards (but the APR filter is usually designed to filter only specific chemicals and will not protect responders in oxygen-deficient atmospheres); and (d) Level D – the basic station work uniform – provides only minimal protection. Individual responders, and their supervisors, must take special care in determining and selecting the appropriate level of protection needed for the situation at hand.

Caution also should be used by anyone called to the scene of a multi-casualty incident involving suspicious signs and symptoms, particularly respiratory distress. In addition to staying uphill, upstream, and upwind of the incident site, it is important that responders: (a) be aware of any invisible dangers that may be present; (b) summon trained hazmat teams to the site if there is any suspicion of toxic dangers; and (c) select the correct level of the protective equipment needed.

A final but very helpful rule of thumb also to remember is this: If and when two, three, or more patients are

complaining of similar symptoms, that in itself may well be the first clue needed to alert responders to a possible bio-terror event.

For additional information on:
Department of Homeland Security – National Response Plan, visit http://www.fema.gov/emergency/nrf/

National Library of Medicine/National Institutes of Health Medline Plus – Biodefense and Bioterrorism, visit http://www.nlm.nih.gov/medlineplus/biodefenseandbioterrorism.html

Occupational Safety and Health Administration, visit http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9767

The Centers for Disease Control and Prevention bioterrorism information, visit http://www.bt.cdc.gov/bioterrorism/

U.S. Food and Drug Administration Bioterrorism and Drug Preparedness, visit http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/default.htm

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Christina Spoons holds a Masters in Public Administration with a concentration in Homeland Security and is currently completing her Ph.D. in the same discipline with a concentration in Terrorism, Mediation, and Peace, both from Walden University. Her emergency services experience includes several years as a Firefighter/EMT and instructor with the American Red Cross. She has been active in the development of firefighter curricula at both the state and national levels and also is involved with several National Fire Protection Association committees, including those focused on Firefighter professional qualifications and electronic safety equipment. She teaches homeland security and public policy and administration courses at Ashford University, and fire science courses at Columbia Southern University.

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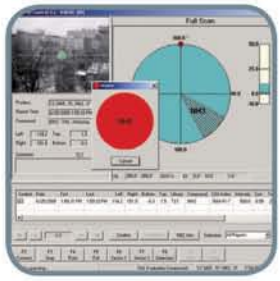

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An Exercise in Utility: The Role of Public Health

By Raphael M. Barishansky & Audrey Mazurek, Public Health

Effective emergency preparedness requires, among many other things, drills and exercises of various types to test the preparedness, response, and recovery capabilities of the numerous agencies and individual responders involved. Regardless of the professional discipline – law enforcement/public safety, emergency management, homeland security, and/or public works – it is particularly important: (a) to have a well-established emergency plan in place that is based on realistic pre-identified hazards; and (b) to exercise that plan on a regular but not necessarily "routine" basis. In public health, there is still a need to fully develop applicable emergency plans – and, subsequently, to drill and exercise those plans.

The drills and exercises for public health agencies and organizations are not really much different than those for other response agencies; for one thing, they usually use similar terminology, and also rely heavily on the participation of, and input provided by, a number of partners. Most emergency preparedness exercises fall into two principal categories, as follows:

1. *Discussion-based exercises* – workshops, seminars, and tabletops that bring together the partners involved to stimulate discussions focused on a hypothetical situation; and

2. *Operations-based exercises* – drills, which test a single, specific operation or function in a single agency; functional exercises, which are conducted by one or more agencies to evaluate capabilities and functions through use of a simulated response; and full-scale exercises, which involve two or more agencies and jurisdictions and test many interrelated facets of emergency response and recovery operations.

A helpful rule of thumb to follow is to begin an exercise cycle with a discussion-based exercise so that all agencies and organizations that are assigned roles and responsibilities in a response can fully understand them before proceeding further and testing their own operational capabilities.

Essential Reading: Preparedness Guidance

In that context, a helpful resource to develop a better understanding of various exercises, and how to conduct them to one's best advantage, is the federally developed and capabilities-based DHS Homeland Security Exercise and Evaluation Program (HSEEP) that provides the standardized guidance and terminology used for exercise design. It is imperative that there are personnel in the health department, at every level of government, who have actively participated in HSEEP training and understand the various elements involved in developing, conducting, and evaluating an effective exercise.

Such training is appropriate for all types of exercises – including, for example: (a) a local health department scheduling a "call down" drill with the incident command staff; (b) a county or regional health authority planning a functional exercise to test the movement of POD (point of dispensing) materials to a predesignated POD site; and (c) a state health department carrying out a full-scale exercise with external partners to test the preparedness and response capabilities – of all of the agencies participating – required to cope with the outbreak of a deadly disease such as a pandemic influenza.

Not coincidentally, there have been several reports and/or policy papers issued over the past 13 months that underscore the overall importance of the readiness capabilities – again, at all levels of government – needed to respond to large-scale events. Two of those documents – the Public Health Preparedness Capabilities, released in March 2011 by the U.S. Centers for Disease Control and Prevention (CDC); and the Department of Health and Human Services (HHS) Healthcare Preparedness Capabilities, released in January 2012 by the Department's Assistant Secretary for Preparedness and Response (ASPR) – focus special attention on the realities facing the agencies and organizations involved in the public health response. Those realities include, but are not necessarily limited to: (a) the type of events the participating agencies may encounter; (b) the capabilities required to respond to such events; and (c) the assessment of the potential gaps that might exist between what is needed and what is available. One of the

most important elements in understanding and eventually filling the gaps identified is the development of, and participation in, various emergency exercises.

Public Health Preparedness Exercises: A Clear Focus on ESF #8

State health authorities frequently take the opportunity to exercise with their local jurisdictions and partners on a regular basis. One example of this is that many state-level public health authorities tested their pandemic preparedness and response capabilities through various exercises in the wake of the H1N1 pandemic. The scenario of these functional or full-scale exercises with local counterparts was the time period in the middle of a pandemic in what the World Health Organization (WHO) refers to as the Pandemic Alert Period – during which there is limited human-to-human transmission and the virus might evolve into a strain increasingly adapted to humans. These exercises dealt primarily with the various elements of Emergency Support Function (ESF) #8 (Public Health and Medical) responsibilities, and typically included: (a) the opening of both state and local emergency operations centers (EOCs); (b) fulfilling of Strategic National Stockpile (SNS) requests – from the states involved, to the federal government; and (c) communications with hospitals, emergency medical services (EMS) agencies, and other health partners likely to be involved.

Federal health agencies – usually HHS and/or DHS – also exercise their preparedness and response roles, emergency plans, and collaboration with state, territorial, regional, and local partners on a regular basis. National Level Exercises (NLEs) are a series of congressionally mandated preparedness exercises designed to prepare federal, state, local, private-sector, and international partners, departments, and agencies to respond, collectively as well as individually, to a broad spectrum of potentially catastrophic events and incidents.

The June 2011 NLE – "Operation Dark Winter" – was designed as a bioterrorist attack simulation. The tabletop exercise started with a scenario that postulated a localized

smallpox attack on Oklahoma City that quickly spread to several other states and required that federal resources be requested. The overarching goal of the exercise was to establish preventive measures and response strategies by increasing governmental and public awareness of the magnitude and destructive potential of such a threat, particularly one posed by a terrorist group using biological weapons.

Other NLEs have included similar public health elements. More specifically:

1. The 2003 NLE (previously referred to as TOPOFF) was a full-scale exercise designed to identify vulnerabilities in the nation's incident management capabilities. The scenario postulated that a terrorist organization had: (a) detonated a simulated radiological dispersal device in Seattle, Washington; and (b) released the pneumonic plague bacteria into several metropolitan areas in and around Chicago.

2. The 2010 NLE scenario used a simulated terrorist act involving an improvised nuclear device and tested the readiness of federal, state, and local partners to demonstrate and assess their individual and joint emergency preparedness capabilities.

The Short- and Long-Range Goals: Continuous Quality Improvement

Establishing and following a continuous quality improvement cycle – i.e., plan, train, exercise, implement corrective actions to the plans, then repeat the cycle – continues to be a common and, in some jurisdictions, a mandated practice by public health authorities. The principal components of this cycle include: (a) exercising plans; (b) ensuring that staff are fully and effectively trained; and (c) building and maintaining the capabilities needed to respond to a major emergency.

Unfortunately, the fiscal resources that many public health and healthcare organizations rely on – funds provided through the Cities Readiness Initiative (CRI), Hospital Preparedness Program (HPP), and Public Health Emergency Preparedness (PHEP) programs – have been cut back significantly over the past few years. Nonetheless, even as budgets and staff continue to decline in the foreseeable future, it remains critical that public health departments continue to plan and conduct effective, realistic exercises. Doing so can be a daunting task, but there are a few common-sense recommendations – including the following – that will help compensate for the reduced funding and are already in effect in various jurisdictions throughout the country:

1. *Maximize the benefits available from state-level exercises* – When a state agency plans an exercise, use that exercise to simultaneously test various other aspects of an agency's preparedness plans.

2. *Regionalize* – Combine resources with neighboring jurisdictions to exercise as a region.

3. *Collaborate* – Combine resources with other response agencies and/or healthcare facilities within the same or neighboring jurisdiction to exercise jointly.

Regardless of the specific type of event being exercised, it is essential that members of the public health sector understand not only the plan and goal(s) of any exercise, but also the specific roles and responsibilities of each agency participating. It is also important to ensure that public health agencies are represented in the after-action discussion and evaluation processes to: (a) document the lessons learned; (b) comment constructively about the exercise; (c) address the gaps and issues involving current plans and/or processes that have been identified; and (d) most important of all, develop and implement an improvement plan. Involvement in such discussions will in itself facilitate a continuous quality improvement process.

For additional information on:
The tools, resources, and templates related to the design, development, conduct, evaluation, and improvement of the exercise planning process, visit https://hseep.dhs.gov

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IN A CHEMICAL NERVE AGENT ATTACK

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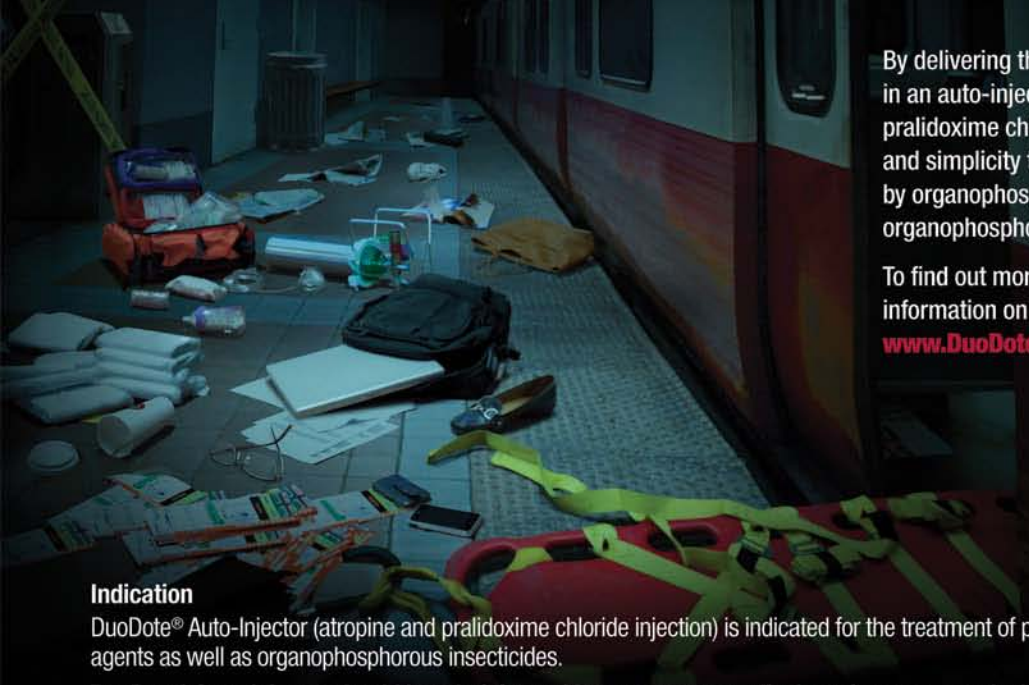

By delivering the 2 recommended antidotes in an auto-injector, DuoDote® (atropine and pralidoxime chloride injection) offers the speed and simplicity to help you respond to poisoning by organophosphorous nerve agents or organophosphorous insecticides.[1-3]

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Indication

DuoDote® Auto-Injector (atropine and pralidoxime chloride injection) is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides.

DuoDote® Auto-Injector should be administered by emergency medical services personnel who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication. DuoDote® Auto-Injector is intended as an initial treatment of the symptoms of organophosphorous insecticide or nerve agent poisoning; definitive medical care should be sought immediately.

Important Safety Information

Individuals should not rely solely upon agents such as atropine and pralidoxime to provide complete protection from chemical nerve agents and insecticide poisoning. Primary protection against exposure to chemical nerve agents and insecticide poisoning is the wearing of protective garments including masks designed specifically for this use. Evacuation and decontamination procedures should be undertaken as soon as possible. Medical personnel assisting evacuated victims of nerve agent poisoning should avoid contaminating themselves by exposure to the victim's clothing.

In the presence of life-threatening poisoning by organophosphorous nerve agents or insecticides, there are no absolute contraindications to the use of DuoDote® Auto-Injector. When symptoms of poisoning are not severe, DuoDote® Auto-Injector should be used with extreme caution in people with heart disease, arrhythmias, recent myocardial infarction, severe narrow angle glaucoma, pyloric stenosis, prostatic hypertrophy, significant renal insufficiency, chronic pulmonary disease, or hypersensitivity to any component of the product. Elderly people and children may be more susceptible to the effects of atropine. DuoDote® Auto-Injector is Pregnancy Category C and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Safety and effectiveness in children have not been established.

Muscle tightness and sometimes pain may occur at the injection site.
The most common side effects of atropine can be attributed to its antimuscarinic action. Pralidoxime chloride can cause changes in vision, dizziness, headache, drowsiness, nausea, tachycardia, increased blood pressure, muscular weakness, dry mouth, emesis, rash, dry skin, hyperventilation, decreased renal function, excitement, manic behavior, and transient elevation of liver enzymes and creatine phosphokinase. When atropine and pralidoxime are used together, the signs of atropinization may occur earlier than might be expected when atropine is used alone.

DuoDote® AUTO-INJECTOR
(atropine and pralidoxime chloride injection)

READY TO RESPOND

Please see brief summary of full Prescribing Information on adjacent page.

References: 1. Agency for Toxic Substances and Disease Registry. Medical Management Guidelines (MMGs) for nerve agents: tabun (GA); sarin (GB); soman (GD); and VX. http://www.atsdr.cdc.gov/MHMI/mmg166.html. Updated August 22, 2008. Accessed May 20, 2010. **2.** DuoDote Auto-Injector [package insert]. Columbia, MD: Meridian Medical Technologies, Inc.; 2007. **3.** Rebmann T, Clements BW, Bailey JA, Evans RG. Organophosphate antidote auto-injectors vs. traditional administration: a time motion study. *J Emerg Med*. 2009;37(2):139-143.

MERIDIAN MEDICAL TECHNOLOGIES™

DuoDote® AUTO-INJECTOR
(atropine and pralidoxime chloride injection)

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

Rx Only
Atropine 2.1 mg/0.7 mL
Pralidoxime Chloride 600 mg/2 mL

Sterile solutions for intramuscular use only

FOR USE IN NERVE AGENT AND INSECTICIDE POISONING ONLY

THE DUODOTE™ AUTO-INJECTOR SHOULD BE ADMINISTERED BY EMERGENCY MEDICAL SERVICES PERSONNEL WHO HAVE HAD ADEQUATE TRAINING IN THE RECOGNITION AND TREATMENT OF NERVE AGENT OR INSECTICIDE INTOXICATION.

INDICATIONS AND USAGE

DuoDote™ Auto-Injector is indicated for the treatment of poisoning by organophosphorus nerve agents as well as organophosphorus insecticides.

DuoDote™ Auto-Injector should be administered by emergency medical services personnel who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.

DuoDote™ Auto-Injector is intended as an initial treatment of the symptoms of organophosphorus insecticide or nerve agent poisonings; definitive medical care should be sought immediately.

DuoDote™ Auto-Injector should be administered as soon as symptoms of organophosphorus poisoning appear (eg, usually tearing, excessive oral secretions, sneezing, muscle fasciculations).

CONTRAINDICATIONS

In the presence of life-threatening poisoning by organophosphorus nerve agents or insecticides, there are no absolute contraindications to the use of DuoDote™ Auto-Injector.

WARNINGS

CAUTION! INDIVIDUALS SHOULD NOT RELY SOLELY UPON ATROPINE AND PRALIDOXIME TO PROVIDE COMPLETE PROTECTION FROM CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING.

PRIMARY PROTECTION AGAINST EXPOSURE TO CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING IS THE WEARING OF PROTECTIVE GARMENTS INCLUDING MASKS DESIGNED SPECIFICALLY FOR THIS USE.

EVACUATION AND DECONTAMINATION PROCEDURES SHOULD BE UNDERTAKEN AS SOON AS POSSIBLE. MEDICAL PERSONNEL ASSISTING EVACUATED VICTIMS OF NERVE AGENT POISONING SHOULD AVOID CONTAMINATING THEMSELVES BY EXPOSURE TO THE VICTIM'S CLOTHING.

When symptoms of poisoning are not severe, DuoDote™ Auto-Injector should be used with extreme caution in people with heart disease, arrhythmias, recent myocardial infarction, severe narrow angle glaucoma, pyloric stenosis, prostatic hypertrophy, significant renal insufficiency, chronic pulmonary disease, or hypersensitivity to any component of the product. Organophosphorus nerve agent poisoning often causes bradycardia but can be associated with a heart rate in the low, high, or normal range. Atropine increases heart rate and alleviates the bradycardia. In patients with a recent myocardial infarction and/or severe coronary artery disease, there is a possibility that atropine-induced tachycardia may cause ischemia, extend or initiate myocardial infarcts, and stimulate ventricular ectopy and fibrillation. In patients without cardiac disease, atropine administration is associated with the rare occurrence of ventricular ectopy or ventricular tachycardia. Conventional systemic doses may precipitate acute glaucoma in susceptible individuals, convert partial pyloric stenosis into complete pyloric obstruction, precipitate urinary retention in individuals with prostatic hypertrophy, or cause inspiration of bronchial secretions and formation of dangerous viscid plugs in individuals with chronic lung disease.

More than 1 dose of DuoDote™ Auto-Injector, to a maximum of 3 doses, may be necessary initially when symptoms are severe. **No more than 3 doses should be administered unless definitive medical care (eg, hospitalization, respiratory support) is available.**

Severe difficulty in breathing after organophosphorus poisoning requires artificial respiration in addition to the use of DuoDote™ Auto-Injector.

A potential hazardous effect of atropine is inhibition of sweating, which in a warm environment or with exercise, can lead to hyperthermia and heat injury.

The elderly and children may be more susceptible to the effects of atropine.

PRECAUTIONS

General: The desperate condition of the organophosphorus-poisoned individual will generally mask such minor signs and symptoms of atropine and pralidoxime treatment as have been noted in normal subjects.

Because pralidoxime is excreted in the urine, a decrease in renal function will result in increased blood levels of the drug.

DuoDote™ Auto-Injector temporarily increases blood pressure, a known effect of pralidoxime. In a study of 24 healthy young adults administered a single dose of atropine and pralidoxime auto-injector intramuscularly (approximately 9 mg/kg pralidoxime chloride), diastolic blood pressure increased from baseline by 11 ± 14 mmHg (mean ± SD), and systolic blood pressure increased by 16 ± 19 mmHg, at 15 minutes post-dose. Blood pressures remained elevated at these approximate levels through 1 hour post-dose, began to decrease at 2 hours post-dose and were near pre-dose baseline at 4 hours post-dose. Intravenous pralidoxime doses of 30-45 mg/kg can produce moderate to marked increases in diastolic and systolic blood pressure.

Laboratory Tests: If organophosphorus poisoning is known or suspected, treatment should be instituted without waiting for confirmation of the diagnosis by laboratory tests. Red blood cell and plasma cholinesterase, and urinary paranitrophenol measurements (in the case of parathion exposure) may be helpful in confirming the diagnosis and following the course of the illness. However, miosis, rhinorrhea, and/or airway symptoms due to nerve agent vapor exposure may occur with normal cholinesterase levels. Also, normal red blood cell and plasma cholinesterase values vary widely by ethnic group, age, and whether the person is pregnant. A reduction in red blood cell cholinesterase concentration to below 50% of normal is strongly suggestive of organophosphorus ester poisoning.

Drug Interactions: When atropine and pralidoxime are used together, pralidoxime may potentiate the effect of atropine. When used in combination, signs of atropinization (flushing, mydriasis, tachycardia, dryness of the mouth and nose) may occur earlier than might be expected when atropine is used alone.

The following precautions should be kept in mind in the treatment of anticholinesterase poisoning, although they do not bear directly on the use of atropine and pralidoxime.

- Barbiturates are potentiated by the anticholinesterases; therefore, barbiturates should be used cautiously in the treatment of convulsions.
- Morphine, theophylline, aminophylline, succinylcholine, reserpine, and phenothiazine-type tranquilizers should be avoided in treating personnel with organophosphorus poisoning.
- Succinylcholine and mivacurium are metabolized by cholinesterases. Since pralidoxime reactivates cholinesterases, use of pralidoxime in organophosphorus poisoning may accelerate reversal of the neuromuscular blocking effects of succinylcholine and mivacurium.

Drug-drug interaction potential involving cytochrome P450 isozymes has not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility: DuoDote™ Auto-Injector is indicated for short-term emergency use only, and no adequate studies regarding the potential of atropine or pralidoxime chloride for carcinogenesis or mutagenesis have been conducted.

Impairment of Fertility: In studies in which male rats were orally administered atropine (62.5 to 125 mg/kg) for one week prior to mating and throughout a 5-day mating period with untreated females, a dose-related decrease in fertility was observed. A no-effect dose for male reproductive toxicity was not established. The low-effect dose was 290 times (on a mg/m^2 basis) the dose of atropine in a single application of DuoDote™ Auto-Injector (2.1 mg).

Fertility studies of atropine in females or of pralidoxime in males or females have not been conducted.

Pregnancy:

Pregnancy Category C: Adequate animal reproduction studies have not been conducted with atropine, pralidoxime, or the combination. It is not known whether pralidoxime or atropine can cause fetal harm when administered to a pregnant woman or if they can affect reproductive capacity. Atropine readily crosses the placental barrier and enters the fetal circulation.

DuoDote™ Auto-Injector should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Atropine has been reported to be excreted in human milk. It is not known whether pralidoxime is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DuoDote™ Auto-Injector is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of DuoDote™ Auto-Injector in pediatric patients have not been established.

ADVERSE REACTIONS

Muscle tightness and sometimes pain may occur at the injection site.

Atropine

The most common side effects of atropine can be attributed to its antimuscarinic action. These include dryness of the mouth, blurred vision, dry eyes, photophobia, confusion, headache, dizziness, tachycardia, palpitations, flushing, urinary hesitancy or retention, constipation, abdominal pain, abdominal distention, nausea and vomiting, loss of libido, and impotence. Anhidrosis may produce heat intolerance and impairment of temperature regulation in a hot environment. Dysphagia, paralytic ileus, and acute angle closure glaucoma, maculopapular rash, petechial rash, and scarletiniform rash have also been reported.

Larger or toxic doses may produce such central effects as restlessness, tremor, fatigue, locomotor difficulties, delirium followed by hallucinations, depression, and, ultimately medullary paralysis and death. Large doses can also lead to circulatory collapse. In such cases, blood pressure declines and death due to respiratory failure may ensue following paralysis and coma.

Cardiovascular adverse events reported in the literature for atropine include, but are not limited to, sinus tachycardia, palpitations, premature ventricular contractions, atrial flutter, atrial fibrillation, ventricular flutter, ventricular fibrillation, cardiac syncope, asystole, and myocardial infarction. (See **PRECAUTIONS**.)

Hypersensitivity reactions will occasionally occur, are usually seen as skin rashes, and may progress to exfoliation. Anaphylactic reaction and laryngospasm are rare.

Pralidoxime Chloride

Pralidoxime can cause blurred vision, diplopia and impaired accommodation, dizziness, headache, drowsiness, nausea, tachycardia, increased systolic and diastolic blood pressure, muscular weakness, dry mouth, emesis, rash, dry skin, hyperventilation, decreased renal function, and decreased sweating when given parenterally to normal volunteers who have not been exposed to anticholinesterase poisons.

In several cases of organophosphorus poisoning, excitement and manic behavior have occurred immediately following recovery of consciousness, in either the presence or absence of pralidoxime administration. However, similar behavior has not been reported in subjects given pralidoxime in the absence of organophosphorus poisoning.

Elevations in SGOT and/or SGPT enzyme levels were observed in 1 of 6 normal volunteers given 1200 mg of pralidoxime intramuscularly, and in 4 of 6 volunteers given 1800 mg intramuscularly. Levels returned to normal in about 2 weeks. Transient elevations in creatine kinase were observed in all normal volunteers given the drug.

Atropine and Pralidoxime Chloride

When atropine and pralidoxime are used together, the signs of atropinization may occur earlier than might be expected when atropine is used alone.

OVERDOSAGE

Symptoms:

Atropine

Manifestations of atropine overdose are dose-related and include flushing, dry skin and mucous membranes, tachycardia, widely dilated pupils that are poorly responsive to light, blurred vision, and fever (which can sometimes be dangerously elevated). Locomotor difficulties, disorientation, hallucinations, delirium, confusion, agitation, coma, and central depression can occur and may last 48 hours or longer. In instances of severe atropine intoxication, respiratory depression, coma, circulatory collapse, and death may occur.

The fatal dose of atropine is unknown. In the treatment of organophosphorus poisoning, doses as high as 1000 mg have been given. The few deaths in adults reported in the literature were generally seen using typical clinical doses of atropine often in the setting of bradycardia associated with an acute myocardial infarction, or with larger doses, due to overheating in a setting of vigorous physical activity in a hot environment.

Pralidoxime

It may be difficult to differentiate some of the side effects due to pralidoxime from those due to organophosphorus poisoning. Symptoms of pralidoxime overdose may include: dizziness, blurred vision, diplopia, headache, impaired accommodation, nausea, and slight tachycardia. Transient hypertension due to pralidoxime may last several hours.

Treatment: For atropine overdose, supportive treatment should be administered. If respiration is depressed, artificial respiration with oxygen is necessary. Ice bags, a hypothermia blanket, or other methods of cooling may be required to reduce atropine-induced fever, especially in children. Catheterization may be necessary if urinary retention occurs. Since atropine elimination takes place through the kidney, urinary output must be maintained and increased if possible; intravenous fluids may be indicated. Because of atropine-induced photophobia, the room should be darkened.

A short-acting barbiturate or diazepam may be needed to control marked excitement and convulsions. However, large doses for sedation should be avoided because central depressant action may coincide with the depression occurring late in severe atropine poisoning. Central stimulants are not recommended.

Physostigmine, given as an atropine antidote by slow intravenous injection of 1 to 4 mg (0.5 to 1.0 mg in children) rapidly abolishes delirium and coma caused by large doses of atropine. Since physostigmine has a short duration of action, the patient may again lapse into coma after 1 or 2 hours, and require repeated doses. Neostigmine, pilocarpine, and methacholine are of little benefit, since they do not penetrate the blood-brain barrier.

Pralidoxime-induced hypertension has been treated by administering phentolamine 5 mg intravenously, repeated if necessary due to phentolamine's short duration of action. In the absence of substantial clinical data regarding use of phentolamine to treat pralidoxime-induced hypertension, consider slow infusion to avoid precipitous corrections in blood pressure.

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Dual-Use Disasters: Lessons for Preparedness Professionals

By Earl Stoddard, Public Health

Much of emergency preparedness focuses on reducing, preventing, and/or mitigating risk. However, there are certain circumstances whereby a risk is actually created in order to help mitigate or diminish a second, and even greater, risk. Whether that approach is reasonable and/or necessary has caused considerable debate, which is focused primarily on the value of "dual-use" biomedical research – a major subject of discussion at an eBriefing presented on 2 February 2012 by the Emerging Infectious Diseases & Microbiology Discussion Group of the New York Academy of Sciences.

Dual-use research is essentially defined as scientific exploration of the tools, products, and/or findings that could be used in benevolent and productive ways to improve human health or, alternatively, cause significant harm if accidentally or intentionally released upon the public. It seems clear, though, that – despite the fact that the debate between the scientific and homeland security communities over the safety and benefits of such research is extremely important – the emergency preparedness community also must focus on the potential impact that dual-use laboratories have on local planning and preparedness efforts.

The H5N1 Avian Influenza Episode

In December 2011, the scientific journal *Science* approached the National Science Advisory Board for Biodefense (NSABB) to discuss a manuscript being considered for publication. The research that generated the manuscript in question involved laboratories, in the United States and Denmark, that had successfully adapted the H5N1 avian influenza virus to be transmitted through airborne means to ferrets – i.e., the animal model that most closely resembles human influenza infection.

The *Science* editors were concerned about the potentially malevolent uses that this research could have and for that reason sought guidance on the appropriateness of its full publication. Ultimately, the NSABB recommended publication of an amended and somewhat truncated article in which information about the scientific methods used had been deleted – thereby, it was and is hoped, preventing replication of the experiments for unscrupulous or even criminal purposes.

The U.S. and Denmark studies were funded principally through federal grants provided by the U.S. National Institutes of Health (NIH) and, therefore, probably should have received closer scrutiny long before the research had progressed to the point of publication. This perceived lack of proper oversight has raised concerns about other research of a similar nature that might already be ongoing in academic or private laboratories both in the United States and in a number of other nations.

Benefits and Risks of Dual-Use Research

Continuing with the H5N1 example: The potential medical benefits gained by a better understanding of the virus are clear. As of 26 March 2012, there had been 352 deaths – out of 598 human cases of H5N1 reported to the World Health Organization (WHO); that number translates into a mortality rate of close to 59 percent.

Fortunately, the number of human infections has been relatively limited, and the virus has thus far not adapted well enough in humans to spread efficiently from one person to another. However, if the virus does start to mutate in such a fashion, the public health and preparedness communities could be facing a pandemic the consequences of which might closely resemble those caused by the 1918 Spanish Flu – estimated by WHO to have killed 20 to 40 million, or more, worldwide. For purposes of comparison, the more recent and much less severe 2009-2010 H1N1 pandemic, according to WHO, had killed just over 18,000 people worldwide as of the end of May 2010 (there is some disagreement on the final total, but it seems likely it will not be much higher than the WHO estimate).

Research such as that soon to be reported in *Science* might well provide valuable insights into possible evolution of the virus into a form that could lead to more efficient human transmission. Such research therefore might give U.S. public health officials the ability to analyze current and future strains in the time needed to detect any shift that could lead down such a dangerous path. Here it also should be noted that the laboratory research already carried out produced strains that: (a) will allow medical professionals to better understand how an H5N1 pandemic might play out in humans; and (b) might lead to the advance development of a novel vaccine and/or other treatments.

On the other hand, though – and this also should be emphasized: the public health benefits might indeed be evident, but so are the risks. Human error can and in fact has in the past led to lethal laboratory accidents – one recent example was the 2009 death of a 60-year-old researcher in Illinois who contracted the plague after a laboratory exposure. In the case of a highly pathogenic and infectious disease such as influenza, of course, the consequences of such laboratory exposure are considerably higher.

Another factor to be considered is that such research also might serve, unintentionally, as "proof of principle" for potential terrorist organizations or rogue states to begin work on building new weapons of mass destruction. For that reason alone it is obvious that, while recognizing that the NSABB recommended limiting publication of the methodology used in the H5N1 research, such a recommendation, even if followed to the letter, does not necessarily and/or completely eliminate the risks involved.

New Challenges for The Preparedness Community

Given the demonstrable risks involved, dual-use research represents an ongoing and often under-appreciated threat that public health, emergency management, and preparedness professionals must always keep in mind in their risk-analysis judgments and decisions. The most significant challenge in this area is simply to maintain constant awareness. Domestic laboratories are mandated under federal law to self-identify through the National Select Agent Registry – which is jointly maintained by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). However, the information possessed and/or provided to those two agencies does not necessarily trickle down to state and local responders – or even to the political leaders legally responsible for making the final go/no-go decisions.

Nonetheless, when a fire department vehicle or ambulance arrives at the scene at a laboratory accident, the responders themselves also must be fully aware of any potential exposure risks involved. Similarly, senior hospital officials should be provided with the information needed, and available, about any biological hazards within their communities – even if those hazards are maintained in well protected laboratories and/or other secure environments.

Some states have a direct registration process for laboratories to ensure that they have access to current information about the various agents being studied within their states. Maryland, for example, maintains a Biological Agents Registry (BAR) program in its Department of Health and Mental Hygiene's Office of Laboratory Emergency Preparedness and Response (OLEPR). The BAR program requires that all laboratories – both academic and private-sector – register with the state and report, in writing, whenever changes are made to a facility's select agent research inventory. This information is then relayed to specific state, local, and municipal officials in an effort to improve and expand overall situational awareness. It is recognized, of course, that the open sharing with the public of the types and locations of certain agents might present a security risk, but providing limited and appropriate access to such information is an important aspect of preparedness.

Risks vs. Rationale – but a Murky Conclusion

Efforts to improve communication between and among the public, first responders, and the laboratory community can occur even at the local level. For example, Frederick, Maryland, is home to Fort Detrick, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and its supporting private laboratories. In November 2010, the City of Frederick and the Frederick County Board of Commissioners established the Containment Laboratory Community Advisory Committee (CLCAC).

Since then, the committee has defined its priorities to include: (a) establishing a strong relationship between local governments and their military counterparts at Fort Detrick; (b) informing group members about the missions, risks, and benefits of the research being conducted within their community; and (c) providing an avenue for community feedback, questions, and concerns. The CLCAC membership includes local and municipal government officials, a number of private citizens, and representatives of the laboratory community. The Committee also has started to develop the information needed to reassure the general public that residents and other citizens are kept fully informed about the ongoing research being carried out within their community.

Dual-use laboratories present yet another risk for potential emergencies, but they also afford the preparedness community the rationale needed for identifying and engaging another segment of its community in emergency preparedness endeavors – i.e., the research laboratories, which are usually willing partners. One recent example of this type of


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engagement was through the Regional Center for Excellence (RCE) in Biodefense and Emerging Infectious Diseases program – which is administered by the National Institute of Allergy and Infectious Diseases (NIAID). The RCE program funds basic and translational science research in biodefense and emerging infectious diseases. The program also establishes the requirement, as a funding commitment, that the RCEs engage local, state, and regional partners in public health emergency preparedness matters, particularly by serving as subject matter experts on various biological events.

The RCEs have engaged in public health laboratory capacity building and community education by providing expert advice. Thus, although the future of the program's funding remains somewhat murky (in large part because of already difficult funding restrictions), the RCEs serve as an excellent model for engaging academic laboratories in their joint venture in emergency preparedness. Searching for similar opportunities will offer the preparedness community improved collaborations, an earlier as well as more comprehensive identification of local risks, and, it is hoped, new partners in emergency preparedness.

For additional information on:
The February 2012 eBriefing presented by the New York Academy of Sciences, visit http://www.nyas.org/Events/Detail.aspx?cid=f7d2e65c-9f8d-4418-b25e-bff21bb0a6cb

H5N1 Avian Influenza, visit http://www.who.int/influenza/human_animal_interface/en/

National Select Agent Registry, visit http://www.selectagents.gov/

Maryland Biological Agent Registry (BAR), visit http://dhmh.maryland.gov/laboratories/docs/BAR_FAQs.pdf

RCE Programs, visit http://www.niaid.nih.gov/labsandresources/resources/rce/

The Frederick, Maryland, Containment Laboratory Community Advisory Committee (CLCAC), visit http://www.cityoffrederick.com/index.aspx?NID=127

Earl Stoddard is the Public Health Program Manager for the University of Maryland Center for Health and Homeland Security (CHHS). In that post, his responsibilities include overseeing many of the Center's public health efforts, working with regional partners on public health preparedness efforts, and improving the interface between the public health and emergency management communities. He also assists several local governments, hospitals, and regional organizations in identifying shortfalls, improving planning, and strengthening their collaboration and communications efforts with their partners.

Charting New Waters in Biosecurity

By Catherine Feinman, Editorial Remarks

Research that can either save lives, by helping to develop new vaccines, or cause considerable harm by releasing biohazardous agents (either intentionally or unintentionally) on an unsuspecting public – that is at the heart of a major dilemma currently facing the biosecurity world. In the previous article by Earl Stoddard, originally published in the 4 April 2012 issue of the *DPJ Weekly Brief* (and reprinted in this monthly issue), Stoddard addresses such "dual-use" biomedical research. His principal thesis in the article is that this type of research, even though well motivated and intended to be objective scientific exploration, could nonetheless lead to possible harmful results.

The primary example used in Stoddard's article was the tentative publication of research carried out by Dr. Ronald Fouchier at Erasmus Medical Center in The Netherlands and his colleagues on the transmissibility, between mammals, of the H5N1 avian influenza virus. The National Science Advisory Board for Biosecurity (NSABB) recommended last year that Fouchier's article be published, but in a redacted form (to avoid the sharing of critical information that might be used with malicious intent – by terrorists, for example).

However, even as Stoddard was preparing his article for publication in the *DomPrep Journal*, the NSABB held another meeting (on March 29-30) to reconsider its earlier decision. This second meeting was called primarily to review revisions that Fouchier and his colleagues had made to the original manuscript.

On April 11, the NSABB released its final "Findings and Recommendations" report on Fouchier's research. In that report, the board members agreed that:

- Pandemic influenza preparedness requires global cooperation;
- Appropriate conditions were used to conduct the research carried out by Dr. Fouchier;
- Policies for the oversight and communication of dual-use research that could cause legitimate scientific concern are urgently needed; and
- An appropriate mechanism for the dissemination of such sensitive scientific information also is urgently needed.

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Cautions, Concerns, Areas of Disagreement

There were, on the other hand, two key issues on which at least some of the board members disagreed. First, most members of the board said they believe that Fouchier's revised article does not contain data that would immediately and/or directly be useful to terrorists or other evildoers – but other members of the board believe that the article does contain such harmful information. Second, although there was a general consensus that the data in the revised article could in fact benefit public health and surveillance efforts, a few members disagreed on the relevancy and/or immediate usefulness of that same data.

The NSABB concluded, therefore, that:

- The data, methods, and conclusions presented in the revised manuscript should be published – but with additional changes (to eliminate the potentially harmful uses of certain information);
- National and international policies must be developed as soon as possible for the oversight and communication of information relevant to dual-use research that might raise similar concerns in the future; and
- An effective and appropriate mechanism for controlling access to sensitive scientific information is needed – on an urgent basis.

An Additional Mutation, A Dual-Use Cookbook, the Proverbial Straw

To add to the "dual-use" debate, on April 12, Dr. Michael Osterholm, Director of the Center for Infectious Disease Research and Policy, and a member of the NSABB himself, wrote a letter of concern in which he described the March 29-30 meeting that he attended as being "one-sided." Significantly, Osterholm also stated that his previous recommendation in favor of publishing the revised version in full has changed. He expressed particular concern about setting a precedent for future research and publication, and mentioned as an example Fouchier's other work, which is likely to appear in a future article, on an "additional mutation that now confers H5N1 transmissibility between mammals without ferret passage."

Coincidentally, to address other concerns that have been raised about such dual-use research, the Obama administration spelled out a number of highly relevant new regulations on 29 March 2012 – in a position paper ("United States Government Policy for Oversight of Life Sciences Dual-Use Research of Concern") that is now available on the National Institutes of Health's Office of Biotechnology Activities website.

The purpose of such oversight, officials said, is to avoid similar controversial situations in the future in which research is carried out and a report on that research is ready for publication before a red flag is raised. By providing a "pretty complete cookbook," as Osterholm himself pointed out, "the next mutation paper [may well] prove to be the straw that breaks the camel's back."

For additional information on:
"Dual-Use Disasters: Lessons for Preparedness Professionals," by Earl Stoddard, visit http://www.domesticpreparedness.com/Medical_Response/Public_Health/Dual-Use_Disasters%3a_Lessons_for_Preparedness_Professionals/

Letter by Michael T. Osterholm, visit http://news.sciencemag.org/scienceinsider/NSABB%20letter%20final%2041212_3.pdf

Findings and Recommendations of the NSABB, 11 April 2012, visit http://oba.od.nih.gov/oba/biosecurity/PDF/03302012_NSABB_Recommendations.pdf

President Obama's "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," visit http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf

Earl Stoddard's blog on "CHHS Weighs In on Obama's New Plan for High-Risk Biological Research," visit http://www.mdchhs.com/blog/chhs-weighs-obamas-new-plan-high-risk-biological-research

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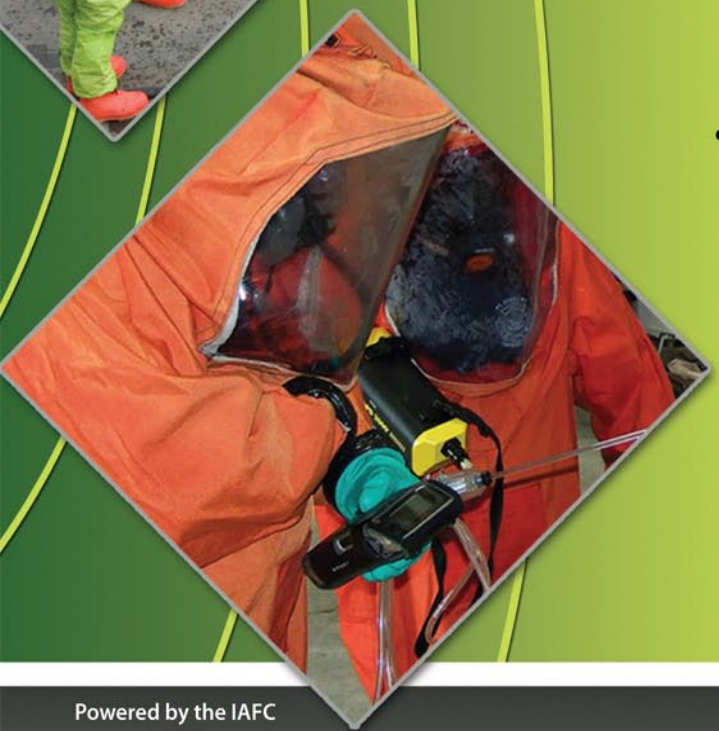
Catherine Feinman is Associate Editor of the DomPrep Journal. She joined the DomPrep team in January 2010, and has over 20 years of experience in publishing. She previously served as Journal Production Manager and Subscription Manager for Bellwether Publishing Ltd. She received a bachelor's degree from the University of Maryland, College Park, in International Business/French. She is a member of the Lake Shore Volunteer Fire Company in Pasadena, Md., and the Anne Arundel Community Emergency Response Team (CERT).



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