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Editor's Notes

By James D. Hessman

There have been huge improvementsin recent years – in response capabilities, in preparedness planning, in healthcare, and in both science and technology. But there is still much more that must be done, especially in the field of medical countermeasures.

This monthly "roundup" issue of *DPJ* focuses special attention on a topic that is always timely, but especially so during the flu season: How to cope with infectious diseases, particularly those that spread rapidly, are difficult to detect, and are capable of killing not just thousands but millions of people worldwide. Patrick Rose, the first of nine highly qualified contributors to this "Medical Countermeasures" issue, points out that a repeat of the 1918-1920 Spanish Flu today would probably kill several times as many victims. The reasons why: The world's population is now much larger; global travel is both cheaper and easier; and there are now exponentially larger crowds at numerous "special events."

Kay Goss follows Rose with a progress report on the 12-hour "Push Packages" of vaccines, medicines, and medical countermeasures created by the federal Centers for Disease Prevention and Control (CDC) and ready for shipment to local distribution sites throughout the nation. Thomas Zink provides a common-sense "Viewpoint" analysis that asks a related and relevant question: Because an estimated half-million anti-anthrax doses are intentionally destroyed each month (when their shelf-life has expired), why are they not used to inoculate the thousands of local responders who volunteer their services to help others during major emergencies, including pandemics?

Sarah Keally adds an interesting commentary on yet another closely related issue: The planning and operational difficulties involved in the necessary dispensing, in many situations, of both anthrax vaccines and antibiotics. Ann Lesperance points out that there are still at least four major policy issues – economic redevelopment, waste management, fatality management, and cleanup priorities – that also have not yet been fully resolved. Sara Rubin seconds the motion by pointing out that there also are three important gaps (in funding, the responder workforce, and community resilience) that must be fully and honestly addressed just as soon as possible.

Chris Mangal focuses on another important but little noticed milestone of progress that has made the nation safer in recent years: creation of the Laboratory Response Network (LRN) to quickly and accurately identify and, if possible, isolate infectious diseases whenever and wherever they break out. The Network encompasses literally thousands of "sentinel" clinical labs, an estimated 160 or so "reference" labs, and most Department of Defense as well as CDC labs. Greg Burel makes a strong case for the continued growth of healthcare and response-agency partnerships at all levels of government, starting in local jurisdictions and escalating as and when necessary to the federal level. Joseph Cahill rounds out the issue by wisely pointing out that, as happened during the 9/11 attacks, even the best plans sometimes are not adequate to cope with unprecedented emergencies and, in such situations, it is sometimes necessary to "break the rules" in order to save lives.

About the Cover: In laboratories around the world, scientists work behind the scenes to examine possible threat agents. The results then are used to provide valuable and timely information to help determine the the most appropriate course of treatment and the best medical countermeasures to address the incident at hand. (iStockPhoto)

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Identifying & Isolating Bio-Threats Before They Present

By Patrick Rose, Public Health

In the field of biosecurity, the often unseen threats of infection during a mass gathering are becoming a much higher priority. Largely because of the growing number of natural or man-made biological agents to which people are exposed, such gatherings have become high-risk targets for possible terrorist attacks. In 2012 alone, various events throughout the world – at the London Olympics, the annual Muslim pilgrimage to Mecca, and the World Expo in Yeoso, South Korea, for example – attracted millions of visitors.

In an era when modern aviation enables people to travel, literally, from anywhere in the world to almost anywhere else in the world within 24 hours or less, the ease of travel has contributed to: (a) the re-emergence of infectious diseases such as polio and tuberculosis; (b) the spread of communicable diseases to regions where some of these diseases were never before experienced (Dengue virus, yellow fever, Ebola); and (c) the emergence of novel and potentially pandemic infectious diseases (H5N1, SARS). Moreover, because certain infectious diseases take several days before appearance of the first symptoms, those infected can return to their home countries without realizing they are also transporting – and possibly transmitting – a potentially dangerous pathogen. For that reason among others, effective biodefense planning will require the adoption of international public health policies based on a *global* health security platform to improve the biosecurity capabilities of every nation.

Although significant steps already have been taken to augment various medical countermeasure procedures, an effective defense against biological threats necessarily begins by enforcing control measures that rely on non-medical public health interventions to detain not only those already exhibiting symptoms of a pandemic disease but also many others who might reasonably be suspected of having been exposed. The lack of established procedures for quarantining or isolating those who have been infected but are not yet symptomatic can have devastating results. In 1918, for example, as global travel started to increase almost exponentially, and with little or no regard for public health interventions, health officials estimated that one-third of the world population at that time were infected with the so-called "Spanish Flu."

A similar deadly pandemic would have an even greater impact on today's much more "globalized" society than it did a century ago. Making this problem even more serious is the fact that public health experts have difficulty predicting patterns of disease transmission in a mixed population. Because the next pandemic or bioterrorism attack cannot be accurately predicted – combined with the fact that the most recent U.S. Government Accountability Office report shows that existing "sentinel surveillance systems" are still not capable of countering such an attack – the use of basic public health measures is probably the most useful tool currently available to effectively mitigate biosecurity threats.

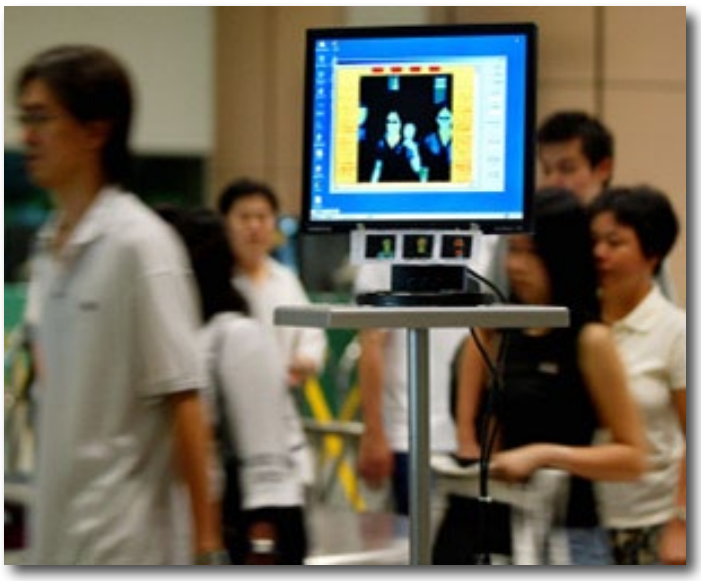
Whether the real danger is the natural spread of emerging infectious diseases or a malicious biological attack, the potential for loss of life is nonetheless immense – and the threat to the nation's economy, infrastructure, and stability is great. For these reasons, and others, it is important that a medical countermeasure response program include provisions for quarantine and/or isolation when the threat of a potentially dangerous communicable disease is suspected.

Detaining, Isolating & Quarantining

Although most U.S. hospitals and other healthcare facilities already isolate patients diagnosed as having a communicable disease, the quarantine of others – event participants, airline passengers, etc. – who do not yet exhibit signs of illness but are reasonably believed to have been exposed still meets with resistance. This is despite the fact that enforcing the legal authority to contain an infectious disease can mean the difference between a dozen or so people, rather than hundreds or thousands, being infected with a potentially fatal disease.

Whatever the reason, the challenge of protecting the greater population through the practices of quarantine and isolation almost always evokes ethical and political issues ranging from legal rights and individual liberties to major inconveniences, economic losses, and various personal hardships. Forced social separation also more or less revokes the right to privacy and freedom from involuntary detention, and in extreme cases sometimes seems to promote discrimination of one type or another.

At an airport or any other port of entry, infrared thermal imagers can be used to identify potentially infected persons before a truly definitive medical diagnosis can be made. Although a decrease in social mixing is the only non-medical option currently available to contain an emerging epidemic, the increased burden on the passengers detained may in some cases seem to outweigh the risks posed by dissemination of the infection into a larger population. To streamline the process to at least some extent, airlines follow guidelines established by international aviation and public health organizations that spell out the protocols that must be followed if a passenger with a communicable disease is identified. Those protocols include but are not necessarily limited to: isolation of the infected person(s); communication with medical advisory channels; and, when advisable, contact with legal authorities at the ports of entry.



The World Health Organization recognizes such concerns and specifically states on its website that, "after all voluntary measures to isolate such a patient have failed," quarantine efforts should meet the criteria spelled out in the "Siracusa principles" – i.e., the list of civil and political rights enunciated by the U.N. Commission on Human Rights at a 1984 meeting in Siracusa, Sicily. To ensure that the rights of the detainees are being protected, at least one of the following must be met: (a) the restriction must be provided for and carried out in accordance with the law; (b) the restriction must be in the interest of a legitimate objective of general interest; (c) the restriction must be necessary in a democratic society to achieve that objective; (d) there must be no less-intrusive and/or restrictive means available to accomplish the same objective; and (e) the restriction must be based on scientific evidence and not drafted or imposed arbitrarily – i.e., in an unreasonable or otherwise discriminatory manner.

Fortunately, the quarantine of infected people meets with less resistance when the health, rights, and needs of the individual are prioritized. Earning trust in a quarantine situation by making the situation completely transparent to travelers who are detained will usually make the establishment of authority easier to accept. In situations where a person believed to have been infected refuses containment, the public health official should and would be granted the authority needed to use the minimal means available – e.g., police force – to restrain that person.

Racing the Clock

Time is a key variable in the success or failure of implementing a quarantine strategy that puts an acceptably safe distance between the non-infected population and those who have been exposed to a communicable disease. The 2003 Severe Acute Respiratory Syndrome (SARS) outbreak provides an excellent example of how the basic public health interventions available at that time helped control the global spread of the disease. The SARS outbreak traveled from its origins in Guangdong Province, China, to Hong Kong, Vietnam, Taiwan, Canada, and Singapore. Five international flights were associated with and played an unhelpful part in the SARS transmission – which spread from an infected passenger to other passengers and crew members. Although an estimated 500 or so infected people died as a result of the epidemic, by isolating known cases, quarantining contacts, minimizing social gatherings, and limiting the spread of infection through local and international travel, further spread of the disease was limited.

To stop a natural or man-made disease from spreading – when the asymptomatic period is longer than the actual travel time involved, and/or when preventive actions are initiated as a result of reasonable suspicion rather than outward signs of illness – biodefense preparedness plans must begin at the site of origin. Whether through a stronger engagement in international organizations such as the World Health Organization or through direct collaboration with the host nations of mass gatherings, ensuring that biosecurity threats are mitigated both as quickly and as effectively as possible begins by strengthening the prevention and response capabilities at ground zero.

In addition to serving as an investment in national security, such capacity building – both in disaster management and in public health preparedness – also provides a firm foundation for local development, peace, and stability. Efforts to mitigate and identify biosecurity threats, therefore, must be the essential components of a cooperative, sustainable, and truly global effort before the next version of the 1918 Spanish Influenza or other lethal and rapidly spreading disease is identified.

For additional information on:

U.S. Government Accountability Office Report on Biowatch, visit http://www.gao.gov/products/GAO-12-810

World Health Organization's "Guidance on human rights and involuntary detention for xdr-tb control," visit http://www.who.int/tb/features_archive/involuntary_treatment/en/index.html

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Nontraditional Partnerships Advance Medical Countermeasure Dispensing

By Greg Burel, Public Health

During and immediately after a major public health emergency – e.g., a bioterrorism attack, an influenza pandemic, a chemical or radiological event, or a natural disaster – lifesaving medical countermeasures are not always readily available to every person affected. At a time when the nation's state and local governments are balancing public health preparedness activities with diminishing resources and decreased funding, there is a real need for creative, smarter, and more efficient ways to change this scenario and ensure that everyone has access to the medical countermeasures that are needed.

In light of recent budget cuts, it comes as no surprise that the staffing levels of state and local public health departments have dramatically decreased in the past several years. In fact, economic impact studies carried out by the National Association of County and City Health Officials (NACCHO) show that, since 2008, nearly 50,000 state and local public health jobs have been lost. An estimated 34,400 of those positions were in local health departments. NACCHO data further show that, between July 2010 and June 2011: (a) more than half of all local health departments affected reduced or eliminated at least one program; and (b) emergency preparedness ranked second on the list of programs experiencing significant reductions.

Moreover, in addition to the loss of staff, many jurisdictions also have been forced to implement staff furloughs and struggle in other ways with the inability to maintain staff for sustained planning and preparedness operations. When these realities are coupled with a declining tax base and an eroding public health infrastructure, it becomes obvious that a crisis is offstage just waiting to happen.

With the realities of an ever-changing budget environment and the need to continuously improve the U.S. response posture, a new era of public health planning for emergencies has surfaced where federal, state, and local planners are working together to develop and implement innovative ways to ensure that medical countermeasures efficiently reach those who need them in an emergency. At the forefront of these plans are partnership opportunities to build distribution and dispensing capabilities at the state and local levels – both to improve access to lifesaving medicines and to share responsibility across the community.

This approach requires that non-traditional public health partners – e.g., private businesses, academia, community agencies, faith-based organizations, healthcare facilities, and governmental entities, including military installations – participate during an emergency to ensure that lifesaving medicines and other material resources are provided to more people in a shorter amount of time.

Federal staff at the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile – the largest government stockpile of medical countermeasures that can be deployed in a public health emergency – have embarked on a mission to help state and local jurisdictions forge these outside partnerships in order to not only improve countermeasure distribution and dispensing capabilities but also to increase access to critical medications at the time of a public health emergency.

How States Receive Medical Countermeasures in an Emergency

The Strategic National Stockpile – a repository of antibiotics, chemical antidotes, antitoxins, vaccines, antiviral drugs, and other lifesaving medical material – was created by Congress in 1999 as a federal asset designed to store medical countermeasure resources and to remain poised to deliver them to the site of a national emergency, if needed. At the time of an emergency, a state (or U.S. territory or freely associated state) will determine if there is a need for federally stockpiled assets and would then formally request federal assistance.

Following a request to the U.S. Department of Health and Human Services, discussions between state and federal organizations are initiated and a decision is then made at the federal level on whether to distribute the countermeasure resources that have been requested. After federal, state, and local health officials determine what is needed, the materials provided are delivered to a pre-determined site; state and local authorities then become responsible for further distribution. It is at this point that the responsibility for distribution, dispensing, storage, and maintenance of the countermeasure resources is assumed by the state and, ultimately, local jurisdictions.

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Medical countermeasures then must be dispensed in a clinically relevant timeframe, as dictated by the specific emergency. For instance, current clinical guidance mandates that, in order to be protected, people exposed to anthrax must receive countermeasures within 48 hours of exposure. In this scenario, public health personnel at the federal, state, and local levels must request and deploy products from the Strategic National Stockpile, deliver them to the state and distribute them to local jurisdictions, set up various points of dispensing (PODs), communicate essential information to the public about where to receive countermeasures, and dispense pills to those who have been exposed – all in a maximum of 48 hours. In this type of rapid emergency response, mass-dispensing methods will be used, as prescriptions are not needed to dispense medications to those who are affected.

Nontraditional Partners Assist in Mass-Dispensing Efforts

In a public health emergency that requires countermeasures from the Strategic National Stockpile, state and local public health are often working against the clock to quickly distribute and dispense medical countermeasures to the affected population. Nontraditional partners in the dispensing process can make a major impact in such emergencies by supplementing local efforts to get lifesaving countermeasures to those in need. With this kind of support, local public health personnel can then focus on other essential activities like surveillance, epidemiology, public information and communications, and reaching vulnerable populations.

Enhancing public-private partnerships and creating new points of distribution are two ways that the U.S. Centers for Disease Control and Prevention are able to dispense medical countermeasures not only faster but also at lower cost.

One successful approach in improving response capabilities is through a partnership where public and private organizations assist with dispensing medications to their own pre-identified populations through dispensing sites called "closed" PODs. Medications are provided to closed POD partners at no cost, and public health personnel collaborate with and assist the partners in planning, training, and exercising. For many partners, medical countermeasures are offered to employees and their families not only as a benefit provided by the organization but also as a way to redirect these specific populations away from the public PODs.

Here it is worth noting that, in a recent pilot project focusing on the hospitality industry, public health planners tested the concept of using a national business to operate closed PODs in multiple locations across the country for an event requiring the mass dispensing of antibiotics. In addition to verifying that large national businesses are both interested in and capable of conducting dispensing operations in support of a public health emergency, the pilot project showed that the operation of closed PODs ultimately allows nontraditional partners an improved continuity of operations by helping their staff to either: (a) return to normal duties within the organization more quickly; or (b) continue to assist public health officials by volunteering.

Federal staff have now expanded their own role in fostering such partnerships between nontraditional partners and state and local public health planners by devoting full-time personnel to recruiting, training, and pairing public health jurisdictions with these types of partners.

Improving Access to Antiviral Drugs Through Controlled Dispensing

Whereas an anthrax response may and frequently does require mass antibiotic dispensing to large numbers of potentially exposed people, there are other scenarios – an influenza pandemic, for example – that could require prescription-based countermeasure dispensing over an extended period of time for the duration of an outbreak. Largely for that reason, CDC has initiated another innovative project to explore the use of private partnerships for alternative methods of distributing and dispensing antiviral drugs during a pandemic.

Making the antiviral drugs held in the Strategic National Stockpile available through pharmacies with a prescription – a practice known as controlled dispensing – is a logical solution for an influenza response that requires the distribution and dispensing of prescription drugs over the course of several months. However, this proposed model is not operationally useful, or appropriate, for

responses that require rapid, short-term deliveries to large numbers of people, as would be the case to cope with a more complicated event such as a biological attack – with anthrax, for example.

Using the pharmaceutical supply chain – pharmaceutical distributors and pharmacies – to distribute and dispense drugs during an emergency can help improve access to antiviral drugs during a pandemic and relieve some of the local dispensing burden during an extended event. In order to assess the feasibility of using the pharmaceutical supply chain in an influenza event, CDC partnered with a large chain pharmacy in an urban setting, and with a small retail pharmacy in a less populated community, to "exercise" the scenario and determine possible pharmacy dispensing throughput during an emergency. That exercise produced several favorable results involving the use of pharmacies for the controlled dispensing of medical countermeasures. Other studies also have been carried out exploring related topics and issues such as feasibility, acceptability, costs, and overall impact of using pharmaceutical distributors and pharmacies as partners in distributing and dispensing medicines and drugs during an influenza pandemic.

Nontraditional Partnerships Vital to Securing Nation's Health

Following the 11 September 2001 terrorist attacks, a greater focus has been placed on medical countermeasure planning and response. In the 11 years that have passed since the attacks, planning has continued to evolve to incorporate lessons learned from many other emergency responses, including those carried out following Hurricane Katrina and the 2009 H1N1 pandemic. Collectively, those lessons have persuaded public health personnel to realize the value of leveraging everyday systems – and nontraditional partners – to advance and enhance distribution and dispensing plans.

As long as state and local budgets continue to decrease, while staffing levels remain threatened, the use of nontraditional partnerships to support distribution and dispensing efforts will become even more important in sustaining the response capabilities necessary for securing the nation's health during and in the wake of major disasters. Fortunately, the initial partnerships already formed show that all involved can benefit by reducing the strain on diminished public resources – while also facilitating the continuity of operations for nontraditional partners that, in turn, provide their specific populations with the lifesaving use of appropriate medical countermeasures.

Nonetheless, if public health is to continue to promote the certainty that medical countermeasures will be available to protect lives in future times of emergency, it is vitally necessary to develop and use additional innovative and creative ways to further improve emergency preparedness and response capabilities. By sharing the responsibility with willing and capable partners, public health personnel will be able to save more lives by effectively and efficiently getting medical countermeasures to those who need them the most during a real-life emergency.

For additional information on:
NACCHO's economic impact studies, visit http://www.naccho.org/press/releases/12-20-2011.cfm

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Greg Burel is the Director of the Strategic National Stockpile managed by the Centers for Disease Control and Prevention. As head of the nation's largest stockpile of medicines and supplies available for emergency use, he is a leading expert on medical countermeasure distribution and dispensing throughout the United States. With more than 30 years of civil service, he has risen through the ranks of the federal government, beginning his career at the Internal Revenue Service and serving in leadership roles in both the General Services Administration and the Federal Emergency Management Agency. In 2006, he assumed the helm of Strategic National Stockpile operations. In addition to his professional interests at CDC, he is past flotilla commander of the United States Coast Guard Auxiliary's Flotilla 24 headquartered in Lake Lanier, Georgia.

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State & Local Medical Countermeasures: The 12-Hour Push

By Kay C. Goss, Emergency Management

Emergency managers are working hard, on a continuing basis, to improve and support the national capability to assist in providing assets to affected areas during an extreme biological incident or emergency requiring medical countermeasures. The U.S. Centers for Disease Control and Prevention (CDC) leads this effort and recently reformulated what are called the "12-hour push packages" – assets designed to provide immediate help on a broad spectrum of potentially beneficial interventions urgently needed in the early hours of an emergency, even when information on the extent and content is incomplete.

CDC, in consultation and collaboration with state and local emergency managers, has already increased the number of storage locations available, enhancing the quality and speed of distribution across the country. The ability to distribute large quantities of medicines and other countermeasure resources in a very short window of time, to communities throughout the nation, is evolving from a possibility to a likelihood and will soon become a certainty. The growing partnership between CDC and local emergency managers continues to dramatically shorten the crucial time window even further.

Transferring and transporting medical products to the people who need them most during an emergency depends in large part on: (a) the building of a capable infrastructure; and (b) advance planning at the state and local levels not only county by county but even neighborhood by neighborhood. That is why CDC now stockpiles and delivers medical countermeasure assets to support its partners at *all* levels of government. It also is why state and local emergency managers are working to develop and refine their own abilities to effectively receive and use the assets provided. All partners in the supply chain are focused particularly on delivery and disbursement.

Difficult Challenges & Best Practices

One profound challenge facing all responders involves the shelf-life extension of medical resources. The Department of Defense has initiated a special Shelf Life Extension Program (SLEP) and is partnering with states and lower jurisdictions to meet this challenge. In fact, many state and local governments have already purchased and are storing antivirals and antibiotics as countermeasures against bio-terrorism attacks. These stockpiles are typically designed both to ensure early access for first responders and to provide critical-infrastructure personnel the resources they need to carry out the initial response actions required to deal with sudden disasters and other emergencies throughout the entire country.

Fortunately, the Baltimore (Md.) Department of Homeland Security's Urban Area Security Initiative (UASI) has already provided a helpful best-practice example of how this upgraded approach works. Several years ago, the City of Baltimore and several surrounding counties purchased stockpiles of ciprofloxacin and doxycycline for use not only by regional responders but also by an estimated 106,000 other responders from the area's fire services, emergency medical services, emergency managers, law enforcement, and public safety communities. By doing so, the City and the responders combined their efforts to take the absolutely mandatory steps needed to ensure the safety and security of the items stored, complying not only with manufacturer humidity and temperature requirements but also federally mandated FDA (Food and Drug Administration) guidelines. It is estimated that, to stay current and effective without the SLEP, the Baltimore UASI would have had to turn over its stockpile every two to three years – at an estimated replacement cost of $500,000 per turnover cycle.

The CDC also is exploring several innovative ways to dispense countermeasures more quickly to local communities by, among other things, cultivating strong collaborative partnerships between and among planners, emergency managers and responders, and even businesses at the state and local levels. CDC provides the funding needed through what are called Public Health Emergency Preparedness cooperative agreements – augmented and supported by technical assistance, pre-approved distribution plans, and performance measurement consultations.

Outreach Programs & Multiagency Partnerships

The technical assistance provided to state and local partners includes significant input from state health department outreach programs. That input includes but is not limited to the following: information related to receiving and dispensing medical assets; on-site and video teleconference consultations; support for various training and exercise

programs, including national training summits; and the tools needed to design and test response plans.

The national partnership with state and local jurisdictions and operational personnel has evolved over time not only through the provision of much-needed guidance, assistance, and other support but also through the recognition of changing needs and the opportunities provided by new discoveries. The end result is a significant increase in the availability and use of direct on-site technical assistance to jurisdictions both large and small – again, at all levels of government. That assistance ranges from the interpretation of guidelines to the development and refining of plans to the conduct of training and exercises to the evaluation of both capabilities and performance. Here it should be noted that the evaluations are developed by the dedicated CDC training, exercise, and response teams who not only conduct a broad spectrum of training exercises in Atlanta, Georgia (where CDC is headquartered), but also provide on-site training and exercise support at many other venues throughout the country.

Most state and local public health responders depend, in varying degrees, on both the implementation of emergency contracts and, in some cases, the mobilization of volunteer workforces to distribute medical countermeasures during an actual operational event or incident. The use of volunteers is in fact increasingly critical to the effective dispensing of medical countermeasures during an incident, and for that reason a number of grant-funded pilot studies have been carried out to examine innovative ways to recruit the number of volunteers needed. All of these functions feed into and support the ongoing development of the capabilities critical to the effective dispensing of medicines and medical countermeasures to the emergency communities of all states and numerous local jurisdictions as well.

Tailor-Made Plans & Improved Information Sharing

Every state has developed and maintains its own unique plans to receive, distribute, and dispense the medical countermeasures stockpiled by the CDC. A common denominator of almost all of these various plans is that they:

(a) govern the local infrastructure and supporting government and commercial partnerships at the state and local levels of government; (b) are evaluated and exercised by the stockpile coordinators at the same levels; and (c) are reviewed annually – and to the same standards everywhere in the country.

The CDC also funds and maintains several forums through which promising practices and innovative concepts are shared and discussed by health and emergency staff at all levels of government. In addition, several modeling tools have been developed and are used both to facilitate planning at all of these same levels and to evaluate the plans thus developed and promulgated. This process saves significantly in the scheduling and evaluation of resource-costly drills and exercises.

To evaluate the effectiveness of individual state plans for the use of medical countermeasures, regularly scheduled Technical Assistance Reviews – a quantitative objective tool – are conducted annually to help identify any remaining gaps in such plans. The principal purpose of these technical assistance and performance measurement consultations is to ensure the continuing availability of the flexible framework needed for the delivery – through partnerships with air and ground transportation providers – of medical countermeasures from a national network of storage locations. Within this framework, it is now possible to determine the optimum combination of location and method of transportation required to support the delivery of medical countermeasures within the specific time frame postulated to cope with an ongoing emergency situation.

During the 2009-2010 H1N1 influenza pandemic response operations, many helpful lessons were learned when antiviral drugs and personal protective equipment were needed both to minimize overall illness and the number of deaths. CDC rapidly deployed large quantities of key medical assets, including 11 million regimens of antiviral drugs as well as the personal protective equipment needed by states, tribes, and territories throughout the nation. In addition, the CDC released 300,000 bottles of Tamiflu® for pediatric use – both to compensate for production gaps and to meet the increase in demand – plus 234,000 additional bottles of the suspension.

State and local emergency managers not only understand the current threats but also make continued progress toward their own preparedness goals; even closer cooperation with federal authorities will be needed far into the future – particularly in situations involving potential biothreats.

Meanwhile, the U.S. Department of Health and Human Services (HHS) was authorizing the release, to those same jurisdictions, of 59.5 million respirators. The end result was that, despite a few "close calls," the timelines set forth in the plans developed at all levels of government were in fact achieved.

The lessons learned from the H1N1 response, and other potential disasters, are regularly and routinely applied to other crises and emergency situations occurring anywhere in the country. To cite but one example, California relied on its own extensive public health preparedness, planning, and training programs to respond to an outbreak of whooping cough in 2010. Immediately after that outbreak had been evaluated and identified, the California Department of Public Health not only offered free vaccines but also encouraged hospitals and local health departments to support the vaccination of new mothers and newborn caregivers. Meanwhile, county public health departments across the state, among the most proactive in the country, applied their own planning and public health preparedness experience to develop and disseminate the educational materials and clinical guidance needed.

These and other prompt actions not only helped raise community awareness but also led to the designation of accessible and innovative vaccine dispensing points – including the assignment of mobile clinics to grocery stores – to reach all communities throughout the state that needed immediate and continuing assistance.

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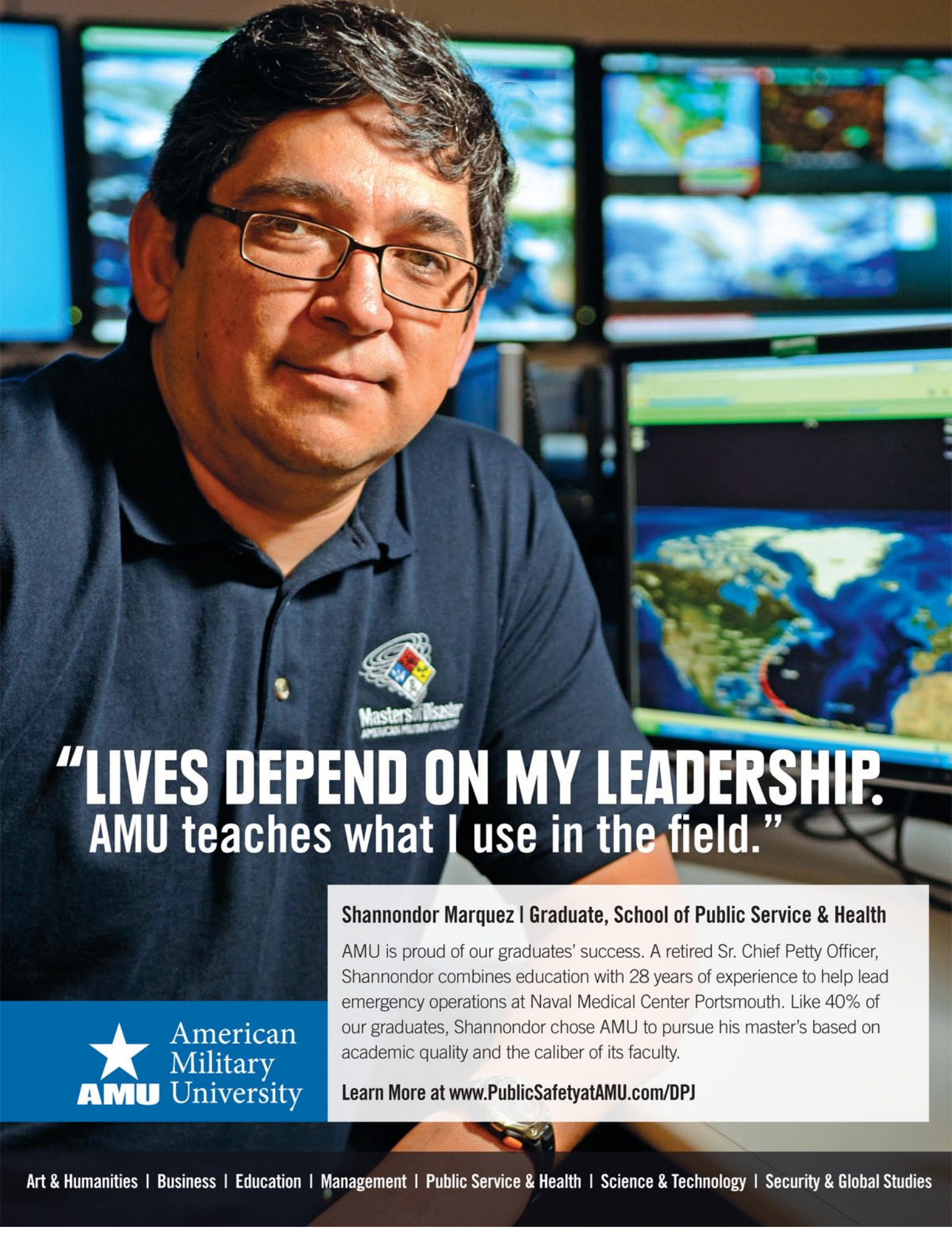

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Protecting Civilian Emergency Responders Against Anthrax

By Thomas Zink, Viewpoint

One of the principal goals of the initiative known as Project Equal Immunization Policies & Practices (EQUIPP) is to help gain approval for the preventive vaccination of civilian emergency responders against anthrax. Since 2008, this grassroots campaign has fought vigorously to eradicate the disparity of access to the only vaccine licensed by the U.S. Food and Drug Administration for anthrax prophylaxis. More specifically, Project EQUIPP has and continues to reverse the upside-down status quo wherein only the second wave of federal WSD-CST (Weapons of Mass Destruction Civil Support Team) personnel – rather than local civilian responders – are preventively immunized.

As a result, some important milestones have been reached. One example is that the anthrax vaccine adsorbed (AVA) is now included as a covered countermeasure in the U.S. Department of Health and Human Services' 2008 Public Readiness and Emergency Preparedness (PREP) Act. This status provides not only important injury compensation awards but also the appropriate indemnification mechanisms needed for the manufacturing, distribution, delivery, administration, and receipt of AVA.

Half a million doses of anti-anthrax vaccine are routinely destroyed each month. Meanwhile, untold thousands of local responders are not yet eligible for the pre-event immunization that might save their own lives.

In addition, equal policy guidance supporting the preventive vaccination of emergency responders is now in place, thanks to the publication (in 2010) of the 2009 report on the Final Recommendations from the U.S. Centers for Disease Control & Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). Although these CDC guidelines do not specifically call for the routine pre-exposure vaccination of all emergency responders, they do affirmatively state that "responder units engaged in response activities that might lead to exposure to aerosolized *Bacillus anthracis* spores may offer their workers voluntary pre-event vaccination."

Continuing Inequality But With a Ray of Hope

In retrospect, increased understanding of the dangers posed by an anthrax "weapon" attack – combined with additional information on the supply, safety, and acceptance of AVA – can be credited as having been particularly helpful in advancing this ongoing policymaking process. In that context, there are three key points of particular importance worth emphasizing:

1. In the context of an attack with a weapon or device carrying antibiotic-resistant anthrax bacteria, post-exposure antibiotics will fail and the infected victims will almost always succumb before AVA can confer immunity. As is the case with all types of vaccines, the best and, realistically, only time to immunize is prior to exposure.

2. Since 2008, approximately 500,000 AVA doses in the Strategic National Stockpile (SNS) have been destroyed every month because of expiration dating. It has been estimated that more than 20 million doses of AVA have been wasted in various ways since the October 2007 Government Accountability Office (GAO) admonishment to the U.S. Department of Health and Human Services (HHS) on its management of the SNS materiel. Obviously, therefore, using surplus AVA *before* its expiration date to immunize civilian emergency responders who meet the ACIP criteria mentioned earlier could protect hundreds and perhaps thousands of other personnel who might well be needed to help cope with a future anthrax WMD attack.

3. In an unpublished 2009 survey carried out by the Missouri State Emergency Management Agency, with a group of 223 emergency responders (73 of which were randomly selected to be asked the question on their willingness to be immunized with the anthrax vaccine), it was determined that approximately two thirds of the civilian emergency responders participating said that they do want to have the option of receiving a voluntary pre-exposure vaccination against anthrax.

Unfortunately, two years after the report on the Final ACIP Recommendations was published, equality in the practice of providing anthrax immunization for local civilian emergency responders has still not been mandated. However, there is a ray of hope from the written testimony delivered by Dr. James Polk, Deputy Chief Medical Officer of the U.S. Department of Homeland Security (DHS), to the Subcommittee on Emergency Preparedness, Response, and Communications of the House Committee on Homeland Security. In the testimony released on 17 April 2012, Polk commented on 2011 discussions between CDC-SNS and the DHS Office of Health Affairs about "the idea of working collaboratively to determine a use for anthrax vaccine with a short shelf life rather than disposing of the unused vaccine."

"Our national response capability to a wide-area anthrax attack," Polk also said, "would be enhanced by having pre-vaccinated responders, able to deploy immediately and confident that they have been afforded as much protective status as possible for these activities." The "pre-event vaccination of these responders," he further asserted, "will increase the [federal government's] ability to save lives, maintain social order, and ensure continuity of government after a wide-area anthrax attack."

Polk also commented on the creation of a federal interagency working group to discuss the key decision points of a DHS/CDC-SNS program designed to evaluate the possible provision of soon-to-expire AVA to federal departments and agencies as well as to some state and local jurisdictions. In addition, twelve different federal departmental subject matter experts discussed the scientific medical data and policy implications involved, and also developed AVA prioritization guidance for immunization in the event that the vaccine supply available could not fully meet the demand.

The first step in this process, according to Polk, would be to pilot a pre-event AVA vaccine distribution program on a relatively small and manageable scale with the goal of eventually building a full-scale program that would be safe, reliable, functional, and sustainable. The pilot would: (a) include two federal departments or agencies and two state or local jurisdictions; and (b) continue for at least 18 months, time enough to accommodate the lengthy "priming" vaccination series anticipated.

The Future of Pre-Event Vaccination

Despite Polk's testimony that planning began more than a year ago, no publicly discoverable information has been released, and there have been no pre-solicitations or solicitations. Moreover, recent inquiries submitted earlier this year to the DHS Office of Health Affairs by Project EQUIPP, and by at least one state that has volunteered as a pilot location, have yielded no response.

There are several possible reasons for this official silence. It could be, perhaps, that any further action by DHS and CDC-SNS would require an examination of the potential benefits from pre-event/pre-exposure vaccination weighed against the probable resource requirements to implement and maintain the vaccination schedule in the context of the potentially adverse events associated with vaccination. Another possibility is that the unexplained delays can be attributed to a contrarian position that: (a) mandates the presence of a "calculable risk" before changing the modus operandi; and (b) is not satisfied with a programmatic decision based solely on an estimated/presumed risk-benefit assessment.

A third possibility is that the yet unexplained opposition and/or reluctance to make a firm decision is fueled by the belief that, depending on the occupational activities of the vaccine recipient(s), pre-event or pre-exposure vaccination might not completely eliminate the need for the purchase and distribution of appropriate personal protective equipment and post-exposure antibiotics.

Despite the above rationale, it seems reasonable to suggest that the final release of the 26 January 2012 National Response Team Emergency Responder Health Monitoring and Surveillance (ERHMS) Technical Assistance Document would acceptably serve as a safe harbor, if not a catalyst, for a pre-event vaccination program. The ERHMS documentation provided from the National Institute for Occupational Health and Safety is a product of significant consultations with not only the U.S. National Response Team but also a large number of federal agencies, state health departments, labor unions, and volunteer emergency responder groups. In addition to the operational benefits described above, that same document would also:

- Provide the guidelines needed to protect emergency responders operating over a full range of emergency types and settings;
- Serve as an invaluable resource for all who are involved in the deployment and protection of emergency responders – including but not limited to incident management and response organization leaders as well as health, safety, and medical personnel – and the emergency responders themselves; and
- Legally defines the anthrax vaccine as an immunization that is appropriate to provide to emergency responders.

In a community of emergency response professionals who courageously charge toward the danger – while others in the vicinity are running for their lives – the selfless actions of these professionals speak louder than words. The threat is real. The solution, or at least a significant part of it, is known. Now is the time to deliver.

For additional information on:
U.S. Public Readiness and Emergency Preparedness (PREP) Act, 6 October 2008, visit http://www.gpo.gov/fdsys/pkg/FR-2008-10-06/html/E8-23547.htm

CDC's "Use of Anthrax Vaccine in the United States Recommendations of the Advisory Committee on Immunization Practices (ACIP)," 23 July 2010, visit http://www.cdc.gov/mmwr/PDF/rr/rr5906.pdf

U.S. Government Accountability Office's "Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine," 23 October 2007, visit http://www.gao.gov/products/GAO-08-88

Written testimony of Dr. James Polk for a House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications hearing, 17 April 2012, visit http://www.dhs.gov/news/2012/04/17/written-testimony-office-health-affairs-house-homeland-security-subcommittee

The ERHMS "National Response Team Technical Assistance Document," 26 January 2012, visit http://www.cdc.gov/niosh/topics/erhms/document/

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Breaking the Rules to Save Lives

By Joseph Cahill, EMS

In the New York City Fire Department Emergency Medical Services (EMS), patient contacts are documented by using an Ambulance Call Report – a frequently time-consuming but nonetheless valuable process used in gathering important information. During and after a mass casualty incident, this process is sometimes truncated by allowing the use of triage tags to be hung on a victim's neck, wrist, or ankle. The information required to complete a triage tag is significantly less than that needed for an Ambulance Call Report, but the tag still provides enough data to effectively track patients.

Triaging & Medications

Although it is certainly important to track patients through the typical and officially approved response and recovery processes, a valuable lesson can be learned from the makeshift triage procedures used at the scene of the World Trade Center terrorist attacks in September 2001. The first responders on the scene were ordered to stop using triage tags and, if a patient could walk, point him or her east "and keep them moving" away from the destruction and toward possible safety. In short, no documentation or contact was to be offered unless a survivor obviously required significant treatment and/or transportation to the nearest available hospital or other healthcare facility. This single order, "keep them moving," may well have saved hundreds, and perhaps thousands, of lives when the north tower collapsed on and around the triage area that had been originally established.

Medication manufacturers are required by law to assign expiration dates in order to safeguard patients from medications that, over a certain period of time, are or may be: (a) losing potency; (b) breaking down into harmful compounds; and/or (c) becoming contaminated with bacteria. In early 2012, the Texas Medical Board was alerted that some EMS units had been using expired medications when they were unable to obtain the same medications with unexpired dates. In general, the expired medications were used only during life-threatening conditions when there was no readily available substitute.

Outside the Box, But Within the Law

In the first example of intentional rule-breaking cited above, the enormity of the event precluded following the usual prescribed procedure to the letter. The totally unexpected and enormously dangerous conditions that had been created by outside causes took away the responder agency's usual control of the situation. In both of the situations cited, the decision maker was a senior officer of the agency who had the legal authority needed to accept, on behalf of the agency, the increased level of risk involved in departing from previously established, and officially approved, processes and procedures.

In the case of EMS agencies using expired medications, consideration must be given to the federal and state agencies that regulate the use of such medications. Most regulatory agencies may and usually do have an "exception" process available to allow violation of the rules under certain circumstances (but usually mandate additional oversight requirements as well). For example, in situations calling for the use of expired medications, there may be another path, within the overall structure of the rules, that could achieve the same goals. However, technical expertise still is needed in such situations to determine any possible medical ramifications.

In other words, it is not enough for officials on the scene to simply assert that the risk of a negative outcome is outweighed by the likely positive outcome – or even to say before and/or after the fact that the positive outcome is more likely than the negative. Breaking the rules in emergency response situations is an extremely serious business, with significant ramifications. It is certainly not the time for the strategic sergeant on the scene to take control of the situation and make the call. Rather, it is a time to implement a predetermined "plan" designed specifically to cope with a scenario that does not quite fit "within the box."

For additional information on:
American Society of Health-System Pharmacists' list of current drug shortages, visit http://www.ashp.org/DrugShortages/Current/

FDA Drug Shortage Page http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

Texas drug shortage information, visit http://www.tmb.state.tx.us/news/press/2012/120224.php

The U.S. Food and Drug Administration's Current Drug Shortages Index, visit http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm

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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.

The Use of mHealth Technology for Pandemic Preparedness

By Sara Rubin, Health Systems

The influenza pandemic of 1918-1919 killed more than 600,000 people in the United States alone and an estimated 20 million or more victims worldwide. Today, infectious diseases continue to pose a significant health security threat to nations throughout the world. Because of the increasing mobility of the global population, it is likely that newly emerging diseases will spread even faster than the pandemics experienced in the last century. Many smaller communities have difficulty preparing for emergencies. Nonetheless, effective preparedness remains an essential tool for reducing the spread of disease.

In the United States, as federal funding decreases, local health departments are pressed to do more with less. According to a 2011 review of ongoing gaps in preparedness, Trust for America's Health – a nonprofit, nonpartisan health policy organization – found that local health departments face three principal problems:

- *A Funding Gap:* From fiscal year 2005 to 2012, federal funds for state and local preparedness declined 38 percent, and additional cutbacks are expected;
- *A Workforce Gap:* From 2008 to 2011, an estimated 34,400 local health department jobs have been eliminated; moreover, within the next five years, a third of local health department workers will be eligible to retire; and
- *A Community Resiliency Support Gap:* Large-scale disease outbreaks require public health departments to address the additional concerns posed by at-risk special needs and vulnerable populations, but most local health departments lack the staff required to fully engage those populations.

In large part because of the three gaps, innovative solutions may be needed to overcome these and other challenges facing local health departments. One solution believed to have significant potential is described as "mobile health" (mHealth), which is defined as the use of mobile technologies to not only preserve and improve the health of special populations but also to upgrade the capabilities of healthcare delivery systems. Preliminary research shows that mHealth can specifically be directed to: (a) improve communications with the public; and (b) make the dispensing of medical countermeasures more effective during a large-scale pandemic.

Technologies such as mHealth have the potential needed to help reduce the capability gaps created by funding cuts, workforce shortages, and lack of community resilience support. Further discussion is needed to encourage the policy changes required for additional implementation.

Fortunately, technological advances in mobile devices have coincided with an increase in both the access to and usage of mobile technology. The increased frequency with which Americans now use smartphones, coupled with the advanced capabilities of the phones themselves – for text messaging, web browsing, GPS navigation, geo-location services, e-mail access, and a still growing spectrum of other purposes – provides an opportunity for communicating more, and more effective, preparedness information as well. Moreover, it seems clear that, although some new programs have emerged in recent years at local health departments, additional federal guidance could help significantly in determining how mHealth can and should be incorporated into improved preparedness planning at all levels of government.

Communicating & Dispensing Countermeasures During Emergencies

Local health departments are responsible for the critical function of providing information, warnings, and notifications to the public during pandemics. Although many public communication channels already exist, mHealth technology offers a unique way to provide more effective information as well as more frequent reminders, through text messaging programs and mobile apps – related to vaccines, for example, requiring more than a single dose.

One forward-looking health department, Public Health–Seattle (Washington) & King County (PHSKC), has carried out, and

published – in the *Washington State Journal of Public Health Practice* – preliminary research on communicating with the public during major emergencies. In a recent phone survey of about 400 King County residents: (a) the vast majority (82 percent) of respondents said they wanted to receive text messages from PHSKC during an actual emergency; (b) about 50 percent also wanted to receive text messages about how to prepare for an emergency; and (c) 25 percent wanted to receive text messages on a number of other health topics. Because interventions that use mHealth technology must be not only specialized but also personalized to some extent – to meet the needs of a specific population, for example – understanding such variations in interest levels related to the services offered is a key finding.

Other research – reported in a 2010 issue of *Epidemiologic Reviews* – found not only that text messaging is in fact an effective tool for behavior change but also that the beneficial effects range across a broad spectrum of age, minority status, and nationality groups. It seems probable, therefore, that reminder-based text messaging programs can promote behavior change by providing cues to action – a text reminder to return for the second dose of a vaccine, for example, or to complete the full course of a particular medication.

Similar results were found when the communications team of PHSKC conducted a two-year pilot study, beginning in 2010, to determine if parents would opt in, during a mass flu vaccination exercise, for a text message program to remind them to return for their children's second dose of vaccine. In the first year of the pilot, 84 percent of parents did in fact opt into the program, and 95 percent opted in the following year. It should be noted that, although the studies demonstrated the public's desire to receive information, they did not evaluate the effectiveness of the interventions to improve vaccine uptake.

In addition to helping in the dissemination of information, local health departments also play a critical role in rapidly dispensing medical countermeasures during a pandemic. Denver (Colo.) Public Health (DPH) addressed that task by developing a mobile app with the potential to be replicated by other health departments throughout the country. More specifically, DPH designed and implemented the Hand-held Automated Notification for Drugs and Immunizations (HANDI) application as a tool that could be used to collect the essential data needed during mass prophylaxis and immunization incidents and events.

The app addresses issues that were identified by DPH during the 2009-2010 H1N1 pandemic by capturing patient data, and collecting other standardized information, through the use of scanning technology embedded into a mobile device, thereby eliminating the need for manual data entry. Moreover, HANDI also makes it possible – by scanning drivers' licenses, monitoring contraindications, and tracking the prophylaxis/immunizations administered – for health workers at different stations to work as a unified team. In addition, eliminating the need both to fill out paper forms and to manually enter the data required helps medical countermeasures be dispensed more quickly and with fewer staff hours required.

New Challenges, Opportunities & Policy Changes

Despite the considerable evidence suggesting that mHealth provides an unprecedented opportunity for local health departments to develop innovative solutions, the technology now available has yet to be widely adopted. The study published in the *Washington State Journal of Public Health Practice* concluded that, among the main challenges remaining, are the minimal understanding of: (a) how text messages could be used; (b) how to select companies and vendors for the development process; and (c) the cost and effectiveness of the technology.

Another factor that also must be addressed is that, because of the current economic and fiscal state of the nation, many local health departments face increasingly severe budgetary constraints. With limited financial resources, department leadership may be hesitant to invest financial resources in new

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technologies that may not be well understood among staff and/or by the general public. In recent years, many local health departments also have had to reduce the size of their staffs, another factor that might compromise the breadth and depth of the public health programs offered.

A new and more comprehensive evaluation of the cost-effectiveness of mHealth technologies, particularly in comparison to standard preparedness activities, would help strengthen the case for mHealth programs. However, it is important to note that the mHealth technologies currently in use demonstrate that local health departments already have the ability to broaden their reach while at the same time increasing their operational efficiency.

If nothing else, the following four recommendations might serve as the talking points needed for additional policy discussions on the use of mHealth and/or similar technologies to improve and expand local pandemic preparedness capabilities:

Collaboration – Preparedness programs that use mHealth technology could and should be replicated in communities across the country. Instead of developing such programs in local "silos," greater collaboration and additional regional partnerships among health departments and other stakeholders would improve and accelerate the development and expansion of the already proven mHealth technologies for pandemic preparedness.

Federal Guidance – More prescriptive federal guidance to spur development and innovation should be provided to allow and encourage the further advancement and identification of ways in which local health departments can use mHealth. The U.S. Department of Health and Human Services (HHS) and its Centers for Disease Control and Prevention (CDC) already offer some preliminary guidance and tools – e.g., the Text Alert Toolkit, a library of developed text messages for emergencies that could be used for local mHealth programs. As immunization health registries and electronic health records continue to become the norm in public health, mHealth programs can increasingly build upon those frameworks.

Training – More, and more effective, training is required at the local level to develop and implement mHealth programs for pandemic preparedness. Local health department staff could benefit from learning a step-by-step approach to developing, testing, and implementing an mHealth program. In addition, specific training modules could focus greater attention on understanding the different types of mHealth technologies available, the capabilities needed to select a capable and cost-effective vendor or developer, and the signs and symptoms that must be present to evaluate the effectiveness of an intervention.

Public-Private Partnerships – The development of a successful mHealth program requires partnerships across a broad spectrum of organizations – including but not limited to capable private-sector companies and businesses, the multiple levels of government that might be involved, non-profit organizations, researchers, academia, and telephone companies. More work should be done to bring all of these groups together to fully discuss the shift in pandemic preparedness toward implementing mHealth technology.

For additional information on:
The CDC's social media tools, guidelines, and best practices, visit http://www.cdc.gov/SocialMedia/Tools/guidelines/

The Department of Health and Human Services' mHealth Initiative, visit http://www.hhs.gov/open/initiatives/mhealth/index.html

Epidemiologic Reviews' 2010 article, "Text messaging as a tool for behavior change in disease prevention and management," by H. Cole-Lewis and T. Kershaw, visit http://epirev.oxfordjournals.org/content/32/1/56.abstract

Public Health–Seattle & King County's information about using text messages as vaccine reminders, visit www.kingcounty.gov/health/texting

The 2011 Trust for America's Health's report, "Ready or not? Protecting the public's health from diseases, disasters, and bioterrorism," visit http://healthyamericans.org/report/92/

The 2011 Washington State Journal of Public Health Practices article, "What 2 know b4 u text: Short Message Service options for local health departments," by H. Karasz and S. Bogan, visit http://www.wsphajournal.org/V4N1/V4N1_Karasz.pdf

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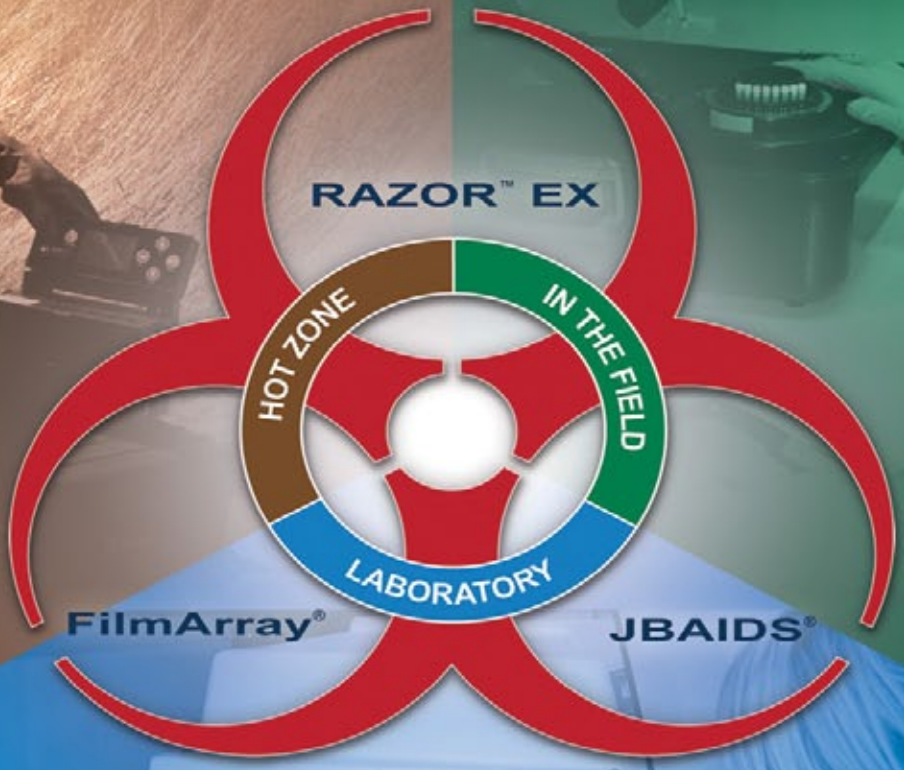

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Addressing Key Policy Issues Before the Next Catastrophe

By Ann Lesperance, Emergency Management

During a major disaster, saving lives and protecting the environment while ensuring public safety are all-encompassing priorities. As a catastrophe unfolds, decision makers at all levels of government are faced with a myriad of questions and/or issues that must be quickly addressed and resolved to return a sense of normalcy to the devastated region. Additional challenges would be presented if the catastrophe was the result of a terrorist attack using a weapon of mass destruction (WMD).

Regional recovery planning over the past several years has surfaced a number of key policy issues that have yet to be resolved. Although not a comprehensive list, four policy-related issues – economic redevelopment, waste management, fatality management, and prioritization of cleanup – are key concerns that must be addressed prior to an event to provide clarity and information to federal officials, state, local, and tribal jurisdictions, the private sector, and nongovernmental organizations to assist in their catastrophic planning and recovery efforts.

Economic Redevelopment

Restarting the economic engine of a community that has been devastated by a catastrophic event is the key to recovery. In its most basic terms, "no jobs" equates to "no recovery." For a WMD terrorist event, recovery is further complicated by lack of a well-defined financial safety net for local governments, businesses, and residences. The Stafford Act for Disaster Relief and Emergency Assistance (originally signed into law in 1988), insurance, and a range of other financial mechanisms are in place to help communities, businesses, and homeowners rebuild from a natural disaster, but these mechanisms do not apply in the case of terrorist-related events.

If a terrorist attack with a WMD were to happen today, non-governmental and faith-based organizations would collect and distribute financial and other resources to support residents, but local governments and businesses would be largely without access to funds to rebuild and kick-start businesses. Although it is reasonable to assume that government would step forward in the face of a WMD attack to support recovery, the absence of a clearly articulated policy for financial assistance impedes recovery planning and slows down recovery.

The Federal Emergency Management Agency should take the lead by: (a) discussing potential remedies with state and local emergency managers, critical infrastructure owners, and a range of business leaders recommending amendments to the Stafford Act; or (b) developing other mechanisms to provide the requested financial resources to retain as many local residents and businesses as possible and accelerate business restart.

Waste Management

Within waste management are also a variety of policy-related issues to address. For example, there is general agreement that waste management or debris management plans must be developed to address collection, treatment, shipment, and disposal of waste contaminated with *Bacillus anthracis* (anthrax) to avoid delays in cleanup in the event of a wide-area bio-terrorist attack. Waste management is a highly regulated industry yet questions remain regarding the regulatory classification of waste contaminated with *Bacillus anthracis* spores. In order to provide clarity, Environmental Protection Agency needs to resolve the waste classification questions to allow appropriate waste/debris management plans to be developed that are compliant with regulations at all levels of government.

Fatality Management

For many municipalities, any large-scale WMD incident resulting in hundreds or even thousands of mass casualties will overwhelm the system. For some, a disaster involving even 30 casualties could overwhelm the fatality management system. Although many look to the military to provide support, there are limits on the extent the military could provide core fatality management functions.

Given the limits of national capacity, a clear strategy involving local, state, federal and military officials, coroners, and medical examiners should be developed that articulates how managing the casualties will be addressed. This strategy would also assist local and state planners in their catastrophic planning activities. The capacity built at major metropolitan areas under FEMA's Regional Catastrophic Preparedness Grant Program have made great strides in regional collaboration and can be a source to further address this issue.

Prioritization of Cleanup

Multi-agency coordination allows multiple jurisdictions to coordinate following a catastrophic event across a broad range of functional areas – fire, law enforcement, public works, public health, etc. Although some municipalities have developed this mechanism to ensure functional areas are effectively integrated through a collaborative approach, few have been tested. Many jurisdictions include privately owned infrastructure that is critical to the recovery of a region, yet many of these private sector owners are not clearly identified as being part of the effort. During a large WMD event, it can be assumed that there will be multiple jurisdictions vying for limited resources. However, the following questions still remain: Who sets priorities for cleanup and restoration for a region, and what are the decision criteria to set priorities? What occurs and what is the process for resolving issues when state and federal cleanup priorities differ from local and private sector priorities?

Responders and emergency managers should not meet each other for the first time at the scene of a disaster. Likewise, collaboration is needed well in advance of a disaster for addressing and resolving critical policy issues. Unnecessary delays equate to adverse impacts on public health, the economy, and the environment.

Ann Lesperance is the Deputy Director at the Northwest Regional Technology Center for Homeland Security, Pacific Northwest National Laboratory (PNNL). In that capacity, she focuses on the identification of technology issues and needs for regional preparedness, response, and recovery to all hazards, with emphasis on chemical, biological, and radiological incidents, port security, and critical infrastructure protection. As part of the PNNL's homeland security programs, she is engaging regional emergency planning professionals in identifying specific requirements and technology applications in the Pacific Northwest.

Significant contributions to this article were made by Steven Stein of the PNNL's Northwest Regional Technology Center for Homeland Security.

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Concurrent Distribution of Anthrax Vaccine & Antibiotics

By Sarah Keally, Public Health

Public health organizations such as the National Association of County and City Health Officials (NACCHO) have recommended that local health agencies include the anthrax vaccine in their plans for the distribution of medical countermeasures. Many local health department preparedness plans, however, currently do not address the potential difficulties caused by the concurrent dispensing of anthrax vaccine and antibiotics to combat an anthrax attack. Although administering the anthrax vaccine as a post-exposure prophylaxis is considered an effective response to an intentional release of anthrax spores, additional and more detailed federal guidance, as well as technical and financial assistance, is still needed.

According to the Anthrax Vaccine Home Page of the U.S. Centers for Disease Control and Prevention (CDC), a major agency of the U.S. Department of Health and Human Services (HHS), "There is a vaccine to prevent anthrax, but it is not yet available for the general public." Nonetheless, the Home Page also says, "in the event of an attack using anthrax as a weapon, people exposed would [still] get the vaccine." Following the passage, in 2008, of the Public Readiness and Emergency Preparedness (PREP) Act, the anthrax vaccine adsorbed (AVA) was added as a medical countermeasure to the CDC's Strategic National Stockpile (SNS) of medicines and other medical resources. In 2010, the CDC's Advisory Committee on Immunization Practices (ACIP) further recommended that persons exposed to anthrax by inhalation should receive three doses of the vaccine, and that the first dose be administered no later than 10 days after exposure.

Information & Mounting Concerns

Although this information has been available for several years, some local health departments may not be aware of the specific requirements mandated and, therefore, have not yet updated their own SNS preparation plans. Of course, the concurrent dispensing of AVA and antibiotics poses some significant operational and logistical challenges for local public health agencies. Therefore, preplanning is essential to ensure that an adequate level of qualified staff who are required and have been properly trained for the response effort needed is quickly available.

Another major concern is that, although many local public health agencies may in fact be ready to dispense antibiotics, they may not be sufficiently prepared, or funded, to mount a vaccination campaign simultaneously with the antibiotics distribution also needed in the wake of an aerosolized anthrax attack. One possible reason for this gap is that health agencies at the local level may be unaware of the ACIP and CDC reports on the use of anthrax vaccine for post-exposure prophylaxis.

In addition, there has been little technical and financial support provided to develop this area of preparedness at the level likely to be needed. To begin with, the concurrent dispensing of antibiotics and vaccines necessarily requires that additional staff be available at the dispensing sites, significantly increasing the burden, therefore, on the local public health agencies involved, and their local partners – who also must provide extra support staff. Another consideration that must be taken into account is that access for at-risk populations must be ensured when planning for the concurrent dispensing of both AVA and antibiotics.

As matters now stand, the general guidance provided by federal agencies suggests that the use of AVA, in addition to antibiotics, offers the best response currently available to cope with an intentional release of anthrax spores. However, an official statement from CDC or one of the other agencies directly involved with respect to implementing plans for the concurrent dispensing of anthrax vaccine and antibiotics would help strengthen overall preparedness efforts at the local level.

The bottom line is that local public health agencies should begin now, well prior to an actual event – and with support provided by the federal government – to: (a) address the logistical and operational issues involved in the complementary vaccine dispensing effort required; and (b) provide adequate training for the licensed and professional staff needed to quickly and safely deliver the federally mandated countermeasures to the public during an actual emergency.

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Critical Intersection of Diagnostics & Countermeasures

By Chris N. Mangal, Public Health

During the past decade, significant federal investments were made to improve the nation's response to bioterrorism, pandemic influenza, and other emerging threats. Those investments supported the development and acquisition of medical countermeasures, such as vaccines, and also strengthened diagnostics capability – that is, the ability for laboratories to detect threat agents. Medical countermeasures and diagnostics capability are currently at a critical intersection – without accurate and rapid diagnostics, it is difficult to determine the appropriate course of treatment or other countermeasure. Although most people may be familiar with vaccines, antibiotics, and antivirals, many are unaware of the behind-the-scenes work of laboratories to detect the causative threat agent.

Identifying, Testing & Characterizing Samples

Formed in 1999 by the Centers for Disease Control and Prevention (CDC), the Association of Public Health Laboratories (APHL), and the Federal Bureau of Investigation (FBI), the Laboratory Response Network (LRN) is the nation's premier system for rapidly identifying, testing, and characterizing potential agents of biological and chemical terrorism and other emerging public health threats. The LRN maintains an integrated national and international network of laboratories that can respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats. State and local public health laboratories comprise approximately 70 percent of the LRN Biological Reference Laboratories and almost 100 percent of the LRN Chemical Laboratories. These laboratories produce high-confidence test results that form the basis for threat analysis and intervention by both public health and law enforcement authorities.

The LRN for Biological Threat Preparedness is organized as a three-tiered pyramid. At the foundation are thousands of sentinel clinical laboratories, which perform initial screening of potential pathogens. When sentinel clinical laboratories cannot rule out the presence of a biological threat agent, they refer specimens and isolates to the appropriate LRN reference laboratory. More than 160 local, state, and federal facilities provide rapid reference testing. At the apex are national laboratories, such as those at the CDC and the Department of Defense. These laboratories test and characterize samples that pose challenges beyond the capabilities of reference laboratories, and provide support for other LRN members during a serious outbreak, public health emergency, or terrorist event. The most dangerous or perplexing pathogens are handled only at the highest level biosafety laboratories (BSL-4) at CDC and the U.S. Army Medical Research Institute of Infectious Diseases.

Diagnostics as a Countermeasure Tool

Following the release of a biological threat agent, clinical diagnostic assays are important tools to distinguish infected, exposed, and "worried-well" populations. The detection of exposures will determine which people need treatment (infected) and which require post-exposure prophylaxis (exposed, but asymptomatic). LRN reference laboratories are conducting ongoing public health surveillance testing on clinical specimens and non-clinical samples, such as food, surface swabs, air filters, and white powders, for a myriad of biological threat agents. These laboratories serve a vital function in all phases of a terrorist or other public health threat: (a) pre-event (surveillance testing); (b) event (rapid diagnostics, connection to sentinel clinical laboratories, local law enforcement/first responders, and FBI for rapid response); and (c) post-event (remediation/clean-up).

In addition to their role in the LRN, state and local public health laboratories play a vital role in protecting the nation's health – whether detecting the next resistant strain of tuberculosis or identifying a novel pathogen such as Influenza A H1N1. These laboratories are at the forefront of the diagnostics that provide guidelines for the use of medical countermeasures such as antibiotics, antivirals, or other non-pharmaceutical intervention – appropriate personal protective equipment, for example.

In the future, it will be important to see a continued commitment from governmental leaders to improve the development of robust rapid assays for the detection of public health threats in clinical samples such as human blood and non-clinical samples such as powders or water. Rapid diagnostics are critical for providing the information necessary to deploy and distribute medical countermeasures.

Chris N. Mangal, MPH, is the director of public health preparedness and response at the Association of Public Health Laboratories (APHL). The recipient of a bachelor's degree in microbiology from the University of Florida, and of a master of public health degree from the University of South Florida, she is responsible for providing programmatic and scientific leadership for preparedness activities for the benefit of APHL members, staff, and partner organizations, such as the Centers for Disease Control and Prevention (CDC). Chris has over ten years of experience working to improve laboratory practice in the detection of public health threats, and to expand and enhance the relationships between APHL member laboratories and CDC, other federal agencies, and private organizations involved in emergency preparedness and response, public health testing, policy, and training.