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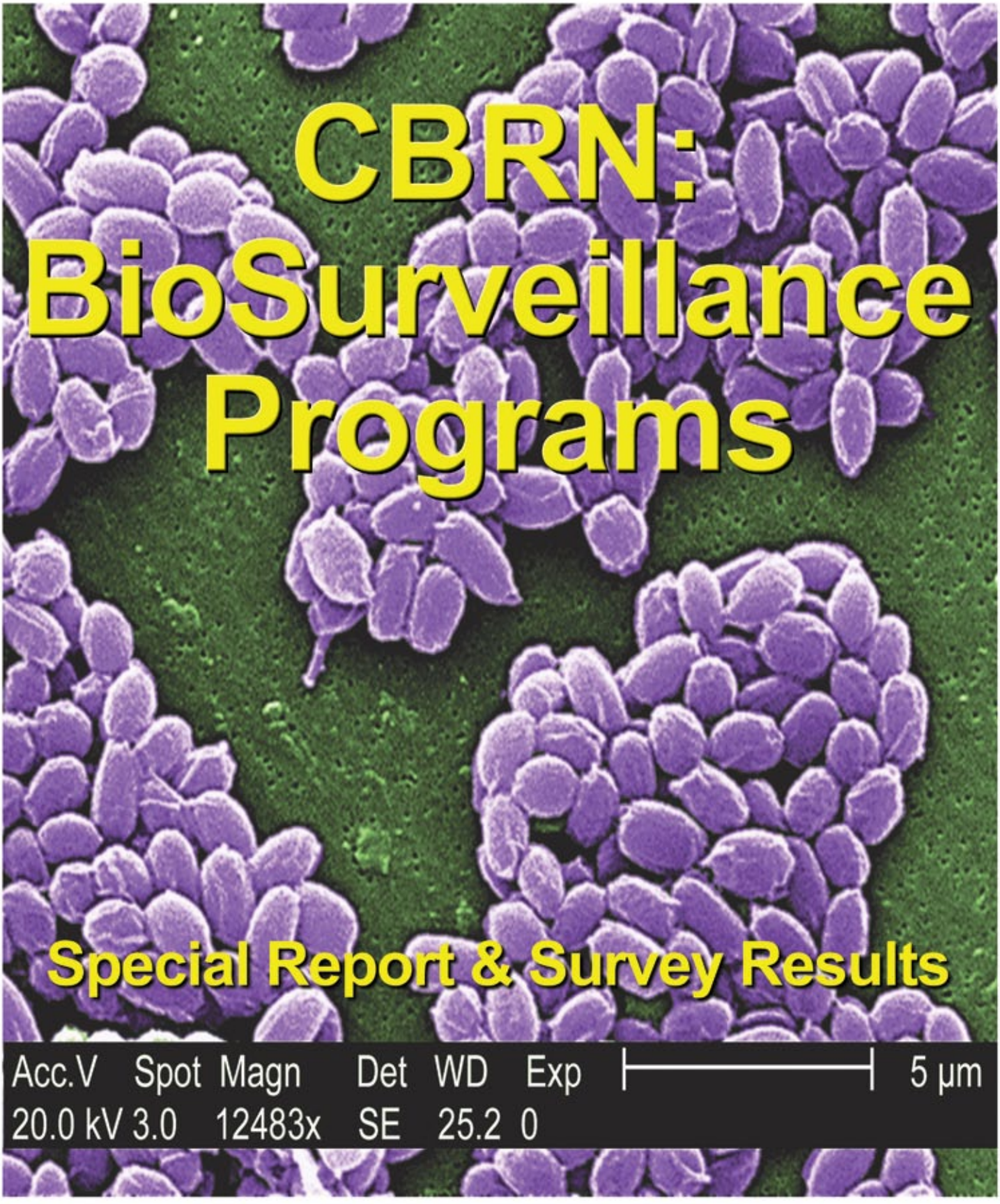
Executive Briefing

Special Report May 2011



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Publisher's Message

By Martin (Marty) Masiuk, Publisher

Greetings and Welcome!

On behalf of the entire staff, we are proud to host this DomPrep Executive Briefing. By design, these briefings are structured to be half-day, power-packed, by-invitation-only meetings that promote the exchange of ideas and provide networking opportunities. Your participation and response are greatly appreciated as our distinguished speakers shed light on the gaps discovered by the DomPrep40 surveys and spark discussions for possible solutions.

The important topic of this briefing is ***CBRN: BioSurveillance Programs – Needed?***; headed by Major General Stephen Reeves USA (Ret.), Former Joint Program Executive Officer for Chemical & Biological Defense, Department of Defense (DoD). General Reeves, along with a panel of other experts, will discuss gaps and synergies evident from the survey. Topics to be addressed include:

- Presidential directives and other government policies related to biosurveillance;
- Interagency cooperation and interoperability efforts across all levels of government as well as private-sector entities;
- Multidisciplinary biosurveillance concerns related to such topics as lead agencies, investment strategies, information sharing, and reporting strategies.

Please take a moment to review the agenda, information about presenters and sponsors, and list of related articles previously published in the DomPrep Journal.

Those who are unable to join us in person will have the opportunity to listen to the proceedings in the Webinar section of DomPrep's website: http://www.domesticpreparedness.com/Webinars/.

Your feedback and input on these briefings are always welcome as DomPrep strives to take preparedness to the next level.

Sincerely yours,

About the Cover: High-magnification (12,483X) scanning electron micrograph, or SEM, depicts spores from the Sterne strain of Bacillus anthracis bacteria. (CDC photo by Janis Haney Carr)

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Speaker Biographies

Major General Stephen Reeves USA (Ret.)

Former Joint Program Executive Officer for Chemical & Biological Defense, Department of Defense (DoD) and DomPrep40 Advisor

Stephen is a highly accomplished senior executive and an internationally recognized expert on chemical and biological defense as well as defense acquisition. He has testified as an expert witness on multiple occasions before the U.S. Congress and has been interviewed numerous times by the national and international print and television press. He also is a frequent speaker at both national and international defense and homeland security conferences. Experienced in leading and managing large, diverse, global, multi-billion dollar organizations, he established, and for seven years led, the first Department of Defense Joint Program Executive Office for Chemical and Biological Defense.

Dr. Karen Remley

Commissioner, Virginia Department of Health

Karen has been Virginia's Health Commissioner since January 2008, serving under Governor Bob McDonnell and former Governor Tim Kaine. As health commissioner, she is the principal public health advisor to the Governor, Secretary of Health and Human Resources, the Virginia General Assembly, and the State Board of Health. She also supervises one of the state's largest agencies, which includes 119 local health departments organized into 35 health districts throughout the Commonwealth.

Rear Admiral Craig Vanderwagen (Ret.)

Former Assistant Secretary for Preparedness and Response, U.S. Department of Health & Human Services (HHS), and DomPrep40 Advisor

Craig is a senior partner with Martin, Blanck, and Associates (MBA). His most recent assignment prior to joining MBA was the Assistant Secretary for Preparedness and Response for the U.S. Department of Health and Human Services (HHS) from 2006 to 2009. He has special interests and experience in biodefense, domestic disaster preparedness and response, international humanitarian and disaster response, federal health delivery systems, innovative organization development and evaluation, and cross-cultural health care.

Robert Hooks

Deputy Assistant Secretary for Office of Health Affairs, U.S. Department of Homeland Security (DHS)

Robert serves as Deputy Assistant Secretary in DHS's Office of Health Affairs. He is responsible for the Department's early detection biodefense programs including BioWatch, the National Biosurveillance Integration Center (NBIC), homeland security programs in animal security and food defense, and biological threat mitigation efforts. Most recently, he served as Director of Transition, in the Science and Technology Directorate (S&T) of DHS. Within the S&T, he served as Chief of Staff and Deputy Director in the Office of Research and Development. Prior to joining the Department of Homeland Security in 2003, he served 20 years in the U.S. Navy.

Lieutenant Colonel Jennifer A. Nicholson

Director for BioSurveillance Strategic Initiatives, Joint Program Executive Office for Chemical & Biological Defense, Department of Defense (DoD)

Jennifer is Director of Biosurveillance Strategic Initiatives, Joint Program Executive Office of Biological and Chemical Defense. She leads a team synchronizing biosurveillance initiatives and biological environmental sensor efforts across services. Previously, she was an Assistant Product Manager at Stryker, Assistant Professor of Military Science and Scholarship Officer at University of Washington, Seattle, Lieutenant (Army Corps of Engineers), Battalion Maintenance Officer, and Chief of the Military Engineering and Topographic Team for USAEUR, Crisis Action Branch. Her duties included managing soldiers, equipment, scholarship funds, and Stryker Brigade resets and vehicle variants. She instructed cadets, monitored and reported engineer activities in Bosnia, aided development of interoperability training with British topographers, deployed to Mosul, Iraq, and oversaw the Qatar Stryker Battle Repair Facility.

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23 May 2011
AGENDA

The purpose of this briefing is to discuss gaps that were uncovered in a recent DomPrep survey. This survey was created and taken by a panel of experts (the DomPrep40). Readers of the DomPrep Journal were then asked to take the same survey, the results of which were compared to uncover gaps that need to be addressed.

0800-0820	Registration & Continental Breakfast
0820-0825	Welcome, Marty Masiuk, Publisher, DomesticPreparedness.com Introduction of Industry Sponsors ◂ ***Opening Remarks***
0825-0840	***CBRN: BioSurveillance Programs - Needed?*** Major General Stephen Reeves USA (Ret.), Former Joint Program Executive Officer for Chemical & Biological Defense, Department of Defense (DoD) and DomPrep40 Advisor ◂ ***Listen to Presentation***
0840-0855	Dr. Karen Remley, Commissioner, Virginia Department of Health ◂ ***Listen to Presentation***
0855-0910	Rear Admiral Craig Vanderwagen (Ret.), Former Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services (HHS), and DomPrep40 Advisor ◂ ***Listen to Presentation***
0910-0930	Questions and Answers ◂ ***Listen to Q&A***
0930-0945	Break and Networking
0945-1000	Robert Hooks, Deputy Assistant Secretary for Office of Health Affairs, U.S. Department of Homeland Security (DHS) ◂ ***Listen to Presentation***
1000-1015	Lieutenant Colonel Jennifer A. Nicholson, Director for BioSurveillance Strategic Initiatives, Joint Program Executive Office for Chemical & Biological Defense, Department of Defense (DoD) ◂ ***Listen to Presentation***
1015-1040	Questions and Answers ◂ ***Listen to Q&A***
1040-1100	Networking and Adjournment

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Craig Vanderwagen
Former Assistant Secretary for Preparedness & Response, HHS

DomPrep Survey

CBRN: BioSurveillance Programs - Needed?

Prepared by Major General Stephen Reeves USA (Ret.), Former Joint Program Executive Officer for Chemical & Biological Defense, Department of Defense (DoD), and DomPrep40 Advisor

Emerging infectious disease and bioterrorism concerns surround the nation's public health, agriculture, and food supply. The World Health Organization (WHO) reports that, since the 1970s, newly emerging diseases have appeared at the rate of one or more per year. There are now nearly 40 diseases that were unknown 20 years ago and, during the past 5 years, WHO has verified 1,100 epidemics worldwide. In 2003, Severe Acute Respiratory Syndrome (SARS) amply demonstrated how rapidly an emerging disease can spread, with 37 countries reporting and confirming outbreaks within a three-week period. More recently, in 2009, H1N1 influenza was a largely unexpected global pandemic.

Against this background, in 2007, Homeland Security Presidential Directive-21 was published establishing, among other things, a requirement for a national biosurveillance capability. In 2009, in the immediate wake of the H1N1 pandemic, Presidential Policy Directive 2, The National Strategy for Countering the Proliferation of Biological Threats, was published as implementing guidance. This policy again directed the establishment of a worldwide biosurveillance program. The federal government's intent was, and still is, clear: develop a nationwide, robust, and integrated biosurveillance capability, with connections to international disease surveillance systems, in order to provide early warning of deliberate or emerging biological threats, and ongoing characterization of disease outbreaks in near real-time.

Both presidential directives called for interagency cooperation across federal, state, and local governments. Both recognized the challenges and need for more personnel, better training, and new equipment and systems. Yet, as the Government Accountability Office (GAO) noted in June 2010, neither presidential directive established an appropriate leadership mechanism – e.g., an interagency council or national biosurveillance director – to provide a focal point with authority and accountability for developing a national biosurveillance capability. At present, primary responsibility is given to the U.S. Department of Health & Human Services' (HHS) Centers for Disease Control and Prevention (CDC) for human health, the U.S. Department of Agriculture (USDA) for plant and animal health, USDA and HHS's Food and Drug Administration (FDA) for food responsibilities, and the U.S. Department of Homeland Security (DHS) for a reporting responsibility under its charter for securing the homeland.

The present U.S. biosurveillance system is highly dependent on state and local public health officials, veterinarians, and agricultural agents to voluntarily report diseases and crop infections. In addition to challenges in both the speed of reporting and dealing with volumes of unstructured data, there is also an issue of training in a rapidly evolving field as well as available personnel. In December 2008, the Association of Schools of Public Health estimated that by 2020 the nation would face a shortfall of over 250,000 public health workers. The USDA likewise has reported expected nationwide veterinarian shortages.

Finally, there is the issue of what really constitutes biosurveillance. Traditional disease and biological threat surveillance relies on vigilant healthcare providers, public health agencies, veterinarians, and agricultural agents to report suspicious outbreaks. In most cases, reporting is slow, which is largely due to a reliance on scientific certainty and sophisticated laboratory testing.

In contrast, biosurveillance uses actionable information from both medical and nonmedical sources – both domestically and internationally – in the shortest possible time.

Key Findings

- The majority of respondents agree that biosurveillance is an important part of state and local emergency planning, but many state and local biosurveillance programs are currently inadequate.
- The vast majority of respondents believe that additional investments are needed in developing interoperability between public health and healthcare institutions, in addition to better point-of-care diagnostics and attribution methodologies.
- Roughly half of respondents believe that what constitutes an "actionable" biosurveillance report differs depending on the subject of the threat, thus reflecting additional challenges that decision makers face when analyzing the reports.
- The vast majority of respondents were unaware of the fact that there are many agencies, each of which holds primary responsibility and authority for biosurveillance activities, depending on whether it covers human, animal, plant, food, or environmental surveillance.

Survey Results

The current survey was designed to address all of these issues and seek insight into how an integrated national strategy, encompassing all stakeholders with biosurveillance responsibilities, can be used to guide the systematic identification of risk, assessment of resources needed to address those risks, and prioritization and allocation of investment across the entire biosurveillance enterprise.

Recognizing that great ideas at the federal level are not always great ideas at the state and local level, Question 1 revealed general agreement between the readership and the DomPrep40 Advisors (70% and 65%, respectively) that biosurveillance was indeed important to state and local emergency planning. However, the adequacy of existing local biosurveillance brought local perspective into sharp focus with roughly 50% of the readership believing state and local biosurveillance programs were inadequate and another 27% thought their programs were underfunded but potentially capable, while 60% of the DomPrep40 found their local programs inadequate (Question 5). Interestingly, when biosurveillance systems were addressed as a whole, there was broad consensus (~70%) that current human, animal, plant, food, and environmental systems are not adequate to provide early warning and situational awareness during a biological mass-casualty event (Question 2).

To address these issues, there was strong agreement (84% readers, 79% DomPrep40) that additional investment in interoperable systems among public health and delivery institutions (e.g., hospitals), better point of care diagnostics, and attribution methodologies are needed (Question 8). This agreement was echoed and somewhat reinforced with the finding that biosurveillance should focus on all diseases and biologically anomalous activity (53% readers, 65% DomPrep40), although nearly 20% of the readers believe a focus only on highly contagious diseases is adequate (Question 4).

Underlying Question 3 is the issue of timely reporting. Generally, the higher the level of confidence required in reporting, the greater the delay in reporting. Although a slim majority of both the readers and DomPrep40 members (43% and 55%, respectively) chose "it depends" on if the issue is human, animal, plant, or food, the responses also reflect the very real leadership challenges in deciding on appropriate action based on those reports.

Question 7 goes straight to the issue of "who is in charge" of multidisciplinary biosurveillance. A majority of both readers and the DomPrep40 (41% and 39%, respectively) believe it is the responsibility of the CDC, which is correct for human health. However, as noted in the introduction, USDA, FDA, and DHS also have important roles in biosurveillance. Less than 3% of the readers and just over 11% of the DomPrep40 correctly marked, according to the GAO, "none of the above."

Once it is determined who is in charge, then the federal government needs to determine where to focus its biosurveillance investment strategy. According to readers and DomPrep40, 19% and 25% (respectively) want the focus to be on an integrated national and international reporting network. However, at least half of both groups want the focus to be broader to include recruiting workforces, more early warning surveillance, and bioinformatics (Question 6).

Conclusion

Based on the results of the DomPrep CBRN BioSurveillance Programs – Needed? survey, it is apparent that the majority of experienced practitioners across multiple disciplines and jurisdictions believe that biosurveillance should be an integral part of the emergency planning process. In respondents' views, more needs to be invested in the areas of biosurveillance interoperability, diagnostics, and methodologies, but exactly where and how much to invest will be the next question.

Tracking all diseases and biologically anomalous activities would require varying degrees of involvement by multiple government agencies. Without a federal focal point having authority to oversee all biosurveillance activities among these various agencies, it becomes much more difficult to determine who is in charge, on what should the investment strategy focus, and when does a report become actionable. Establishing an interagency council or national biosurveillance director would be the first step to creating an integrated biosurveillance reporting network to enhance early warnings by utilizing a united workforce and information sharing tools.

Post-Action Report

Experts, practitioners, senior state and federal policy officials, and DomPrep readers all agree that biosurveillance is and will be critical in protecting the nation's health, animals, agriculture, and food supply. Although there are numerous biosurveillance programs created and/or being carried out by multiple local, state, and federal agencies, serious gaps remain not only in synchronizing and coordinating their efforts but also in developing a broad-based "actionable" biosurveillance system that provides early warning of potential new dangers. That gap was amply reinforced and demonstrated in the past few days as a virulent E. coli strain, which was not under surveillance in the United States, killed more than a dozen people, and continues to sicken thousands, in Europe.

For that reason alone, significant investments, in terms of both dollars and training, as well as establishing a federal focal point for biosurveillance activities and operations, are both needed. Appointment of a National Biosurveillance Director responsible for integrating the biosurveillance activities of various federal agencies would be an excellent way to start. Considering the current reliance on local public health and agricultural agents, there should be a similar effort to fund state and local governments to permit them to contribute to a national biosurveillance network. At a time when budget restrictions may not allow a surprise biowarfare attack or incident to be addressed by maintaining large infrastructures with multiple overlapping capabilities, the ability to recognize and respond as soon as possible to a biological event, even in a more limited way, will be a critical requirement in developing an effective 21st-century defense capability.

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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)

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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.

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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.

MERIDIAN MEDICAL TECHNOLOGIES™

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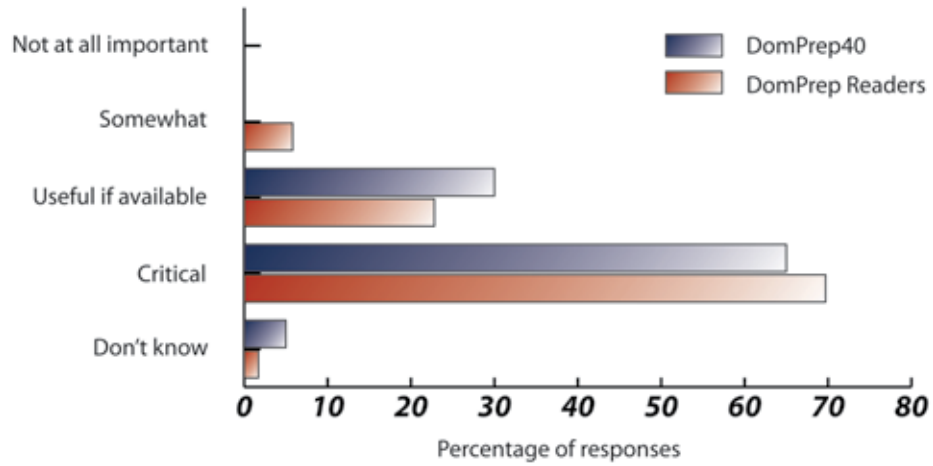
Survey Results

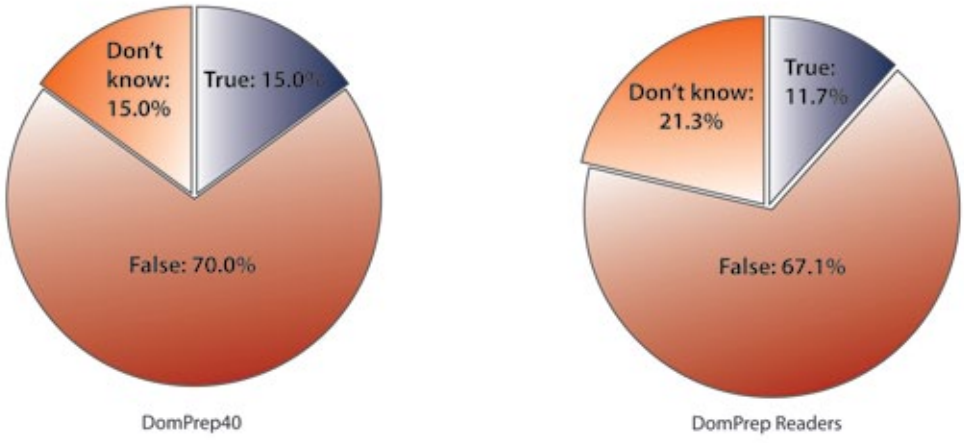
QUESTION ONE

How important is biosurveillance in state and local emergency planning?



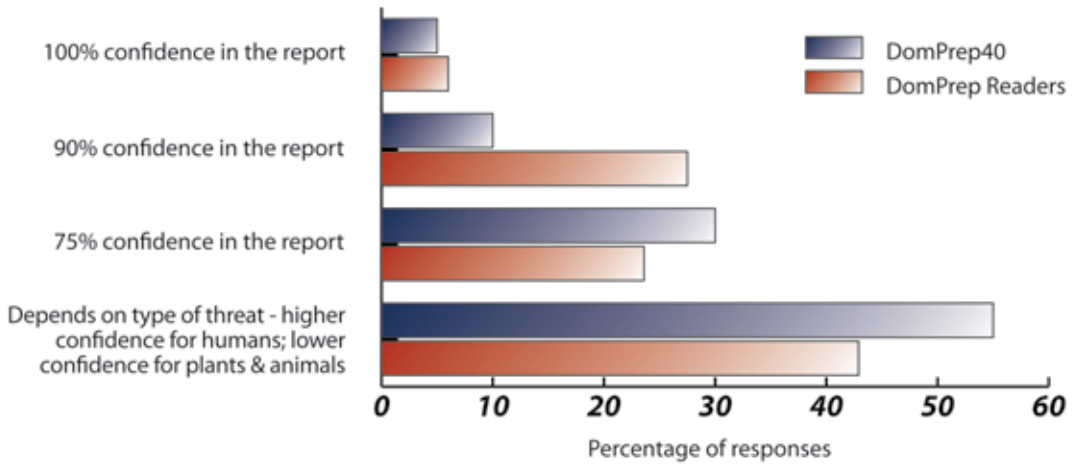
QUESTION TWO

Current human, animal, plant, food, and environmental surveillance systems provide adequate situational awareness to provide early warning and situational awareness during a biological mass-casualty situation.



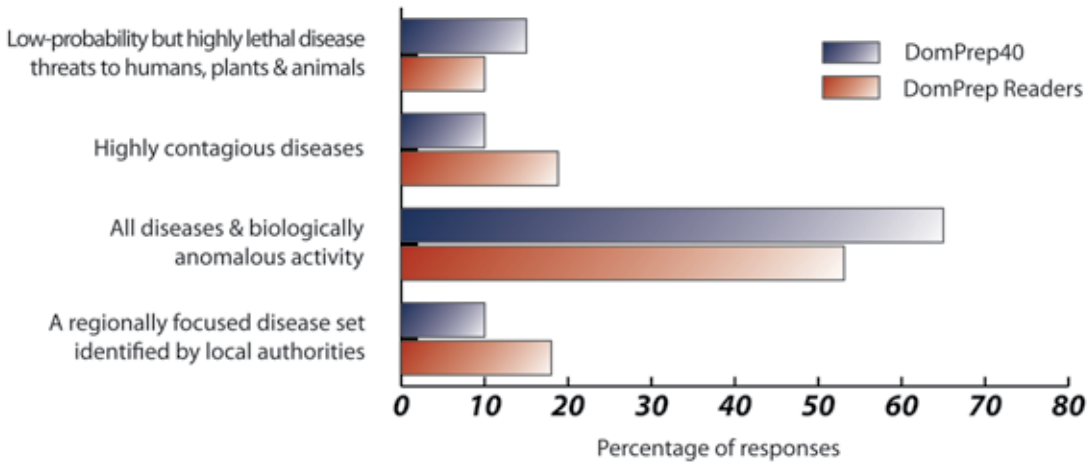
QUESTION THREE

What constitutes an "actionable" biosurveillance report?



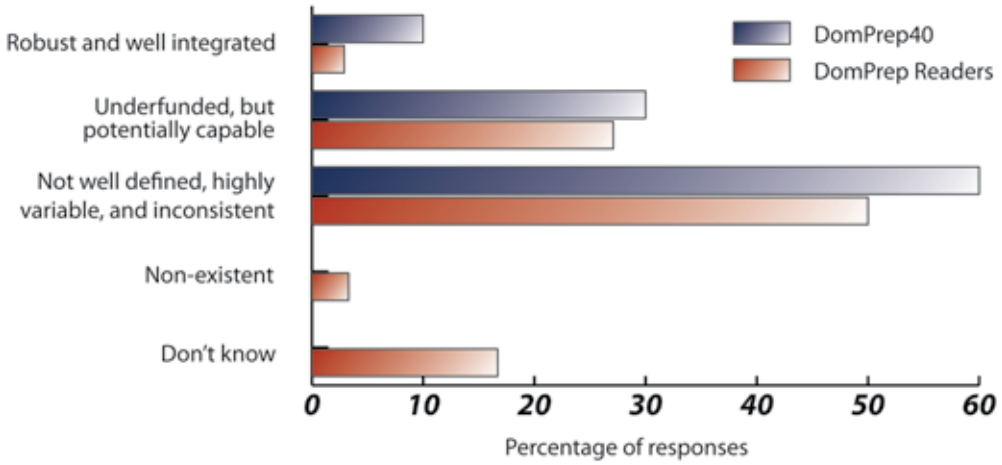
QUESTION FOUR

To ensure the earliest possible warning, biosurveillance should focus on:



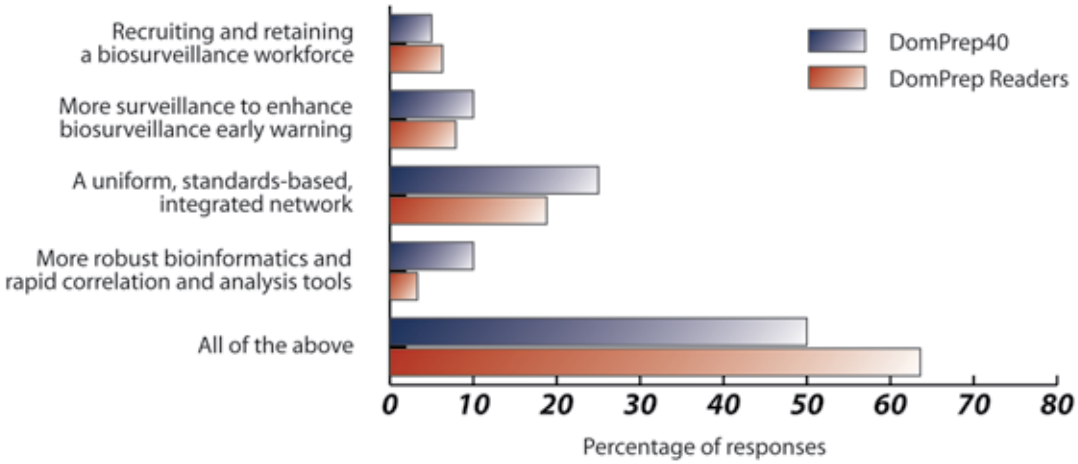
QUESTION FIVE

State and local surveillance programs serve as the foundation for an integrated national biosurveillance system. The current state and local biosurveillance reporting is:



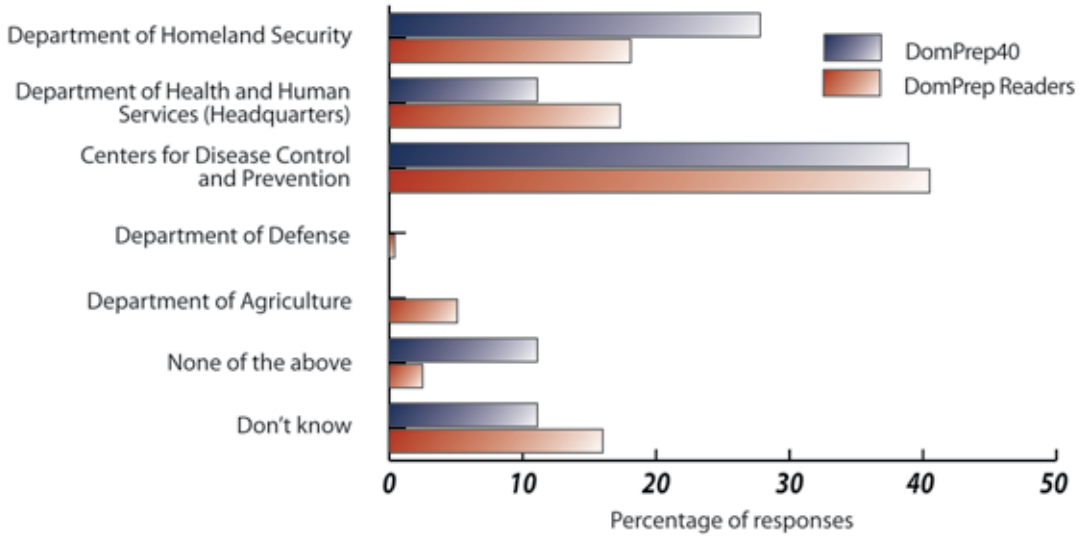
QUESTION SIX

The federal government should focus its biosurveillance investment strategy on:



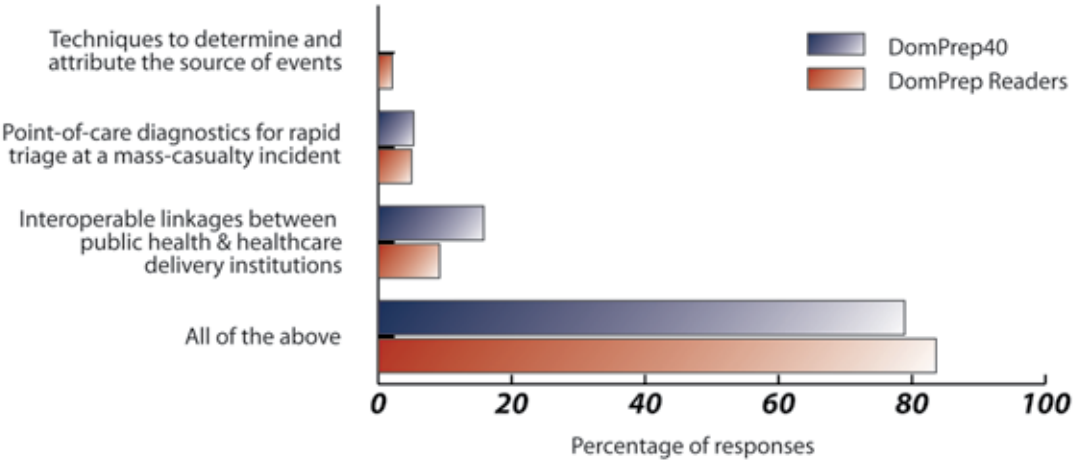
QUESTION SEVEN

The federal focal point with responsibility and authority for ensuring the development of a robust, integrated, national biosurveillance capability (human, animal, plant, food, and environmental surveillance) is:



QUESTION EIGHT

Biosurveillance also provides situational awareness after a biological event. Therefore, additional investments are required in:



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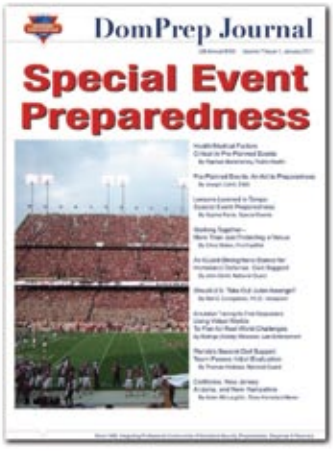
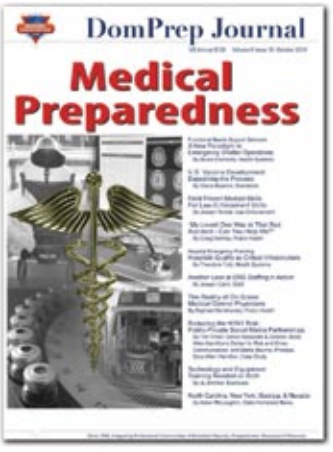
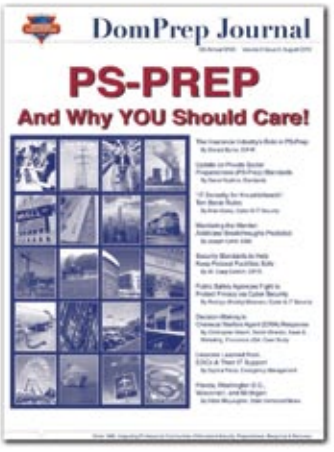
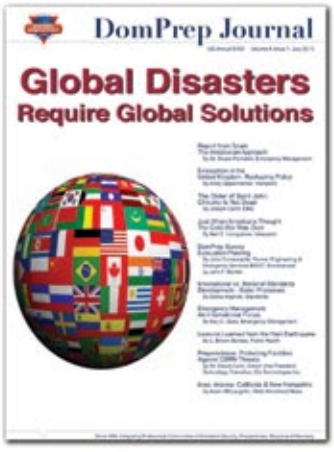
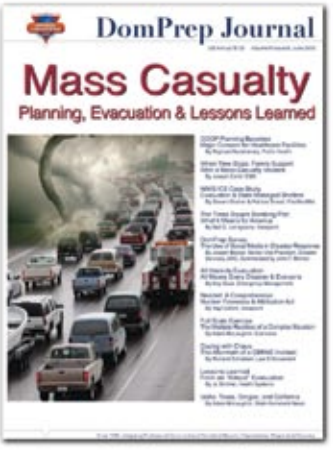
Critical Information for the Preparedness, Response & Recovery Communities

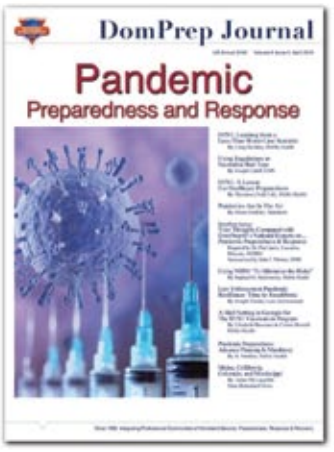












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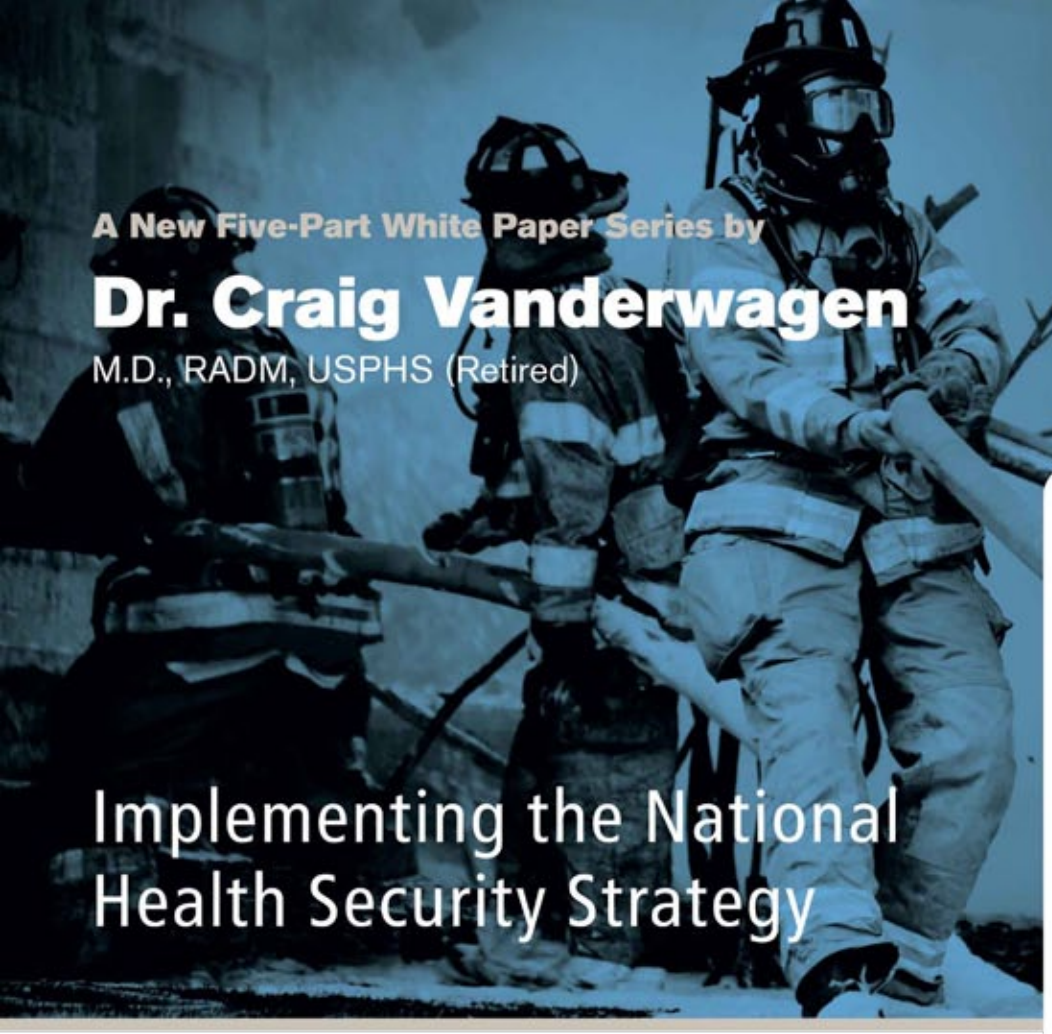

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