Special Report

Advancing Technology in Biological Surveillance and Detection

27 September 2012
The Harvard Faculty Club
Cambridge, MA
(Date and Location of the Briefing)

Publisher's Message

By Martin (Marty) Masiuk, Publisher

Dear DomPrep Readers,

On 27 September 2012, DomPrep hosted an Executive Briefing on biological detection, specifically *Advancing Technology in Biological Surveillance and Detection,* at Harvard University's Faculty Club in Cambridge Massachusetts.

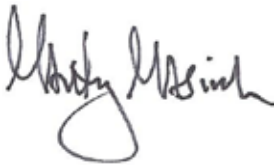
The briefing was lead by DomPrep40 Advisor Jeffrey W. Runge, MD, Principal of The Chertoff Group, and former Assistant Secretary for Health Affairs and the first Chief Medical Officer at the U.S. Department of Homeland Security (a position he held from 2005 to 2008).

Dr. Runge lead a panel of subject matter experts as they discussed gaps and synergies evident from a recent DomPrep audience survey. Key points addressed include:

- The requirement for biodetection in the face of terrorism risk;
- Strengths and limitations of the current systems and the operational impact on state and local officials;
- A process for further development of biodetection methods using an operational requirement construct and advances in decision science; and
- Building unity of effort among officials and leaders at all levels of government to achieve a better preparedness posture.

Your feedback and input on this report is welcome as DomPrep strives to take preparedness to the next level. Thank you for your participation.

Sincerely yours,



Martin D. (Marty) Masiuk, Publisher
publisher@domprep.com

27 September 2012
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 (DomPrep40 Advisors) as well as the readers of the *DomPrep Journal*, the preliminary results of which were compared to uncover gaps that need to be addressed.

8:00-8:20	Registration & Continental Breakfast
8:20-8:30	Welcome and Industry Sponsors Introductions Martin Masiuk, Publisher, DomesticPreparedness.com

8:30-9:15	**Session 1 - The Mandate for Biodetection**
	Discussion of the case for biodetection under the threat of bioterrorism, the 2003 response which was the genesis of the BioWatch program, and the local operation and its effects on state and local emergency management.
	• *The threat of intentional release of a biological agent: The case for environmental detection*
	  • Jeffrey W. Runge, MD, Principal at The Chertoff Group LLC, and DomPrep40 Advisor
	• *The origin of the BioWatch program in response to a presidential mandate*
	  • Major General Stephen Reeves, USA (Ret.), and DomPrep40 Advisor
	• *The conundrum for state and local emergency managers: Response to the biological signal and the interface with the federal government*
	  • David Ladd, Director, Hazardous Materials Emergency Response at Massachusetts Department of Fire Services

9:15-9:30	Questions & Answers, Discussion

9:30-10:30	**Session 2 - Achieving Advances in Bio-Detection Through Technology Requirements and Decision Science**
	Experts will discuss different approaches to develop and meet requirements for early warning through biodetection and advances in the science of decision making.
	• *A requirements-based approach to technological problem solving and system design*
	  • Vayl Oxford, Pacific Northwest National Laboratory and DomPrep40 Advisor
	• *A model for decision making following bio-detection warnings*
	  • Christopher Glazner, Ph.D., Mitre Corporation

10:30-10:45	Questions & Answers, Discussion
10:45-11:00	Break & Networking
11:00-11:45	**Session 3 - Assisting Policymakers to Forge Unity of Effort Across Agencies and Departments in the Homeland Security Enterprise** A discussion with the founder and co-director of the National Preparedness Leadership Institute – a joint program of the Harvard School of Public Health and the Harvard Kennedy School of Government – on development and uses of meta-leadership to build unity of effort in preparedness policies and response execution through collaboration at the local, state, and federal levels. • Leonard Marcus, Ph.D., Harvard University with Jeff Runge, MD
11:45-12:00	Questions & Answers

Speaker Biographies

Jeffrey W. Runge, MD

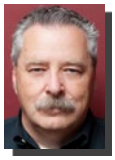
Principal, The Chertoff Group LLC, and DomPrep40 Advisor

Jeff W. Runge, MD, is a Principal with the The Chertoff Group and a consultant in biodefense, medical preparedness, and emergency medical care. In 2005, he became the Department of Homeland Security's (DHS) first Chief Medical Officer and founded the Office of Health Affairs at DHS, where he was Assistant Secretary for Health Affairs until 2008. As such, he was responsible for DHS' biodefense and medical readiness programs as well as providing support to the Secretary and the DHS components on all medical and public health issues. From 2001 to 2005, he served as head of the National Highway Safety Administration where he drove changes in vehicle design and equipment and safety belt programs that contributed to a 30% reduction in fatalities over the decade. He is board certified in emergency medicine, having practiced and taught in a high-volume emergency and trauma center for 20 years. He is now an Adjunct Professor in the University of North Carolina School of Medicine in Chapel Hill, NC.

Major General Stephen Reeves USA (Ret.)

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

MG Stephen Reeves, USA (Ret.), 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.



David Ladd

Director, Hazardous Materials Emergency Response, Massachusetts Department of Fire Services

David Ladd has served as the Director of Hazardous Materials Emergency Response for the Massachusetts Department of Fire Services since June 1999. His 37 years of emergency services experience include 19 years as a Paramedic and 5 five years as Chief of Emergency Medical Services Operations for the City of Boston, Massachusetts. He serves as a subject matter expert on various national homeland security activities including the Inter-Agency Board, the Stakeholders Panel on Agent Detection Assays, and Chair of the responder working group on development of the Association for Testing of Materials' Recommended Practices for Response to Suspected Bio-Terrorism Substances (ASTM-WK26640) and revision of the Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents from Nonporous Surfaces (ASTM-E-2458-06).

Speaker Biographies

Vayl Oxford

National Security Executive Policy Advisor, Pacific Northwest National Laboratory, and DomPrep40 Advisor

Vayl Oxford assumed the position of National Security Executive Policy Advisor at the Pacific Northwest National Laboratory (PNNL) as of 1 May 2012. He is the former Director of the Department of Homeland Security's (DHS) Domestic Nuclear Detection Office (DNDO). Prior to DHS, he served as Special Assistant for Policy Planning in the DHS Science and Technology Directorate, Acting Director of the Homeland Security Advance Research Projects Agency, and Director for Counterproliferation at the National Security Council. At the Department of Defense, he was the Deputy Director of technology development at the Defense Threat Reduction Agency (DTRA) and Chief of counterproliferation programs at the Defense Special Weapons Agency/ Defense Nuclear Agency.

Christopher Glazner, Ph.D.

Research Engineer, The Mitre Corporation

Christopher Glazner, Ph.D., is a research engineer at the MITRE Corporation, where he leads development of decision-oriented models of socio-technical systems for various federal agencies, including the Department of Homeland Security, the Department of Energy, Department of Veterans Affairs, Census Bureau, and the U.S. Courts. His research focuses on rapid development of models that improve learning and understanding at the intersection of technology and organizations. He is co-author of the forthcoming book, "The Enterprise Dynamics Sourcebook." He holds a Ph.D. in Engineering Systems and an M.S. in Technology Policy from Massachusetts Institute of Technology, and bachelor degrees in Electrical Engineering and Plan II from the University of Texas at Austin.

Leonard Marcus, Ph.D.

Founder & Co-Director, National Preparedness Leadership Initiative, Harvard University

Leonard Marcus, Ph.D., is founding Co-Director of the National Preparedness Leadership Initiative, a joint program of Harvard School of Public Health and Harvard's Kennedy School of Government. With his colleagues, he pioneered development of the conceptual and pragmatic basis for "Meta-Leadership" – overarching leadership that strategically links the work of different agencies and levels of government in order to forge cross-sector unity of effort. Recent research activities have taken him to the center of emergency preparedness and response through direct observation and immediate interviews with leadership during the early H1N1 response, the 2009 and 2006 wars in Israel, the 2010 BP oil spill, and the 2005 hurricanes Katrina and Rita on the Gulf Coast.

DomPrep40 Advisors

Elizabeth Armstrong
Chief Executive Officer, International Association of Emergency Managers

Ross Ashley
Executive Director, National Fusion Center Association (NFCA)

James Augustine
Chair, EMS/Emergency Department Physician

William Austin
Former Chief, West Hartford (CT) Fire Department

Ann Beauchesne
Vice President, National Security & Emergency Preparedness, U.S. Chamber of Commerce

H. Steven Blum
Lieutenant General USA (Ret.), Former Deputy Commander, U.S. Northern Command

Marko Bourne
Principal, Booz Allen Hamilton (BAH)

Joseph Cahill
Medicolegal Investigator, Massachusetts Office of the Chief Medical Examiner

John Contestabile
Former Director, Engineering & Emergency Services, MDOT

Craig DeAtley
Director, Institute for Public Health Emergency Readiness

Nancy Dragani
Former President, NEMA, Executive Director, Ohio EMA

Ellen Embrey
President & Chief Executive Officer, Stratitia Inc

Ellen Gordon
Member, Homeland Security Advisory Council & Naval Postgraduate School Center for Defense

Kay Goss
Former Associate Director, National Preparedness Training & Exercises, FEMA

Stephen Grainer
Chief, IMS Programs, Virginia Department of Fire Programs

Jack Herrmann
Senior Advisor, Public Health Preparedness, NACCHO

Cathlene Hockert
Continuity of Government Planning Director, State of Minnesota

Dennis Jones
Director of Public Health Solutions, Intermedix EMSystems

Robert Kadlec
Former Special Assistant to President for Homeland Security & Senior Director, Biological Defense Policy

Douglas Kinney
Crisis Planning & Management Consultant, Diplomatic Security for U.S. Department of State

Dean Larson
Commissioner on the Indiana Emergency Response Commission

Anthony Mangeri, Sr.
Manager, Strategic Relations, Fire Services & Emergency Management, American Public University

Vayl Oxford
Former Director, Department of Homeland Security DNDO

Joseph Picciano
Deputy Director, New Jersey Office of Homeland Security & Preparedness

Chad Priest
Chief Executive Officer, MESH Inc.

Stephen Reeves
Major General USA (Ret.), Former Joint Program Executive Officer Chem/ Bio Defense, DoD

Albert Romano
Senior Vice President of Homeland Security, Michael Baker Jr. Inc.

Glen Rudner
Former Northern Virginia Regional Hazardous Materials Officer

Jeff Runge
Former Chief Medical Officer, Department of Homeland Security

Paula Scalingi
Executive Director, Bay Area Center for Regional Disaster Resilience

Richard Schoeberl
Former FBI Executive & National Counterterrorism Center Official

Dennis Schrader
Former Deputy Administrator, National Preparedness Directorate, FEMA

Robert Stephan
Former Assistant Secretary of Homeland Security for Infrastructure Protection

Joseph Trindal
Former Director, National Capital Region, Federal Protective Service, ICE

Theodore Tully
Director, Trauma & Emergency Services, Westchester (NY) Medical Center

Craig Vanderwagen
Former Assistant Secretary for Preparedness & Response, HHS

DomPrep Survey

Advancing Technology in Biological Surveillance and Detection

Prepared by Jeffrey W. Runge, MD, Principal of The Chertoff Group LLC

In September 2001, following the sophisticated terrorist attacks on U.S. soil and the anthrax letters soon after, the reality of the nation's vulnerability to biological attack was acute and in need of rapid and sure response. Even as a national strategy was being developed, the nation's leadership was taking certain actions based on the nature of biological attacks. It had to deal with a potential attack with no "boom" until hundreds of thousands of people were ill and in need of critical medical care, reverberating to the point of threatening confidence in the U.S. government.

In his State of the Union speech in 2003, President George W. Bush addressed this threat and the nation's vulnerability by announcing the deployment of biological detectors in major urban areas of the country. This feat of acquisition and logistics, known as BioWatch, was completed in just over one month. The BioWatch program incorporated off-the-shelf environmental sample collectors deployed in urban areas and standard polymerase chain reaction (PCR) tests performed in local public health laboratories to detect the presence of a small number of unaltered biologic agents believed to be of interest to terrorists. Within a year or two, the BioWatch program was fully institutionalized in a federated network, planned and funded centrally and implemented locally. Upon the formation of the U.S. Department of Homeland Security (DHS), its Science and Technology Directorate assumed the federal funding and coordinating role.

A year later, a national strategy was issued by the President, Biodefense for the 21st Century, Homeland Security Presidential Directive 10 (HSPD-10), based on four pillars of activity: (a) threat awareness; (b) protection and prevention; (c) surveillance and detection; and (d) response and recovery. The BioWatch system thus fulfills a central requirement of this strategy.

Following the deployment of the early BioWatch system, its limitations were well known to DHS, including limitations of off-the-shelf environmental sample collectors, infrequency of sample collection and processing, slowness of reporting, and tortuous decision making following the detection of the presence of pathogens in the environment. DHS issued a request for proposals for fully autonomous detectors operating in continuous mode to cut down the response time, which is critical to enable the distribution of post-exposure countermeasures. Responding to the request were a few small technology companies as well as large defense and aerospace corporations; the broader biomedical industry was not well represented. Nine years after introducing the BioWatch program, DHS has still not been able to deploy a system that meets all of the requirements, including and especially the cost requirements set by the department. As the nation faces the need for extreme budgetary discipline, cost estimates to deploy a system of autonomous biodetectors are greater than $3 billion, in addition to a hefty operations and maintenance bill every year.

The question of whether there are new technologies that can leapfrog PCR at a lower cost has been raised. Biomedical companies that compete in the space of rapid pathogen identification are in abundance, but their innovation has not been applied to this national defense purpose. Biomedical pathogen detection and identification does not require the same degree of sensitivity coupled with 100-percent specificity as BioWatch, and does not need to operate outdoors in hostile environments. Yet, the question remains whether biomedical innovation can step up to help solve this national security conundrum.

Key Findings and Survey Result Summary

The survey, "Advancing Technology in Biological Surveillance and Detection," provides interesting insights into the preferences and beliefs of the key constituency of the U.S. Department of Homeland Security (DHS) – i.e., those who will plan, equip, train for, and execute a response to an intentional release of a biological agent. The results reflect where the nation is in the evolution of its biodefense readiness posture.

A healthy consensus among the respondents reinforces the underlying requirement for a robust environmental detection system for biological agents:

1. The risk of a bioterrorist attack is the same or higher;

2. Detection in the environment is necessary before sick people present to emergency departments; and

3. In the absence of a robust system, the first warning likely will appear when people start getting sick.

There is also broad consensus on the importance of shortening detection times to a cycle occurring several times a day, although nearly half of the respondents are concerned with the expense of doing so, probably given the cost estimates of the current system. The truncation of the response time is needed to allow for the distribution of countermeasures in the window of effectiveness and the need for rapid attribution to identify the enemy and prevent subsequent attacks.

What may seem surprising is the response to questions aimed at optimizing specificity and sensitivity of the instruments. An overwhelming majority of respondents were willing to live with some false positives from the instruments, indicating a willingness to contextualize and further adjudicate the signal before launching a countermeasure response. This is surprising because the BioWatch Generation 3 system is predicated on 100% specificity – i.e., no false positive signals. With any high-performance instrument, the bulk of research and development costs are spent on the "last nines" of reliability, as 99.9999% is effectively the target. The respondents seem to be saying, "Save the money, and we will interpret the signals." This is an important finding that should be further examined.

Likewise, the respondents seem to be saying responses imply, "Deploy the detectors, even if they can't pick up every intentional pathogen or genetic variation, and deal with the problems later". A related issue is the consensus opinion that the biomedical industry, if properly engaged, could contribute solutions to the problems of the current systems in later

generations, even though most respondents are unaware of better technology than the current instruments based on polymerase chain reaction (PCR).

What is not surprising is the lack of consensus around decision making. There is nearly an even split among the respondents as to who is in the best position to interpret the signal and activate a response. This has been a central theme since the advent of the issue. There has been agreement that federal officials are responsible for supplying the technology, and local officials are tasked with the immediate response. Few at the local level, however, have faith in the decision-making capability at the federal level and thus far have not seen any integrated plan or planning guidance come from the federal government for any of the five biological national planning scenarios. Lacking a plan usually leads to some form of chaos, and disagreement about command, control, and coordination is expected. By addressing the need for better decision science, hopefully action can be inspired at all levels of government.

Conclusion

- Respondents agree on the mandate for timely environmental detection of intentionally released pathogens.

- Respondents agree that lacking a system will lead to a no-notice presentation of sick people to healthcare providers, which could have severe consequences in light of limited health resources.

- Respondents are willing to live with the limitations of the sensitivity of current systems and would tolerate less specificity, presuming that the signal would require further context and adjudication.

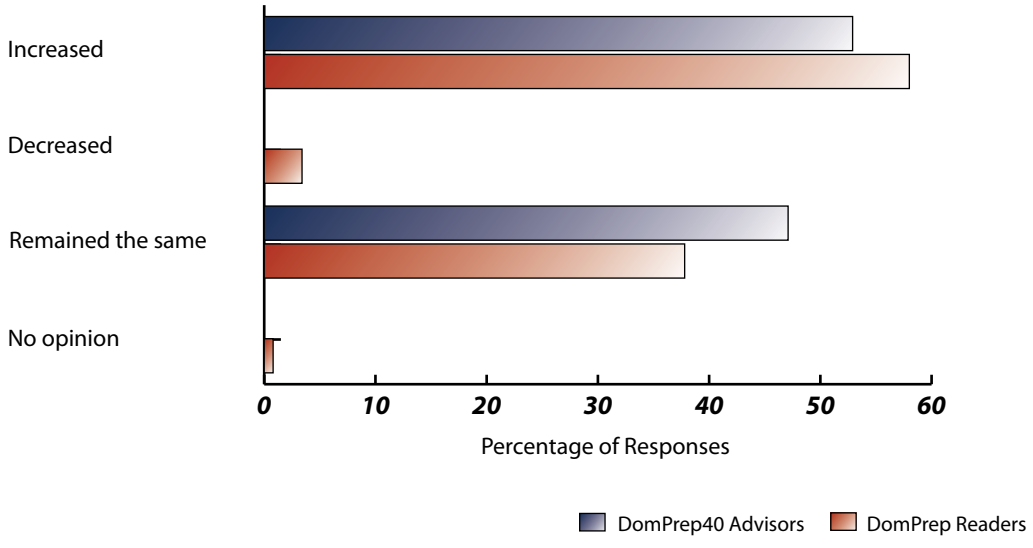
- Although few are aware of better technologies than the current "Gen 3," respondents believe that the biomedical industry could address the limitations of current instruments.

- There is broad disagreement on command, control, and coordination of detection and response, as is expected with the lack of an integrated strategic plan and subsequent operational plans.

Survey Results

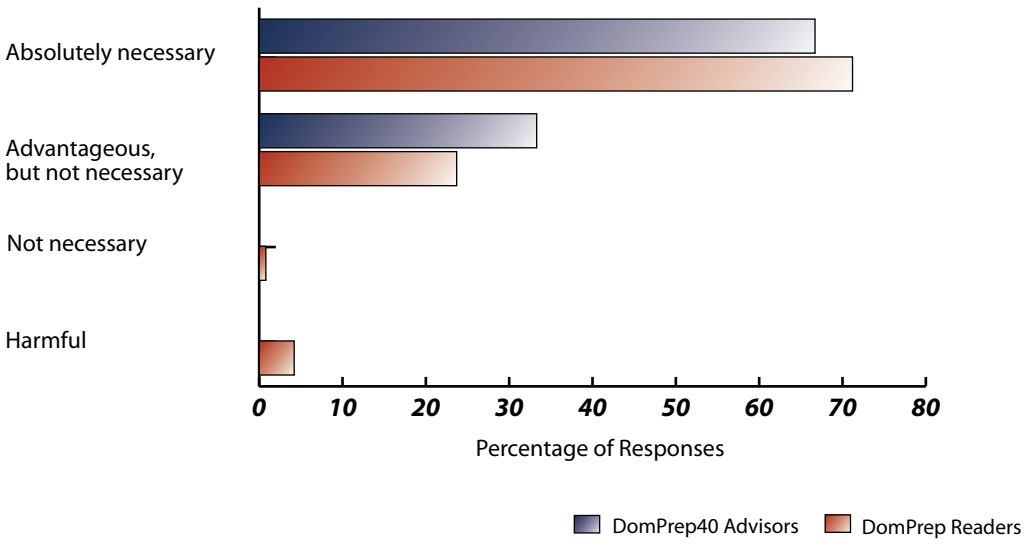
QUESTION ONE

In your opinion, over the past decade the risk of bioterrorism has:



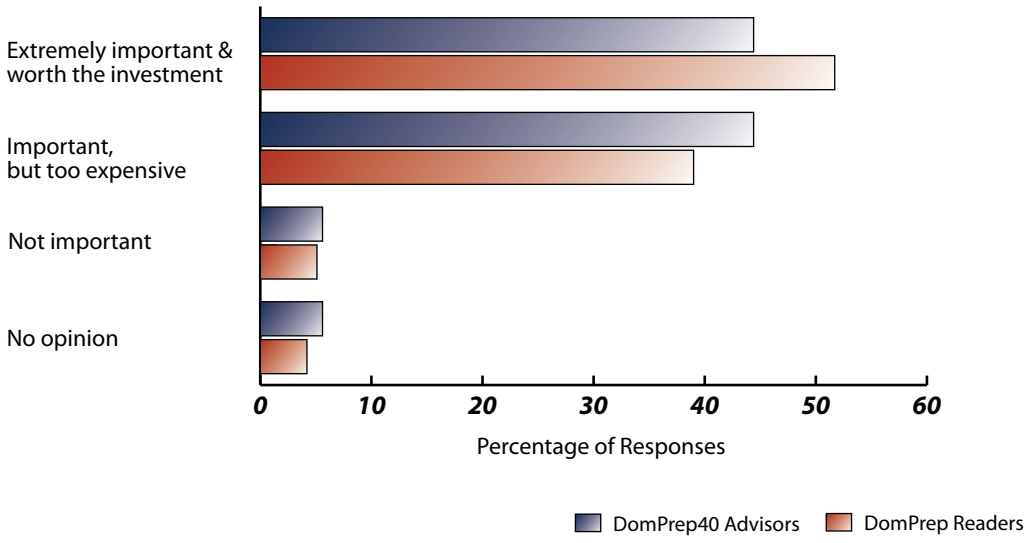
QUESTION TWO

Detection of biological agents in the environment prior to clinical symptoms appearing in the population is:



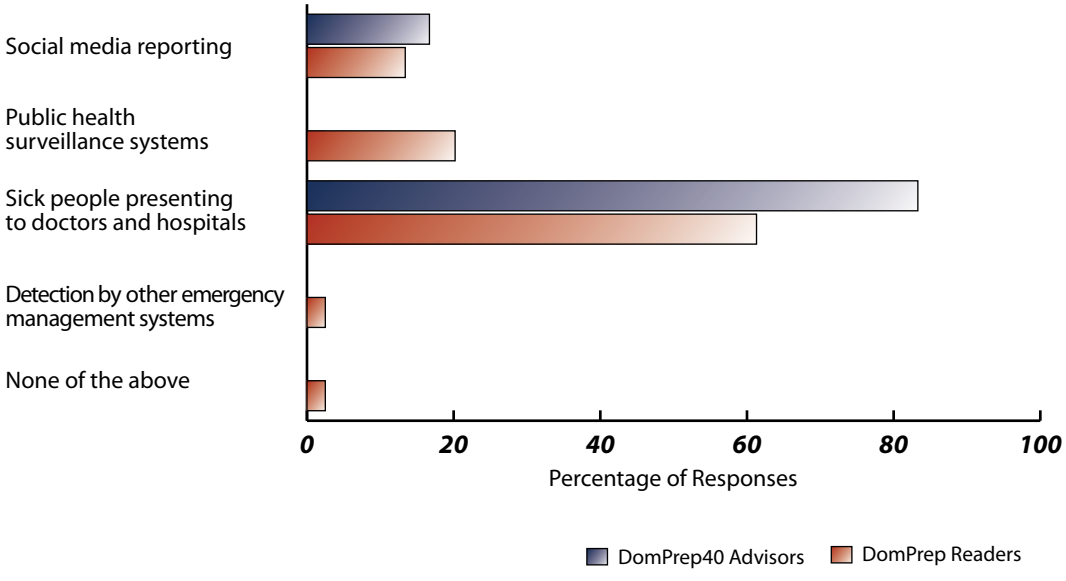
QUESTION THREE

Decreasing the warning time from its current 12-36 hours to a constant cycle of warning every 4-6 hours is:



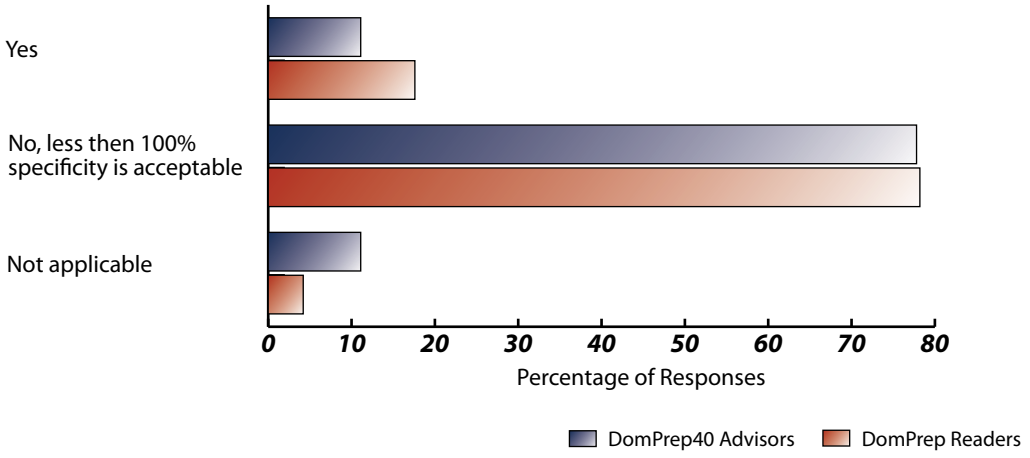
QUESTION FOUR

In the absence of a functional environmental detection system, of these warnings the first indication of an attack will MOST likely appear via:



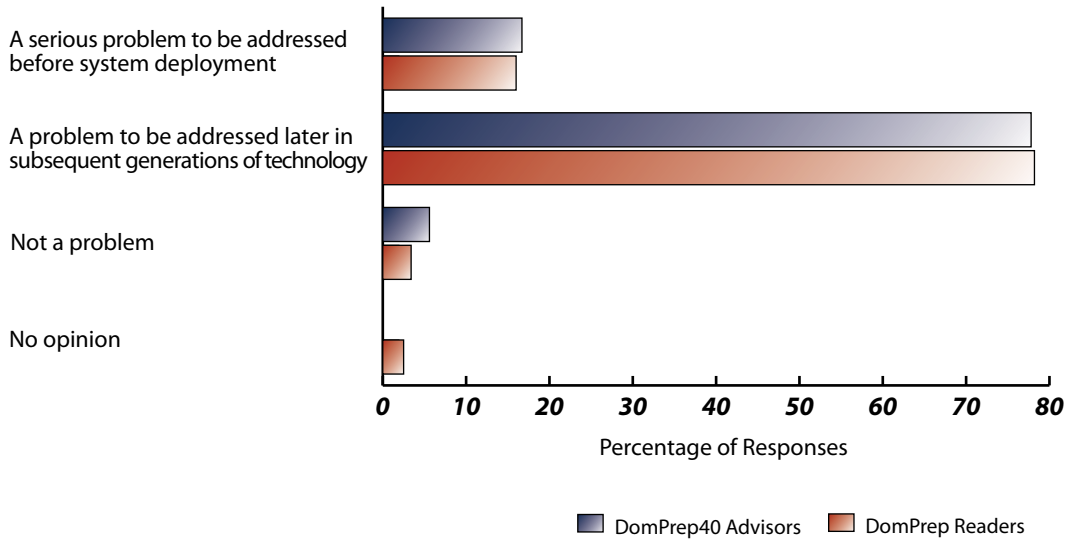
QUESTION FIVE

If you believe that environmental detection is necessary and valuable, must the technology be 100-percent specific (i.e., no false positives - it will never alert if a dangerous pathogen is not present)?



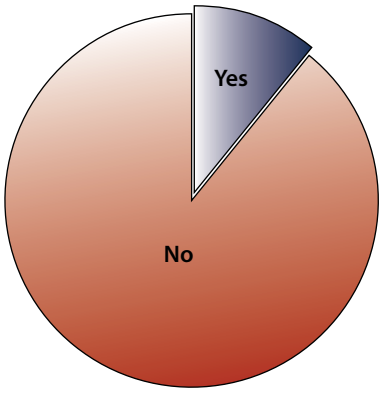
QUESTION SIX

Because PCR testing looks for certain nucleic acid sequences or "signatures" on specific pathogens, there is a possibility that BioWatch detectors would not detect a pathogen not on its "list." This possibility is:



QUESTION SEVEN

Are you aware of any technologies that could address the limitations of the current generation of autonomous detectors (e.g., limited number of pathogens targeted; dependence on nucleic acid, cost of procurement, operations, and maintenance)?



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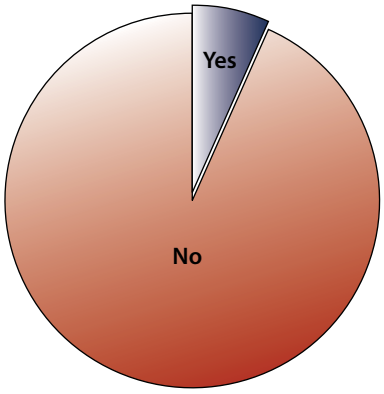
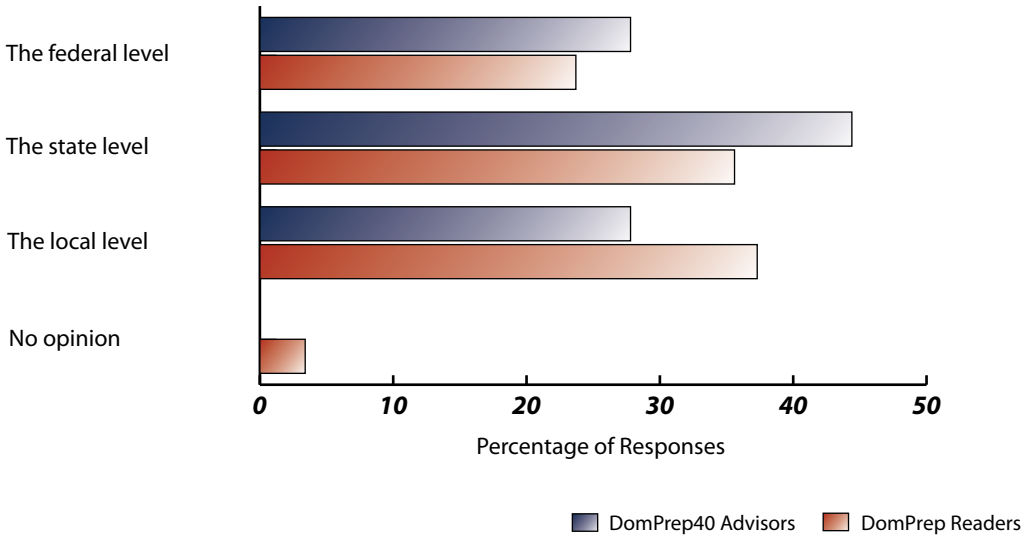


DomPrep Readers

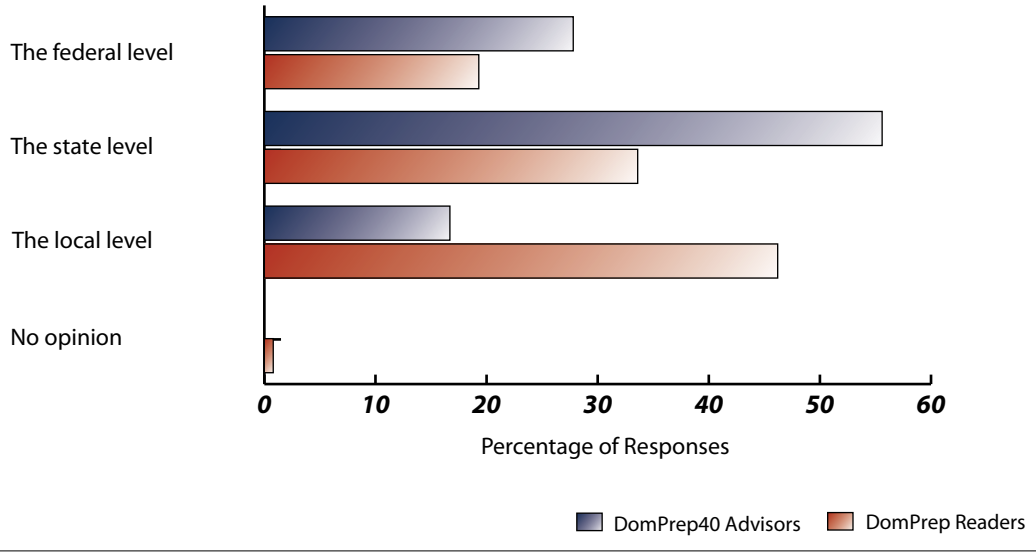
QUESTION EIGHT

With response to post-alert decision making, the veracity of the signal and its consequences are best interpreted at:



QUESTION NINE

With respect to post-alert decision making, the decision to activate a full-scale response (e.g., sheltering in place or evacuation; distribution of post-exposure prophylaxis and vaccine; medical surge response) are best described at:



QUESTION TEN

Given adequate market potential or incentives, do you believe that greater engagement by the biomedical industry can address the technical and operational limitations of the current generation of environmental biodetection?