INSTITUTE FOR DEFENSE ANALYSES

Written Testimony of Dr. Deena Disraelly, Project Lead and Institute for Defense Analyses Research Staff Member, before the House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications titled "BioWatch Analysis of Alternatives"

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June 2014
IDA Paper NSD-5145
File name: E3 0604 NSP-5145 AoAWrittenTestimony_rev7 0614 Final

A. Introduction

Good morning Chairman Brooks, Ranking Member Payne, and distinguished members of the House Subcommittee on Emergency Preparedness, Response, and Communication. My name is Dr. Deena Disraelly. I am a Research Staff Member at the Institute for Defense Analyses (IDA) and the Project Lead for the BioWatch Analysis of Alternatives (AoA). I am honored to appear before you today to discuss this study and its results.

In October 2012, the BioWatch Program Office asked IDA, a Federally Funded Research and Development Center (FFRDC) assisting the Department of Defense and other Federal agencies in addressing issues of national security, to conduct an AoA of capabilities to meet the biosurveillance mission. According to U.S. Department of Homeland Security (DHS) guidance, an AoA provides "a systematic analytic and decision-making process to identify and document an optimal solution for an identified mission capability gap."[1] The BioWatch AoA addresses a capability gap identified in Homeland Security Presidential Directive (HSPD)-10 *Biodefense for the 21st Century*, namely the requirement for an "early warning, detection, or recognition of biological weapons attacks to permit a timely response to mitigate their consequences."[2] This AoA identified material (technology) and non-material (activity) biological surveillance capabilities—comprised of one or more technologies or related activities—with the potential to reduce mortality and morbidity from an aerosolized release of a pathogen. Specifically, the AoA focused on four candidate alternatives that will be defined later in this presentation.

While the objective of this study was to identify and compare capabilities, IDA was not asked to provide DHS with any recommendations about the disposition of the BioWatch Generation-3 (Gen-3) system.

The IDA team's *BioWatch Analysis of Alternatives*[3] was delivered to the BioWatch Program Office in December 2013. What follows is a brief discussion of the AoA objectives, methodology, and findings extracted from the more detailed discussion in that paper.

B. Analysis of Alternatives (AoA) Background and Objectives

In accordance with *HSPD-10*, the DHS BioWatch Program is intended to provide "a nationwide biosurveillance capability to monitor for select aerosolized biothreat agents in highly populated areas…and is a partnership between federal, state, and local governments for the purpose of ensuring the protection of the nation's population against

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1 U.S. Department of Homeland Security (DHS), *Acquisition Management Instruction/Guidebook*, DHS Instruction Manual 102-01-001, Appendix G (Washington, DC: DHS, 2011), G-3.

2 President George W. Bush, *Biodefense for the 21st Century* (hereafter: *HSPD-10*), Homeland Security Presidential Directive HSPD-10 (Washington, DC: The White House, 2004).

3 Deena Disraelly et al., *BioWatch Analysis of Alternatives*, Institute for Defense Analyses (IDA), Paper P-5083 (Alexandria, VA: IDA, 2013).

biological threats."[4] The objective of the BioWatch collectors is to monitor the air continuously for agents of concern and provide regular analyses of the results. The goal is to field a system that is operational 24 hours per day, 365 days per year and able to signal an attack early enough to promote quick response.[5]

The BioWatch Program was created in 2003 "to provide early warning, detection, or recognition of biological attack."[6] The first environmental collectors (Generation-1) were deployed in March of 2003, with deployment eventually reaching twenty major metropolitan areas. The program began a second deployment (Generation-2) immediately in the wake of the previous deployment, adding ten jurisdictions and "indoor monitoring capabilities in three high-threat jurisdictions and provided additional capacity for events of national significance, such as major sporting events and political conventions."[7] Generation-1 and Generation-2 collectors are predominantly located in outdoor environments and the overall system, as currently implemented, relies on both the collectors and teams of field and laboratory personnel. The 2009 DHS Appropriations Act established the appropriations for an improved biodetection capability.

In 2010, DHS published its first *Acquisition Directive* (DHS Directive 102-01),[8] which requires DHS Components pursuing acquisition programs to perform an AoA or Alternatives Analysis[9] during procurement. Two years later, the Homeland Security Studies and Analysis Institute published the *BioWatch Gen-3 Program Acquisition Assessment*. Soon after, the U.S. Government Accountability Office (GAO) published GAO-12-810, *BioSurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Gen-3 Acquisition*. Both reports recommended that the BioWatch Program Office perform an AoA for the BioWatch Program. Subsequently, the BioWatch Program Office asked IDA to conduct an AoA of biosurveillance capabilities in accordance with applicable DHS guidance.

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4 DHS, Office of Health Affairs (DHS/OHA), *Gen-3 [Generation-3] Autonomous Detection System, Operational Requirements Document (ORD) v 2.2* (hereafter: *Gen-3 ORD*) (Washington, DC: DHS, 2012), ES-1, For Official Use Only (FOUO).

5 DHS/OHA, *Gen-3 ORD,* FOUO; Bush, *HSPD-10*.

6 U.S. Government Accountability Office (GAO), *BioSurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition* (hereafter: *BioSurveillance – Reevaluate Mission Need*), GAO-12-810 (Washington, DC: GAO, 2012), 9.

7 Ibid.

8 DHS published an interim *Acquisition Directive 102-01* in November 2008; this document includes the requirement for a capability development plan "including the initial ground rules for the Analysis of Alternatives (AoA) or Alternatives Analysis (AA)…to begin the Analyze/Select phase" once the Mission Needs Statement (MNS) is approved. DHS, *Acquisition Directive 102-01*, version 1.9, Interim (Washington, DC: DHS, 2008), 14.

9 DHS, *Acquisition Management Directive 102-01* (hereafter: *AMD 102-01*) (Washington, DC: DHS, 2010), 6; this document has since been supplemented and collated into DHS, *Acquisition Management Directive 102-01*, Revision 2 (hereafter: *AMD 102-01 Rev. 2*) (Washington, DC: DHS, 2013).

C. AoA Project Methodology

1. Methodology Overview

The first step in the AoA process was to consult relevant studies and literature on biosurveillance and conduct a market survey of all biosurveillance capabilities and their component technologies/activities (hereafter referred to simply as capabilities). During the course of the market survey, the IDA team identified approximately 500 biosurveillance capabilities that are either readily deployable or in development. Constraints were defined then used to identify selected candidate alternatives that could fulfill the BioWatch mission need and requirements.[10] Specifically, the selected candidate alternatives met the following constraints:

1. Include technologies and activities at, or equivalent to, technology readiness level (TRL) 6.[11]
2. Be available to deploy within two to three years and be fully fieldable within two to five years of the completion of the AoA.[12]
3. Be able to detect an aerosolized biological attack for, at least, the same five threshold biological agents as required for Gen-3.[13]
4. Are anticipated to be fully fieldable and sustainable within the budget already allocated for BioWatch over the next five years (the budget figure is in fiscal year 2013 (FY2013) dollars and is not adjusted for inflation or other time-dependent increases).[14]
5. Fill a capability gap as defined in the *BioWatch Gen-3 Mission Needs Statement* and align with (or have) a viable concept of operations.

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[10] DHS, *Mission Needs Statement for BioWatch Gen-3 Autonomous Detection System* (hereafter: *Mission Needs Statement v.2.0*), Version 2.0, DRAFT (Washington, DC: DHS, 2012), FOUO.

[11] "Department of Homeland Security Research & Development Partnerships Group: Product Realization Guide," DHS, accessed January 7, 2013, https://www.dhs.gov/sites/default/files/publications/product-realization-guide-partnership-focus-508-1.pdf. Technology readiness level 6 indicates that the capability of a representative model or prototype system has been tested in a relevant environment, including a laboratory or simulated operational environment. Taken from: Homeland Security Institute, *Department of Homeland Security Science and Technology Readiness Level Calculator*, Version 1.1 (Washington, DC: Homeland Security Institute, 2009), B-23.

[12] This is based on the stated assumption that a BioWatch Gen-3 detector will be available and fielded within two to five years.

[13] DHS, *BioWatch Gen-3 Systems Engineering Life Cycle Tailoring (SELCT) Plan for the BioWatch Generation-3 Program, Version 1.1* (Washington, DC: DHS/OHA, 2012), A-1, FOUO; and DHS/OHA, *Gen-3 ORD*, 3-1, FOUO.

[14] In the final evaluation of alternatives, budget should be a constraint and is, therefore, listed here. Budget, however, is not used as a hard boundary in this AoA because the exact BioWatch budget is not known. GAO, *BioSurveillance–Reevaluate Mission Need*, 26, 30–31; and, DHS, "BioWatch Gen-3 Phase II Industry Day," briefing, Washington, DC, September 12, 2011.

Based on these criteria, the IDA team proposed four alternatives for additional analyses. Additional analyses included casualty modeling, life cycle cost estimates, and evaluation of the Net Present Value and Return on Investment.

2. Selected Alternative Biosurveillance Candidates

The four selected candidate alternatives identified through the AoA process and approved as reasonable capability representatives by the DHS Acting Principal Deputy Assistant Secretary of Health Affairs[15] are (in alphabetical order)

1. Autonomous Identification:[16] Autonomous and integrated multi-component systems that perform all environmental sampling and on-site testing without human intervention or control.
2. Clinical diagnosis/diagnostics with mandatory U.S. Centers for Disease Control and Prevention (CDC)/local public health disease reporting (hereafter Clinical Diagnosis/Diagnostics): Technologies and activities used in combination to evaluate and assess the disease manifesting in symptomatic individuals, combined with notification to the CDC regarding the detection of specific diseases in a timely manner.
3. Environmental collection with manual sample retrieval with analytical laboratory (hereafter Environmental Collection[17]): Technologies that collect aerosol samples that are manually retrieved and transported to an analytical laboratory for analysis.
4. Sentinel population with technological collectors with analytical laboratory (hereafter Sentinel Population): A limited portion of the population (e.g., law enforcement officers) wearing lightweight, portable, personal air samplers to collect samples for detection/identification of biological agents with subsequent laboratory analysis.

3. Metrics, Scenarios, and Assumptions

a. Mission Tasks, Measures of Effectiveness (MOE), and Measures of Performance (MOP)

Upon the selection of the four alternatives, the next step in the AoA process was to formulate a hierarchy of metrics including mission tasks, measures of effectiveness, and measures of performance.

Per *HSPD-10* and the BioWatch documentation, a BioWatch system has four specific mission tasks:[18]

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[15] Sally Phillips, "DHS Office of Health Affairs (OHA) Review of Candidates Selected for BioWatch Analysis of Alternatives (AoA)," memorandum to Deena Disraelly, May 24, 2013.

[16] Proposed as an autonomous detection platform, BioWatch Gen-3 would be an example of an autonomous identification capability.

[17] Environmental Collection simulates the current BioWatch Generation-2 system.

[18] Bush, *HSPD-10*, 6; DHS, *Mission Needs Statement v.2.0*, C-5, FOUO; and DHS/OHA, *SELCT Plan*, 3-4, FOUO.

- Early warning: Detect an aerosolized biological agent attack 24 hours per day, 365 days per year;
- Reinforce existing systems: Utilize concept of operations, processes, and other biosurveillance activities that have been accepted by Federal, state, and local authorities to evaluate a BioWatch Actionable Result (BAR);[19]
- Timely response: Identify a BioWatch actionable result and initiate an appropriate public health intervention in a timely manner; and
- Operate in Multiple Environments: Operate in outdoor, indoor, and mixed (indoor and outdoor) environments.

Based on the mission tasks, three measures of effectiveness were identified: (1) availability—degree that a system or group of systems are operationally capable of performing an assigned mission;[20] (2) casualties—number of exposed and infected individuals who eventually manifest disease symptoms following a BioWatch actionable result and a subsequent trigger of a public health intervention,[21] estimated as a function of the systems' ability to respond within an allotted time and the speed or delay between steps in a biosurveillance system;[22] and (3) probability of detection—effectiveness of the alternative at detecting aerosolized biological weapons attacks, measured using the probability of detection calculation as a proxy as described below.[23]

The IDA team then identified five measures of performance that were mapped to the measures of effectiveness (see Figure 1). These measures of performance included coverage, number of detectable and identifiable agents, operational environment, probability of detection, and time to detect/identify.

b. Operational and Modeling Scenarios

The four selected candidate alternatives were evaluated against three operational scenarios each with its own operational setting—outdoors (represented by metropolitan Chicago), indoors (represented by O'Hare International Airport, Chicago), and inside a

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[19] In this instance, the term BioWatch Actionable Result (BAR) denotes the positive presence of a biological threat agent in an environmental or clinical sample; for the purposes of this study, the BioWatch actionable result triggers a response in the form of a stakeholder meeting/teleconference to discern if a threat exists and determine what, if any, public health intervention is required.

[20] Defense Acquisition University, "Operational Availability," in *Glossary of Defense Acquisition Acronyms and Terms*, 15th ed., December 2012, accessed July 30, 2013, https://dap.dau.mil/glossary/Pages/2331.aspx.

[21] For each candidate alternative, casualties are calculated following a BioWatch actionable result, which triggers a public health intervention.

[22] Douglas N. Klaucke et al., "Guidelines for Evaluating Surveillance Systems," *Morbidity and Mortality Weekly Report (MMWR)* 37, no. S-5 (1988): 1–18; and Ruth A Jajosky and Samuel L Groseclose, "Evaluation of Reporting Timeliness of Public Health Surveillance Systems for Infectious Diseases," *BioMed Central (BMC) Public Health* 4, no. 29 (2004): 1–9.

[23] Nerayo P. Teclemariam et al., *BioWatch Technical Analysis of Biodetection Architecture Performance*, Sandia Report, SAND2012-0125 (Livermore, CA: Sandia National Laboratories, 2012), 16, FOUO.

transportation center (represented by Grand Central Terminal, New York). These scenarios were intended to replicate the scenarios outlined for BioWatch Gen-3 in its concept of operations document.[24] This evaluation used results derived from earlier modeling efforts conducted by Sandia National Laboratories (SNL) and Los Alamos National Laboratories (LANL), which represented attacks with three biothreat agents (*Bacillus anthracis*, *Yersinia pestis*, and *Francisella tularensis*)[25] and variable attack sizes, locations, and times of day.

The operational scenarios were modeled to determine the amount of time required to detect and identify an agent, the time to establish a point of distribution (POD) to begin dissemination of prophylaxis, the probability that a given alternative would detect an attack, and the number of casualties resulting from the attack. Figure 2 illustrates the modeling process used in this AoA. Life cycle cost estimates were constructed independently for the four alternatives. Next, modeling and life cycle cost estimates results were combined to evaluate Net Present Value and Return on Investment.[26]

c. Assumptions

Several assumptions were included in the modeling process. They are as follows:

1. Each biological surveillance alternative capability can be assessed independently or in combination with other capabilities.
2. Three diseases—anthrax, plague, and tularemia—are assumed to be representative of the diseases in the BioWatch Gen-3 operational requirements document (ORD).
3. Biological exposure and contagious spread (if any) are restricted and limited to specific geographical location/region where the release occurred.
4. A BioWatch Gen-3 autonomous biological agent detector would be available for deployment in two to five years.
5. One biological identification is a BioWatch actionable result.
6. Casualty estimates are given in days (rather than hours) to avoid implying a higher level of precision than is supported by the relevant literature.

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[24] DHS, *Acquisition Concept of Operations (CONOPS) for BioWatch Gen-3* (Hereafter: *Acquisition CONOPS for Gen-3*), version 0.1 (Washington, DC: DHS, 2012), FOUO.

[25] Due to the diversity of these agents with regard to contagion, lethality, and long term care requirements, these three diseases were considered representative of the diseases resulting from aerosolized exposure to the five threshold biological agents required for Gen-3.

[26] Net Present Value is the present value of calculated benefits and costs over a defined number of time periods—for the purpose of IDA's study, 20 years. Return on Investment is the net benefit expressed as a percentage of the investment amount. Net Present Value and Return on Investment may also be negative depending on perceived risk of attack and value of human life for three of the four alternatives. Clinical Diagnosis/Diagnostics always has a positive Net Present Value and Return on Investment.

7. Notional classes of capabilities are an appropriate representation of alternatives.
8. Timeliness of the response is a function of when the public health intervention occurs as defined by the antibiotic prophylaxis points of distribution being opened to the public.
9. Twenty-four hours is required from the decision to deploy the strategic national stockpile for antibiotic prophylaxis to the opening of the points of distribution with an additional 24 hours to distribute the prophylaxis[27] for all candidate alternatives and excursions.
10. The study assumes that antibiotic prophylaxis is distributed to the entire population on the day the points of distribution open; prophylaxis is effective one day later.
11. The population is assumed to be 100% compliant in taking the directed course of antibiotic prophylaxis.
12. For the outdoor release, all individuals with a given aerosolized agent concentration at a given latitude and longitude receive the same exposure.[28]
13. Detections in a scenario are independent of any other nearby alternative employments (e.g., there are no outdoor detections for an indoor scenario).[29]
14. Casualties are evaluated as a function of exposure to a biological agent and the resulting symptomatic illness; mass casualty medical interventions are not included in the modeling.
15. Life cycle cost estimate calculations are made in U.S. Government FY2013 dollars, with results presented at the 50% confidence level.[30]
16. Each year in the life cycle cost estimate is based on the FY, which runs from October 1 to September 30 and program costs are incurred beginning on October 1, 2013.
17. Estimates assume a twenty year operational lifespan beginning in FY2014 and ending in FY2033, with full implementation of material solutions by FY2018.

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[27] Mark Whitworth, *RSS Analysis Project Final Report* (Cambridge, MA: Center for Emergency Response Analytics, 2009), 7.

[28] Roebert L. Stearman, *Protection Against Chemical Attack Provided by Buildings*, Technical Report DPG-S-TA-85-05 (Dugway, UT: U.S. Army Dugway Proving Ground, 1985).

[29] The versions of the outdoor and indoor transport and dispersions models employed in this study to estimate agent concentrations were unable to exchange data between one another, making it very difficult to transfer agent concentrations from one domain to another.

[30] See footnote 1 in "Certification of Acquisition Funding" (memorandum from Peggy Sherry, Chief Financial Officer, to Component Senior Financial Officers, Department of Homeland Security, December 2, 2012).

18. Material solutions were assumed to be deployed to 50 cities per the concept of operations for BioWatch Gen-3.[31]
19. The IDA team excluded the costs of construction/base operation of certain public health infrastructure, notably hospitals and analytical or clinical laboratory facilities.
20. Estimates do not include either the cost of patient treatment once a decision has been made to establish points of distribution for prophylaxis or the cost of remediation (e.g., facility decontamination).
21. Estimates include an information management system (IMS) that was developed and costed independent of each alternative.
22. The cost of decommissioning hardware is assumed to be similar for all material systems.
23. Unless otherwise noted, life cycle cost estimates do not include the cost of equipment being further designed and developed using Government funds, assuming that solutions are fully developed and could be purchased from a vendor. Additionally, unless otherwise noted, test and evaluation costs are not included. Both these assumptions could increase life cycle cost estimates.

D. AoA Project Findings

1. Modeling Findings

The biosensor alternatives—specifically Autonomous Identification, Environmental Collection, and the Sentinel Population alternative—would benefit from improved probability of detection. Probability of detection can be improved by either increasing the number of systems deployed (for the Autonomous Identification and Environmental Collection systems) or by increasing the sensitivity[32] of these systems. Improved probability of detection, however, may also increase system costs.

For the biosensor alternatives in an outdoor attack, probability of detection is approximately 50% or less for attacks that cause 100 or more casualties and 65% or less for 10,000 casualties. Indoors, probability of detection is greater, approaching 100% in those cases in which there are upwards of 10,000 casualties, resulting in less reliance on clinical diagnostics/diagnoses to trigger the distribution of prophylaxis.

In general, for attack scenarios modeled in this AoA

- All four alternatives demonstrated approximately equivalent availability for aerosolized biological agent events: i.e., equivalent coverage of 50 (or more) cities; ability to detect the five threshold BioWatch agents or more; and capability to operate in a variety of environments.

[31] DHS, *Acquisition CONOPS for Gen-3*, 45–47, FOUO.

[32] System sensitivity is the amount of mass of agent required to be present in a sample for it to be identified by a detector or in a laboratory process.

- Autonomous Identification was consistently the quickest alternative to identify any of the three agents (at six hours), followed by the Sentinel Population alternative (generally at 18 hours), Environmental Collection (at 34 hours), and Clinical Diagnosis/Diagnostics (at 4–13 days, depending on the agent). Timeliness is illustrated in Figure 3.
- Clinical Diagnosis/Diagnostics has the highest probability of detection (i.e., all agents will ultimately be detected) for both indoor and outdoor scenarios.
    - Environmental Collection and the Sentinel Population alternative approach 99% detection indoors depending on the scenario.
    - The probability of detection for Environmental Collection and the Sentinel Population alternatives is less than 50% for the outdoor scenario; for Autonomous Identification, it is less than 25%.
    - More detail on the probability of detection results are in Figure 4.
- For detected attacks, Autonomous Identification and Sentinel Population alternatives lead to the fewest casualties, followed by Environmental Collection and Clinical Diagnosis/Diagnostics, though the magnitude of differences between alternatives tends to be agent dependent. Given the high concentrations found in the indoor scenarios, resulting in the more rapid onset of severe disease symptoms, the biosensor alternatives were less effective at reducing casualties for the indoor scenarios.
- These casualty results are illustrated for anthrax and plague in Figure 5.

Several factors have the potential to change these findings. They include sensor sensitivity, number of sensors deployed, number of detections required to initiate a public health intervention, frequency of sampling, new diagnostic protocols/tools, leadership's willingness to act, different concept of operations and employment, and human behavior. There are also several non-quantified considerations that should be kept in mind, including false positive rates, situational awareness and characterization, rapidly confirmable information, possibility of exposure limitation through facility closure (indoor scenario), and the availability of forensic samples (wet or dry).

2. Cost Findings

Life cycle cost estimates were developed based on the major cost drivers for selected candidate alternatives over the 20-year life span. The Sentinel Population alternative has the highest life cycle costs, roughly an order of magnitude higher than Autonomous Identification and Environmental Collection, which are approximately equivalent. Clinical Diagnosis/Diagnostics, which assumes a pre-existing public health infrastructure and includes only the costs of testing (not treating) a small population of patients and the deployment of an information management system, is the lowest cost alternative. The life cycle cost estimates are illustrated in Figure 6, with Clinical Diagnosis/Diagnostics as the least expensive option at approximately $43 million. Sentinel Population was the most expensive option ($16.4 billion). Environmental Collection and Autonomous Identification were estimated at $3.7 and $4.2 billion respectively.

Cost-effectiveness was evaluated by comparing cost against a variety of effectiveness measures. Life cycle cost estimates were compared to the probability of detection, the casualties for a number of representative attacks, and the detection adjusted casualties.[33] The Sentinel Population alternative often achieves the lowest detection adjusted casualties value, owing to its high probability of rapid detection and high cost due to its large number of samples. Conversely, although Clinical Diagnosis/Diagnostics has the highest probability of detection, the relatively long time before a detection can be obtained (and therefore extended time before antibiotic prophylaxis can be administered), results in the highest detection adjusted casualties value. Environmental Collection and Autonomous Identification are roughly equivalent in terms of cost and detection adjusted casualties for most scenarios.

E. Concluding Remarks

The principal BioWatch AoA findings are

- Any biosurveillance solution involves a combination of material and non-material capabilities as well as defined doctrine and procedures to facilitate decisions by local and state leadership, and public health, law enforcement, emergency management, public works, transportation, and other public and private stakeholders.
- Improved probability of detection for the biosensor alternatives options will result in earlier detection and decreased casualties and, therefore, lower detection-adjusted casualties.
- Autonomous Identification, Clinical Diagnosis/Diagnostics and Environmental Collection were all below the life cycle cost constraint of $5.8 billion (as cited by the GAO).[34] The Sentinel Population alternative exceeds the constraint due to the high number of deployed collectors and the associated laboratory and processing requirements.
- The selected candidate alternatives were evaluated against a variety of metrics. These findings, as summarized in Figure 7, present a number of criteria which could, independently or in combination, inform future BioWatch discussions.

The choice of alternative (whether Autonomous Identification, Clinical Diagnosis/Diagnostics, Environmental Collection or a combination) depends on a variety of system factors, as well as factors with the potential to assist and influence decision makers using BioWatch system information. Table 1 shows several criteria that DHS might consider, independently or in combination, when selecting a BioWatch alternative

[33] Detection adjusted casualties estimates the expected number of casualties as a function of the probability of detection. It is a weighted average of casualties that occur when there is a detection and when there is no detection.

[34] "In June 2011, DHS provided a risk-adjusted estimate at the 80 percent confidence level of $5.8 billion [2010 dollars];" GAO, *BioSurveillance – Reevaluate Mission Need*, 3.

and the corresponding system potentially best suited (given each criteria) for systems deployed outdoors, indoors, and in combined environments.

There is a positive Net Present Value and Return on Investment for each of the four alternatives, depending on the perceived risk of attack and value associated with a human life. Clinical Diagnosis/Diagnostics is the least expensive alternative with the highest probability of detection but also is likely to result in the highest number of casualties due to delays in disease detection and identification. Indoors, both Autonomous Identification and Environmental Collection have roughly equivalent detection adjusted casualties values. Autonomous Identification shows reductions in casualties as compared with Clinical Diagnosis/Diagnostics for detected attacks due to the system's timeliness of warning, while delays in warning for Environmental Collection are ameliorated by its higher probability of detection.[35] Outdoors, Environmental Collection has the lowest detection adjusted casualties due to its higher probability of detection as compared to Autonomous Identification and its timeliness as compared to Clinical Diagnosis/Diagnostics.

Insofar as there is a requirement for earlier warning and detection, employing a biosensor system according to a planned concept of operations—with appropriate response by decision-making authorities and timely engagement by public health officials—would yield fewer casualties and potentially non-quantifiable benefits, including forensic samples, rapidly confirmable information, situational awareness and characterization, and improved planning and preparedness.

Homeland Security Presidential Directive (HSPD)-10, *BioDefense for the 21st Century* states:

> Early warning, detection, or recognition of biological weapons attacks to permit a timely response to mitigate their consequences is an essential component of biodefense…creating a national bioawareness system will permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption.[36]

HSPD-10 is still in effect. This directive requires DHS to maintain a detection and early warning system. This Analysis of Alternatives provided DHS with information with which to evaluate alternate approaches to providing that capability.

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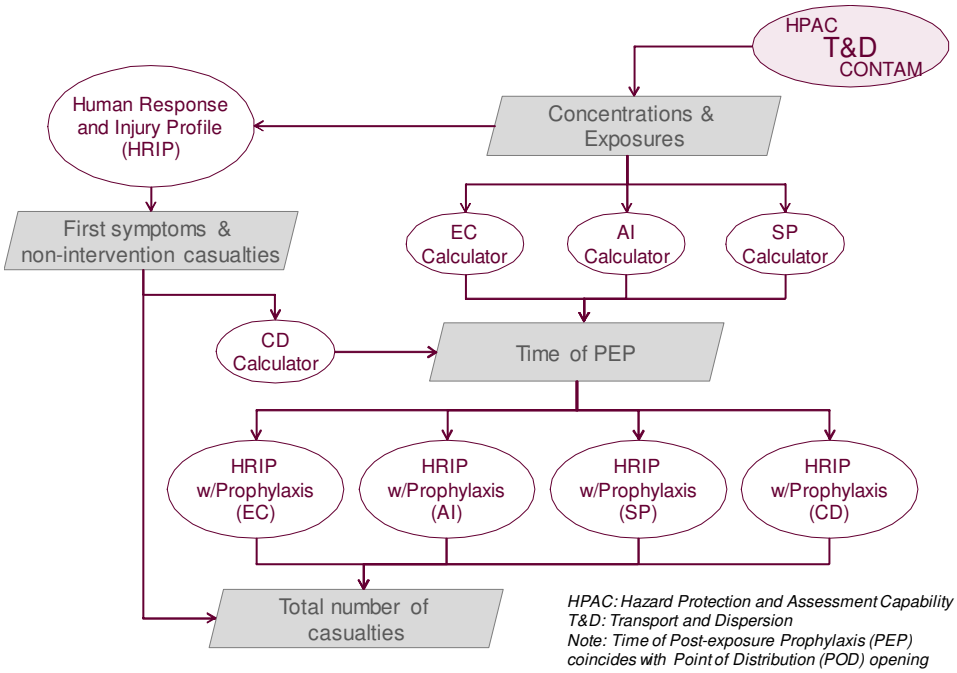
[35] It is important to remember that the AoA used *Gen-3 ORD* values for Autonomous Identification sensitivity rather than a specific system data as no representative system has yet been selected. Demonstrated improvements in system sensitivity beyond those required in the *Gen-3 ORD* improve the system probability of detection and detection adjusted casualties as discussed in Section 6.

[36] Bush, *HSPD-10*, 6.

Referenced Figures and Tables

Mission Tasks	Detect 24/7/365	X		X
	Timely response		X	
	Multiple environments			X
	CONOPS to evaluate a BAR			X
MOEs		**Probability of Detection (Pd)**	**Casualties**	**Availability**
MOPs	Coverage			X
	Number of detectable and identifiable agents			X
	Operational environment			X
	Probability of detection	X		
	Time to detect		X	
	Time to identify		X	

Figure 1. Mapping Mission Tasks, Measures of Effectiveness (MOE), and Measures of Performance (MOP)



Note: AI = Autonomous Identification; CD = Clinical Diagnosis/Diagnostics; EC = Environmental Collection; SP = Sentinel Population alternative.

Figure 2. Modeling Process Flow

Time to Agent Detection & Identification (BAR): Alternative	Anthrax	Plague	Tularemia
Autonomous Identification	6 hours		
Environmental Collection	34 hours		
Sentinel Population	18-26 hours	18 hours	
Clinical Diagnosis	4 days	5 days	13 days

BioWatch Actionable Result (BAR): A BAR is defined as "one or more polymerase chain reaction (PCR)-verified positive result(s) from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents."

Base Case: Agent release at beginning of collection cycle

- Autonomous Identification: 4 hour collection/ 2 hour processing
- Environmental Collection: 28 hour collection/ 6 hour processing
- Sentinel Population: 50% tested outdoor; 12 hour collection/6 hour processing
- Clinical Diagnosis: Test at fulminant stage; 3 hour collection/24 hour processing

Collection cycle: sample collection, manual collection & transport

Time of PEP Administration: Alternative	Anthrax	Plague	Tularemia
Autonomous Identification	2 days	2 days	2 days
Environmental Collection	3 days	3 days	3 days
Sentinel Population	2-3 days	2 days	2 days
Clinical Diagnosis	5 days	6 days	14 days

Figure 3. Modeling—Timeliness, Base Case

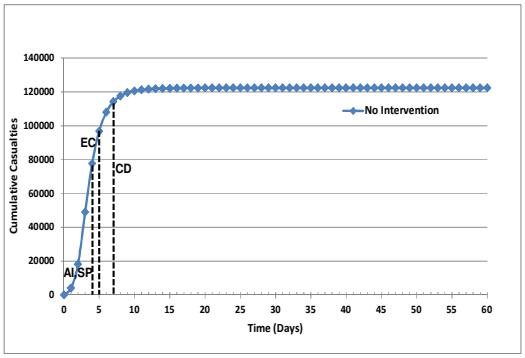
Alternative (Probability of detection for attacks causing >100 casualties)	Chicago Outdoor			O'Hare Airport			Grand Central Terminal		
	Anthrax	Plague	Tularemia	Anthrax	Plague	Tularemia	Anthrax	Plague	Tularemia
Autonomous Identification	23%	23%	23%	45%	42%	40%	82%	77%	77%
Environmental Collection	42%	41%	41%	65%	65%	61%	99%	99%	99%
Sentinel Population	44%	42%	46%	92%	91%	90%	99%	99%	99%
Clinical Diagnosis	100%	100%	100%	100%	100%	100%	100%	100%	100%

Note: Probability of detection for attacks causing greater than 10,000 casualties rapidly approaches 99% for indoor locations.

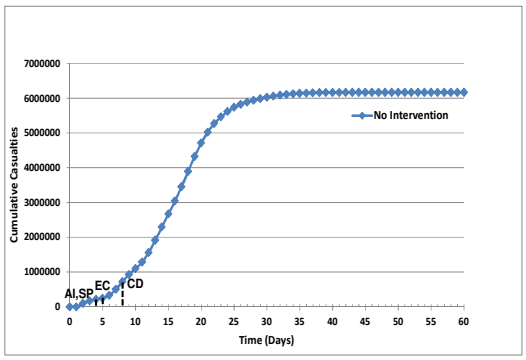
Sources: Nerayo P. Teclemariam et al., *BioWatch Technical Analysis of Biodetection Architecture Performance*, Sandia Report, SAND2012-0125 (Livermore: Sandia National Laboratories, 2012), FOUO; and IDA modeling work as documented in Disraelly et al., *BioWatch Analysis of Alternatives*, Institute for Defense Analyses (IDA) Paper P-5083 (Alexandria, VA: IDA, 2013).

Figure 4. Modeling—Probability of Detection

Anthrax – Representative Chicago Attack

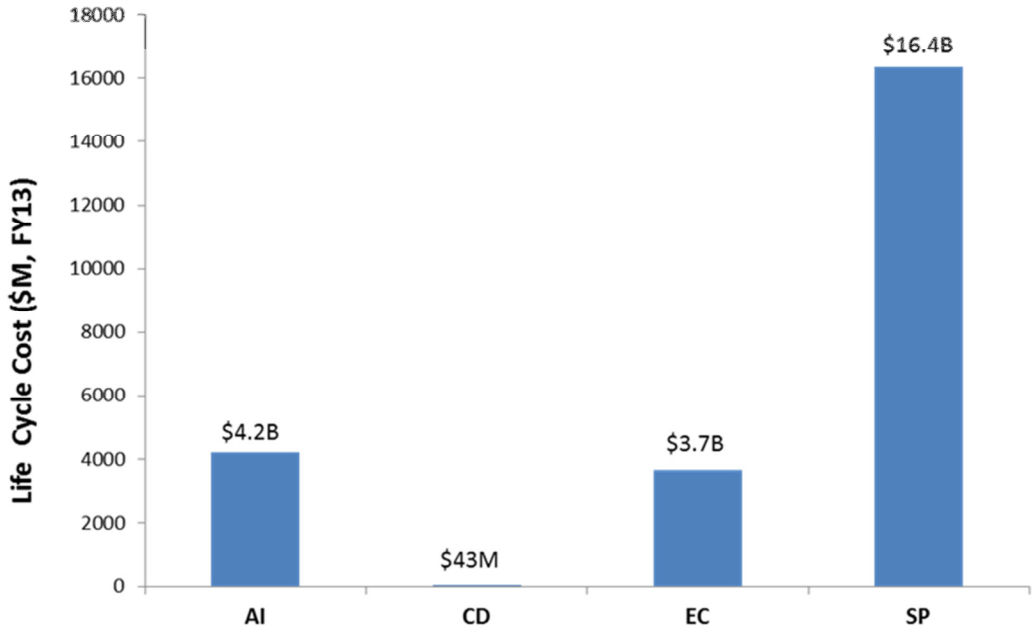


Plague – Representative Chicago Attack



Note: AI = Autonomous Identification; CD = Clinical Diagnosis/Diagnostics; EC = Environmental Collection; SP = Sentinel Population alternative.

Figure 5. Modeling—Casualties Over Time, Base Case



Note: AI = Autonomous Identification; CD = Clinical Diagnosis/Diagnostics; EC = Environmental Collection; SP = Sentinel Population alternative.

Figure 6. Cost Estimation—Life Cycle Cost Estimate Summary ($M, FY13, 50% Risk Adjusted)

MOEs & MOPs/ Alternatives	EC	AI	SP	CD
Availability	**Approximately equivalent for aerosolized biological agent events**			
Coverage	50 cities	50 cities	50 cities	Cities w/hospital lab capability
Detectable and identifiable agents (fatality risk)	100%	100%	100%	100%
Operational environment	1	1	1	1
Probability of Detection	**41-99%**	**23-82%**	**42-99%**	**100%**
Casualties	**Casualties are a function of agent & time to PEP administration, vary by attack**			
Time to detect/identify	34 hours	6 hours	18-26 hours	4-13 days
Time to PEP Administration	3 days	2 days	2-3 days	5-14 days
Life Cycle Costs constrained at $5.8B (GAO 2012)				
	$3.7B	$4.2B	$16.4B	$43M

Note: AI = Autonomous Identification; CD = Clinical Diagnosis/Diagnostics; EC = Environmental Collection; SP = Sentinel Population alternative; PEP = Post-exposure Prophylaxis.

Figure 7. Alternatives versus Measures of Effectiveness, Measures of Performance

	Combined[2]	Outdoors	Indoors
Detection Adjusted Casualties	not applicable[3]	EC	AI/EC
Probability of detection	CD[4]	CD[4]	CD[4]
Casualties	AI	AI	AI
Timeliness	AI	AI	AI
Cost[5]		CD[4]	

Table 1. Selected Candidate Alternatives under Various BioWatch Selection Criteria[1]

Note: AI = Autonomous Identification; CD = Clinical Diagnostics/Diagnosis; EC = Environmental Collection; SP = Sentinel Population alternative.

1. The cost of the Sentinel Population alternative is well above any cited BioWatch budget figure and therefore is considered outside the study constraints; subsequently, the Sentinel Population alternative is not considered in the table.
2. The combined environment is one that includes co-located indoor and outdoor spaces (e.g., transportation facilities, stadiums).
3. The modeling data did not allow for modeling of a release in a combined environment, or a mixed indoors and outdoors transportation environment, therefore, the exact number of casualties, probability of detection, and detection adjusted casualties could not be modeled.
4. The findings shown above for Clinical Diagnosis/Diagnostics consider only the current use and existing or mass casualty protocols; any change in systems, number of diagnostic samples, and protocols would require a reevaluation of the alternative's utility and costs.
5. Cost was assessed for the complete deployment of material and non-material solutions across all locations. Therefore, the most cost-effective solution is shown at left.