Attachment H

United States Government Accountability Office

GAO

Report to Congressional Committees

November 2008

HEALTH INFORMATION TECHNOLOGY

More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program

GAO-09-100

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More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program

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Highlights

Highlights of GAO-09-100, a report to congressional committees

Why GAO Did This Study

In 2003, the Centers for Disease Control and Prevention (CDC), an agency within the Department of Health and Human Services (HHS), developed an electronic syndromic surveillance system called BioSense that uses health-related data to identify patterns of disease symptoms prior to specific diagnoses. In late 2007, CDC began to redesign the program to improve collaboration with stakeholders and address identified management weaknesses. Pursuant to House Report 110-231, GAO evaluated the BioSense program, focusing on the cost and timeline estimates and performance measures and benchmarks for implementing the program, among other objectives. To accomplish this, GAO analyzed relevant program documentation and interviewed CDC officials responsible for developing and implementing BioSense.

What GAO Recommends

GAO is recommending that CDC develop reliable cost and timeline estimates and outcome-based performance measures for implementing the redesigned BioSense program. In written comments on a draft of this report, HHS stated it welcomed the conclusions and recommendations and provided updated information about current efforts intended to address the recommendations.

To view the full product, including the scope and methodology, click on GAO-09-100. For more information, contact Valerie C. Melvin at (202) 512-6304 or melvinv@gao.gov.

What GAO Found

While CDC identified annual and long-term cost and timeline estimates and performance measures for the initial design of BioSense, these estimates and measures did not reflect the implementation of its redesigned program. CDC subsequently developed a draft plan for the redesigned program that described high-level cost and timeline estimates; however, the estimates are not reliable, and the plan did not include performance measures.

- According to best practices, cost estimates should be well-documented, comprehensive and accurate, and must be credible before they can be considered to be reliable. However, CDC's cost estimates for the redesigned program are not reliable because they are only partially documented, are not comprehensive and accurate, and therefore are not credible.

- Best practices for reliable timeline estimates include the identification of resources to complete each task, establishment of a critical path, and analysis of risks to the schedule. However, the agency has not implemented these practices, resulting in timelines for the redesigned program that are not reliable.

- The Office of Management and Budget directs agencies to define outcome-based performance measures to gauge program results early enough for stakeholder review, and industry experts describe the need for stakeholder input in developing performance measures in order to monitor performance. While CDC established performance measures and benchmarks for the initial implementation of the BioSense program, it has not yet developed outcome-based performance measures to monitor the progress of the redesigned program and does not intend to complete their development until the end of 2009.

Until program officials develop reliable cost and timeline estimates and outcome-based performance measures for the redesigned BioSense program, they will lack key components needed to effectively manage the program, increasing the risk that the agency will perpetuate weaknesses identified in its initial implementation of the program and related system.

Contents

Abbreviations

CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
ESSENCE	Electronic Surveillance System for the Early Notification of Community-based Epidemics
HHS	Department of Health and Human Services
NBIS	National Biosurveillance Integration System
NHIN	Nationwide Health Information Network
OMB	Office of Management and Budget
RODS	Real-time Outbreak and Disease Surveillance
VA	Department of Veterans Affairs

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United States Government Accountability Office
Washington, DC 20548

November 20, 2008

The Honorable Tom Harkin
Chairman
The Honorable Arlen Specter
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Dave Obey
Chairman
The Honorable James T. Walsh
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
House of Representatives

In 2002, President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act, which required specific activities aimed at improving the nation's preparedness for bioterrorism and other public health emergencies.[1] In response to the passage of this act, the Centers for Disease Control and Prevention (CDC), an agency within the Department of Health and Human Services (HHS), developed, in 2003, an electronic syndromic surveillance information system called BioSense.[2] In 2004, CDC established the BioSense program office to improve the nation's capabilities for conducting syndromic surveillance by providing federal, state, and local public health officials access to existing data from health care organizations across the country through use of the BioSense system. In late 2007, the agency initiated efforts to redesign the program to improve collaboration with public health stakeholders and to

[1]42 U.S.C. § 247d-4(b).

[2]According to CDC, syndromic surveillance is a technique that uses health-related data to identify patterns of disease symptoms prior to specific diagnoses. Effective use of this technique can provide both situational awareness—knowledge of the size, location, and rate of spread of an outbreak—and early event detection, signaling a probability of an outbreak sufficient to warrant a public health response and leading to early identification of illnesses and other events of public health importance.

address management weaknesses identified in its initial implementation. CDC's National Center for Public Health Informatics is responsible for managing the program.

Pursuant to House Report 110-231,[3] we evaluated BioSense, focusing on (1) the costs and benefits of operating the BioSense system as compared to other state and local surveillance systems, (2) the usefulness of data provided by the system to hospitals and state and local public health officials, and (3) the cost and timeline estimates and performance measures and benchmarks for implementing the program. We provided subcommittee staff with preliminary results from our study on April 1, 2008, and subsequently agreed with your offices to continue our evaluation of CDC's plans for implementing BioSense, focusing on the annual and long-term cost and timeline estimates and performance indicators and benchmarks for implementing a redesigned program. On August 26, 2008, we provided your offices with briefing slides that outlined the final results of our study. The purpose of this report is to issue the published briefing slides to you and to officially transmit our recommendations to the Director of the Centers for Disease Control and Prevention. The slides, which discuss our scope and methodology and incorporate edits made since we initially provided the briefing, are included in appendix I.

We conducted this performance audit from October 2007 to August 2008 at CDC's headquarters in Atlanta, Georgia, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, our study highlighted the following:

- The costs and benefits of using data from the current BioSense system and other similar syndromic surveillance systems are difficult to measure and compare. Further, public health and hospital officials with whom we spoke said that because of the difficulty of doing so, they do not track the costs and benefits of using syndromic surveillance systems.

[3]H.R. Rep. No. 110-231, at 122 (2007).

- Federal, state, and local public health officials expressed mixed views on the usefulness of BioSense data as compared with the usefulness of data from similar systems. While stating that they find the data from the BioSense system useful to varying degrees, about half of the officials with whom we spoke said that they rely on other systems as their primary tool for syndromic surveillance. For example, officials with the Department of Defense (DOD) stated that, rather than BioSense, the department's public health personnel use DOD's Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE). In contrast, Department of Veterans Affairs (VA) public health personnel do not regularly rely on syndromic surveillance system data; however, they use the civilian version of ESSENCE more often than BioSense. Both DOD and VA officials stated that ESSENCE allows more flexibility in evaluating and viewing data than BioSense.[4]

- Although CDC identified annual and long-term cost and timeline estimates and established performance measures and benchmarks for the initial implementation of the BioSense program and its related system, these estimates and measures did not reflect the implementation of its redesigned program. CDC subsequently developed a draft plan for the redesigned program that described high-level cost and timeline estimates; however, these estimates were not reliable, and the plan did not include performance measures.

    - According to best practices, cost estimates should be well-documented, comprehensive and accurate, and must be credible before they can be considered to be reliable. However, CDC's cost estimates for the redesigned program are not reliable because they are only partially documented, are not comprehensive and accurate, and therefore are not credible.

    - Best practices for reliable timeline estimates include the identification of resources to complete each task, establishment of a critical path, and analysis of risks to the schedule. However, the agency has not implemented these practices, resulting in timelines for the redesigned program that are not reliable.

    - The Office of Management and Budget directs agencies to define meaningful annual and long-term outcome-based performance

[4]DOD developed the ESSENCE system in 1999. A civilian version of the system is available, at no charge, to any health department that wants to use the system locally.

measures to gauge the results of a program or activity early enough to allow time for stakeholder review, and industry experts describe the need for stakeholder input in developing performance measures in order to monitor project performance. CDC has not yet developed outcome-based performance measures to monitor the progress of the redesigned program and does not intend to complete their development until the end of 2009.

Until program officials develop reliable cost and timeline estimates and outcome-based performance measures for the redesigned BioSense program, they will lack key components needed to effectively manage the program.

Conclusions

The costs and benefits of using data from the current implementation of the BioSense system and other similar systems are difficult to measure and compare, and public health and hospital officials with whom we spoke do not document or track the costs and benefits of using these systems. These officials also expressed mixed views on the usefulness of BioSense data as compared to data from other systems.

While BioSense program officials have developed cost and timeline estimates for the initial implementation of the program, they have not yet reliably estimated costs and timelines for the redesigned program. Additionally, program officials do not expect to complete the development of outcome-based performance measures for the redesigned BioSense program before the end of 2009. Until CDC develops these key components of effective information technology program management, BioSense officials will lack the management and planning tools needed to gauge the success of the redesigned BioSense program in improving federal, state, and local partners' abilities to respond to public health events and will risk perpetuating weaknesses identified in the initial implementation of the program and its related system.

Recommendations for Executive Action

To ensure that CDC defines reliable plans for effectively managing the development and implementation of the redesigned BioSense program and its related system, we are recommending that the Director of CDC instruct the Director of the National Center for Public Health Informatics to take the following three actions while in the planning phase of the redesigned BioSense program:

- develop reliable cost estimates for the program that are well-documented, comprehensive and accurate, and credible;
- develop reliable timeline estimates for implementing the program; and
- with stakeholder input, develop outcome-based performance measures that address all phases of the program and that focus the success of the program on CDC's federal, state, and local partners' use of the system for responding to public health events.

Agency Comments and Our Evaluation

The Department of Health and Human Services' Assistant Secretary for Legislation provided written comments on a draft of this report. In the comments, HHS welcomed the conclusions and recommendations discussed in our report.

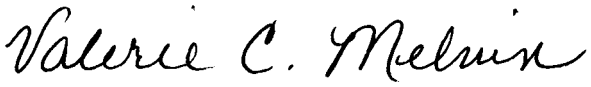
In its comments, HHS provided information about steps the department has begun taking to address the conclusions and recommendations in our report. In particular, the department stated that it has launched a planning and implementation process to ensure that the program develops reliable cost estimates and timelines and identifies appropriate outcome-based performance measures. According to the department, among other activities, the program has initiated working groups of internal and external stakeholders to establish detailed tactical plans for projects, tasks, deliverables, and resources. The department stated that it intends to use the tactical plans to derive future cost and timeline estimates and involve stakeholders in establishing outcome-based performance measures. It added that a program plan for the redesigned Biosense is scheduled for completion by February 2009. If effectively implemented, HHS's stated actions toward developing reliable cost and timeline estimates and defining outcome-based performance measures should help improve the department's management of the redesigned BioSense program.

Finally, with regard to the program, the department stressed the importance of noting that BioSense is not intended to replace local systems, but rather to add value by providing data, tools, and funding intended to improve surveillance efforts. HHS's written comments are reproduced in appendix II.

DOD and VA also reviewed the draft report and provided technical comments, which we have incorporated as appropriate.

We are sending copies of this report to interested congressional committees, the Director of the Office of Management and Budget, and the Secretaries of the Departments of Health and Human Services, Defense, and Veterans Affairs. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

Should you or your staffs have any questions concerning this report, please contact me at (202) 512-6304 or melvinv@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix III.



Valerie C. Melvin
Director, Human Capital and Management
Information Systems Issues

Appendix I: Briefing Slides

Health Information Technology: More Detailed Plans Needed for The Centers for Disease Control and Prevention's Redesigned BioSense Program

Briefing for Staff Members of the

House and Senate Subcommittees on Labor, Health and Human Services, Education, and Related Agencies, Committees on Appropriations

August 26, 2008

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Introduction

A catastrophic health event could cause hundreds of thousands of casualties, weaken our economy, damage public morale and confidence, and threaten our national security. Threats of bioterrorism and high-profile disease outbreaks, such as a pandemic influenza outbreak, have drawn attention to the need for surveillance systems for the early detection of and response to public health emergencies.

In 2002, President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act, which required specific activities intended to improve the nation's preparedness for bioterrorism and other public health emergencies.

- The act required the Secretary of Health and Human Services to establish an integrated system of public health alert communication and surveillance networks among federal, state, and local public health officials, and laboratories, hospitals, and other health care facilities.

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Introduction

In response to the passage of this act, in 2003 the Centers for Disease Control and Prevention (CDC) developed an electronic syndromic surveillance information system called BioSense.

In 2004, the agency established the BioSense program office to improve the nation's capabilities for conducting surveillance by providing federal, state, and local public health officials access to existing data from health care organizations across the country through the use of the BioSense system. In late 2007, CDC initiated efforts to redesign the program in order to improve collaboration with federal, state, and local public health stakeholders and to address management weaknesses identified in the initial implementation of BioSense. The program is managed by CDC's National Center for Public Health Informatics.

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Introduction

According to CDC, syndromic surveillance is a technique that uses health-related data to identify patterns of disease symptoms prior to specific disease diagnoses. Effective use of this technique can provide both situational awareness and early event detection.

- Situational awareness is the knowledge of the size, location, and rate of spread of an outbreak.
- Early event detection provides signals that a sufficient probability of a disease outbreak exists to warrant public health response and lead to the early identification of illnesses and other events of public health importance.

In this regard, syndromic surveillance can facilitate preventing and controlling the spread of diseases.

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Introduction

Pursuant to House Report 110-231,[1] we evaluated BioSense, focusing on the costs and benefits of operating the BioSense system as compared to other state and local surveillance systems; the usefulness of data provided by the system to hospitals and state and local public health officials; and cost and timeline estimates and performance measures and benchmarks for implementing the program. As agreed with staff of the House Committee on Appropriations, Subcommittee on Labor, HHS, Education, and Related Agencies, we provided preliminary results from our study on April 1, 2008. Subsequently, we agreed with staff of the House and Senate Committees on Appropriations, Subcommittees on Labor, HHS, Education, and Related Agencies to continue our evaluation of CDC's plans for implementing BioSense, focusing on the annual and long-term cost and timeline estimates, and performance indicators and benchmarks for implementing a redesigned program.

[1]H.R Rep. No. 110-231, at 122 (2007).

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Objectives

The specific objectives addressed in our study were to

- Compare the cost and benefits of operating the BioSense system with the cost and benefits of operating state, local, and private surveillance systems.
- Identify the views of hospitals and federal, state, and local public health officials on the usefulness of data provided by the BioSense system versus data provided by local surveillance systems for responding to emergencies.
- Identify annual and long-term cost and timeline estimates and performance indicators and benchmarks for the initial implementation of BioSense, and evaluate CDC's plans for implementing the redesigned BioSense program, focusing on annual and long-term cost and timeline estimates, and performance indicators and benchmarks.

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Scope and Methodology

To compare the cost and benefits of operating the BioSense system with the cost and benefits of operating other similar state, local, and private surveillance systems, we

- identified from CDC's fiscal year 2009 budget and planning documentation the agency's expected cost and projected benefits of operating the BioSense system;
- reviewed cost and benefits information related to the use of the BioSense system and available information on cost and benefits reported for other surveillance systems used by hospitals and state and local public health organizations; and
- discussed with the BioSense users selected for our second objective the cost of and benefits realized from using data provided by the BioSense system.

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Scope and Methodology

To determine the views of federal, state, and local public health officials and hospitals on the usefulness of BioSense data versus local surveillance data, we selected and interviewed officials of organizations that conduct syndromic surveillance using BioSense, other systems, or BioSense together with other systems. These organizations include:

- the three federal agencies that have access to the BioSense system—CDC, the Department of Defense (DOD), and the Department of Veterans Affairs (VA); and
- three state and five local public health departments and two hospitals
  - state public health departments in Arizona, Georgia, and North Carolina;
  - local public health departments in Dallas, El Paso, and Tarrant counties in Texas; Maricopa County in Arizona; and the East Metro Health District in Georgia; and
  - Gwinnett Medical Center in Lawrenceville, Georgia, and a Tenet Healthcare hospital in El Paso, Texas.

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Scope and Methodology

- To select these organizations, we obtained from CDC the program office's list of BioSense users from the most recent month at the time of our request—October 2007.
  - According to CDC, there are more than 500 users of the BioSense system, and they are located throughout 150 hospital, federal, state, and local facilities, including CDC.
- We selected organizations from different geographic areas that use BioSense and other syndromic surveillance systems.
  - We sorted users by state to identify a subset of organizations from a wide geographic dispersion.
  - From that subset, we selected states with varying numbers of BioSense users.
  - From those states, we selected a final set of states with high, midrange, and low numbers of BioSense users, based on the average number of users across the selected states.
- We then selected local health departments in municipalities with populations that varied from large to small.

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Scope and Methodology

- From among the BioSense users we selected, we further identified organizations that also use BioSense and other commercial or locally-developed systems based on literature research and our knowledge of the syndromic surveillance system user population.
- We also included in our selection BioSense facilities that have not opted to use the data provided by the system.
- We discussed with the selected users the usefulness of BioSense data as compared with data from other similar systems.

To supplement our discussions with selected users, we met with officials from two public health associations to obtain their views on the usefulness of BioSense and of syndromic surveillance systems in general. We held discussions with officials from:

- the Association for State and Territorial Health Officials, and
- the Council for State and Territorial Epidemiologists.

We also interviewed public health officials from four other state and local jurisdictions at a meeting arranged for us by the National Association of City and County Health Officials.

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Scope and Methodology

In addition, we asked the federal, state, local, and hospital representatives with whom we spoke to identify any lessons they had learned from developing and implementing other similar surveillance systems.

Our selection of BioSense users does not provide a statistically-valid sample; therefore, the information provided by the organizations we selected cannot be generalized across the entire BioSense user population.

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Scope and Methodology

To identify annual and long-term cost and timeline estimates and performance indicators and benchmarks for implementing the initial design of BioSense, we reviewed and assessed CDC's relevant program management and budget justification documentation for the program.

To evaluate CDC's plans for implementing the redesigned BioSense program and related system, we obtained CDC's draft plan for and other documentation relevant to implementing the redesigned BioSense program. We evaluated the costs, schedule, and performance components addressed in this documentation against criteria established by federal guidance to determine if CDC followed best practices to develop these components of its plan.[2]

- We analyzed CDC's documented cost estimates for implementing the redesigned program, as well as documentation describing the practices that cost estimators followed to estimate costs of the program.
- We assessed CDC's estimated time frames for completing the strategic activities described in the plan.

[2]Executive Office of the President, Office of Management and Budget, *Planning, Budgeting, Acquisition, and Management of Capital Assets,* Circular No. A-11, Part 7 (Washington, D.C.: June 2008). See also, U.S. Government Accountability Office, *Cost Assessment Guide: Best Practices for Estimating and Managing Program Costs*, Exposure Draft, GAO-07-1134SP (Washington, D.C.: July 2007).

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Scope and Methodology

- We reviewed CDC's documented approach for developing performance measures described in the plan and compared it to the Office of Management and Budget's (OMB) guidance and industry practices to determine if the agency's documented approach was consistent with federal and industry guidance.[3]

[3]Executive Office of the President, Office of Management and Budget, *Guide to the Program Assessment Rating Tool*, (Washington, D.C.: January 2008); Thomas Wettstein and Peter Kueng, "A Maturity Model for Performance Measurement Systems," *Management Information Systems 2002--Incorporating GIS and Remote Sensing* (Southampton: WIT Press, 2002),113-122; and Karen J. Richter, Ph.D., Institute for Defense Analyses, CMMI® for Acquisition (CMMI-ACQ) Primer, Version 1.2 (Software Engineering Institute, May 2008).

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Scope and Methodology

We supplemented our documentation reviews with interviews of officials from CDC's BioSense program office to obtain additional information about the development of current and future plans for BioSense. We did not independently verify CDC's cost or timeline estimates for the program.

We conducted this performance audit from October 2007 to August 2008 at CDC's headquarters in Atlanta, Georgia, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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Results in Brief

The cost and benefits of using data from the current BioSense system and other similar syndromic surveillance systems are difficult to measure and compare. The state and local public health and hospital officials with whom we spoke stated that documenting the cost and benefits of using syndromic surveillance systems such as BioSense is difficult and that they do not develop or track cost or benefits of using these systems.

Federal, state, and local public health and hospital officials expressed mixed views on the usefulness of BioSense data as compared with the usefulness of other similar systems' data. While they stated that they find the data from the BioSense system useful in varying degrees, about half of them stated that they rely on other systems as their primary tool for syndromic surveillance. Officials from two public health associations differed in their views on the usefulness of nationwide surveillance overall and BioSense in particular. While an official from one of the associations noted that other methods of conducting syndromic surveillance were more useful than electronic syndromic surveillance systems, officials from the other association stated that establishing a national syndromic surveillance system is essential. Further, preliminary results of a study on the use of syndromic surveillance systems conducted for CDC reiterated public health and hospital officials' views of the usefulness of BioSense data.

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Results in Brief

Although CDC identified annual and long-term costs for the initial implementation of the BioSense program, these estimates did not reflect the cost of implementing the redesigned program and its related system. CDC subsequently developed a draft plan for the redesigned program with high-level cost estimates based on program officials' professional judgment. Best practices require cost estimates to be well-documented, comprehensive and accurate, and credible before they can be considered to be reliable. However, CDC's cost estimates for the program are not reliable because they are only partially documented, are not comprehensive and accurate, and are not credible.

According to program officials, CDC is in the strategic planning phase of the redesigned program and is only able to provide high-level cost estimates during this phase. Program officials stated that they intend to reflect more accurate and refined estimates as the program plans evolve and the technical and performance requirements of the program are better defined. Until program officials are able to define the information needed to develop cost estimates that are comprehensive and accurate, CDC will not be positioned to provide reliable cost estimates for implementing the BioSense program.

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Results in Brief

CDC also identified annual and long-term timeline estimates for the initial implementation of the BioSense program. However, the timelines were not relevant to the goals of the redesigned program. While CDC has developed timeline estimates for implementing the redesigned BioSense program, they are not reliable. Best practices for reliable timeline estimates include, among other things, the identification of resources to complete each task, establishment of a critical path, and analysis of risks to the schedule. However, the agency has not assigned resources to activities, established a critical path, or analyzed risks to the schedule to ensure that its estimates are reliable.

According to BioSense program officials, the redesigned program is in the early stages of planning, and they have not yet completed tactical plans that would identify resources needed to complete tasks and a critical path for the schedule. Until program officials consider these components, CDC will not be positioned to provide reliable timeline estimates for its plans to fully implement the BioSense program.

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Results in Brief

CDC established performance measures and benchmarks for the initial design of the BioSense program. However, the performance measures defined in the business case were not focused on intended results of the redesigned program. OMB directs agencies to define meaningful annual and long-term performance measures to gauge the intended results of carrying out a program or activity early in the program to allow time for stakeholder review. Additionally, industry experts describe the need for performance measures to be developed with stakeholders' input early in a project's planning process to provide a central management and planning tool and to monitor the performance of the project against plans and stakeholders' needs.

CDC's plan for the redesigned BioSense program describes a need to develop outcome-based performance measures. However, program officials stated that they do not intend to complete development of performance measures until the end of 2009. Until BioSense program officials develop these measures, they will lack an effective management and planning tool for gauging the success of the program against plans and against federal, state, and local partners' use of the BioSense system for responding to public health events.

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Results in Brief

We are recommending that the Director of the Centers for Disease Control and Prevention instruct the Director of the National Center for Public Health Informatics to take the following three actions while in the planning phase of the redesigned BioSense program:

- develop reliable cost estimates for the program that are well-documented, comprehensive and accurate, and credible;
- develop reliable timeline estimates for implementing the program; and
- develop performance measures that address all phases of the program and focus the success of the program on CDC's federal and state partners' use of the system for responding to public health events.

We received oral comments on a draft of this briefing from BioSense program officials, including the Director of CDC's National Center for Public Health Informatics. The officials generally agreed with the information included in the draft and provided additional information and technical comments which were incorporated into the briefing as appropriate.

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Background

Historically, disease outbreaks have been recognized based either on accumulated case reports of diseases by local public health departments or by clinicians and laboratorians who alert public health officials about potential disease outbreaks.

Complete responsibility for disease surveillance is shared among health care providers, including public health officials from 59 state and territorial health departments; more than 3,000 county, city, and tribal health departments; multiple federal agencies, including CDC; and more than 180,000 public and private laboratories.

- States take the lead in conducting disease surveillance and supporting local emergency response efforts through a public health infrastructure that is made up of state and county, city, and tribal health departments—i.e., local health departments. State health departments are responsible for collecting surveillance information from local health departments, coordinating investigations and response activities, and sharing disease surveillance data with CDC.

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Background

Local health departments are responsible for conducting the initial investigations into reports of diseases. Initial response to a public health emergency is generally a local responsibility that could involve multiple local health departments in a geographical region, with state health departments providing additional support when needed.

The federal government's role in disease surveillance traditionally has been to collect data from state and local health departments and perform nationwide analyses of the aggregated state and local data using surveillance systems. CDC uses information and communications systems to share disease surveillance information with state and local health departments and provides funding and technical expertise to support surveillance at the state and local levels.

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Background

For nearly 10 years, federal, state, and local public health organizations, private companies, and academic institutions have been developing systems for collecting and analyzing electronic surveillance data from sources such as hospital emergency departments, clinical laboratories, and pharmacies. These systems are intended to better support efforts to detect disease outbreaks through electronic syndromic surveillance and to more efficiently communicate information to public health officials. For example:

- The University of Pittsburgh and Carnegie Mellon University developed the Real-time Outbreak and Disease Surveillance (RODS) system in 1999.
- DOD developed the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) in 1999. A civilian version of the system is available, at no charge, to any health department that wants to use the system locally.
- According to CDC, about 20 states have developed electronic surveillance systems.

CDC officials stated that, as tools to share information more quickly and efficiently become available, the roles of federal, state, and local public health agencies in conducting disease surveillance are likely to evolve.

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Background

According to BioSense program officials, the initial vision for the program was to provide real-time health data to federal, state, and local public health organizations and participating hospitals in order to:

- provide health situational awareness by enabling public health officials at the federal, state, and local levels to monitor the size, location, and rate of an outbreak;
- support early event detection by enabling public health officials to detect a potential public health emergency at the earliest possible time; and
- assist public health officials in responding to a disease outbreak or other emergency.

A key component of the program is the BioSense system—an electronic information system which CDC developed to provide data and analytical tools for public health and other health organizations to use in conducting syndromic surveillance.

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Background

The system is made up of (1) the hardware and software that enable BioSense to collect relevant data from public health organizations and hospitals and (2) software that analyzes the collected data and provides the analyzed data and analytical tools via a Web-based application for use by public health and hospital officials who conduct syndromic surveillance activities.

The current system collects site-specific data directly from (1) state and local public health departments that collect hospital data from within their jurisdictions and (2) hospital, DOD and VA facility, health department, and laboratory data sources. The collected data are stored in a central CDC data repository.

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Background

To provide data to the system, facilities must electronically store and maintain the data, and they must establish data-sharing agreements with CDC. As part of these agreements, CDC provides to facilities, at minimal or no charge, the hardware and software needed to collect and translate the facility's data into a standard format to enable transmitting the data to BioSense.

According to CDC, the agency has agreements with and the system currently collects data from about 570 hospitals, 320 DOD military treatment facilities, 860 VA hospitals and outpatient clinics, and other data sources that provide public health officials with the information needed to conduct syndromic surveillance, such as patients' reasons for seeking medical attention, over-the-counter drug sales, prescription drug information from clinicians, and clinical laboratory test requests that could indicate disease outbreaks.

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Background

The BioSense data analysis software aggregates and analyzes the electronic data collected from these facilities to identify disease syndromes within state and local jurisdictions. The system then displays graphical views of the presence of syndromes across time and geographical locations in the form of charts, graphs, and maps via a Web-based application. BioSense users can access the application via the Internet at no charge.

- The views displayed by the BioSense Web-based application can be accessed by public health and health care professionals, such as public health epidemiologists and hospital infectious disease clinicians, who use the system to facilitate their ability to track the outbreak, treatment, and spread of diseases within their own jurisdictions.[4]
- CDC reports that there are more than 500 users of the BioSense system, and that they are located throughout 150 hospital, federal, state, and local facilities, including CDC.

[4] Users can access data for neighboring jurisdictions or other locations only with additional approval from the other jurisdictions involved and from CDC.

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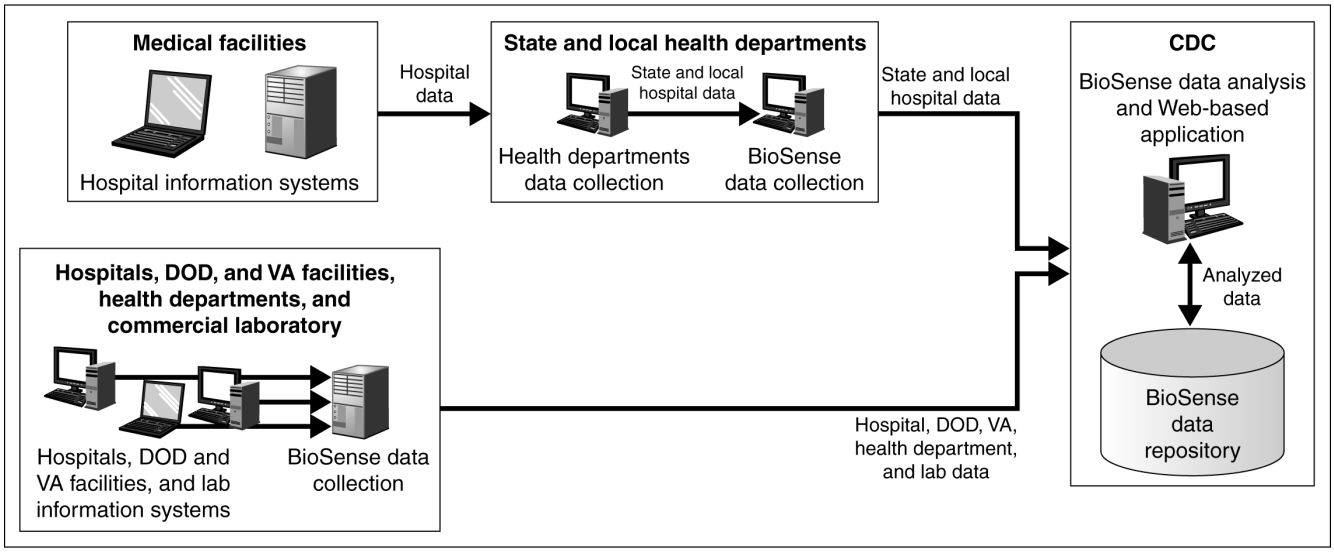
GAO
Accountability * Integrity * Reliability

Background

The following graphic provides an overview of the current BioSense system.



Source: GAO analysis of CDC data.

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GAO
Accountability * Integrity * Reliability

Background

According to program officials, the current BioSense system

- collects data directly from medical facilities or local public health departments, VA and DOD facilities, or from state public health departments that have already collected the local health department and hospital data within their jurisdictions; the collected data are analyzed and stored in a central CDC data repository;
- is not integrated with other federal public health information technology initiatives, such as CDC's electronic disease surveillance system; and
- was designed and developed with limited collaboration between CDC and state and local public health stakeholders.

In June 2005, we reported on federal agencies' progress in implementing public health information technology initiatives. We noted that public health officials said they did not find the BioSense system useful because of limitations in the data being collected.[5]

[5] GAO, *Information Technology: Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure*, GAO-05-308 (Washington, D.C.: June 2005).

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GAO
Accountability * Integrity * Reliability

Background

In 2006, an independent contractor evaluated the BioSense program and identified about 50 management weaknesses that increased program risks, including the lack of a clear, consistent vision and supporting plans to guide and constrain the scope of the program.

During the third quarter of fiscal year 2007, a new director that CDC hired to lead the National Center for Public Health Informatics initiated efforts to redesign the BioSense program.[6]

- According to BioSense officials, the redesigned program includes a new strategy that emphasizes increased collaboration with state and regional public health officials by providing more opportunities for stakeholder training and holding round-table meetings with stakeholders to gain a better understanding of their needs.
- BioSense officials stated that, as part of the program's redesign, they intend to address all of the weaknesses identified by the contractor's evaluation that are relevant to the new strategy.

[6] The BioSense program is managed by the National Center for Public Health Informatics within CDC.

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Background

- The officials also told us that they plan to reengineer the BioSense system to reflect the redesigned program's new mission to "provide a system that comprehensively monitors the health care system of the United States for evidence of acute health threats to the public."

Program officials intend for the redesigned BioSense system to:

- collect and analyze already-aggregated data from states and health information exchanges, rather than collect site-specific data from individual data sources as the current system does;
- store results of the analyzed data in a central data repository at CDC (the data collected from state and health information exchanges will remain with their original sources);
- include enhanced, user-customizable data analysis tools to allow users to easily tailor the application to better detect disease outbreaks and emergencies within their own jurisdictions;

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Background

- allow states to share data and views across jurisdictions by building regional data-sharing collaboratives;
- incorporate case detection technology for use in catastrophic as well as routine public health capacities; and
- be integrated with other public health information technology components, such as CDC's electronic notifiable disease surveillance systems and electronic laboratory reporting, the Department of Homeland Security's (DHS) National Biosurveillance Integration System (NBIS),[7] and with the planned Nationwide Health Information Network (NHIN).[8]

According to program officials, Web-based analytical tools and data views will still be available to BioSense users via the Internet.

[7] The National BioSurveillance Integration System is a federal effort to combine multiple data streams from sector-specific agencies—those with medical, environmental, agricultural, and intelligence data—to give DHS situational awareness that is intended to allow earlier detection of events and to assist response activities.

[8] The Nationwide Health Information Network is a critical portion of the HHS Office of the National Coordinator for Health Information Technology's agenda intended to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and health care. It is planned to be a "network of networks" built out of state and regional health information exchanges and other networks to support the exchange of health information by connecting these networks.

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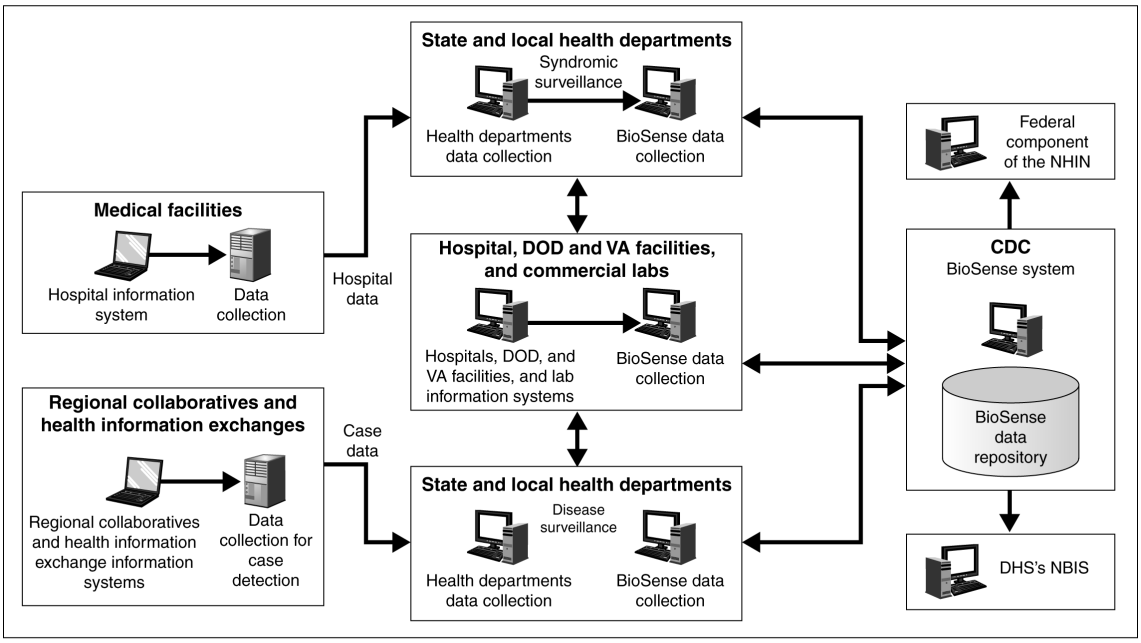
GAO
Accountability * Integrity * Reliability

Background

The following graphic provides an overview of CDC's initial proposal for the redesigned BioSense system.



Source: GAO analysis of CDC data.

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Background

In May 2008, BioSense program officials developed a draft plan that outlined a vision for implementing the redesigned BioSense program within a four-year timeframe.[9] The draft plan articulates four strategic goals for the redesigned program along with strategic-level activities for accomplishing the goals. The four strategic goals are:

- sponsor regional collaboration and health information exchanges,
- pursue open collaborative development,
- transition to a federated data model,[10] and
- expand case detection technology.

BioSense program officials intend for the four goals to be accomplished by the end of 2012 and stated that they will continue to update the plan and incorporate more tactical and operational planning details throughout 2008 and 2009.

[9]Centers for Disease Control and Prevention National Center for Public Health Informatics, *BioSense Strategic Plan, FY 2008 – 2012, Version 6 (Draft);* (Atlanta, Ga.).

[10]A federated data model supports data sharing across a large community despite having data stored in different geographic locations. Use of this model would be expected to enable the public health community to store data locally, in state and local public health departments, while enabling CDC and other organizations to access and analyze that data.

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Background

The plan describes 2008 as a transitional year during which CDC will continue to support ongoing initiatives and work to expand collaboration with its stakeholders.

- Program officials incorporated into the new strategy for BioSense ongoing initiatives, such as proof-of-concept efforts for evaluating technology solutions for a federated data model and case-detection, and linked the outcomes of these initiatives to the new program goals.

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Background

BioSense program funding covers costs for the program office, including staff, equipment, and contractor support to develop, implement, maintain, and support the BioSense system. It also covers extramural activities, such as stakeholder round-table meetings, and research grants and cooperative agreements with universities and other public health researchers to evaluate the usefulness of the system for supporting early event detection, situational awareness, and emergency response. CDC reported spending about $184 million on the program from 2003 through June 2008.

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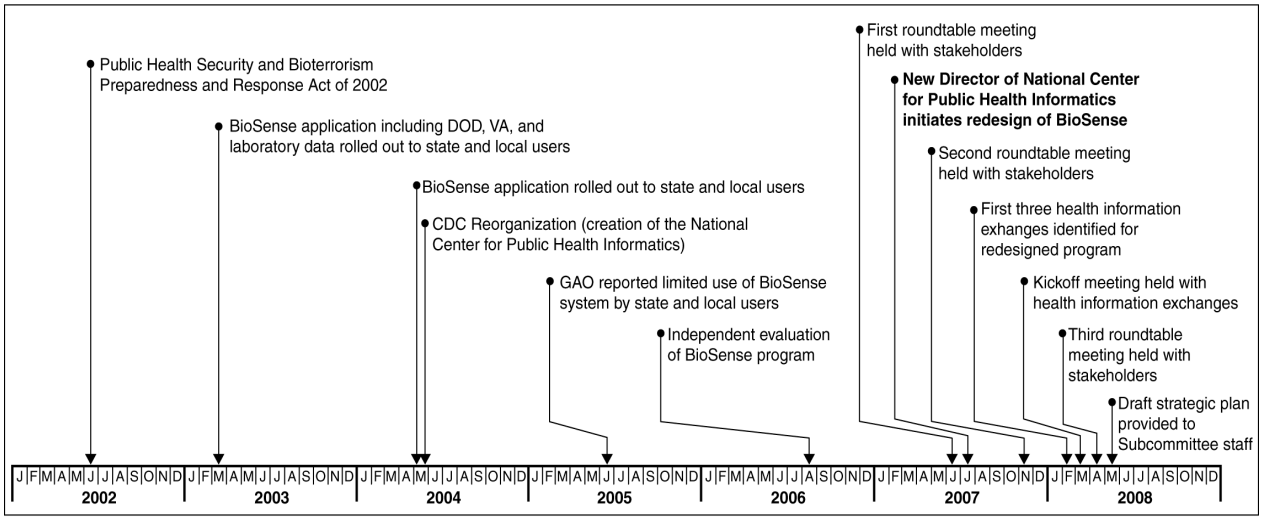
Background

The following graphic illustrates the evolution of the BioSense program and system since the initiation of the system's development.



Source: GAO based on CDC data.

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Results
BioSense Costs and Benefits

Costs and benefits of using data from BioSense and other syndromic surveillance systems that public health officials rely on are difficult to measure and compare. The state and local public health and hospital officials with whom we spoke stated that documenting costs and benefits of using syndromic surveillance systems such as BioSense is difficult and that they do not develop or track the costs or benefits of using these systems. Factors limiting the ability to compare the costs and benefits of operating BioSense with other surveillance systems include:

- Some of the systems in use, including BioSense, are provided to state, local, and hospital users at very low or no cost and require little investment by users.[11] Therefore, any additional data provided by these systems are beneficial. Without a need to justify a substantial investment in the systems, these organizations have not tracked costs or benefits.
- Costs of developing and implementing systems can vary widely depending on the approach used to acquire, maintain, and monitor surveillance data.

[11]Three organizations in our review reported that the only cost for using surveillance systems was staff time for using the systems, which is performed in combination with other activities. Most state and local users in our review used federal or state grant funding to cover system costs.

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Results
BioSense Costs and Benefits

- Implementation of syndromic surveillance systems varies widely in scope by the type and volume of data collected, size of the jurisdiction, and number of data providers. BioSense is the only national system that centrally supports federal, state, and local public health and hospital users and that evaluates nationwide data to provide a national view of the country's health. In contrast, DOD and state and local public health departments' systems are intended specifically for use within their jurisdictions, such as within military bases or state and local public health districts.
- System costs and benefits are difficult to track within the wide range of response activities that are undertaken during outbreaks. Syndromic surveillance activities are conducted as a component of a wide range of emergency response activities, including activities such as identifying available hospital beds and identifying specific patients, and it is difficult to segregate the costs of specific tasks from the overall response effort.

Consistent with other public health officials' experiences in using syndromic surveillance systems, BioSense program officials have not widely reported actual quantifiable benefits of using the BioSense system.

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Results
Usefulness of BioSense

Views on the usefulness of data provided by the BioSense system as compared with the usefulness of other similar systems' data are mixed. The federal agencies that use the BioSense system for syndromic surveillance reported mixed views on the usefulness of the data provided by the system.

- BioSense program officials stated that CDC's epidemiologists and infection control analysts find the data provided by the BioSense system useful for detecting and monitoring potential events that could have a nationwide impact on public health and for notifying local public health officials about potential outbreaks in their jurisdictions. Program officials reported that, in 2007, BioSense data were useful in identifying ten local public health events.
  - Among these events, one of them was detected by CDC personnel using data from BioSense before it was detected by the local health department.
- DOD and VA officials stated that their departments' public health personnel do not rely on data provided by the BioSense system to conduct syndromic surveillance activities.

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Results
Usefulness of BioSense

- DOD officials told us that they use ESSENCE because it provides the ability for users to monitor the local populations for which they are responsible—i.e., populations within military installations—whereas the current version of BioSense presents aggregated information at the state level. Therefore, the results of the BioSense system do not provide information that DOD can act on within its jurisdiction.
  - VA officials stated that their public health personnel do not regularly rely on data provided by BioSense or any other system to conduct syndromic surveillance activities. They told us that they use the civilian version of ESSENCE more often than BioSense, though both systems are occasionally monitored.
- Both DOD and VA officials stated that ESSENCE allows them more flexibility in evaluating and viewing data than BioSense does.

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Results
Usefulness of BioSense

Epidemiologists and infectious disease personnel at state and local public health organizations and hospitals use data from the BioSense system, other similar systems, and manual techniques for conducting syndromic surveillance. Many organizations operate multiple syndromic surveillance systems simultaneously, allowing access to multiple sources of data that help them identify and respond to emergencies.

- For example, one county public health department we visited used a "dashboard" that employs BioSense, ESSENCE, and RODS to conduct syndromic surveillance.

Of the ten organizations and hospitals we contacted—five local public health departments, three state health departments, and two hospitals—eight reported that they use data provided by the BioSense system.

All but one of the eight state and local public health departments and hospitals that use the BioSense system reported that they also use other electronic syndromic surveillance systems. The following table identifies these users and the systems.

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Results
Usefulness of BioSense

Organization	BioSense	ESSENCE [a]	RODS	State-developed system	Locally-developed system	Manual analysis
Local public health departments						
Maricopa County, AZ	X		X		X	
Gwinnett County, GA	X			X		
Tarrant County, TX	X	X	X			
El Paso, TX	X		X			
State public health organizations						
Arizona	X		X	X		X
Georgia	X			X		
North Carolina	X			X		
Hospitals						
Tenet Healthcare, El Paso, TX	X					X
Total	**8**	**1**	**4**	**4**	**1**	**2**

Source: GAO analysis based on data provided by state and local public health organizations and hospitals.

[a] The civilian version of ESSENCE is used by state and local health departments.

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Accountability * Integrity * Reliability

Results
Usefulness of BioSense

The users we interviewed at the public health departments and hospitals expressed mixed views about the usefulness of the data provided by the BioSense system.

- Seven of the eight users we interviewed stated that they use the data for situational awareness and that the system was useful for this activity. Although some users stated that they use BioSense for early event detection, they found that the system was only somewhat useful for this activity because it does not provide sufficient health-related data for event detection within their jurisdiction.
- Six of the eight BioSense users we interviewed stated that they use the data either weekly or daily. Three of these users stated that the BioSense system is their most important electronic syndromic surveillance tool; two of these users stated that BioSense is the only tool that they use for syndromic surveillance.[12]
- Three of the seven users who also use other electronic syndromic surveillance systems stated that the BioSense system is less important to their overall syndromic surveillance efforts because the other systems they use better enable them to evaluate and view data based on specific needs of their jurisdictions.

[12]One of the two users stated that, although other tools were used at the facility, they were not used specifically for syndromic surveillance.

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Results
Usefulness of BioSense

The users we interviewed stated that deficiencies in the data provided by the BioSense system limited their ability to use the data to conduct syndromic surveillance in their jurisdictions:

- Limited data about health within jurisdictions—Seven of the users we interviewed indicated that the BioSense system would be more effective if its analysis included data from more hospitals in the jurisdiction. For example, one local health department stated that the BioSense system analyzes and provides its users with data for only seven of the 27 hospitals within its jurisdiction.
- Limited flexibility to query data on multiple symptoms—Three of the users we interviewed explained that the BioSense system does not provide the ability to query and report on multiple symptoms or to tailor the system to detect emerging threats specific to their jurisdictions. Users stated that this type of system flexibility—which is available in other systems such as ESSENCE and RODS—enables public health officials to more accurately identify health conditions that have more than one symptom, such as influenza, and to detect and monitor new illnesses as they appear within their own jurisdictions.

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Results
Usefulness of BioSense

- Inability to access patient-level data—Five users we interviewed cited the inability to access patient-level data as a significant limitation of the BioSense system. According to these users, the BioSense system does not provide these data, while other systems, such as ESSENCE, can be enabled to allow access to data about specific patients. Without this ability, local health officials may be limited in their ability to quickly identify an infected patient in their local areas.[13]

While these users expressed mixed views about the usefulness of the data provided by the BioSense system and stated that the system does not yet fully address their needs, when asked if BioSense helped them to better respond to emergencies, six of them stated that the data provided by the BioSense system was useful for this purpose. According to four of these users, the system provides an additional data resource for confirming data provided by the other syndromic surveillance systems that they use.

[13]In their comments on a draft of this briefing, BioSense program officials stated that individual patient-level data are available from application-level views provided by the BioSense system.

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Results
Usefulness of BioSense

Of four additional local public health officials with whom we spoke at a meeting arranged by the National Association of County and City Health Officials, three stated that their organizations use the BioSense system on a very limited basis because their locally-developed systems provide access to more, better, or more detailed data, and allow more flexibility in using the data. The one other organization does not use any electronic system for syndromic surveillance, but instead relies on manual data analysis because the hospitals within its jurisdiction do not provide electronic data to be processed by any electronic surveillance system.

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Results
Usefulness of BioSense

Additionally, the public health experts from the two associations with whom we spoke offered differing views on the usefulness of the BioSense system and other similar electronic syndromic surveillance systems.

- The Council for State and Territorial Epidemiologists official with whom we spoke stated that surveillance for disease and outbreak detection has been accomplished primarily by astute clinicians and physicians within a jurisdiction, and that communication support is more important for detecting outbreaks across jurisdictions than syndromic surveillance systems. Some capabilities developed through the BioSense program, such as the data-viewing tools and the collection of real-time hospital data, have been very useful, and the BioSense system has been shown to be helpful in monitoring cases of disease outbreaks, such as influenza.

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Results
Usefulness of BioSense

- On the other hand, the Association for State and Territorial Health Officials representatives with whom we spoke believe that establishing a national syndromic surveillance system is essential and there is no question about the need to have such a system. They pointed out that a national system such as BioSense should be made up of multiple systems instead of a single system, build on existing local and state capabilities, and include local and state health officials as integral partners in its design. While these officials had concerns with the initial design of BioSense, they stated that they are pleased with CDC's new plans.

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Results
Usefulness of BioSense

In October 2006, CDC funded four institutions to conduct evaluations of syndromic surveillance systems. The results of the studies are intended to be used together to evaluate the usefulness of the BioSense system at the federal, state, and local levels of public health for supporting early event and situational awareness activities.

Preliminary results for one of the studies were published in 2007.[14] Initial case studies for this evaluation focused on a large salmonella outbreak and a tornado in Georgia, the 2006-2007 influenza season, and a wildfire in south Georgia and north Florida. The study is to be completed in November 2008. The preliminary results of the evaluation reiterated the views of the users we contacted and found that:

- Among the four events, the utility of syndromic surveillance was greatest for monitoring the influenza season.
- In most instances, BioSense was not used because of the lack of local real-time hospital data from local hospitals and the inflexibility of the system.

[14]James W. Buehler, M.D., Alexander P. Isakov, M.D, M.P.H., Michael J. Prietula, Ph.D.,Donna J. Smith, M.A., Ellen A. Whitney, M.P.H., *Preliminary Findings from the BioSense Evaluation Project* (Rollins School of Public Health, School of Medicine, and Goizueta Business School, Emory University, Atlanta, Ga.; 2007).

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Results
Usefulness of BioSense

- Syndromic surveillance systems used first were those that were developed locally to support state and local public health and health care practices and relationships.

In addition to BioSense system users, officials at BioSense facilities who do not use the system offered several explanations for not doing so.

- An official we spoke with at one hospital said that they had never used the system because they use the state's system; they stated that they rely on relationships with state and local public health departments for conducting surveillance and use the state-level system, which was designed to meet specific needs of their jurisdiction.
- Officials at one local health department stated that they had accessed the BioSense system only once during the past year. The department uses ESSENCE, RODS, and manual analysis to conduct syndromic surveillance. These officials stated that they do not use BioSense because the system lacks adequate data for their jurisdiction and because BioSense does not provide the flexibility available in ESSENCE and RODS, such as allowing users to perform multiple queries on the data or to customize views of the data analyzed by the systems.

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Results
Usefulness of BioSense

State and local public health and hospital officials we interviewed identified lessons they had learned from their experiences in developing, implementing, and sustaining syndromic surveillance systems to ensure the systems are useful. They reported learning that:

- Systems should be developed incrementally. Officials with experience in developing or implementing state and local systems emphasized that systems should be developed incrementally based on users' needs and lessons learned from each increment.
- Systems must be sustainable at the local level. Initiatives to develop and implement systems must build in support for IT infrastructure, installation and maintenance, and staff training.
- Stakeholder communication and involvement in determining requirements is critical. The development and implementation of syndromic surveillance systems must involve frequent, effective communications with stakeholders while defining, documenting, and sharing project requirements.

These experiences provide valuable lessons that BioSense program officials could apply to their approach for reengineering the system to help ensure that the data provided by the system are useful for BioSense stakeholders.

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Accountability * Integrity * Reliability

Results
BioSense Plans: Cost Estimates

OMB has made developing accurate life-cycle cost estimates a priority for agencies in properly managing their portfolios of capital assets, including information technology, that have an estimated life of two years or more.[15] In addition, the draft *Cost Assessment Guide*, which we developed based on best practices, defines characteristics of reliable cost estimates for federal agencies' information technology programs.[16] The guide describes reliable cost estimates as those that are well-documented, comprehensive and accurate, and credible.

- Well-documented cost estimates are those that include source data and their significance, clearly detailed calculations and results, and explanations of why particular methods and references were chosen. The data used to estimate the costs can be traced to their source documents.
- Comprehensive and accurate cost estimates have enough detail to ensure that cost elements are neither omitted nor double counted, and all cost-influencing assumptions are detailed in the estimates' documentation.

[15]OMB Circular A-11, Part 7.
[16]GAO-07-1134SP.

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Results
BioSense Plans: Cost Estimates

- Cost estimates are credible when limitations of the analysis are discussed, assumptions made about the costs are varied, and outcomes are recomputed to determine how sensitive they are to changes in the assumptions. Risk analyses are also performed to determine the level of risk associated with the estimate. The estimate's results are cross-checked, and an independent cost estimate is developed to determine whether other estimating methods produce similar results.

By addressing these characteristics, program officials should be better able to define reliable cost estimates that are comprehensive and accurate and that can be easily and clearly traced, replicated, and updated. Additionally, program officials should reliably estimate costs before proceeding too far into development or production to reduce the risk that the program will not be able to meet its established cost targets.

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Results
BioSense Plans: Cost Estimates

CDC identified cost estimates for the initial BioSense in its fiscal year 2009 business case that was submitted to OMB in September 2007.[17] Program officials estimated the total cost for the program through 2013 to be $369 million. However, these estimates did not reflect the cost of implementing the redesigned program and its related system.

[17]OMB requires agencies to submit business cases through OMB Exhibit 300's for major information technology programs to establish cost, schedule, and measurable performance goals.

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Results
BioSense Plans: Cost Estimates

In May 2008, CDC included in its plans for the redesigned program cost estimates for completing the strategic activities that are intended to provide an operational program by 2012.[18] Program officials report the total estimated cost of implementing the redesigned program from 2009 through 2012 to be about $314 million. The estimates cover costs of completing each of the strategic activities, such as federating existing data sources, developing case detection methodologies, and supporting research and development for real time surveillance. According to program officials, the estimates also cover the costs of existing BioSense operations including the program office's staff, travel, transportation, and contractor support.

[18]According to program officials, CDC's cost estimates reflect the agency's plan to complete the development and implementation of the redesigned BioSense program and its related system by 2012 rather than 2013, as its previous plans reflected.

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Results
BioSense Plans: Cost Estimates

CDC's cost estimates for implementing the redesigned BioSense program are only partially documented. Specifically, the documentation for the estimates consisted only of explanations of the methods and references chosen to compute the estimates. According to an official with CDC's Financial Management Office, the initial cost estimates for the redesigned BioSense program were developed based on program officials' professional judgment.[19] As professional judgment estimates, the official did not believe that the agency was required to develop or maintain supporting documentation.

[19]CDC defines its professional judgment estimates as informal estimates provided to Congress. According to CDC officials, the agency provides professional judgment estimates without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed.

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Results
BioSense Plans: Cost Estimates

Additionally, the cost estimates for BioSense are not comprehensive and accurate because the estimates were developed without considering all cost elements. According to program officials, the estimates do not include the cost of technology required to support new methods for measuring performance of the system, such as tools for simulating emergency response scenarios to estimate the impact that use of the BioSense system has on the time required to respond to health threats.

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Results
BioSense Plans: Cost Estimates

Finally, the cost estimates do not meet the criteria for credibility as defined in our cost estimation guide. The BioSense cost estimators did not vary major assumptions to determine whether and to what extent outcomes are sensitive to changes in the assumptions. Program officials did not conduct risk and uncertainty analyses to determine the level of risk and the extent to which the actual costs may vary from the initial estimates. Additionally, the cost estimates for BioSense have not been independently reviewed and verified to determine if other estimating methods would produce similar results.

Program officials stated that the cost estimation activities were conducted in the early planning phases of the redesigned program and that they intend to refine cost estimates for a more accurate reflection of the cost to fully implement the BioSense program and its related system as the program requirements are defined in more detail.[20] Until program officials develop well-documented, comprehensive and accurate, and credible cost data, CDC will not be able to reliably estimate the cost of fully implementing BioSense.

[20]BioSense program officials stated that they intend to use the refined estimates for the preparation of future congressional budget submissions.

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Results
BioSense Plans: Timeline Estimates

Our draft Cost Assessment Guide identifies best practices for estimating project timelines and schedules, which include

- defining, sequencing, and estimating the duration for each activity;
- assigning resources (e.g., labor, material, and overhead) to all activities;
- identifying the critical path for all activities;
- identifying float time—the amount of time a task can slip before affecting the critical path—between activities; and
- conducting a schedule risk analysis using statistical methods to determine the amount of time to reserve for contingencies.

By following these practices, program officials should be better able to define reliable timeline estimates that can be used to identify when problems or changes may occur and the impact they may have on the success of the program. Further, according to OMB guidance,[21] reliable timeline estimates should be defined before program officials proceed too far into development or production to reduce the risk that the program will not be able to meet its time frames and to reduce the risk of undesirable outcomes.

[21] Executive Office of the President, Office of Management and Budget, *Memorandum on Conducting Acquisition Assessments with Guidelines for Assessing the Acquisition Function* (Washington, D.C.: May 21, 2008).

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Results
BioSense Plans: Timeline Estimates

CDC's fiscal year 2009 OMB business case for the initial BioSense program identified annual and long-term timelines and milestones for meeting program goals through fiscal year 2013. CDC also reported the goals and the status of the program's efforts to meet the goals for fiscal years 2006 and 2007. For example, the business case identified a milestone to support research related to BioSense algorithms, bioterrorism, and pandemic flu in 2006 and reported that the program had met that milestone.

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Results
BioSense Plans: Timeline Estimates

In its draft plan for the redesigned program, CDC defined the timelines for completing the program's strategic activities and goals within a four-year time frame, as shown in the following table.[22] According to BioSense program officials, these timelines were defined based on experiences and knowledge gained from implementing prior and ongoing pilot projects.[23]

Strategic goals	Strategic activities	Timeline
Sponsor regional collaboration and health information exchanges	Expand state and local partnerships with the CDC and develop regional collaboratives for real time surveillance	2008 - 2010
	Support linkages between public health and health information exchanges for real time surveillance	2009 - 2012
Pursue open collaborative development	Pursue open source collaborative development	2009 - 2012
Transition to a federated data model	Federate existing state and local real time surveillance data sources	2009 - 2010
Expand case detection technology	Refine and deploy BioSense case detection technologies	2009 - 2012
	Enhance incentives for clinical providers to transmit data to public health	2009 - 2011

Source: CDC's National Center for Public Health Informatics

[22]According to program officials, CDC's timeline estimates were developed to support completion of the development and implementation of the redesigned BioSense program and its related system by 2012 rather than 2013, as its previous plans reflected.

[23] CDC officials described an additional activity, support for research to develop innovative and promising technologies for real time surveillance, as a cross-cutting activity that supports each goal from 2009 through 2012.

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Results
BioSense Plans: Timeline Estimates

While program officials have defined timelines for the program's strategic-level activities, they have not completed the detailed plans needed to estimate reliable timelines for implementing the redesigned program.

- While the strategic activities were defined and sequenced, resources have not yet been assigned to the activities, a critical path for the program's schedule has not been identified, float time between activities has not been determined, and a schedule risk analysis has not been performed to plan for contingencies.

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Results
BioSense Plans: Timeline Estimates

BioSense program officials stated that the program is still in the early stages of its redesign and that they have recently begun to develop tactical-level plans that include the detailed information needed to define more specific timelines for completing the program's strategic activities. In this regard, they drafted a document that reflects timelines for completing specific activities in fiscal years 2008 and 2009 and stated that they intend to finalize a detailed tactical plan for the program by September 30, 2008.

Until the program completes detailed plans that define the steps and resources needed to accomplish the plan's strategic activities, identify the schedule's critical path, and perform a schedule risk analysis, CDC will not be positioned to provide reliable timeline estimates that can be used to identify when problems or changes may occur and the impact they may have on CDC's plans to fully implement BioSense by 2012.

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Results
BioSense Plans: Performance Measures

OMB directs agencies to define and select meaningful annual and long-term outcome-based performance metrics that measure the intended result of carrying out a program or activity.[24] Additionally, industry experts describe the need for performance measures to be developed with stakeholders' input early in a project's planning process to provide a central management and planning tool and to monitor the performance of the project against plans and stakeholders' needs.[25] According to the Software Engineering Institute, performance measures are effective mechanisms for providing credible evidence of a program's progress.[26]

[24]OMB, *Guide to the Performance Assessment Rating Tool.*

[25] Thomas Wettstein and Peter Kueng, "A Maturity Model for Performance Measurement Systems," and Karen J. Richter, Ph.D., Institute for Defense Analyses, *CMMI® for Acquisition (CMMI-ACQ) Primer, Version 1.2*.

[26] GAO, *Veterans Benefits Administration: Progress Made in Long-Term Effort to Replace Benefits Payment System, but Challenges Persist*, GAO-07-614 (Washington, D.C.: April 2007).

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Results
BioSense Plans: Performance Measures

In the fiscal year 2009 business case for BioSense, program officials identified performance measures for the initial implementation of the program and reported the status of the program in meeting benchmarks for 2006 and 2007. For example, a decrease in the time required to update BioSense after receipt of data from data providers was identified as a performance measure with a benchmark to reduce the time from an average of 2.81 hours in 2006 to no more than 2 hours in 2007. However, the performance measures defined in the business case were not focused on intended results of the redesigned program.

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Results
BioSense Plans: Performance Measures

CDC's draft plan for the redesigned BioSense program describes a need to develop outcome-based performance measures that focus the success of the program on federal, state, and local partners' use of the BioSense system. They stated that new performance measures for the redesigned system are to be included in the program's plan by the end of calendar year 2009.[27] However, it is important to complete the development of performance measures early in the planning phase of the program to provide an essential planning tool that can be utilized throughout all phases of the development and implementation of BioSense.

Unless BioSense program officials develop outcome-based performance measures based on stakeholder input during the planning phase of the program, they will lack an effective management and planning tool needed to monitor the performance of the program against plans and stakeholders' needs throughout all phases of the program.

[27]In commenting on a draft of this briefing, BioSense program officials stated they intend for federal, state, and local partners to be engaged in the development of outcome-based performance measures early in the detailed planning process, beginning in November 2008.

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Conclusions

The costs and benefits of using data from the current implementation of the BioSense system and other similar systems are difficult to measure and compare, and state and local public health and hospital officials with whom we spoke do not document or track costs and benefits of using these systems. Additionally, these officials expressed mixed views on the usefulness of BioSense data as compared to the usefulness of data from other systems.

BioSense program officials have developed initial high-level cost and timeline estimates for completing the implementation of a redesigned BioSense program and related system that are intended to address weaknesses of the initial implementation of the program and improve the usefulness of the system for CDC's stakeholders. However, program officials have not yet reliably estimated costs and timelines for fully implementing the redesigned BioSense and for managing the development and implementation of the program. Additionally, program officials do not expect to complete the development of performance measures before the end of calendar year 2009, which increases the risk that they will not be able to effectively monitor the performance of the program against plans and stakeholders' needs throughout all phases of development and implementation.

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Conclusions

Until BioSense officials develop reliable cost and timeline estimates and outcome-based performance measures, CDC's plans for the redesigned program and its related system will lack key components needed to effectively manage the program throughout all phases of the program. Further, the agency will lack management and planning tools needed to effectively gauge the success of the BioSense system's performance toward improving federal, state, and local partners' abilities to respond to public health events. Moreover, the agency remains at risk that it will perpetuate weaknesses identified in the agency's initial implementation of the program and related system and will continue to spend money on a program that does not provide intended results or meet stakeholders' needs.

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Recommendations for Executive Action

To ensure that CDC defines reliable plans for effectively managing the development and implementation of the redesigned BioSense program and its related system throughout all phases of the program, we are recommending that the Director of the Centers for Disease Control and Prevention instruct the Director of the National Center for Public Health Informatics to take the following three actions while in the planning phase of the program:

- develop reliable cost estimates for fully implementing the program that are well-documented, comprehensive and accurate, and credible;
- develop reliable timeline estimates for implementing the program; and
- with stakeholder input, develop outcome-based performance measures that address all phases of the program and that focus the success of the program on CDC's federal, state, and local partners' use of the system for responding to public health events.

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Agency Comments and Our Evaluation

We received oral comments on a draft of this briefing from CDC's BioSense program officials, including the Director of the National Center for Public Health Informatics. The officials generally agreed with the information included in our draft briefing and provided additional information and technical comments related to the program, which we have incorporated as appropriate.

BioSense program officials acknowledged areas of deficiencies in the initial design of the BioSense system and stated that the current managers of the program, with extensive user engagement through BioSense roundtable meetings, had identified the shortcomings detailed in our briefing. They stated that they are consequently taking steps to reconfigure the system and to address these problems, as outlined in the draft BioSense Strategic Plan and as described in this briefing.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 10 2008

Valerie C. Melvin
Director, Human Capital and Management Information Systems
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Melvin:

Enclosed are the Departments comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Health Information Technology: More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program" (GAO 09-100).

The Department appreciates the opportunity to comment on this report before its publication.

Sincerely,

Jennifer R. Lucas
for Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HEALTH INFORMATION TECHNOLOGY: MORE DETAILED PLANS NEEDED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S REDESIGNED BIOSENSE PROGRAM (GAO-09-100)

The Centers for Disease Control and Prevention (CDC) wishes to thank the Government Accountability Office (GAO) for the opportunity to review and comment on this Draft Report. We appreciate the effort and professionalism that went into the thorough evaluation of the BioSense program and welcome the recommendations and conclusions therein. In this regard we respectively submit the following general comments.

In the Report's opening page, under "What GAO found" the authors note that *"...cost estimates for the redesigned program are not reliable because they are only partially documented, are not comprehensive and accurate, and therefore are not credible"*, and *"... the agency has not implemented these practices, resulting in timelines for the redesigned program that are not reliable."*

A planning and implementation process has been launched to ensure that the BioSense program develops reliable cost estimates and timelines, and identifies appropriate outcome-based performance measures. This process follows a phased approach that focuses on work products being vetted through internal and external stakeholders to ensure maximum input and impact to public health.

This first phase of this process focused on identifying the steps necessary to implement the strategic objectives outlined in the redesigned BioSense strategic plan. The program initiated a series of working groups integrating stakeholders from the Association of State and Territorial Health Officials, National Association of County and City Health Officials, Council of State and Territorial Epidemiologists, and Association of Public Health Laboratories, as well as those internal to CDC. Each working group had representation by one or more of the partner organizations. The main deliverables were a series of work breakdown structures[1] for each strategic objective.

The second phase focused on synthesizing these work breakdown structures and refining the steps identified by the working groups to develop a tactical roadmap and define associated performance outcomes. The draft tactical plan and comprehensive breakdown structure deliverables are currently under review by CDC's National Center for Public Health Informatics (NCPHI) leadership to be delivered to working group members on 11/14/08.

To determine comprehensive and accurate cost estimates and performance outcome measures, the BioSense program is preparing to implement two complementary efforts: Program Planning and Performance Measurement. The program planning effort expands the focus areas identified in the tactical plan into projects, detailed tasks, deliverables, and resources required. Cost estimates will be developed to implement these tasks, and activities will be prioritized accordingly. This activity is targeted for completion on 12/30/08. Once finalized, the program plan will include all projects and their related tasks and costs. The program plan is scheduled for completion in February 2009.

[1] A **work breakdown structure** or *WBS* is a tree structure that permits summing of subordinate costs for tasks, materials, etc., into their successively higher level "parent" tasks, materials, etc. It is a fundamental tool commonly used in project management and systems engineering.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HEALTH INFORMATION TECHNOLOGY: MORE DETAILED PLANS NEEDED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S REDESIGNED BIOSENSE PROGRAM (GAO-09-100)

The program plan will be managed to ensure reliable, timely and accurate activity and cost forecasting.

A performance measurement working group will engage stakeholders, state and local representatives and subject matter experts such as members of ASTHO, NACCHO, CSTE, APHL and the NCPHI Board of Scientific Counselors to:

- Review and adjust the proposed performance outcomes
- Identify baseline and target performance measures
- Develop a tracking and reporting process

CDC has preliminarily identified 24 milestones with accompanying target completion dates. Of these 24 milestones, six have been completed, four are in progress and fourteen are planned with estimated completion dates ranging from two weeks to 12 months.

With regards to the statement made several times that BioSense is seen by many state personnel as not as useful as the state systems (ESSENCE, RODS, etc), it is important to note that BioSense is not intended to replace local systems. Rather, BioSense adds value to local systems by 1) aggregating data from local systems for regional or national view, 2) making national datasets available, 3) making software tools available, and 4) funding regional collaboratives, health information exchanges (HIEs) and research to improve the field overall.[2]

In closing, CDC appreciates GAO's review and recommendations. CDC is committed to continuing and enhancing its efforts to develop reliable cost and timeline estimates and engaging stakeholders in developing outcome-based performance measures for the redesigned BioSense program.

[2] With regards to progress on establishing regional collaboratives, grants have been awarded to four sites: National Capital Region, Missouri -Kansas, Pennsylvania-Ohio, Southeast Region (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee). In addition, three funded HIEs have already begun work: Indiana, New York, Eastern Washington/Western Idaho

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Valerie C. Melvin, (202) 512-6304 or melvinv@gao.gov

Staff Acknowledgments

In addition to the contact named above, key contributions to this report were made by Teresa Tucker (Assistant Director), Heather A. Collins, Neil J. Doherty, Amanda C. Gill, Nancy E. Glover, Franklin D. Jackson, Mohammad S. Khan, and Lee A. McCracken.

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