

BioSense: Using Clinical Data for Early Event Detection and Situational Awareness
Lynn Steele, MS, CIC
Senior Advisor
Coordinating Office of Terrorism Preparedness and Emergency Response (COTPER)
September 7, 2005

Overview

Traditional public health surveillance and investigations often involve manual reporting of cases to public health agencies and phone calls to healthcare providers for more detailed information. The timeliness, completeness, and breadth of coverage of these manual processes can be problematic especially during a public health emergency. With increasing amounts of healthcare and health-related data in electronic form and a national focus on the value of exchanging health data electronically, there are now opportunities to use existing electronic data to better support public health functions.

BioSense is a national program to advance this new type of biosurveillance at the national, state, and local levels. Using streams of health data and advanced algorithms for analyzing and visualizing these data streams, the new methods supported by BioSense address the needs of monitoring for infectious diseases, for biological and chemical attacks, and for naturally occurring emergencies. BioSense supports the situational awareness necessary to confirm and identify possible events, to track and manage their size and spread, and to provide public health and government decision makers the information needed to manage preparedness and response.

CDC's has four Over-arching health protection goals—

Healthy People in Every Stage of Life.

Ensuring people have the best quality of health in every stage of life.

Healthy People in Healthy Places.

Focusing on healthy places where people live work and play being protected and promoted.

People Prepared for Emerging Health Threats.

Protecting communities from infectious, occupational, environmental, and terrorist threats.

Healthy People in a Healthy World.

Ensuring that CDC understands and has a strategic approach to how we contribute to healthy people in a healthy world.

This BioSense initiative most closely aligns with the overarching **preparedness goal**. Of the nine specific, defined preparedness goals, BioSense clearly supports four of them (as indicated below):

Pre -Event	Event	Post-Event
<p><i>Prevent</i></p> <p>1. Increase the use and development of interventions known to prevent human illness from chemical, biological, radiological agents, and naturally occurring health threats.</p> <p><i>Detect</i></p> <p>2. Decrease the time needed to classify health events as terrorism or naturally occurring in partnership with other agencies.</p> <p>3. Decrease the time needed to detect and report chemical, biological, radiological agents in tissue, food or environmental samples that cause threats to the public's health.</p> <p>4. Improve the timeliness and accuracy of communications regarding threats to the public's health.</p>	<p><i>Investigate</i></p> <p>5. Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.</p> <p><i>Control</i></p> <p>6. Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.</p>	<p><i>Recover</i></p> <p>7. Decrease the time needed to restore health services and environmental safety to pre-event levels.</p> <p>7. Improve the long-term follow-up provided to those affected by threats to the public's health.</p> <p><i>Improve</i></p> <p>8. Decrease the time needed to implement recommendations from after-action reports following threats to the public's health.</p>

BioSense - part of public health response.

Just as there are many organizations and information systems involved in health care, there are many organizations and systems that are critical for biosurveillance and public health. The Public Health Information Network (PHIN) is CDC's architecture for advancing fully capable and interoperable information systems in the many organizations that participate in public health and ensuring that these systems connect to broader national health IT activities. PHIN is a national, multi-organizational business and technical architecture for public health information systems. At the core of PHIN are accepted health data and technical standards including HL7, SNOMED, and LOINC.

BioSense is a component of the PHIN architecture that advances the nation's capabilities for biosurveillance as well as connecting and coordinating biosurveillance systems at the local, state, and national levels. BioSense, as part of PHIN, is immediately advancing biosurveillance capabilities, while also using PHIN standards and architecture to advance interoperable biosurveillance systems and health information technology nationally.

Vision and Approach

The vision for BioSense is to provide situational awareness – before, during and after a health event, to help confirm or refute the existence of that event, to characterize the size, location, rate of spread of a health event. BioSense will enable the ability to examine streaming health data in real-time as situations arise in order to understand best what is occurring. Its is intended to provide more than most initial event detection or syndromic surveillance systems, with a focus on clinical diagnostic data and real-time utilization information.

The approach will enable emergency room and acute care data from hospitals to transmit to BioSense in real-time. Electronic views or screens of data, analytics and reports will be made available for public health, at national, state and local levels as well as to the hospitals submitting those data.

Current BioSense Capabilities

Since 2003, CDC has a BioSense program that is receiving data from certain healthcare data sources, but not in real-time. Currently, CDC provide analytics and geographical displays of data that help assist in early event detection through translating ICD-9 codes into syndromes that are then put through algorithms to look for data anomalies. Six data monitors review these data on a daily basis. Ambulatory care diagnostic and procedure data are received from the Department of Defense and the Veterans Affairs ambulatory care facilities, including emergency rooms. Again, these data are not currently received in real-time. BioSense also receives clinical laboratory test order data from one of the largest clinical lab service providers in the country, and results from environmental filters processed through the national Laboratory Response Network. CDC is also in final stages of discussions to receive other national health data sources such as the Poison Control Center.

New BioSense Priority: Real-Time Clinical Connections

In 2005, one or more sentinel hospitals from at least ten major metropolitan cities will be transmitting data to CDC's BioSense program. In 2006, at least one hospital in each additional major metropolitan area will be targeted for the BioSense program. Over time, participation of hospitals throughout the country is anticipated to become more widespread, thus enabling more comprehensive community population-based assessments of health issues occurring in real-time.

Hospitals recruited for phase one implementation (the first ten) will be prioritized by the following:

- Hospitals in large metropolitan areas;
- Hospitals with a high volume emergency department for that region;
- Health systems with multiple hospitals in multiple target cities.
- Hospitals with existing advance IT infrastructure and minimally an electronic ED system; and
- Hospitals with existing data reporting relationships with CDC.

Implementation concepts

BioSense implementation efforts should be coordinated with state and local public health to augment existing early event detection systems, and advance ability to provide situational awareness and outbreak characterization, in real-time. BioSense will use existing clinical diagnostic and health information and does

not require any kind of data entry or any changes in clinical care by clinicians. Industry accepted standards will be used in the coding and transmission of data so that the effort is consistent with those of Dr. David Brailer in the HHS Office of the Chief Health Information Technology, and will support efforts toward electronic health records. BioSense will require and fund hospitals to transmit data using HL7, SNOMED, LOINC, and other standard codes. Funding is available for hospitals or healthcare systems to address the costs to have their data put into standard frameworks for transmission.

Hospital or healthcare system data will flow to CDC and be made available through the BioSense application to registered users at state and local public health as well as the hospital and healthcare system. As soon as CDC is able to visualize the data, so will the local community through the BioSense system or application, which will not be a distributed application, but will be maintained as a Web-based application and accessed through a secure data network. State and local public health will have access to information coming from hospitals or patients within their jurisdiction. The data feed from the hospital can also be split to provide data to CDC and local public health simultaneously. State or local public health agencies who select to receive data must have a mechanism to manage, store, and analyze those data. CDC will be providing the analytics, screens and the views of the data through the BioSense system.

Clinical Data of Interest

Data of interest include hospital utilization information, clinical diagnostic data, chief complaint, symptoms, vital signs, discharge disposition from the emergency department, and certain diagnostic and laboratory test orders and results. Patient names or medical record numbers will not be collected. An encounter link for each emergency department visit will be generated, and will enable longitudinal information for admissions to the hospital.

Value of BioSense

Simultaneous access of health data by all levels of public health will help decrease delays in recognition of a problem and help identify resources and where those resources should be distributed. Neighboring jurisdictions will have more information for their use by being able to understand both where patients are presenting for care and where they reside. A national system translates to having data available in a way that combines both national and local resources.

For jurisdictions that currently don't have a way to look at early event detection, the BioSense system in the future can become an out-of-the-box system where hospitals become participants in order to provide broader population-based community view. Regardless of local public health's current efforts in systems, BioSense can augment local health surveillance efforts. Many local public health jurisdictions have not yet started to connect with hospital data or may have just begun discussions with area hospitals; BioSense can be the platform for some of those discussions. In other cases, local public health may be supporting a regional health information organization (RHIO) or some kind of data exchange or cooperative, and may be able to provide an advocacy for obtaining data for this BioSense initiative.

The value to the hospitals and healthcare systems is being able to contribute already existing data to provide a window on community health for public health purposes. It can help reduce information that currently and traditionally has been relayed via phone calls between hospitals and local public health. Participating hospitals will have access to analytics and surveillance reports available to them on their data through CDC's BioSense system.

The funding available can assist a hospital by providing people, processes or whatever technical activities are needed to enable standards-based interfaces and data extraction. These efforts can contribute to supporting the interoperability of local healthcare and public health information, and begin to advance the development of electronic health record activities in each of the regions.

Legal Authorities

As part of the public health code Title 42, it states the secretary of HHS shall provide for the establishment of an integrated system for public health alerting, communications and surveillance networks, which is to include not just federal, state and local public health officials, but public and private health related laboratories, hospitals and other healthcare facilities.

Under the Health Insurance Portability and Accountability Act (HIPAA), hospitals may disclose protected health information to public health authorities who are authorized to collect or receive such information for the purpose of surveillance, investigations and public health interventions. Even though CDC and public health are authorized to receive private health information according to the interpretations of HIPAA, CDC will not be receiving named data.

Funding

Funding is available to compensate hospitals for costs associated with data transmission. Examples include costs needed to help hospitals develop standard interfaces, such as HL7, where those currently don't exist; all manners of formatting, mapping and coding; any necessary hardware or software components that would be needed for data transmission, and internal IT support costs.

Clinician Partnering

What can the clinical partner organizations can do to help this initiative? CDC wants the support of the clinical community. Hospitals wishing to volunteer for participation in BioSense may contact BioSenseHelp@cdc.gov.

Questions and Answers

Are there any current North Carolina hospitals who already submit data through BioSense?

Again, only VA and DOD facilities are currently submitting data, and there are VA and DoD facilities in North Carolina. In regard to the new BioSense initiative to get real-time clinical data from hospital emergency departments, there are no hospitals submitting data yet. CDC is just beginning to meet with hospitals, and work with state and local public health so they are aware that CDC is talking to hospitals within their jurisdictions. CDC has initiated discussions with some health systems that cross multiple state lines. There are no cities in North Carolina that are currently on the targeted list for phase I of the BioSense clinical data initiative.

For the past couple of years through the CDC emergency preparedness grants and also through the HRSA hospital preparedness grants, many states and some cities far more progressive than in South Carolina have looked at early event detection, syndromic surveillance, chief complaints, ICD-9, the litany of early event detection methodologies; many of these states have progressed a long way with some of these federal funded initiatives. How do you see this as either augmenting, taking the place of, beginning work that many states and cities have already begun and have already developed partnerships with those hospitals in providing that real-time on a very local level with regards to either astute clinicians knowing how best to call and not waiting for a statistical algorithm, but maybe several hours, on a good side, to maybe 24 hours on a bad side, to let them know about something that's already occurring within their facility?

There has been a lot of focus locally on having some kind of system for initial event detection. Funding for these programs has not derived just from CDC and HRSA initiatives, but also from the Department of Homeland Security. Most systems focus on analysis of emergency department chief complaint data. There are limitations to the data in that it is not specific, especially if there is a surge of people with similar symptoms presenting to emergency departments. Diagnostic data from a clinician who has examined the patient, ordered diagnostic or lab tests on a patient, and other clinical data should provide more valuable information to inform suspicion of illness.

In this first phase, CDC will be working to develop and show value to this system for enabling "health situational awareness." The data will not just be used to attempt initial event detection or syndromic surveillance. The question is "how can public health benefit from existing health data streams to answer questions as an event is happening?" It's a different concept. I agree with you. I think the astute clinician is the one who helps us identify when we have cases of illness or disease; there has been some demonstrated usefulness of these types of approaches for initial detection, but that's not what this new BioSense system is targeting.

Health situational awareness has different use cases. For example, if a city environmental monitor detects the presence of a biological agent associated with a possible terrorist attack, can health data confirm the presence of illness rapidly? If pandemic influenza occurs in the US, the BioSense system can assist in monitoring disease occurrence and track transmission of a large widespread outbreak in order to help make decisions about directing resources. From the emergency events of the last four years, such as SARS and even the anthrax events of 2001, when we know something has occurred, there is an immediate need for more health information. What else can we know about what we're seeing? If we have inhalational anthrax cases seen in New York, we would be asking if we're seeing cases in Boston or Miami or Washington D. C. or elsewhere.

Beginning with a sentinel hospital approach to provide a window on the community from just a single hospital in multiple cities is a way to start. We don't believe at this time BioSense should replace any of the population-based systems that communities have developed, but can augment existing health information. Again, BioSense will be developed to provide a picture nationally of what is occurring in multiple jurisdictions and will progress toward a more comprehensive approach and more hospital participation. By utilizing already existing clinical data, CDC is developing a system with robust yet flexible analytic capability to be able to quickly answer public health questions when situations arise.

As a follow-up to that, I think many of the states have some of those analytical tools that are very similar to what CDC uses in many venues, whether it's EARS or the same algorithms that BioSense used to capture that information already on a local or state or jurisdictional level, so I guess I'm looking at it from the standpoint of when do those lines start blurring as far as responsibilities for initiation of activities or monitoring?

Are you asking if there's a data anomaly, whose responsibility is it to investigate?

I guess it's more of a, as you put it, the situational awareness approach has repercussions both on a local, state and federal level, and many times, as we've seen in the past couple of days, it's the local entities on a jurisdiction level who have the best feel for what their needs are in their particular communities.

Right, but being able to collate all of those local communities to provide a broader picture in real time is what BioSense can provide. I just want to be clear that I agree that public health response and how events are managed is local; but that doesn't mean that each local jurisdiction has to build the system.

We are trying to develop a system that capitalizes on existing data. We've had a number of questions about increasing burden on public health personnel, which is a bit hard for me to answer because frankly these data exist; public health does not have access now. We're trying to create a way that existing data can be made useful to public health for reasons of better understanding events occurring in real time.

I think this is a bit of a paradigm shift, but I think that it makes information more readily available to everyone who has the need to know; not to bypass state or local public health. Again, I can't stress strongly enough that the views and the ability to query that data will reside with state and local public health, so it's not that they will have to request from CDC to look at their data. CDC will make the data available to look at through the BioSense system.

This is kind of analogous, and I'll end my follow-up questions with this; this is somewhat analogous to how our routine reportable conditions flow, but in that model, the information first flows to the locals, then to the states and then to CDC. This is kind of like throwing a reverse on that process, correct?

It's making data available at the same time to all those levels of the government. Again, to be clear, notifiable disease surveillance and the way that occurs will not change. Detailed information required for each of the specific notifiable diseases and the ability to get follow-up information from clinicians is part of the reporting line, which flows from local public health to state public health to CDC. That is still needed, but we also have to recognize that reporting for some diseases is low, and we can't rely on that type of reporting to help public health understand what is going on in a real-time picture.

Would it be a continuous model of an algorithm to actually have the flow going the same way then from the local healthcare facility to the local health department state, and then to the feds?

The data can be sent to local public health at the same time it is transmitted to CDC if desired. In developing the BioSense application system, CDC will be using what has been learned over the last several years to inform systems development. Use of syndromes and other appropriate analyses for the real-time data are being examined. The real value of the real-time clinical data will most likely be realized through the ability to examine and query information when situations arise. The system has to be built with that kind of analytical flexibility. We can't build that in all of the local jurisdictions.

My question may have been partly answered, and it has to do with early detection. There are gaps due to the several day delay in the processing of the diagnostic ICD-9 information in real-time, and then there's also some data that would be really great to have from key sources like vets. These could potentially be bridged by active syndromic surveillance systems like – there's one call SYRIS that I know was developed at Sandia Labs and currently through Aries.

As I understand CDC border projects is using it in a demonstration model as well as forty-something Texas counties. Are there any plans to add this piece to get at the early detection in the first couple of days and put it into BioSense?

Over the past year, CDC has been looking at many data sources as part of BioSense. The priority we've been given from HHS is to focus on obtaining real-time clinical data from hospitals. The system may not rely on waiting for ICD-9 coded data coming from each hospital's administrative or billing coding system. What CDC is seeking emergency department systems where presumptive or differential diagnoses based on a clinician's review can be provided in real-time. That's the first priority. Additional hospital clinical data are also being considered.

The second part is as part of this broader view to look at other national healthcare data sources that might make sense as part of the overall BioSense program. I mentioned the Poison Control Center data; CDC also initiated exploration of veterinary laboratory data, pharmaceutical claims data, and other national similar data sources, but the priority CDC has been given this year is to be able to have hospital data in real time. Again, all of these may become part of BioSense, a program able to provide both real and near real-time information in order to help inform public health events.

Are you going to involve the centers for public health preparedness and any of this outreach to hospitals and health departments?

A number of the CDC-funded Centers for Public Health Preparedness are University hospitals. For those that don't know, the Centers for Public Health Preparedness represent almost 50 university programs that are funded through CDC to help provide preparedness education and training for existing public health or healthcare workers and/or students. The list of those universities with CPHPs in the cities of interest will be compiled, and at your suggestion, we will contact the acting program official, Andrea Young, to put a discussion of this BioSense initiative on an upcoming meeting agenda, and think about how the universities might be involved.

CDC is not working with an unending list of hospitals. We have a target to make sure that we have ten cities with hospital data flowing by the end of 2005. I described a bit of the prioritization. The list is narrowed down to hospitals in key jurisdictions that are the most likely candidates to work with, and that has been done primarily with discussions between CDC and local public health. We're not ready to make that list public because we haven't reached out yet to all the hospitals. There are timing issues related to outreach to and ensuring we are working with public health. If the hospitals we have targeted --- those with high emergency department volume, or advanced IT systems --- turn us down, we will need to expand our efforts.

Are you going to be putting out any RFPs or do you have contractors already working on it, specifically the outreach and the coordination with hospitals, the IT part of it, the integration part, the decision support tool part of it?

No. There are no RFPs for this work. The support will be to hospitals who agree to participate, and will be available via contract mechanisms. Funding will enable hospitals to translate their existing data to the standard format requirements needed to transmit those data to CDC.