U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

August 25, 2006

Patrick J. McConnon, MPH
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard Ste 303
Atlanta, GA 30341-4015

Dear Mr. McConnon,

Thank you for the letter and recommendations. As the Chief Medical Officer for the Department of Homeland Security (DHS), one of my primary responsibilities is to serve as Secretary Chertoff's principal medical advisor. In this regard, the Office of the Chief Medical Officer (OCMO) has been working to ensure the Department has a unified approach to medical preparedness, as well as coordinating the Department's Federal, State, Local, and Tribal government biodefense activities. I am also responsible for providing real-time incident management guidance, so I share your sentiment regarding the critical importance of timely and accurate information for public health and medical response. My colleagues at the Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC), and Environmental Protection Agency (EPA), all are dedicating significant time and resources to the very issues your Council illustrated in its July 27, 2006 letter.

DHS is dedicated to improving information-sharing partnerships to enhance homeland security. There are several on-going initiatives that will increase the Federal government's ability to collate, integrate, and disseminate information to decision makers at all levels of government. One example is our interagency effort to establish the National Biosurveillance Integration System (NBIS); designed to integrate Federal and non-governmental human, animal, plant, and environmental biosurveillance activities to provide early recognition of emergent biohazard events of potential national significance. We realize timely response will be dependent on our ability to improve information sharing and enhance situational awareness with our State, Local, and Tribal partners.

Your letter's *desired actions to be taken*, highlight a few of the very complicated, yet critically important issues that are being addressed by DHS.

Sincerely,

Jeffrey W. Runge, MD, FACEP
Chief Medical Officer
Department of Homeland Security

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

SEP 25 2006

Patrick J. McConnon, M.P.H.
Executive Director
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Dear Mr. McConnon:

Secretary Leavitt has asked me to thank you for your letter regarding the Council of State and Territorial Epidemiologist' (CSTE) position statement 05-ED-03 entitled "Coordinated state, federal, and local public health surveillance using BioSense for situational awareness." He has asked me to respond directly to you. Please excuse the delay of this response.

Enclosed are the Centers for Disease Control and Prevention's (CDC) responses to the CSTE position statement.

I appreciate the opportunity to provide a response to CSTE's position statement. CDC remains dedicated to assisting states and local communities in their surveillance efforts to most effectively respond to public health emergencies. We look forward to continued collaboration with CSTE regarding BioSense and other public health issues of mutual concern.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

Enclosure

Centers for Disease Control and Prevention (CDC) Comments

CSTE Position Statement #06-EC-03

Title: "Coordinated state, federal and local public health surveillance using BioSense for situational awareness."

Statement of desired action(s) to be taken:

1. A letter of response by CDC to the CSTE letter dated September 5th, 2005.
2. CSTE requests that CDC collaborate with CSTE and state and local health departments in the following ways:
    a. CDC should work with CSTE and other state and local organizations to develop a clear mission and plan of desired outcomes for BioSense.
    b. CDC should work with participating state and local public health, hospitals and CSTE to develop mutually agreed upon protocols for rapid response when statistical anomalies (aberrations) as noted by the CDC, state or local health departments are determined to be events that may be of urgent public health consequence. The workload needed to respond to such anomalies should be evaluated in the event additional resources may be required.
    c. CDC should engage CSTE in dialogue about issues surrounding confidentiality and transmission of the minimum dataset required by BioSense.
    d. The results of the BioSense evaluation projects should be used to inform the character of the program as it is rolled out. Ongoing evaluation should continue after the roll out. CSTE and its members should be involved in helping develop the evaluation tools and in the ongoing evaluation of the program. The evaluation should assess epidemiologic as well as informatics aspects of the project.
    e. CDC should clarify what data will be shared with the Department of Homeland Security or other federal programs.

3. CSTE requests that BioSense data be made available in the following ways:
    a. We understand that raw data are currently available to be sent from hospitals to state and local health departments. We would like CDC to also consider making raw data available for download from the CDC website for use by state and local health departments. Further discussion of the feasibility of this should take place.
    b. State and local health departments should have access to standardized metadata and a BioSense procedure manual.

4. BioSense should use and support existing local or state electronic data exchange initiatives and mechanism when those mechanisms can reasonably meet the technical information requirements for BioSense data. Healthcare data system development and support should integrate BioSense with electronic notifiable conditions reporting, build healthcare infrastructure (such as use of standardized vocabularies), and result in simultaneous electronic dataflow of fully identified case data to state and/or local health agencies, as required by state laws, for state notifiable conditions and de-identified case data for BioSense.

CDC Comments:

CDC agrees that strong relationships, with clear roles and responsibilities among local, state, regional, and national authorities are critical. CDC appreciates your continued support and interest in the BioSense program. Unfortunately, we are not in receipt of a CSTE letter dated September 5, 2005. If you would be so kind as to resubmit same we will reply post haste.

We agree that more collaboration with CSTE and other stakeholders such as ISDS, NACCHO, and ASTHO, is needed for BioSense. This is a Beta development year for BioSense, therefore, many opportunities for working together still exist. CSTE is a valued partner to CDC and the BioSense program, and we welcome contributions from you and our other stakeholders as we continue to move forward building this program. For example, we will soon begin hosting topical working groups around several issues such as monitoring protocols and application functionality. Members of CSTE and other BioSense users are invited to participate in these working groups.

We also understand that the mission and vision that has led the work of BioSense to date has not been clear to many of our stakeholders. As part of the initial assessment of BioSense done by the Gartner Group, they have recommended several strategies to CDC for clarifying the vision and mission of the program. We will be implementing these soon, and asking for comments from CSTE and others.

In addition to work on our part in clarifying the vision, we are also redirecting resources to help implement a comprehensive outreach plan that includes more frequent and consistent communications with our stakeholders, as well as, more frequent opportunities for interaction with the BioSense program. Beyond the implementation of the plans we already have in place, we welcome your suggestions on how you would like this collaboration to be structured.

Public health preparedness requires collaboration at all levels of the local, state, and federal governments to be as successful as possible. Since the recruitment of local hospitals began as real time data sources for BioSense in 2005, the local and state public health departments have always been involved with CDC in helping to identify and facilitate the work CDC is doing to implement BioSense data feeds. Support from the local and state public health departments has been extremely important for the success BioSense has had thus far. We look forward to working with CSTE to determine how we can improve relationships and dispel misunderstandings where they exist in the public health community, so that progress toward meeting our goals is not hindered. BioSense is still a system in development, and there continue to be many opportunities for local and state public health departments to contribute as the program continues to evolve.

CDC agrees that a procedure manual or protocols for local and state health department personnel need to be developed on the most effective ways to use the information available in BioSense. This was one of the most commonly expressed recommendations that emerged from our recent BioSense Users Meeting in May. As a result, topical discussion working groups are being established and one group will focus on BioSense Monitoring Protocol Development. We began meeting with these groups in August.

All of the data that are transmitted to BioSense are standardized at the source prior to transmission. In addition, we are in full agreement that detailed information regarding BioSense data requirements and specific data fields received from local hospitals and other data sources should be made easily available to state and local public health; both through the BioSense application and as requested to support the local use of data. We expect this to be another topic for the BioSense working groups.

To respond to your concern about the amount of data being transmitted to BioSense; we recognize that BioSense is assessing the usefulness of more clinical data than typical syndromic surveillance systems developed to date. CDC will be conducting, and funding, evaluation activities to help validate the data and determine the best methodologies for use of these new data types. CDC will also be relying on participation from health department and hospital users to provide comments on the most useful data for their needs. In addition, CDC continues to work closely with the AHIC Biosurveillance Workgroup, whose newly recommended Data Steering Committee will be examining what data would best constitute a recommended minimum data set for nationwide electronic biosurveillance. CDC will use those recommendations to guide the further development of BioSense. Health situational awareness is a fairly new concept in public health, so at this time we are looking at a breadth of data that have not traditionally been readily available for public health investigations. As the utilization of these data are tested, BioSense will be refined to include those that are most useful to public health preparedness at every level.

CDC has engaged in preliminary discussions with the Department of Homeland Security (DHS) to determine what aggregated data would be most useful for sharing as part of the National Biosurveillance Integration System (NBIS) data integration efforts. In previous discussions, DHS has indicated that they are not interested in receiving anonymized patient level data, but rather some form of an aggregate report, with less detail, that will coordinate with information from other federal agencies. As the NBIS system becomes operational, these discussions will continue and CDC will be able to share more information about this collaboration.

CDC has been very straightforward with the hospitals involved as data sources about the funding available to them for implementation and maintenance. Each hospital signs a Statement of Work with CDC's contractor SAIC for the implementation and short-term on-site maintenance of equipment necessary to enable data transfer to BioSense. Each hospital is aware, prior to commitment to BioSense participation, that long-term maintenance, ensuring local data standardization, will be assumed as a hospital responsibility. Assessment of hospital IT support that may be needed in out years will be initiated following this first Beta development year. CDC will provide long-term technical assistance for hospital IT staff through a help desk.

How CDC may use BioSense data is outlined in the Data Sharing Agreement that each healthcare system and BioSense data source signs with CDC. Data related issues covered in the Data Sharing Agreement are fully compliant with both state and federal privacy regulations. The agreements are between CDC and the hospitals to ensure compliance with these Federal laws. State and local health departments are not generally signatories on the Data Sharing Agreements, not because they are excluded from the data sharing, but because of the nature of the data sharing, defined broadly for public health, and the privacy regulations themselves.

Policies and procedures will be designed and implemented to ensure that all data users are required to comply with these regulations, including other federal agencies and state and local health departments who have access to BioSense under a Data Sharing Agreement.

We agree and also recognize that there are many stakeholders that we need to engage around the issues of privacy and confidentiality as BioSense evolves. At this time we are working on the best strategy to engage the appropriate stakeholders, and we will most certainly include CSTE in the discussion once our plan is in place.

CDC has identified the need to perform evaluations of BioSense as it is developing. CDC is working with the Gartner Group, a major independent IT consulting firm, to complete an assessment of the BioSense system to ensure the chosen architecture and implementation approach is in alignment with industry best practices. This assessment began in May, 2006 and will be completed over a six month period. The purpose of the study is to do a thorough review of all aspects of the BioSense technical architecture, platform and operations. The study will identify strengths and weaknesses as well as make recommendations for improvements. CDC is also committed to investing in extramural research and scientific evaluation of the BioSense project. Plans include a cooperative agreement to evaluate a number of aspects of the BioSense system including usability, validity of data, usefulness of data types, and cost-effectiveness. Extramural funding plans also include additional Centers of Excellence in Public Health Informatics and grant monies.

In addition, as you are already aware, CDC is seeking more informal feedback on BioSense from the state/local public health and hospital users. This began in the form of the Users Meeting held in May. The goals of the meeting were to allow users an opportunity to contribute ideas and recommendations for the BioSense application and to open an ongoing communication channel with the user community. To begin with, follow up from the Users Meeting includes topical discussion working group forums, quarterly updates from the BioSense leadership team, and monthly update emails. We are happy to include CSTE in these efforts where you have an interest. In addition to the Users Meeting, approximately 25 nationally recognized experts in informatics and biosurveillance were invited to CDC on June 27, 2006, to focus on the science of BioSense. Discussions included comparisons of analytic algorithms, analysis and visualization techniques, and data streams of interest. Ongoing involvement from this group is part of the outreach plan for 2006 as well.

We agree that BioSense should support existing local or state data exchange activities where they are in use. As part of the expanded implementation approach, CDC will work with existing state and local syndromic surveillance systems to transmit patient level data from hospital and other health care environments to BioSense.

CDC recognizes the individual challenges each state has regarding biosurveillance and electronic data exchange, and we will continue to work with states to assist in responding to those needs. CSTE is a most valuable partner in this effort, and we look forward to a mutually beneficial collaboration around the BioSense project. In addition to our responsibility to the states, we must also balance our national obligation to ensure the advancement of a nationwide

biosurveillance program that will enable important cross jurisdictional sharing of health information available in real time. Thank you again for your interest in the BioSense program. If you have any additional concerns, please contact Ms. Lynn Steele, Division Director and BioSense Lead, at (404) 639-7600.