May **XX**, 2006

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

The American Health Information Community (AHIC) identified and prioritized several "breakthroughs", health information technology applications that could produce a specific tangible value to healthcare consumers. The Biosurveillance Workgroup was therefore charged as follows:

- **Broad Charge for the Workgroup:** Make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government agencies.
- **Specific Charge for the Workgroup:** Make recommendations to the Community so that within one year, essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours.

The Workgroup's deliberations highlighted a number of key issues with respect to the specific charge:

1. Define the necessary steps to determine the data and technical specifications needed to support key public health functions.
2. Share data in a way that supports all levels of public health while ensuring that traditional public health roles are maintained.
3. Protect patient confidentiality
4. Define clear goals, metrics and rigorous program evaluations to inform recommendations for new programs, on-going programs and the broader charge.

This letter provides both context and recommendations for how these issues can be addressed to enable the transmission of ambulatory, emergency department and lab data from electronically enabled health care systems to public health systems.

BACKGROUND AND DISCUSSION

The threat of significant naturally occurring or man-made health events is a critical issue for the nation. The ability to detect events rapidly, manage the events and appropriately mobilize resources in response can save lives. Information from hospital emergency departments can be electronically reported and monitored without identifying patients

and serve to provide a real-time view of the health of our communities. These data can be shared with and among local, state, and federal public health agencies to support shared and unique needs at all levels of government. Also, information from public health agencies can be shared in real-time with clinical providers in emergency departments to improve their ability to respond to rapidly evolving events.

At the onset, the Biosurveillance Working Group agreed that the biosurveillance functions to be supported with advanced, enhanced, or real-time transmission of electronic health data are initial event detection, situational awareness, outbreak management and response management. Accomplishing these functions will require a coordinated effort across federal, state and local public health agencies, as well as partnering with the clinical care delivery system.

Placeholder – Describe high level WG processes

In April 2006, the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) surveyed the state, territorial and large (>200,000 population) local health departments across the nation regarding their capacity to receive, in electronic format, clinical care data to support biosurveillance efforts.

Responses to the ASTHO survey were received from 29 states, three territories and the District of Columbia. Several important findings emerged from this survey:

- The majority of state public health agencies have the capacity and the need to participate in biosurveillance efforts. These results emphasize the need for public health to be actively engaged in the electronic exchange of health information.
- 82% of all responding agencies indicated that they are receiving, or plan to receive within the next six months, electronic data from clinical care settings for one or more biosurveillance capabilities.
- 89% of all respondents reported that they have an active relationship with some clinical partners to develop capacity for electronically receiving, processing, and using data for either notifiable disease reporting or biosurveillance efforts.
- 82% of all respondents indicated a lack of funding and 70% of all respondents indicated a lack of trained personnel as the primary obstacles for participating in a nationwide biosurveillance project.

Responses to the NACCHO survey were received from 93 large (>200,000 population) local public health agencies. The key findings from this survey include:

- The majority of the large local public health agencies have the capacity and the need to participate in biosurveillance efforts.
- 68% of all responding agencies indicated that they are receiving, or plan to receive within the next six months, electronic data from clinical care settings for one or more biosurveillance capabilities.
- 98% of all respondents reported that they have an active relationship with clinical partners for local preparedness planning.

- 68% of all respondents indicated a lack of funding and 51% of all respondents indicated a lack of a technology infrastructure as the primary obstacles for participating in a nationwide biosurveillance project.

These findings informed the preliminary recommendations with respect to the specific charge as described below.

PRELIMINARY RECOMMENDATIONS:

I. Data Strategy

A minimum data set is necessary to meet the specific charge to obtain data in a biosurveillance program to enable key public health functions including initial event detection, situational awareness, outbreak management, and response management,. The types of data necessary for the specific charge were recognized by the Workgroup but not at the level of detail needed for the implementation of a program. The Workgroup recognized it might not be feasible to get all data elements in the minimum data set from every emergency department, lab or ambulatory care setting. This led to consideration of two strategies for data collection. One data strategy would target receiving the minimum data set from a limited number of clinical data providers and would support initial event detection, situational awareness, outbreak management, and response management. The second data strategy would be based on data that is easily obtained and potentially provides broader geographic coverage while still providing support for at least one of the public health functions.

In determining the value of data needed for the breakthrough, consideration needs to be given to subjective and objective types of data – subjective may be impacted by worried well, or chief complaint notes such as, "my wife made me come to the hospital". In addition, data may need to be filtered with consideration to usefulness in public health functions balanced with sensitivity of information.

Recommendation 1.0 HHS, in collaboration with ASTHO and NACCHO, should establish and convene by 6/30/06 a Data Steering Committee with the appropriate public health experts to identify the data elements and the necessary filtering of data from ambulatory care, emergency departments and laboratories needed to enable the key public health functions as outlined above. HITSP should identify the technical specifications for these data requirements by 9/30/06. CDC and others should provide HITSP with the public health expertise and funds needed to perform this task.

Recommendation 1.1 By 8/15/06, the Data Steering Committee should identify the data sources and requirements necessary to allow for collection of a more limited set of data across a broader geographic area.

II. Roles of Local, State and Federal Public Health Agencies

The Workgroup recognizes that public health investigations are led by local jurisdictions. Local jurisdictions might ask states or CDC to participate in an investigation when necessary but, typically, states become involved in investigations that cross local jurisdictional boundaries and CDC becomes involved in investigations that cross state jurisdictional boundaries.

> ***Recommendation 2.0*** For the purposes of a biosurveillance breakthrough initiative, CDC should establish memorandum of understanding for the purposes of ensuring simultaneous data flow from data providers to local, state, and federal public health while preserving traditional investigation roles at local and state public levels whereby local jurisdictions continue to have lead role in public health investigations. State and local public health agencies should ensure such memoranda of understanding are put into place and supported.

III. Protecting Patient Confidentiality

Data from clinician encounters is very important to public health authorities for the purposes of biosurveillance. Critical in the use of these data are the needs for protecting patient privacy and supporting authorized public health investigation of critical health events. Although HIPAA allows for named reporting of appropriate public health data, many are concerned about protecting the needs of protecting patient privacy. HIPAA "de-identification" relates to protecting patient privacy in data used for public release and other purposes such as scientific research. Some of these data, such as general localizing information, are critical for public health to establish that an event is occurring and how it may threaten the general population. So while full HIPAA de-identification, may provide maximum protection from a privacy and security prospective, it makes it virtually impossible for public health authorities to have information needed to identify, monitor and respond to public health emergencies.

At the other end of the spectrum, public health authorities, at times, get named data as required by state law to ensure to allow follow-up on notifiable diseases. In the context of biosurveillance use of health care data, a significant amount of public health value can be derived from data that do not include patient names or medical record numbers and since many are concerned about the use of named data in this type of monitoring, most do not use named data for these broader biosurveillance purposes. The Workgroup agrees that identifiers, such as medical record numbers or patient names, should not be included in a biosurveillance breakthrough. However, public health agencies should be able to link back to data sources as necessary to identify individuals in the event of an authorized public health investigation.

ASTHO has reported that some States and local jurisdictions believe that explicit State-level authorization might be necessary to permit the exchange of data for biosurveillance. (ref ASTHO issue brief). While data collected under a biosurveillance breakthrough

would not be available for public release, the only data that should be shared with public health is that which is necessary to meet the core public health functions.

Recommendation 3.0 HHS should develop sample data use agreements to facilitate the sharing of data from health care providers to local, state and federal public health authorities.

Recommendation 3.1 By 8/30/06, HHS should offer practical implementation guidance to data providers and state and local public health agencies to address HIPAA concerns about transmitting data (with obvious identifiers removed) for public health purposes.

Recommendation 3.2 HHS, in collaboration with ASTHO and NACCHO, should develop public communication materials to educate the general public about the information that is used for biosurveillance including the benefits to public health and the protection of patient confidentiality by 9/30/06.

IV. Program Evaluation

The overarching goal of this breakthrough is to build on existing programs and capacity in local, state and federal health departments to implement a biosurveillance program to transmit data from electronically enabled clinical care settings across the country simultaneously to local, state, and federal public health departments as feasible. Clear, measurable metrics are needed to guide the implementation, monitoring and evaluation of this effort in the short and long-term. Program evaluation should be designed and implemented by public health officials experienced in biosurveillance programs.

Recommendation 4.0 CDC and other public health officials with first hand experience in managing ongoing biosurveillance programs should design and conduct evaluations of the biosurveillance breakthrough. These parties should establish goals, develop outcome measures and metrics for evaluation of the breakthrough by 9/30/06.

Recommendation 4.1. HHS, in collaboration with ASTHO and NACCHO, should ensure that the Data Steering Committee continuously monitors the progress and interprets the results of program evaluations of the biosurveillance breakthrough initiatives with respect to the value of the data exchanged, the protection of patient confidentiality, and the need for modifications to the program. The Data Steering Committee should only consider large-scale implementation and direct modifications to data collection when sufficient evidence exists that demonstrates the value of the information derived or lack thereof.

Sincerely yours,
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Co-Chair XXX AHIC Workgroup

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References: