

06-EC-03

Committee: Executive Committee

Title: Coordinated state, federal and local public health surveillance using BioSense RT for early detection of possible public health emergencies

Statement of the Problem:

Public health preparedness needs collaboration at all levels to be as successful as possible. The national approach to enhancing public health surveillance to more rapidly and sensitively detect and characterize possible public health emergencies must include interagency coordination, a plan for data protection, and an evaluation plan. In addition, federal funding for these activities must be justified since it is diverted from other state and local preparedness and core public health activities.

The BioSenseRT deployment must include input from state epidemiologists and other interested state and local public health entities, as noted in a position statement from CSTE in 2004 (04-EC-04). At this time there are 67 current BioSense RT users, with federal plans to have 350 hospitals on board by the end of 2006.

Despite a dialogue between CDC and CSTE since September 2005, the following issues are still unresolved:

- Data acquired from participating hospitals are still not available to states even though 32 hospitals in 10 cities are transmitting real-time data to CDC.
- A procedure manual has not been provided to states
- The stated purpose of the current BioSense RT is situational awareness, although subsets of the collected data could also be used for early event detection. CDC is collecting more data than is needed for situational awareness. CDC representatives have stated that CDC is receiving all HL7 transactions within a hospital, which could include psychiatric consultations, HIV status, detoxification, and other specially protected personal information. These data are not clearly relevant to situational awareness or surveillance for public health emergencies; there is also no clear plan for their use in BioSenseRT.

Statement of the desired actions to be taken:

1. CDC should work with CSTE and other state and local organizations to develop and incorporate a coordinated plan and evaluation of desired outcomes for BioSense.
2. State and local health departments should be parties to all data use agreements involving hospitals and CDC.
3. Data obtained by CDC through BioSense RT should be made available simultaneously to participating state and local health departments using the same interface that CDC uses.
4. State and local health departments should have on-line or other immediate access to raw data and be able to write queries directly or download subsets of data acquired by such systems.
5. State and local health departments should have access to standardized metadata.
6. Any flag or alert generated by the system that is noted by CDC should be immediately communicated to state and local public health officials and state and local public health officials should be tasked with evaluating each alert. The workload necessary to follow up on alerts or aberrations should be evaluated in the event additional resources may be required.
7. CDC should work with participating state, local and hospital officials to develop mutually agreed upon protocols for response to alerts and for deciding the public health importance of each alert.
8. CDC should work collaboratively with CSTE to develop a plan for evaluation of the usefulness and limitations of BioSenseRT data for public health surveillance.

Public Health Impact:

1. Evaluation and accountability for enhanced public health surveillance funding
2. More efficient use of public funding for surveillance for bioterrorism and other public health emergencies
3. More effective surveillance with decreased morbidity and mortality from early detection of possible public health emergencies
4. Prioritization of surveillance funding to projects and initiatives with positive public health outcomes, or with a reasonable expectation of such.

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**Guidelines for US-Mexico Coordination
on Epidemiologic Events of Mutual Interest**
Core Group on Epidemiologic Surveillance and Information Sharing
Health Working Group, US-Mexico Binational Commission

1. Introduction

In 2002, within the framework of the Health Working Group of the US-Mexico Binational Commission, representatives from the U.S. Department of Health and Human Services and Mexico's *Secretaria de Salud* established a binational group on Epidemiologic Surveillance and Information Exchange to address issues of interest to both countries. With the objective of better defining how the two countries should collaborate on epidemiologic events of mutual interest, this binational group has elaborated the present document to provide a set of common guidelines.

The United States and Mexico have a rich tradition of collaboration on epidemiologic events involving the two countries, including infectious disease outbreaks, diseases associated with products from the other country, and the continuity of care for patients with tuberculosis traveling between the two countries. A joint Border Infectious Disease Surveillance project has been in place for several years, and an Early Warning Infectious Disease Project was initiated in 2004. The Binational TB Card Project facilitates access to information for healthcare providers regarding TB patients traveling between the two countries to ensure continuity of therapy. Closely linked to these collaborations, public health professionals from the two countries have regularly sought to keep their counterparts apprised of relevant epidemiologic events.

However, clear standards have not yet been established for what information should be shared and how the sharing should take place. The Core Group on Epidemiologic Surveillance and Information Sharing of the US-Mexico Binational Commission Public Health Working Group has chosen to formulate such a set of guidelines with the objectives of better institutionalizing the exchange of information on epidemiologic events of mutual interest, and promoting collaborative responses when appropriate. Recognizing that productive collaboration already occurs between many 'Sister Cities' along the US-Mexico border and between neighboring states, it should be emphasized that the present *Guidelines for US-Mexico Coordination on Epidemiologic Events of Mutual Interest* (Guidelines) should facilitate continued existing binational cooperation, while at the same time fostering more systematic and comprehensive sharing of information at all levels of government. These Guidelines focus primarily on coordination between the public health agencies/units which have primary responsibility for epidemiologic surveillance. They do not seek to define coordination between agencies/units with major regulatory functions, for which agreements have already been established.

These guidelines are emerging shortly following the adoption by the World Health Assembly on May 23, 2005 of the International Health Regulations (IHR), designed to "better respond to the increasing interaction between countries of the world, and to the changing nature of public health threats". The Guidelines directly address IHR Article 44

- Collaboration and Assistance – which affirms that “State Parties shall undertake to collaborate with each other” for identifying, investigating and responding to events, for providing technical and logistic support, and in other ways. However, the present document extends beyond the scope of the IHR – which targets public health emergencies of international concern - by presenting guidelines for the sharing of epidemiologic information between the two countries regarding all epidemiologic events of mutual interest. It is not limited to public health emergencies of international concern, but seeks to maximize the capacity of each country to respond to all epidemiologic events of mutual interest.

To identify those cases of infectious diseases which are of interest to both countries, this document uses the term “binational case” to refer to an individual with a confirmed or probable case of a notifiable infectious disease, and:

- who has recently traveled or lived in the neighboring country, or had recent contact with persons who lived or traveled in the neighboring country; or
- who is thought to have acquired the infection in the neighboring country or have been in the neighboring country during the incubation period of the infection and was possibly contagious during this period; or
- who is thought to have acquired the infection from a product from the other country; or
- whose case requires the collaboration of both countries for the purposes of disease investigation and control.

This document includes sections addressing the following:

- General Principles which orient the Specific Guidelines
- The Legal Framework for such binational coordination
- The Scope of Epidemiologic Events to which these guidelines are meant to apply
- Specific Guidelines for different classes of epidemiologic events

These Guidelines are meant to serve as a standard of conduct for public health agencies and their staff in responding to epidemiologic events of shared interest to both countries. While the Guidelines are not binding, it is planned they will lead to the development of shared protocols to facilitate their full implementation.

2. General Principles

The guidelines of this document are based on the following principles:

2.1. The Need to Share Information

The primary mission of public health agencies of the US and Mexico is to protect and promote the health of their citizens. However, epidemiologic events involving both countries – by geographic proximity, by cross-boundary movement of their citizens,

or by exchange of their products – require the sharing of information between counterpart institutions. Such sharing has the objectives of providing information about potential risks and facilitating an appropriate response for the protection of the health of the public, in whichever country they reside. Adequate preparation for the risks of bioterrorism or other public health emergencies further requires that well-functioning channels of communication be established prior to the occurrence of such an event, to facilitate effective sharing of crucial information, and articulation of coordinated responses, to ensure the greatest protection possible of the public's health.

In addition to sharing information to directly protect the public's health, counterpart agencies are also expected to share information on other public health matters affecting both countries, such as revised policies on travel or imported products from the other country. Such alterations in one country's positions will create important demands on the public health agency of the other country, for which they should be as well prepared as possible to respond.

2.2. Timely Sharing of Information

The value of epidemiologic information is closely linked to its timeliness. When needed, the sharing of such information between the US and Mexico should occur in a time frame which allows the other country to respond to the specific health need in as timely a manner as possible, maximizing the potential for effective public health action to prevent avoidable disease, disability and mortality. As such, information shared may be preliminary in nature and subject to change as events evolve. Preliminary information should be clearly communicated as such, and should not be disseminated outside the purview of relevant public health authorities unless by mutual agreement.

2.3. Quality of Information

The value of the epidemiologic information being shared depends on its accuracy and completeness. The national and state public health authorities of both countries need to commit to providing the most comprehensive and current epidemiologic information available.

2.4. Communication Pathways

Clearly defined pathways between public health agencies of the US and Mexico for communication of such epidemiologic information are needed to ensure rapid delivery to the appropriate agency and a high potential for action based on the information. When a specific need for binational information exchange arises, public health agencies at the local, state or federal levels of one country should communicate with their counterpart agency of the same level in the other country (ie. local-local, state-state, or federal-federal). This should be conducted in parallel with communication to national partners, as defined by national policies. Communication to other levels of government (local-state, state-federal) is the responsibility of the agencies of each country, not of agencies in the neighboring country. Thus, once an agency in the second country is notified of an epidemiologic event, the responsibility lies with that same agency to notify partner public health agencies of the same country, unless specific guidelines dictate otherwise. While communications

transmitted in the language of the other country are encouraged, those receiving communications should be sufficiently fluent in the language of the other country to understand messages composed in that language.

2.5. Joint Action to Respond to an Epidemiologic Event

When an epidemiologic event occurs involving both countries and both have an interest in investigating the event (such as an outbreak investigation), the two countries should make a determined effort to conduct the investigation together. In this situation, the national public health agency of the country in which the study will take place has jurisdiction and will assume the coordinating role. Each country should be expected to provide the technical and financial support needed for its participation. Sharing of resources, eg. laboratory testing, may be necessary, is highly encouraged, and should be negotiated in a timely fashion. The timeliness of the investigation should be accorded a high priority by both countries. When rapid action is appropriate, the deployment of the team in the country where the outbreak is occurring should not be slowed by the delayed mobilization of the corresponding team from the other country.

2.6. Differences between Health Systems

The roles of public health agencies of the United States and Mexico at the different levels of government are not always the same. In the United States, the public health sector is primarily state-based, while Mexico's health system is more centrally directed by the national *Secretaria de Salud*. Such differences must be taken into consideration in mounting the necessary responses when the two countries face an epidemiologic event requiring collaboration.

2.7. Respect for the Sovereignty and Laws of Each Country

The responsibility for all public health responses to binational epidemiologic events lies with the public health agencies of the country where the respective activities will take place. All parties recognize the need for these same public health agencies to operate within the legal framework established by that country. If legal barriers are identified which limit the capacity of public health agencies to collaborate with counterpart agencies of the other country in the most effective way, such barriers should be addressed by the appropriate authorities with the objective of maximizing the benefit to the public's health in each country.

3. Legal Framework

The following section reviews the legal framework currently in place for implementing these guidelines, from the perspective of the US federal and state governments and the government of Mexico.

Federal and State Governments of the United States

The Public Health Service Act (42 USC § 241 et seq) provides the Department of Health and Human Services (HHS) with a broad authority to conduct activities relating to the prevention and control of diseases and injuries. It also authorizes HHS to participate

with other countries in cooperative endeavors to advance health sciences and improve the health of Americans. Requirements for disease reporting are typically defined in laws at the state and local level. The Centers for Disease Control and Prevention (CDC), however, together with the Council of State and Territorial Epidemiologists (CSTE) have defined a national list of notifiable diseases, and states provide information on these diseases to CDC's National Notifiable Diseases Surveillance System. In addition, ships and airlines are required by federal regulation to report deaths or ill passengers to CDC quarantine stations. CDC also operates various surveillance systems that track particular disease problems of national interest.

The Privacy Act (5 USC § 552a) regulates certain terms of use by federal agencies of "systems of records" which include personal identifying information, as might apply to surveillance databases. While the Act sets controls on the terms by which federal agencies can gather, maintain, disseminate personal information, it also defines circumstances in which disclosure of information is permissible without the subject's consent. This includes disclosure to "cooperating medical authorities" "when a medical emergency affecting the health and safety of others occurs" and pursuant to a routine use as defined in the system of records published by the agency. The system of records applicable to most of CDC's surveillance projects is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

The Freedom of Information Act (FOIA, 5 USC § 552) allows persons to request access to federal agency records. It applies only to federal records, though US states have their own equivalent statutes. The FOIA provides access to all federal agency records except for those records (or portions of records) that are protected from disclosure. While FOIA protects certain classes of information from disclosure, it would not appear to restrict the sharing of public health information with counterparts in Mexico as described in this document.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule regulates how "covered entities" – e.g. healthcare providers, health plans, health billing services – use and disclose certain individually identifiable health information. While CDC is not considered a "covered entity," some state and local health departments may be. The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to "protected health information" (PHI) to carry out their public health mission. The Privacy Rule permits covered entities to disclose PHI, without authorization from the subject, to public health authorities (e.g., CDC, State and local health departments) that are legally authorized to receive such reports for purposes of preventing or controlling disease, injury, or disability. This includes, for example, reporting of disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. At the direction of a public health authority, covered entities may disclose PHI to a foreign government agency that is acting in collaboration with a public health authority [45 CFR 164.512(b)(1)(i)].

Each state must review its laws relating to these guidelines to determine whether legal authority exists to exchange public health information and to collaborate in other

ways with counterparts in Mexico on epidemiologic issues of mutual interest. Some states have examined their legislation, seeking to identify potential barriers to the sharing of epidemiologic information with Mexico.^{1,2} All states are encouraged to complete an analysis of their laws for this purpose. In those cases where barriers are identified, states are encouraged to consider new legislation that would provide such authority, based on the value of such collaboration for the improvement of public health in our countries.

The US Constitution, Article I, section 10, states in relevant part that "No state shall, without the consent of Congress, enter into any agreement or compact with another state, or with a foreign power..." With the approval of the State Department, however, states have the ability to enter into "non-binding" cooperative arrangements with each other and with their Mexican counterparts. Current plans to share epidemiologic information should be able to proceed under such arrangements.

In summary, US federal legislation permits the sharing of epidemiologic information with a foreign country for the prevention or control of disease, with necessary restrictions based on confidentiality. Each state needs to review its own legislation to determine whether barriers exist to the exchange of such information. If present, this legislation should be reconsidered to ensure that state public health officials have the needed authority to improve the public's health through the sharing of such information. With the requisite authority under state law, states would be constitutionally permitted to enter into cooperative arrangements with each other and with Mexican states for the purpose of sharing epidemiologic information.

Government of Mexico

(To be provided by Cuauhtemoc et al.)

Other US-Mexico Collaborations

The HHS and SSA have established Memoranda of Cooperation in health and in epidemiology, respectively. The first defined one of the areas of cooperation as being "Health and human information systems, including telecommunications, statistical methodologies, and information exchange." The second specified the activities to include "Development and implementation of protocols in support of epidemiological surveillance which are of mutual interest" and exchange of resources, including "jointly acquired public health information".

In 2000 the US and Mexico signed an agreement creating the US-Mexico Border Health Commission. Among the functions to be carried out by the Commission is "to conduct or support a binational, public-private effort to establish a comprehensive and coordinated system, which uses advanced technologies to the maximum extent

¹ Barriers to Binational Cooperation in Public Health between Texas and Mexico, Office of Border Health, Texas Department of Health, 2001

² Annual Border Health Status Report, 2001: Barriers to California-Mexico Collaboration in Public Health, California Office of Binational Border Health, California Department of Health Services

possible, for gathering health-related data and monitoring health problems in the United States -Mexico Border Area.” The agreement contemplates significant state involvement in the Commission's activities, requiring that the health officers from each of the ten border states be appointed as Commission members, together with 12 other representatives from the border states of each country.

Other existing mechanisms for collaboration between governments of the two countries on public health issues include the US-Mexico Binational Commission, the US-Mexico Food Safety Cooperative Agreement, the Border Governor’s Conference, the Pan American Health Organization (PAHO) El Paso Field Office, border state Memoranda of Understanding, and Binational Health Councils of border Sister Cities. Joint public health collaborations are in place between the two countries in the areas of tuberculosis (Ten Against TB, Binational TB Card), infectious disease surveillance (Border Infectious Disease Surveillance – BIDS, Early Warning Infectious Disease Surveillance – EWIDS), and others.

In conclusion, the legal frameworks of the two countries at the national level allow for the exchange of information, as proposed in these guidelines. States will need to determine how their legislation relates to the Guidelines provided here. Numerous interfaces are already in place between health authorities of the US and Mexico, reflecting the need and desire to assist each other in confronting shared public health challenges.

4. Scope of Epidemiologic Events

The purpose of this chapter is to characterize the scope or range of epidemiologic events for which both countries agree that exchange of epidemiologic information is appropriate. It is understood that the information to be shared by one country be such that it leads to or facilitates action in the second country which will be of direct benefit to the health of the population of one or both countries. This would include:

- A. Cases of disease identified in one country for which there is evidence or reason to suspect an epidemiologic link to the other country, including diseases detected in animals, or that such a link may occur in the future due to expected cross-border travel;
- B. Similarly, the identification of risk factors for disease in one country which may lead to disease in the other country,.

Types of epidemiologic events which meet these criteria include the following:

- A probable or confirmed case of a severe or otherwise important vector-borne infection occurring in the border region of a border state (eg. dengue or West Nile Virus encephalitis)
- A probable or confirmed case of a severe or otherwise important infectious disease with high potential for spread to the other country

- Infections in animals in the border region with potential for spread of severe disease to humans
- A probable or confirmed case of severe disease suspected of having been intentionally spread
- Disease outbreaks which involve both countries at the time of discovery or which have a significant potential for spread to the other country
- Outbreaks of disease associated with travel or migration to the other country
- Outbreaks of disease or chemical contamination associated with food or other products originating in the other country
- Environmental health emergencies affecting both countries
- Binational cases of notifiable diseases

There is a tremendous interaction between the US and Mexico in the Border region, reflected by the more than 250 million northbound crossings registered in 2002. While the physical proximity and intense interaction of the two countries in the Border region raises the risk of shared exposure to disease-causing agents by citizens from both countries, binational travel and commerce are capable of carrying such exposures far beyond the border. The potential of an epidemiologic event to be binational must be considered throughout the full reach of both countries.

5. Specific Guidelines

This section presents specific guidelines for different types of event and for different areas of collaboration.

5.1 Binational Cases

As stated earlier, a binational case refers to an individual with a confirmed or probable case of a notifiable infectious disease who may have acquired or may transmit the disease in the other country, or who may require binational collaboration for investigation and/or control. An example of a binational case is a person with tuberculosis under treatment who crosses the border during the course of his or her medical care and public health follow-up. Such a binational TB case is thus at risk for interruptions in treatment with the consequent possibility of transmitting TB to others, as well as of developing drug resistant tuberculosis. Based on the “Need to Share Information” (General Principle 2.1) identification of binational cases by public health authorities warrants the sharing of relevant information with counterparts of the neighboring country to assist in finding other cases, to limit the risks of further disease transmission, and to ensure adequate control of the disease among identified cases.

1. **Identification of Binational Cases** - The determination of whether or not a person with a notifiable disease is a binational case requires obtaining information which currently is not routinely gathered. States should encourage health professionals making disease notifications of the need to explore whether cases are binational,

especially in settings where this is more probable (locations with considerable travel between the countries, migrant populations, etc.). In the future, public health authorities should consider the value of incorporating information specifically designed to identify binational cases with the other information to be routinely reported. Questions designed to elicit such information should be prepared as part of the implementation phase of these Guidelines.

2. **Notification of Binational Cases** - Recognizing that binational cases, by definition, imply a public health risk to the neighboring country and usually require prompt public health action, binational cases of notifiable infectious diseases should be promptly reported to the appropriate public health official(s) in the neighboring country. Public health authorities of both countries will need to become familiar with the list of conditions which are notifiable in each country.
3. **Information on Binational Cases** -When necessary, the information shared on binational cases should be sufficient to allow appropriate public health follow-up of the case to take place. In some circumstances, this may entail sharing patient identifying information. Following the public health laws and privacy regulations of both countries, information exchange needs to be handled confidentially.
4. **Timely Reporting of Binational Cases** - Time frames need to be agreed upon by both countries for reporting binational case to public health authorities. Urgently notifiable conditions should be reported within 24 hours of first identification.
5. **Procedures for Notification of Binational Cases** - Clear mechanisms of notification should be agreed to by public health officials of both countries, at the different levels of government, which specify:
 - Counterpart agency and corresponding office to notify
 - Channels for communication which minimize delay in receiving the notification
 - Information to be included regarding the binational case(s)
6. **Follow-up Information on Binational Cases** - The two countries should exchange follow-up information on binational cases so that the effectiveness of binational case notification and coordinated case investigations can be determined.

5.2 Binational Outbreaks

The term outbreak is considered to represent a significant increase over the expected number of cases of a specific notifiable disease or other health problem in a given population over a given time period. The number of cases required to consider a cluster of disease cases an outbreak thus obviously depends on historical epidemiologic data and diagnostic criteria and laboratory resources. A single case of a rare disease, such as rabies or an “eradicated” disease such as smallpox, may constitute an outbreak, while numerous cases of more common diseases such as HIV/AIDS or tuberculosis may be required to be considered an outbreak. Newer diagnostic capabilities such as molecular fingerprinting techniques can identify a cluster of illnesses with indistinguishable

molecular fingerprints; epidemiological investigation is then used to find links between these illnesses in the cluster. This combination of molecular fingerprinting and epidemiological investigation has identified numerous outbreaks, including widely dispersed outbreaks that would otherwise have gone undetected. An outbreak is considered binational:

- when disease exposures occur in one country to visitors or migrants of the other country,
- when disease is associated with products from the other country, or
- when cases appear in border settings involving the population from both countries.

Upon recognition of a binational outbreak, if new cases continue to appear or exposure to causal agents persists, a rapid response is needed to accurately diagnose the illness, to determine the scale of the outbreak, to identify significant risk factors, and/or to implement appropriate control measures. Coordination between public health agencies of the two countries is essential for meeting the needs of all relevant parties and to achieve the most effective use of available resources.

1. **Preparing for Binational Outbreaks** - Pre-event preparations that should be made include:
 - Exchange of lists of binational contacts at the local, state, and federal levels
 - Contact information which provide for round-the-clock availability
 - Mechanisms for communication in both Spanish and English
 - Communications protocols for notification of public health officials and planning of needed responses
 - Mechanisms for the transport of specimens or needed supplies through US and Mexico customs
2. **Communications for Binational Outbreaks** - Once a binational outbreak is identified, the appropriate public health officials should be notified, following a pre-defined communications protocol. The public health authorities from each country should share the available data, and take a decision on the most appropriate response, including an agreement whether to initiate a binational investigation.
3. **Collaborative Investigations of Binational Outbreaks** - Upon binational concurrence to conduct a binational investigation or response effort, a binational oversight team of public health officials from the two countries should meet. Unless defined otherwise, the coordination of the investigation will be the responsibility of the lead public health authority where the outbreak is to be investigated. The oversight team will be responsible for or coordinate:
 - choosing the members of the binational field investigation team, including a lead from each country
 - field work preparation, including arrangements for any necessary travel, personal protective gear, prophylaxis, and availability of supplies and equipment
 - planning and implementation of the investigation

- content of health alerts and press releases
 - determination of control measures based on information provided by field staff
4. **Resources for Collaborative Investigations** - Funding needed for the travel of investigation participants will be the responsibility of their home public health agency. Primary resources needed for the investigation itself will be the responsibility of the lead public health agency where the investigation takes place. In the absence of needed supplies or investigative capacity (eg. select laboratory exams), sharing of resources between counterpart agencies is strongly encouraged.
 5. **Binational Cooperation in Sharing Epidemiology Resources** – National and state public health agencies are encouraged to share informational and other resources designed to strengthen the epidemiology and response capacity of binational counterparts. Joint participation in multinational agencies (eg. PAHO) and NGOs (eg. TEPHINET) provides additional opportunities to identify such needs and appropriate tools which have been developed.

5.2.1. Foodborne Disease Outbreaks

Foods are responsible for many infections and toxic exposures. Within the United States foodborne diseases are estimated to be responsible annually for 76 million illnesses and 5000 deaths. The growing international trade of agricultural products has correspondingly been associated with outbreaks due to pathogens transmitted by foods imported from another country. The United States and Mexico have collaborated in responding to several such outbreaks.

The organization of governmental roles in food safety is often complex, by including multiple agencies in both the health and agricultural sectors. A clear definition of the different roles of such agencies needs to be understood by neighboring countries, including the responsibility of each in responding to outbreaks of foodborne diseases.

At the national level within the United States, the CDC is responsible for surveillance of human illness caused by foodborne disease and for epidemiological and laboratory investigation of outbreaks of foodborne illness. The United States Department of Agriculture (USDA) is responsible for regulating meat, poultry, and processed egg products. The Food and Drug Administration (FDA) is responsible for regulating all other foods, including fruits, vegetables, and shell eggs.

At the state level in the US, the foodborne illness surveillance and investigation responsibility rests with the health agency at the state and local level, while the regulatory responsibility may rest with the agriculture department or the health department at the state level or the local health agency at the local level. When states want assistance from the CDC for foodborne outbreak investigations, state officials must make a formal request to CDC since CDC does not have the authority to send investigators without an invitation from state officials.

At the local government level in the US, there is wide variation in food safety roles and responsibilities among the 3000 local health agencies. In many localities, sanitarians investigate foodborne illness and conduct environmental health inspections in food service establishments, whereas in other localities reports of foodborne illness are investigated by state officials and the local sanitarians serve in a secondary support role.

Within Mexico, as an agency of the Secretaria de Salud, the Federal Commission for Protection against Sanitary Risks (COFEPRIS) is legally responsible for conducting tracebacks of food products associated with foodborne disease. When informed by the United States of a foodborne disease outbreak associated with a product from Mexico, COFEPRIS coordinates internally and externally with other government agencies, according to the nature of the event. COFEPRIS has a Memorandum of Understanding signed with the FDA, as well as with Canadian agencies, for coordination of action in outbreaks of binational interest, to share information, to establish communication contacts and to prepare joint press releases. As part of this trilateral framework procedures for quick and efficient response to address all emergencies are in place to provide protection to the citizens within the three countries.

The complexity of institutional organization on food safety in both countries creates an important need for collaboration between federal, state, and local authorities across international borders.

Foodborne disease outbreaks often imply the need for two or more stages of investigation. The first stage is the primary epidemiologic and environmental investigation which ideally will identify the agent, the food vehicle and how the food became contaminated. Traceback of the food vehicle will indicate whether it is a domestic or imported product. In the latter case, and if the food product is suspected to have been contaminated at its point of origin, further traceback investigation of the implicated food product will determine its source. Additional investigation may identify how the food product became contaminated, where the most effective opportunity for future prevention exists and the need for regulatory action. These investigations represent important opportunities for collaboration between the two countries.

1. **Regulatory Responsibilities in Foodborne Disease Outbreaks** - Given that tracebacks and product recalls resulting from foodborne disease outbreaks fall under the legal responsibility of regulatory agencies, sharing of information needs to be conducted in accordance with the duties of those agencies and within the framework of the existing agreements between the food regulatory agencies in Mexico and the United States.
2. **Trade-related Implications** - Recognizing the important trade-related implications of foodborne outbreaks, epidemiologic conclusions need to be based on highly reliable scientific methods providing results which are shared with counterpart agencies in the other country.
3. **Advanced Diagnostic Technologies** - The use of advanced technologies (eg. pulsed field gel electrophoresis) for subtyping of human and food isolates will be

encouraged, as well as the sharing of findings from such technologies with counterparts in the two countries.

4. **Confidentiality and Information Sharing** - Public health agencies and food safety regulatory agencies are legally obliged in both countries to maintain the confidentiality of patient identification and trade secret information. However, quickly sharing specific information among relevant agencies in both countries on the number and locations of persons who have become ill, the associated epidemiologic information implicating food vehicles, as well as the point of origin and total distribution of the implicated foods, is important to the rapid, appropriate and effective response to a binational outbreak of foodborne disease. The parameters that define which data must be shared and the conditions under which data sharing can legally occur should be determined in advance of binational food safety emergencies.

5.3 Potential Terrorist Events

Recent events have forced the United States to recognize that intentional use of biologic, chemical or radiologic/nuclear to harm people of this country is a risk which it must be prepared to face. The possibility of introduction of such agents by way of the US-Mexico border or the release of an agent in one country with transmission to the other makes this an issue of interest to both countries. Such a scenario could foresee the appearance of cases in the border region which would require close binational coordination.

Recognizing these potential threats, Mexico and the United States are jointly participating in the Global Health Strategic Action Group (GHSAG), and collaborating in the Early Warning Infectious Disease Surveillance Project (EWIDS).

The suspicion or identification of such an event as being intentional would lead to the involvement of law enforcement and potentially other agencies outside the health sector, with which national public health agencies would need to cooperate, as defined in national emergency response plans.

Since disease arising by intentional spread may well appear without previous notice, health officials need to be aware of suggestive features of such an incident, including the following:

- An outbreak of an unusual syndrome or disease, compatible with agents associated with bioterrorism, especially when occurring in a discrete population.
- Many cases of unexplained diseases or deaths.
- More severe disease than is usually expected for a specific pathogen or failure to respond to standard therapy.
- A disease that is unusual for a given geographic area or transmission season.
- Multiple simultaneous or serial epidemics of different diseases in the same population.
- Unusual strains or variants of organisms or antimicrobial resistance patterns different from those circulating.

- Similar genetic typing of agents isolated from distinct sources at different times or locations.
 - Intelligence of a potential attack, claims by a terrorist or aggressor of a release, and other evidence suggesting terrorist intent.
 - Other unusual situations^{3,4}
1. **Emergency Communications Channel** - The program units for public health emergencies in the two countries, including their directors, should be known to each other. Both program units should have a mechanism permitting direct contact on a continuous basis (ie. 24 hours/day, 7 days/week, 365 days/year).
 2. **Communication of Suspected Incident** - Suspicion of any intentional health incident which presents a risk to citizens of the other country is to be urgently communicated to the counterpart agency responsible for such emergencies.
 3. **Ongoing Information Exchange** - As such an incident evolves, information should be regularly exchanged at commonly decided intervals between corresponding public health emergency program units of both countries.
 4. **Resource Sharing in Emergencies** - In preparation for such potential events, agreements should be established between the public health authorities of the two countries – including local, state and federal levels – regarding the sharing of health resources during public health emergencies, together with expedited clearance procedures for cross-border transfer of such resources by immigration and custom officials, when such a public health emergency is formally declared.
 5. **Adherence to Outbreak Guidelines** - Cooperation in the investigation of such incidents is strongly encouraged and should follow the same guidelines as for naturally occurring outbreaks.
 6. **Quarantine of Foreign Citizens** - In the event that a quarantine is considered necessary by the public health agency of a country that will include citizens of the other country, this decision will be communicated urgently to the counterpart public health agency of the other country. The public health agency enacting the quarantine needs to recognize the special needs of citizens of the other country who are caught outside their place of residence, while still ensuring the effectiveness of the quarantine measure.

5.4 Laboratory Issues

Laboratories serve a unique role in both surveillance and investigation of health problems. The purpose of this section is to establish guidelines for laboratories when significant health events of binational interest occur mandating a collaborative response by both nations.

³ Recognition of Illness Associated with the Intentional Release of a Biologic Agent, MMWR 2001 Oct 19;50(41):893-897.

⁴ [Recognition of Illness Associated With Exposure to Chemical Agents — United States, 2003](#), MMWR 2003 Oct 3;52(3):938-940.

The availability of laboratories and the complexity of testing which those laboratories are capable of performing vary along the length of the border in the two countries. This may lead to periodic use of laboratories by border clinicians or patients in the neighboring country. In addition, disease outbreaks or emergency preparedness plans may lead to decisions to share laboratory resources. In such cases, minimizing the time required for laboratory diagnosis and confirmatory testing is critical to timely identification of health problems and disease outbreaks so that appropriate and timely control measures can be implemented. This is particularly important when considering bioterrorism events and outbreaks of highly communicable diseases such as pandemic influenza or Severe Acute Respiratory Syndrome (SARS) which have the potential to cause substantial health, social, and economic problems.

Each of the specific items detailed below must be addressed in establishing an efficient, highly functional, binational framework for laboratories to develop the needed capabilities for responding capably to disease outbreaks and other health challenges impacting both countries.

1. **Binational Reporting of Notifiable Diseases** - When an exam is performed on a resident of one country, in a laboratory of the neighboring country, and provides a positive result for a reportable condition, this information needs to be routinely communicated to the appropriate public health officials where the tested individual resides. State public health agencies should provide such public and private laboratories in neighboring states with contact lists to facilitate such communications.
2. **Transport of Laboratory Samples through Customs** - In cases where specimens of public health interest need to be carried across the border for testing in another laboratory, mechanisms need to be established to assure expedited passage through customs, since excessive delay may compromise the quality of the specimen and the ability to obtain an accurate diagnosis. This is likely to require an advance agreement among the involved agencies, including the customs authority, specifying a clearly defined protocol to be followed for the rapid, cross-border transport of a set of specimens.
3. **Standards for Sample Transport** - Specimens being sent for testing in the neighboring country need to follow national and international standards for the labeling, packaging and transport of such material. In laboratories which may participate in such collaborative testing, specific training on implementation of these standards should be provided to responsible personnel in these areas, together with written instructions.
4. **Authorized Request for Laboratory Testing** - Submission of samples for diagnostic testing by a laboratory of the neighboring country should be preceded by communication between authorized public health officials of the two countries, with approval of the receiving laboratory. Upon arrival of the specimen, confirmation should be sent to the agency submitting the specimens for testing. In situations where there is potential for the laboratory to be sent a

large number of specimens, the receiving laboratory should establish a triaging policy which defines the priority of received samples for urgent testing, and inform referring agencies of this policy.

5. **Reporting of Laboratory Results** - Laboratory results are to be communicated promptly to the requesting public health agency on a confidential basis. Only the agency submitting specimens for testing is authorized to publicly communicate the findings. When appropriate, specific protocols may be agreed upon which dictate alternate procedures.
6. **Binational Laboratory Collaboration** - Collaborative activities between cross-border laboratories is encouraged to enhance the scope of diagnostic capabilities available and the quality of the services provided. This may include training, provision of equipment, supplies and/or reagents, and participation in quality assurance programs. As with cross-border transport of specimens, agreements between public health and agencies and customs authorities should be established to define protocols which facilitate the passage of such material. Roles of national and state public health agencies for coordination of such activities need to be defined by each country.

5.5 Public Health Communications

As expressed throughout this document, successful binational exchange of epidemiologic information for public health depends on timely and clear communication of accurate information between appropriate public health authorities of the U.S. and Mexico. Failure to do so can result not only in inadequate public health response to prevent and control disease among binational populations, but also to misunderstandings between officials and the populations of both countries. Such misunderstandings can undermine mutual trust and confidence and can create distorted and unequal perceptions of the epidemiologic situation affecting the two countries. For these reasons, establishing clear mechanisms and protocols for public health communications between the two countries is paramount.

Communications between Public Health Agencies

1. **Existing Information Sources** - To facilitate the exchange of information recommended in this document, public health agencies should subscribe to those information outlets provided by the other country (eg. publications, press releases, Health Alert Network, Epi-X).
2. **Inter-Agency Communications** - Direct communications between corresponding program staff of counterpart agencies is encouraged (eg. to contact a known staff member in the measles unit to report a case of binational interest). However for cases when program staff are not known or cannot be reached, or for broader issues of common interest, counterpart agencies of the two countries should designate a point-of-contact, with information allowing access to that person at all times, in case of emergency, both during and outside of normal working hours. A

back-up contact should be designated in case the primary contact is not available. In the case of binational events requiring continued collaboration, the communications offices of counterpart agencies should be in regular contact, exchanging relevant information and coordinating the release of information to the public.

Release of Information to the Public

3. **Harmonization of Public Information** - In cases of binational epidemiologic events, information released to the public by the two countries regarding the event, risk factors and preventive measures, should be consistent, based on the best available scientific evidence of the event itself, and the pathogens or substances involved. Ideally, the population of each country should receive such information from their public health authorities in the same time period, to avoid creation of unexpected demands on public health authorities from one-sided releases, and to reinforce their credibility to the public.
4. **Sharing of Information for the Public** - In the case of a binational public health emergency or outbreak affecting the population of both countries, copies of information made available to the public by the respective public health agency should be shared with the counterpart agency of the other country. In non-emergency circumstances, such information should be made available on request.
5. **Travel Notices** - Travel notices are posted by public health authorities to provide information to travelers, the public, healthcare providers and public health authorities regarding outbreaks of disease of public health significance. The character of the notification is based on four criteria relating to disease transmission, containment measures, quality of surveillance, and quality and accessibility of medical care. In the case of such travel notices or other communications to the public which could have negative impact on trade, the counterpart agency should be given prior notice of the action to be taken and the evidence supporting that decision for their review and, if appropriate, their response.

6. Next Steps

The intent of the Core Group on Epidemiologic Surveillance and Information Sharing is that the completion of the Guidelines be followed by the elaboration of a set of protocols to guide the implementation of these recommendations by the public health agencies of the two countries. This process should be undertaken with broad binational participation of the major public health agencies at the state and federal levels.

Finally, the Core Group considers it likely that the present set of Guidelines will evolve over time, based on the experience accumulated in their implementation, and the identification of new or revised needs. In anticipation of this, the Core Group will review this document annually, to assess its continued validity, and to update the Guidelines as needed.