Appendix 1: Explanation of Fact Sheet Data Points

The data points that appear in the individual fact sheets and summary tables are bulleted below, followed by an explanation of their significance.

Laboratories: Biological Capabilities

Participation in Laboratory Response Network (LRN) for biological agents

CDC manages the LRN, a group of local, state, federal, and international laboratories. CDC provides funding through the Public Health Emergency Preparedness (PHEP) cooperative agreement to the 50 states and four localities to establish and maintain LRN biological public health laboratories. In addition to the laboratories that receive PHEP funding, other laboratories that participate in the LRN include state and locally funded public health laboratories as well as federal, military, international, agricultural, veterinary, food, and environmental testing laboratories. LRN provides a critical laboratory infrastructure to detect, characterize, and communicate about confirmed threat agents, decreasing the time needed to begin the response to an intentional act or naturally occurring outbreak.

- *LRN reference and/or national laboratories that could test for biological agents*

  LRN biological laboratories are designated as national, reference, or sentinel laboratories. National laboratories, including those at CDC, are responsible for specialized strain characterizations, bioforensics, select agent activity, and handling highly infectious agents. Reference laboratories perform tests to detect and confirm the presence of a threat agent. Sentinel laboratories are commercial, private, and hospital-based laboratories that test clinical specimens in order to either rule out suspicion of a biological threat agent or ship to reference or national laboratories for further testing. The fact sheets present CDC estimates for the total number of LRN reference and national laboratories that have selected to test for one or more biological threat agents supported by the LRN program office at CDC. For some states and localities, the total number of reference laboratories consists exclusively of public health laboratories, as this is the only type of laboratory that is a part of the LRN for these states. In contrast, other states and localities have both public health and other types of laboratories (federal, military, agricultural, veterinary, food, and environmental testing laboratories) that are a part of the LRN. For these states and localities, both public health and non-public health laboratories are included in the total.

Evaluating LRN laboratory capabilities through proficiency testing

- *Proficiency tests passed by LRN reference and/or national laboratories*

  CDC proficiency tests are composed of a number of unknown samples that are tested in order to evaluate the abilities of LRN reference and/or national biological laboratories to receive, test, and report on one or more suspected biological agents. If a laboratory is unable to successfully test for an agent within a specified period of time and report results, then the laboratory will not pass the proficiency test. If a laboratory fails a proficiency test, it is required to go through remediation proficiency testing to ensure that any problems are corrected.

If a laboratory does not pass remediation testing, then it can no longer perform testing in the LRN for that specific agent. The fact sheets present the total number of proficiency tests passed by reference and/or national laboratories during each year. In states and localities with public health and other types of LRN laboratories (federal, military, agricultural, veterinary, food, and environmental testing laboratories) participating in proficiency testing, all proficiency test results are presented. The results include first-round proficiency tests only; follow-up remediation tests are not included in the totals.

Assessing LRN laboratory competency and reporting through exercises

- *LRN laboratory ability to contact the CDC Emergency Operations Center within 2 hours during LRN notification drill. (Note: One LRN laboratory in DC and in each state is eligible to participate in this drill, with the exception of CA, IL, and NY, where two can participate.)*

  LRN notification drills ensure that biological laboratories can contact the CDC Emergency Operations Center (EOC) to report results to EOC watch staff and duty officers within 2 hours of obtaining a result. These drills are associated with participation in a specific proficiency test; laboratories that cannot participate in the test are excluded from this drill. Reasons for non-participation in the proficiency test include the following: laboratory does not test for agent, facility renovations or permit issues prevent laboratory from accepting samples, and laboratory has equipment issues.

Rapid identification of disease-causing bacteria by PulseNet laboratories

States and the District of Columbia must be able to detect and determine the extent and scope of potential outbreaks and to minimize their impacts. The intent of this performance measure is to determine if a laboratory can rapidly receive, identify, and report disease-causing bacteria within 4 working days of receiving the samples. Laboratories in the PulseNet network use CDC's pulsed-field gel electrophoresis (PFGE) protocols to rapidly identify specific strains of *Escherichia coli* O157:H7 and *Listeria monocytogenes*. The 4 working-day timeframe of the performance measure allows states and the District of Columbia to demonstrate their ability to analyze samples and submit results to the PulseNet database. This database is used by the PulseNet network (consisting of local, state and federal public health and food regulatory agency laboratories), which is coordinated by CDC.

- *Rapidly identified E. coli O157:H7 using advanced DNA tests (PFGE)*
  - *Samples for which state performed tests*
  - *Test results submitted to PulseNet database within 4 working days (target: 90%)*

- *Rapidly identified L. monocytogenes using advanced DNA tests (PFGE)*
  - *Samples for which state performed tests*
  - *Test results submitted to PulseNet database within 4 working days (target: 90%)*

Laboratories: Chemical Capabilities

Participation in Laboratory Response Network for chemical agents (LRN-C)

CDC manages the LRN, a group of local, state, federal, and international laboratories. The LRN provides a critical laboratory infrastructure to detect, characterize, and communicate about confirmed threat agents, decreasing the time needed to begin the response to an intentional act or accidental exposure.

- *LRN-C laboratories with capabilities for responding if the public is exposed to chemical agents (Note: There are three LRN-C levels, with Level 1 having the most advanced capabilities.)*
  - Level 1 laboratories are national surge capacity laboratories that maintain the capabilities of Level 2 and Level 3 laboratories, can test for an expanded number of agents using highly automated analysis methods, maintain an adequate supply of materials to analyze 1,000 patient samples for each method, and can operate 24/7 for an extended period of time.
  - Level 2 laboratories maintain the capabilities of Level 3 laboratories, can test for a limited panel of toxic chemical agents, and stock materials and supplies for the analysis of at least 500 patient samples for each qualified analysis method.
  - Level 3 laboratories work with hospitals, poison control centers, and first responders within their jurisdictions to maintain competency in clinical specimen collection, storage, and shipment.

Evaluating LRN-C laboratory capabilities through proficiency testing

- *Total number of methods successfully demonstrated by Level 1 and/or Level 2 laboratories to rapidly detect chemical agents*

  LRN methods can help determine how widespread an incident was, identify who does/does not need long-term treatment, assist with non-emergency medical guidance, and help law enforcement officials determine the origin of the agent. Level 1 and Level 2 laboratories undergo proficiency testing to determine if they can rapidly detect and measure chemical agents that can cause severe health effects.

- *Core methods successfully demonstrated by Level 1 and/or Level 2 laboratories to rapidly detect chemical agents*

  For 2010, CDC identified eight core methods for detecting and measuring chemical agents, and conducted testing to determine a laboratory's proficiency in these methods (there were six core methods in 2009). The core methods are significant as they offer new technical fundamentals in the methods that provide the foundation of LRN-C laboratory capabilities. This report presents final proficiency testing results as the number of these core methods successfully demonstrated by the laboratories in each state or locality. However, it should be noted that the states and localities with Level 1 and Level 2 laboratories that are not proficient in all core methods may have completed extensive work in the two steps that precede proficiency testing: training and validation in the core methods.

- *Additional methods successfully demonstrated by Level 1 and/or Level 2 laboratories to rapidly detect chemical agents*

  In addition to proficiency in core methods, certain LRN laboratories demonstrate proficiency in additional methods. These methods build upon the foundation established by the core methods, providing modifications to core techniques which allow for laboratories to test for additional agents and thereby expand their testing capabilities. Level 1 laboratories are required to gain proficiency in these additional methods, while Level 2 laboratories may choose to do so or not. In 2010, there were five additional methods in which Level 1 laboratories should have demonstrated proficiency, and up to four additional methods in which Level 2 laboratories could have chosen to become proficient. In 2009, there were six additional methods for Level 1 laboratories and up to five additional methods for Level 2 laboratories, depending on the state or locality needs. (There was a reduction in the number of additional methods from 2009 to 2010, since one of the 2009 additional methods became a core method in 2010). A successful demonstration in the testing indicates ongoing proficiency. The figures presented in the fact sheets represent the number of additional methods for which laboratories in the state or locality demonstrated proficiency. Laboratories may have trained in additional methods, and/or undergone validation for additional methods, which are steps that precede proficiency testing.

Assessing LRN-C laboratory capabilities through exercises

- *LRN-C laboratory ability to collect, package, and ship samples properly during LRN exercise*

  This exercise evaluates the ability of a laboratory to collect relevant samples for clinical chemical analysis and ship those samples in compliance with International Air Transport Association regulations. At least one laboratory located in each PHEP-funded state or locality should participate and pass. For states or localities with multiple laboratories, all results are reported.

- *Chemical agents detected by Level 1 and/or Level 2 laboratories in unknown samples during the LRN Emergency Response Pop Proficiency Test (PopPT) Exercise*

  This exercise tests a laboratory's emergency response capabilities focusing on a laboratory's ability to detect, identify, and quantify unknown agents. This exercise also tests the laboratory's emergency contact process and its ability to report results. To participate in a PopPT exercise, the laboratory must have attained a "Qualified" status for the method. To attain "Qualified" status, a laboratory must have completed training, the validation exercise, and passed at least one scheduled PT exercise. Laboratories participating in the PopPT exercise are called the day before the exercise, are sent a minimum of 10 unknown samples, and must test these samples within a certain number of hours (depending on the methods needed).

- *Hours to process and report on 500 samples by Level 1 laboratory during the LRN Surge Capacity Exercise*

  This exercise demonstrates the ability of each Level 1 laboratory to test and report on 500 samples (a total of 5000 samples) on a 24/7 basis as would be required by a large scale chemical incident. The response time was determined from the time the 500 samples were received until the time the last test result was reported to CDC.

Assessing plans to receive, distribute, and dispense medical assets from the Strategic National Stockpile

The CDC Strategic National Stockpile (SNS) is a repository of antibiotics, chemical antidotes, antitoxins, vaccines, antiviral drugs, and other life-saving medical supplies that are placed in strategic locations around the nation to supplement and resupply state and local public health agencies in the event of a large-scale public health emergency.

- *Technical Assistance Review Scores – National Average for States*

  Every state and directly funded locality has plans for receiving, distributing, and dispensing SNS assets. CDC conducts state TARs to assess these plans on an annual basis to ensure continued readiness. Using a scale from 0 to 100, a CDC state TAR score of 69 or higher in 2007-08 and 2008-09 indicated that a state performed in an acceptable range in its plan to receive, distribute, and dispense medical assets from the SNS. The acceptable threshold score has increased to 79 or higher for 2009-2010. Areas of assessment for the TAR focus on key elements that are regarded as either critical or important planning steps within a variety of functions. The 13 functions are the following:

  Developing a Plan with SNS Elements. A comprehensive, written plan is essential to facilitate the receipt, distribution, and dispensing of SNS assets quickly and efficiently. This plan should be incorporated as part of a state's comprehensive emergency operations plan.

  Management of SNS. The way a state, region, or community manages its response to a public health emergency is considered a program management and command-and-control function. Command and control is how political leadership, emergency management, public health, law enforcement, and other groups coordinate their response to an emergency.

  Requesting SNS. The decision to deploy SNS assets will be a collaborative effort among local, state, and federal officials. It will start at a local level when officials identify a potential or actual situation they believe has the potential to threaten the health of their community. SNS assets are requested from CDC by the affected state's governor (or the governor's designee).

  Communications Plan (Tactical). The availability of robust and redundant communication systems is critical to coordinating response functions during an emergency. Effective and timely communications between emergency response staffs, operation centers, receiving sites, points of dispensing, and hospitals will be needed to meet and resolve the demands of a mass distribution and dispensing emergency. The choice of communication support devices and support of technologies used to tether state, regional, and local networks will be key elements in meeting the need for timely flow of assets to distribution points, dispensing centers and health care facilities.

  Public Information and Communication. During an emergency where medical countermeasure assets are to be dispensed to the public, effective and timely public health communications are needed to ensure the public is informed and guided to appropriate locations to receive them. The development and dissemination of effective messages, methods, and materials to inform, educate, and mobilize the public will be critical to the success of a mass dispensing effort.

  Security. The security of the medical countermeasures and safety of staff involved in the receipt, distribution, and dispensing operations is essential. The arrival and transport of scarce resources will be

newsworthy and may draw attention from persons unwilling to wait for the organized dispensing of prophylactic or treatment medicines. The development of a comprehensive security plan through coordination with law enforcement is essential to maintaining control and order during this period.

Receipt, Stage, and Store. The size, location and characteristics of warehouse facilities used to receive, stage, and store medical countermeasures are important factors that will determine the effectiveness of an emergency response. CDC has established minimum criteria for sites designated to receive, stage, and store federal assets received from the SNS. The development of distribution strategies, site-specific plans, and the assignment and training of staff will determine the ability of jurisdictions to meet the demand for distribution of assets to local populations.

Controlling Inventory. State and local jurisdictions must possess a robust inventory management system to monitor the receipt of medical countermeasures, track their distribution, and record dispensing during a public health emergency. SNS inventory must be properly apportioned and configured in the quantities necessary for points of dispensing and health care facilities to successfully respond in an emergency.

Repackaging. Repackaging of bulk medications for public dispensing remains an SNS function that may be needed in an emergency. In the past, a significant amount of planning and preparation was required to repackage bulk oral drugs contained in the SNS before dispensing them to the public. Much of that effort is no longer necessary since the majority of oral medicines in the SNS now come in prepackaged unit-of-use regimens. However, states may still have to repackage bulk items under some circumstances.

Distribution. The distribution function refers to the physical delivery of SNS assets from the receipt, stage, and store (RSS) facility to dispensing sites, treatment centers, and regional distribution sites. States are responsible for developing distribution networks that account for challenges and barriers unique to their areas. Clear communication between RSS and local and regional planners is paramount to a good distribution plan.

Dispensing Prophylaxis. The SNS dispensing function was originally designed with the focus of providing initial prophylaxis to 100% of the population within 48 hours (*U.S. Department of Homeland Security's Target Capabilities List performance measure for mass dispensing)*. Dispensing planning, however, should be flexible and scalable so that the infrastructure built for meeting this capability can be used for any incident as part of an all hazards plan.

Hospital and Alternate Care Facilities Coordination. A large-scale emergency event can quickly overwhelm available resources at hospitals and other acute care providers. This function stresses the need for and measures the degree of coordination among public health, emergency management, and hospitals or alternative care sites to manage and respond to material needs at healthcare facilities.

Training, Exercise, and Evaluation. This function serves to highlight and document the development of emergency response training and exercise and evaluation programs that are compliant with guidelines set forth by the Homeland Security Exercise and Evaluation Program. Emergency response exercises are intrinsic to the transition of plans to operational response.

- *Technical Assistance Review (TAR) Scores – National Average for the 72 Metropolitan Statistical Areas (MSAs) in CDC's Cities Readiness Initiative (CRI)*

CRI focuses on enhancing preparedness in the nation's major metropolitan areas, where more than half of the U.S. population resides. A CRI location is an MSA composed of multiple counties based on U.S. Census Bureau data. MSAs can consist of one or more jurisdictions (e.g., counties, cities, and municipalities) and can extend across state borders. Local TARs are conducted annually in each jurisdiction and those scores are then combined to compute an average score for the entire MSA.