

Point of Care Systems for Biosurveillance

Identification & Integration of
Essential Information for the
National Strategy for
Biosurveillance

June 17, 2013 • Alexandria, VA USA

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Program Overview

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The National Strategy for Biosurveillance, July 2012, is formulated around four core functions: 1) Scan and discern the environment; 2) Identify and integrate essential information; 3) Alert and inform decision makers; and 4) Forecast and advise Impacts. This workshop will focus on the second core function – Identify and Integrate Essential Information. This function is focused to expedite incident detection and assessment. "Although all incidents have unique aspects, there are common elements of any national public health emergency. As with a health care provider and a new patient, there are certain key questions asked to identify symptoms and narrow probable causes to assist with patient treatment." In order to fulfill this requirement the community must improve diagnostic capability, especially at point-of-care to enable accurate and timely collection of information for early detection and throughout an incident or outbreak.

A point-of-care (POC) system is a hospital or outpatient information system that includes bedside terminals, instrumentation, sensors, or other devices for capturing and entering data at the location where the patients receive their care. Doctors and clinicians use POC systems to record directly the details of patient encounters, to review medical information, and to order tests, referrals, prescriptions, and other services related to the patient's ailments. Modern POC systems are being designed to replace many of the functions previously associated with paper documents.

POC systems are part of the future of biosurveillance. A POC system facilitates the electronic capture of key diagnostic data that is directly or readily translated to computer-interpretable form. POC systems typically include decision

support tools like drug interactions and to even suggest diagnoses. Ideally doctors and clinicians will have sensors that use naturally bodily fluids for initial diagnosis and then the information is transmitted directly into the POC system where further analysis is conducted and feedback provided to doctor or clinician in real time.

Topics to be addressed will include:

- Improve point of care (POC) diagnostics capabilities
- Accurate and real time collection for physicians and clinicians
- POC decision support capabilities – i.e. diagnoses and drug interactions
- POC DNA sequencing
- Link POC results to public health databases and near real time feedback mechanisms
- Data standards for interoperability of POC system, the electronic health record, and biosurveillance-related databases
- Data analysis and modeling supporting POC-generated data – i.e. determining relationship between the completeness of sampling of a population and the size of outbreaks of diseases that can be detected

Conveniently Timed and Co-Located With

Technological Advances In Detection & Identification of Biological Threats

21st International Conference

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Preliminary Agenda

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Monday, June 17, 2013

9:00 Welcome and Opening Remarks

Richard Stouder, Director Technology Development and Deployment, Global Security Directorate, Oak Ridge National Laboratory (ORNL)

9:15 To be announced

9:45 Innovative Strategies for Point-of-Care Diagnostics

Harshini Mukundan, PhD, Principal Investigator, Chemistry Division, Los Alamos National Laboratory

Effective point-of-care diagnosis relies not only on reliable, sensitive and specific detection devices but also on effective assays, ligands, functional surfaces, sampling, and data analysis. This presentation is an overview of the varied developments at LANL that address the above requirements, while highlighting the major challenges to effective application of such platforms.

10:15 Guiding Epidemiological Models by Integrating Point-of-Care Diagnostics with Disease-Surveillance Information

Arvind Ramanathan, PhD, Researcher, Computational Science and Engineering Division, Oak Ridge National Laboratory

A significant challenge in bio-surveillance is the lack of tools to identify and integrate essential information from point-of-care (POC) diagnostics with broader level disease surveillance information from Centers for Disease Control (CDC) and other state and federal agencies. Even if such information becomes available, it is still difficult to analyze this information and present information to decision makers that can ultimately guide their action. To overcome these challenges, we present a novel data analytics platform that will integrate POC diagnostic information with disease surveillance information from state and federal agencies and augment them with widely used disease spread models to predict (1) how diseases may spread, (2) identify vulnerable populations and (3) present scenarios to decision makers on what effective strategies of intervention might best work. We present our initial results on integrating the POC information collected from the Texas Department of State Health Services with the CDC influenza surveillance network and show how both data integration and analytics can improve predictions of disease spread and in addition, provide quantitative insights to decision makers regarding intervention strategies.

10:45 Networking break, exhibit and poster viewing

11:15 Development of a Sample to Answer PCR Instrument

William M. Nelson, MD, President and CEO, Tetracore, Inc.

Tetracore has designed the T-COR 8 to provide its customers with a portable solution for real-time PCR identification of both clinical and environmental biothreat agents. The instrument has a small footprint, is battery operated and rechargeable through a 12 volt source. Tetracore has also developed sample-to-answer protocols for the direct-analysis of both clinical and environmental material. Operating modes include stand-alone (via touch screen) or remote (via Ethernet or computer).

11:45 To Be Announced

12:15 Concluding discussion for the morning session

12:30 Lunch

2:00 Ambient Temperature Assays for Point of Care Systems

Rolf Müller, PhD, President and CSO, Biomatrix, Inc.

Result of a molecular diagnostic assay is highly dependent on the quality of the biological sample and the quality of the reagent used. Molecular analytes such as DNA, RNA and proteins in patient samples, reagents and molecular standards require cold chain management that is difficult to manage, costly and increases failure rates for diagnostic assays. Reagent stabilization through lyophilization can be used in certain cases, but it is difficult to develop and implement at production scale. Biomatrix has developed biostabilization methods for patient samples and assay reagents that allow a complete ambient diagnostic workflow for point of care systems. Thermo-stabilized patient samples and diagnostic assays can be transported globally at ambient temperature.

2:30 To Be Announced

3:00 Results of a Multicenter Clinical Evaluation of Point-of-Care Dengue Rapid Test

Subhamoy Pal, Scientist, Henry Jackson Foundation

Study design and data will be presented for a multicenter clinical evaluation of a Dengue POC diagnostic test, aimed at obtaining FDA clearance. Challenges associated with business risks of orphan diseases will be discussed.

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3:30 **Complying with U.S. Export Controls as a Life Science Researcher**

Betty Lee, PhD, Microbiologist, Chemical and Biological Controls Division Personnel, U.S. Department of Commerce

This presentation is an overview of Department of Commerce regulations and an explanation of the type of commodities relative to biological science research that might require an export license. The United States is a State Party to the Biological Weapons Convention and a member of the Australia Group (an international regime dedicated to non-proliferation of biological weapons). Many of these items are subject to the Export Administration Regulations (EAR) and are controlled for reasons of non-proliferation of biowarfare. Some items and technology may require a license for export. Export controls related to biological research include controls on certain biological agents and toxins, genetic elements of certain biological agents and toxins, certain vaccines, certain biological equipment and technology related to biological equipment production, development, and use and to non-fundamental research on certain pathogens. Items controlled include the Select Agents (even attenuated) as well as other agents that the Australia Group jointly controls. Some dual use or proprietary research and technology may be controlled under the EAR.

Questions as to whether an item will require a license can be addressed through a Commodity Classification Technology (according to the General Technology Note - Supplement 2 to part 774 of the EAR) related to "development" or "production" of Commerce Control List (CCL) items as well as "use" technology for biological equipment is controlled as well. These controls apply when technology is being exported via overseas training, sharing of laboratory protocols, etc. If technology is to be shared with a foreign researcher in the United States, the proper term is deemed export. Note that fundamental research (as defined in the EAR Section 734.8 for CCL items) does not require a deemed export license for technology. The effect of pre-publication review on classification of research as fundamental will also be discussed.

4:00 *Networking break, exhibit and poster viewing*

4:30 **PANEL DISCUSSION: Challenges for Point-of-Care Biosurveillance**

**Moderator - Richard Stouder, Director
Technology Development and Deployment,
Global Security Directorate, Oak Ridge National
Laboratory (ORNL)**

5:30 *Concluding Remarks, End of Symposium*

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Registration Information

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