Emerging Technologies and Partnerships

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Path Forward: PHPR Laboratory Portfolio

Investing in innovative people, processes, and products to advance CDC preparedness and response

- **PRE-EVENT**
  - Prepare
  - Public Health & Applied Research
  - Methods & assay development

- **EVENT**
  - Monitor
  - Information Management
  - Laboratory reporting & data exchange

- **POST-EVENT**
  - Respond
  - Operational Deployment, Sustainment & Use
  - Agent detection, qualified reagents, training, & evaluation

- **Cross-sector partners**
- CDC CIOs
- Federal, state, local, and international partners
Emerging Technologies to Enhance Response
Replacing the Mouse Bioassay

MALDI-TOF based EndoPep MS method to detect botulism

**Objective:** Develop an FDA-cleared, *in vitro* botulinum toxin (BoNT) activity assay to replace the mouse bioassay at US public health laboratories.

**Accomplishments:**

- Developed and validated the first mass spectrometric method to rapidly detect, identify, quantify, and assess functionality all known botulinum toxin types in clinical, food and environmental samples
- Established performance specifications equivalent or better than the gold standard mouse bioassay in a high throughput method.
- Technology transfer to the CDC National Botulism Laboratory Team
- Partnering with BARDA to transition current method to a bench top MALDI-TOF instrument and deploy instrumentation and new capability
Are We Ready?

MALDI-TOF Mass Spectrometry based method to detect anthrax lethal factor (LF) toxin activity

Objective: Develop and validate an *in vitro*, high throughput anthrax lethal factor toxin activity assay

Impact of LF Toxin Activity Measurement:
- 1st fully CLIA validated MS test for LF activity
- Culture independent
- No interference from antimicrobials and can monitor therapeutic interventions
- Earliest marker of exposure- precedes PCR, culture, and capsule detection
- Most abundant toxin, best point of care DX target
- Exquisitely sensitive LOD of 0.005 ng/ml
- High throughput makes the assay ideal for surge capacity testing (~1000 samples/ day)

Large scale event will stress the public health system
Sequencing is not the limiting step. It’s the data deluge.

Objective:
A turn key, intuitive solution developed by DoD and Los Alamos National Laboratory for users with modest to little bioinformatics training

EDGE Capabilities:
- Compact, portable server: Can be used anywhere including OCONUS labs
- Extensible: Open source software with user friendly interface.
- Supports:
  - QC analysis
  - Read-mapping to a reference genome
  - Sequence assembly and annotation
- Remote Assistance: Upon request, bioinformatics specialists can log in remotely and provide support
- Data stays on site
- Self contained: Data can be loaded onto the system, no additional connectivity necessary

Need for Empowering the Development of Genomics Experts

COST OF GENOME SEQUENCING
1990: $1B, 2013: $3K

COST OF FLU TO BUSINESS
1990: $1B, 2013: $3K

5 PATHOGENS RESISTANT TO ALMOST ALL DRUGS
Improving Outbreak Investigations

**Need:** An enterprise platform to integrate, interpret, and visualize surveillance, epidemiology, and laboratory data and real time data sharing between Federal, State, and Local partners.

**Objective:** Implement an enterprise system to 1) electronically integrate diverse data sources 2) visualize outbreak data 3) secure platform for data sharing and, 4) knowledge management.

**Ongoing activities:**
- CDC’s Outbreak Response and Prevention Branch developed the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) in collaboration with Palantir Technologies (Palo Alto, CA).
- SEDRIC utilizes commercial off-the-shelf Palantir Software.
- Exploring enterprise data integration and visualization platform at CDC.
Summary

- Events are local, response must be local
- Effective cross-sector partnerships are critical for developing, validating, and deploying technologies
- Technology creates both challenges and opportunities for public health preparedness and response
  - Next generation sequencing will continue to generate large volume data sets that must be accurately analyzed
  - Newly emerging platform technologies like MALDI-TOF can utilize both threat agnostic methods (microbial ID) and threat specific assays (anthrax LF & BoNT)
  - New tools will help public health better integrate, analyze, and securely share response data at the case level leading to more rapid decision making
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