Health Affairs Biodefense Summit

Healthcare and Biodefense Innovation Panel

Kimothy Smith (chair)
James (Jim) Wilson
Leo Einck
David Noll
Overview

• Brief Introduction by the Chair

• Four topics
  • Point of care (POC)/Point of Need (PON) Molecular Diagnostics (MDx)
    • Kimothy Smith, Chief Technology Advisor to PositiveID Corporation
  • Infectious Disease and Antibiotic Resistance Forecasting
    • Jim Wilson, CEO, M2, Inc., and Director, Nevada State Infectious Disease Forecast Station
  • Vaccine Design
    • Leo Einck, Director of Business Development and Federal Business, EpiVax, Inc.
  • Role of Vaccine Platform Manufacturing Technology
    • David Noll, Strategic Advisor on Biotechnology and Pharmaceutical Industries, Tiber Creek Partners, LLC
Overview (cont’d)

• Each topic will be given approximately 15 minutes
  • 1 minute for Panelist to introduce themselves and present a biosketch
  • 9 minutes to present their topic
  • 5 minutes for questions and discussion – primarily from the audience

• Audience participation is requested!

• Disagreements are normal and welcome but, please conduct yourselves in a professional and collegial manner, e.g., better than Presidential Debate participants
Brief Introduction

• Innovation
  • Defined simply as a "new idea, device, or method"
  • Also, the application of better solutions that meet new requirements, or previously unarticulated needs

• Disruption
  • Disruption “Guru” Clayton Christensen says that, “…disruption displaces an existing market, industry, or technology and produces something new and more efficient and worthwhile. It is at once destructive and creative.”

• Panelists have been asked to present in their topics
  • The Innovation or innovative technology
  • Potential disruptions and challenges
  • Subsequent impacts to medical care, biodefense, and military/defense applications and markets – the lead-in to questions, comments, and discussion
Biosketch – Kimothy Smith

• Education
  • BS Biochemistry
  • DVM
  • PhD in Epidemiology

• Past Experience
  • Department of Homeland Security
    • Science and Technology Directorate, Office of Research and Development
    • Office of Health Affairs
  • Lawrence Livermore National Laboratory
    • Chem-Bio National Security Program
    • Counterterrorism and Incident Response Division

• Current Affiliations
  • PositiveID Corporation
  • Desert Research Institute
  • University of Nevada Reno
The Innovation – POC/PON MDx

- Point of Care/Point of Need Diagnostic Platforms have the potential to
  - Improve patient treatment outcomes
  - Bring substantial savings in overall healthcare costs
- Broad categories of POC/PON Dx devices include
  - Lateral flow devices
  - Desktop and handheld platforms
  - Emergent molecular diagnostic POC systems
  - Wearables
- Broad range of potential applications beyond clinical Dx
The Drivers – POC/PON MDx

• Even though POC tests may (for now) cost more on a per test basis, the cost savings realized by reduced doctor visits and laboratory overhead costs need to be factored in to understand the overall equation

• [POC MDx] is one of the innovations that can potentially have impact on quality of care, as well as on system redesign and a more patient centered approach to care*

• The world will be short 12.9 million healthcare workers by 2035**
  • There will be a shift toward accurate, intuitive tests that can be operated by less skilled personnel and patients outside of a centralized laboratory

*US National Library of Medicine, National Institutes of Health, 2013
**WHO Report, 2013
Examples – POC/PON MDx

Spartan Biosciences, Inc.  
Spartan Cube  

bioMérieux  
Biofire FilmArray  

Roche Diagnostics  
cobas Liat  

Alere, Inc.  
Alere i  

Luminex Corp.  
Aries  

PositiveID Corp.  
Firefly Dx

Examples only, not an exhaustive list. Images are not to a common scale.
The Challenges, Disruptions, and Impacts

- Challenges
  - Design
  - Portability
  - Ease of use
  - Sensitivity, specificity, PPV, LOD
  - Assays
  - Sample prep
  - Cost of unit and per test
  - Reimbursement
  - Incorporation in EMR

- Disruptions
  - How to incorporate into system? Where?
  - Interpretation of results? Who?
  - Centralized laboratory
  - Change patient treatment? Less contact (less revenue to doctors)?

- Impacts
  - Can the Warfighter (and or support to) carry and use? What’s the cost/benefit?
  - Is there a benefit to military medicine and an improvement to quality of care and health outcomes?
  - Can costs be driven down enough to use POC/PON MDx routinely? What would the target price be?
  - Beyond infectious disease diagnostics and detection?
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Thank you for your kind attention!

Questions, Comments, Discussion?