NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

Accelerating the Development & Uptake of Rapid Diagnostics to Address Antibiotic Resistance – A Workshop

October 13, 2022, 8:30 am – 5:00 pm (ET)

October 14, 2022, 8:30 am – 1:00 pm (ET)

NAS Lecture Room/East Court
2101 Constitution Avenue NW Washington, DC 20418

To watch a zoom livestream, please visit the workshop page here.

PURPOSE

This workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation; the Forum on Medical and Public Health Preparedness for Disasters and Emergencies; and the Forum on Microbial Threats; and will provide a venue for stakeholders to discuss the current landscape of rapid diagnostics to address antibiotic resistance, consider challenges and opportunities for spurring innovation, and discuss practical next steps for accelerating the development of new diagnostic tools.

The public workshop will feature invited presentations and discussions to:

- Examine the current state of rapid diagnostic development, including examples of successes and limitations of current approaches.
- Consider the unique challenges for the development and use/uptake of rapid diagnostics in health care settings (e.g., feasibility of clinical utility studies)
- Consider gaps that rapid diagnostics may be best-suited to address (e.g. tools to support targeted treatment decisions in the healthcare setting, tools to enable real-time surveillance based on routine hospital data).
- Discuss practical short- and long-term opportunities for spurring the development and uptake of new diagnostics that can help address antibiotic resistance.

DAY 1: THURSDAY, OCTOBER 13, 2022

8:30 am WELCOME AND OPENING REMARKS (20 MIN)

Kent E. Kester, *Workshop Co-chair*
Vice President, Translational Medicine
International AIDS Vaccine Initiative

Betsy Wonderly Trainor, *Workshop Co-chair*
Alliance Director
CARB-X

8:50 am SESSION I – DEFINING THE NEED FOR RAPID DIAGNOSTICS: WHERE DO WE GO FROM HERE?

Session Objectives:

- Examine the current state of rapid diagnostic development, including examples of successes and limitations of current approaches;
- Consider gaps that rapid diagnostics may be best-suited to address (e.g. tools to support targeted treatment decisions in the healthcare setting, tools to enable real-time surveillance based on routine hospital data);
- Discuss what "success" might look like in future.

8:50 am Fireside Chat (30 mins)

KAREN C. CARROLL, *Keynote Speaker*
Director, Division Medical Microbiology & Professor of Pathology
Johns Hopkins University School of Medicine

9:20 am Panel Discussion (40 mins)

Moderator: Karen Carroll, Johns Hopkins University School of Medicine

Patient Perspective
BRADLEY BURNAM
Founder & AMR Survivor
Turn Therapeutics

Developer Perspective
CRAIG WHITEFORD
Head of AMR Program
Becton Dickinson

Bioethics Perspective
TRACEY L. COHEN
Distinguished Visiting Scholar
Institute for Bioethics & Health Policy, University of Miami Miller School of Medicine

Reimbursement Perspective
SUSAN VAN METER
President
American Clinical Laboratory Association

10:00 am Q&A/Audience Discussion (30 mins)

10:30 am COFFEE BREAK (*30 minutes*)

11:00 am SESSION II – CHALLENGES IN DEVELOPMENT AND USE OF RAPID DIAGNOSTICS IN HEALTHCARE SETTINGS

Session Objectives:

- Consider the unique challenges for the development of rapid point-of-care diagnostics to address antibiotic resistance;

- Discuss lessons learned from other diseases, including COVID-19, for rapid diagnostics development and use; and
- Consider generalizable applications and practical approaches to overcome barriers to the development and use/uptake of rapid diagnostics for drug-resistant bacterial infections.

11:00 am **Presentation 1 (15 mins)**
Lessons Learned from COVID-19 in the U.S. that are applicable to AMR
JOSEPH LUTGRING
Medical Officer, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

11:15 am **Presentation 2 (15 mins)**
Lessons Learned from abroad through the WHO's Access to COVID-19 Tools Accelerator Program
WILLIAM "BILL" RODRIGUEZ
Chief Executive Officer
FIND, the Global Alliance for Diagnostics

11:30 am **Presentation 3 (15 mins)**
Lessons Learned from Programs focused on Accelerating the Development of Rapid Dx's to date
PAUL EDER
Senior Scientific Officer
Concept Acceleration Program – Diagnostics
National Institute of Allergy and Infectious Disease

11:45 am **Panel Discussion (30 mins)**

Moderator: Paul Eder, National Institute of Allergy and Infectious Disease

Clinician Perspective
ALEX GRENINGER
Assistant Professor and Assistant Director of the Clinical Virology Laboratories
University of Washington Medical Center

Regulatory Perspective
KRISTIAN ROTH
Deputy Director
Division of Microbiology Devices, FDA

Industry/Economic Perspective
DAVID PERSING
Head of R+D
Cepheid

12:15 pm **Q&A/Audience Discussion (45 mins)**

1:00 pm **LUNCH BREAK (*1 hour*)**

2:00 pm SESSION III – INCENTIVES AT THE INTERSECTION OF DIAGNOSTICS AND DRUG DEVELOPMENT

Session Objectives:

- Consider common incentives/disincentives for the development of rapid diagnostics and new antibiotics; and
- Discuss innovative ways to foster innovation at the intersection of complementary diagnostics and drug development.

2:00 pm **Setting the Stage (10 mins)**
JOHN BILLINGTON
Head of Commercial Pipeline & Health Security, Policy & Advocacy
GSK

2:10 pm **Panel Discussion (40 mins)**
A Case Study: A new joint venture between a drug and dx developers

Moderator: John Billington, GSK

Developer Perspective
VALÉRIE RAYMOND-SCHWARTZMANN
Companion Diagnostics Program Director
bioMerieux

Therapeutics Perspective
ALITA MILLER
Chief Scientific Officer
Entasis Therapeutics

Biotechnology Perspective
GREGORY FRANK
Director, Global Public Policy
Merck

HHS Perspective
KIM SCIARRETTA
Interdisciplinary Scientist/Project Officer
Biomedical Advanced Research and Development Authority (BARDA)

2:50 pm **Audience Q&A (10 mins)**

3:00 pm **COFFEE BREAK (30 mins)**

3:30 pm SESSION IV – POLICY LEVERS: A MENU OF OPTIONS

Session objectives:
- Lay out a "menu" of policy options for incentivizing the development and use of rapid diagnostics.

3:30 pm **Panel Discussion (1 hour)**

Moderator: Mark Mcclellan, Duke Margolis Center for Health Policy

Industry Perspective
PHYLLIS ARTHUR
Vice President, Infectious Diseases & Diagnostics Policy
BIO

PACCARB Research Perspective
SARAH MCCLELLAND
Health Policy Analyst
U.S. Department of Health and Human Services

Analyst Perspective
JACLYN LEVY
Director, U.S. Policy
AMR Action Fund

Law & Economics Perspective
KEVIN OUTTERSON
Professor of Law, Boston University
Executive Director, CARB-X

4:30 pm **Q&A/Audience Discussion (30 mins)**

5:00 pm **ADJOURN WORKSHOP DAY 1**

DAY 2: FRIDAY, OCTOBER 14, 2022

8:30 am SESSION V – HEALTH EQUITY CONSIDERATIONS FOR DIAGNOSTIC DEVELOPMENT AND USE

Session Objectives:

- Consider the health equity implications for the development and use of rapid point-of-care diagnostics in health care settings; and
- Discuss practical approaches for incorporating diversity, equity, inclusivity, and access into push and pull incentives for spurring diagnostic development.

8:30 am **Keynote (30 mins)**

DIANE SHADER SMITH (Mother of the Late Mallory Smith)
Patient Advocate
"Salt in my soul" Co-author/Producer

9:00 am **Roundtable Discussion (60 mins)**

Moderator: Amanda Jezek, Infectious Diseases Society of America

Bioethics Perspective
NICHOLAS EVANS
Chair, Associate Professor
University of Massachusetts, Lowell

Research Perspective
DAN BAUSCH
Director of Emerging Threats & Global Health Security
FIND, The Global Alliance for Diagnostics

Public Health Perspective
MELINDA PETTIGREW
Professor of Epidemiology and Deputy Dean
Yale School of Public Health

Access and Innovation Perspective
ANTHONY SO
Professor of the Practice; Director, Innovation+Design Enabling Access (IDEA) Initiative
Johns Hopkins Bloomberg School of Public Health

10:00 am **Discussion (30 mins)**

10:30 am **COFFEE BREAK (*30 minutes*)**

11:00 am SESSION VI – INTEGRATING RAPID DIAGNOSTICS AND ANTIBIOTIC STEWARDSHIP

Session Objectives:

- Discuss practical and actionable policy options to integrate rapid point-of-care diagnostics and antibiotic stewardship in healthcare settings;

- Consider the role of reimbursement, incentives, and guideline development for rapid point-of-care diagnostics in healthcare settings.

11:00 am **Panel Discussion (30 mins)**

Moderator: Robin Patel, Mayo Clinic

Stewardship Program Perspective
RITU BANERJEE
Medical Director, Pediatric Antimicrobial Stewardship Program
Vanderbilt University

Lab Clinician Perspective
CAREY-ANN BURNHAM
Professor of Pathology & Immunology, Molecular Microbiology, Pediatrics, and Medicine
Washington University School of Medicine in St. Louis

Industry/Developer Perspective
DIANE FLAYHART
Global Program Leader
Becton, Dickinson and Company

11:30 am **Q&A/Audience Discussion (30 mins)**

12:00 pm SESSION VII – A PATH FORWARD

Session Objectives:

- Based on a menu of policy options, consider practical and actionable next steps that would be most impactful for spurring the development and use of rapid diagnostics in healthcare settings; and
- Discuss practical short- and long-term opportunities for specific stakeholders to take action.

12:00 pm **Roundtable Discussion (50 mins)**

Moderator: Betsy Wonderly Trainor, CARB-X

Dx Developer/Public Health Equity Perspective
JEAN PATEL
Principal Scientific Affairs, Microbiology
Beckman Coulter Diagnostics

Pharma Perspective
JOSEPH LARSEN
Vice President, Clinical Development
Locus Biosciences, Inc.

Clinician Perspective
ROBIN PATEL
ID Physician, Laboratory Director
Mayo Clinic

Regulatory/Policy Perspective
RIBHI SHAWAR

Branch Chief, Division of Microbiology Devices, Office of In Vitro Diagnostic and Radiological Health
Center for Devices and Radiological Health, FDA

Health Equity Perspective
SUSAN VAN METER
President
American Clinical Laboratory Association

12:50 pm WRAP UP DISCUSSION AND CLOSING REMARKS

Kent E. Kester, *Workshop Co-chair*
Vice President, Translational Medicine
International AIDS Vaccine Initiative

Betsy Wonderly Trainor, *Workshop Co-chair*
Alliance Director
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1:00 pm ADJOURN DAY 2