

2016 Public Health Emergency Medical Countermeasures Enterprise Stakeholders Workshop



January 6–7, 2016



*Sponsored by the Biomedical Advanced Research and Development Authority,
Office of the Assistant Secretary for Preparedness and Response*



2016 Public Health Emergency Medical Countermeasures Enterprise Stakeholders Workshop

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KEYNOTE SPEAKERS

RADM Nicole Lurie, MD, MSPH (USPHS)
Assistant Secretary of Health and Human Services for
Preparedness and Response

Amy Pope, JD
Deputy Homeland Security Advisor and Deputy
Assistant to the President, National Security Council,
the White House

RADM Stephen Redd, MD (USPHS)
Director, Office of Public Health Preparedness and
Response, Centers for Disease Control and Prevention

D. Christian Hassell, PhD
Deputy Assistant Secretary of Defense for
Chemical and Biological Defense

Robin Robinson, PhD
Director, Biomedical Advanced Research and
Development Authority, Office of the Assistant
Secretary for Preparedness and Response

George Korch, PhD
Senior Science Advisor, Office of the Assistant
Secretary for Preparedness and Response

AGENDA AT A GLANCE

Time	Wednesday, January 6th	Thursday, January 7th
8:30 - 11:30am	Plenary Session I: Federal Initiatives and Progress Amy Pope D. Christian Hassel George Korch	Plenary Session II: Emerging Infectious Disease Response Lessons Learned Nicole Lurie Stephen Redd Robin Robinson
11:30am- 1:00pm	Lunch	Lunch
1:00-2:15pm	Breakout Session I	Breakout Session III
2:15-2:30pm	Break	Break
2:30-4:00pm	Breakout Session II	Breakout Session IV
4:00-4:30pm	Poster Session and Exhibit Hall	Closing Session: George Korch
4:30-5:00pm	Poster Session and Exhibit Hall	Poster Session and Exhibit Hall

DAY 1

8:30-11:30am

KEYNOTE ADDRESSES

Federal Initiatives and Progress: PHEMCE interagency leadership will discuss governmental partnerships (DHS, DoD), PHEMCE initiatives/priorities and preparedness level; multi-year budget development; DoD/HHS partnerships in planning; and capacity building.

Opening and Welcome

Amy Pope, JD

Deputy Homeland Security Advisor and Deputy Assistant to the President,
National Security Council, the White House

George Korch, PhD

Senior Science Advisor, Office of the Assistant Secretary for Preparedness and Response

D. Christian Hassell, PhD

Deputy Assistant Secretary of Defense for Chemical and Biological Defense

11:30am-1:00pm

Lunch

1:00-2:15pm

BREAKOUT SESSION I

TRACK 1 – END USER CONSIDERATIONS

The PHEMCE Preparedness Assessment Process and Distribution and Dispensing planning

Session Coordinator: **Joanna Prasher, PhD (ASPR)**

David Howell, PhD (ASPR)

A Description of Preparedness Assessment processes: Five determinants of MCM preparedness and data sources being used in assessments

Joanna Prasher, PhD (ASPR)

Strengths and gaps identified to date and a preview of priorities in this area in the 2016 PHEMCE Strategic Implementation Plan

Christine Kosmos, RN, BSN, MS (CDC)

PHEP grant MCM-related capabilities: state-level examples of addressing shortfalls with PHEP resources

Q&A

TRACK 2 – FEDERAL INITIATIVES AND PROGRESS

The revised MCM Requirements Process and updated risk assessments with the Material Threat Assessment 2.0 process

Session Coordinator: **Richard Jaffe, PhD, MT, ASCP (ASPR)**

P. Scott White, PhD (DHS)
Overview of Risk Assessments and the Material Threat Assessment 2.0 process

Tim Lant, PhD (ASPR/BARDA)
Medical and Public Health Consequence Assessments

David McClimans (ASPR)
Overview of the PHEMCE Requirements Process

Q&A

TRACK 3 – INDUSTRY PARTNERSHIPS

“How can we help you make that product?”

Session Coordinator: **Richard Hatchett, MD (ASPR/BARDA)**

Richard Hatchett, MD (ASPR/BARDA); Christopher Houchens, PhD (ASPR/BARDA);

Arlene Joyner, MS (ASPR/BARDA); Tim Belski (JPM MCS);

Gerry Parker, DVM, PhD, MS (TAMUS); and Robert Lindblad, MD (EMMES)

A roundtable discussion on product development, building manufacturing capacity, and services the government can provide to encourage the development of specific countermeasures

Q&A

TRACK 4 – EMERGING INFECTIOUS DISEASES AND PANDEMIC INFLUENZA

The MERS-CoV Connection

Session Coordinator: **George Korch, PhD (ASPR)**

George Korch, PhD (ASPR)
General Background and current epidemiology of MERS CoV

David Spiro, PhD (NIAID)
Development of Animal Models for MERS CoV

Rosemary Humes, MS (ASPR/BARDA)
Point of Care Diagnostics Efforts

Rick Bright, PhD (ASPR/BARDA)
Creation of a Clinical Trials Network for MCM Testing

Q&A

2:15-2:30pm
Break

2:30-4:00pm

Breakout Session II

TRACK 1 – END USER CONSIDERATIONS

Clinical guidance on the use of Medical Countermeasures

Session Coordinator: **Satish Pillai, MD (CDC)**

Satish Pillai, MD (CDC)
CDC’s general approach to developing countermeasure guidance

LCDR Brett Petersen, MD (USPHS) (CDC)
An example: Development of guidance on post-event smallpox vaccine use

LCDR Kevin Chatham-Stephens, MD, MPH (USPHS) (CDC)
Use of systematic reviews to inform the guidance development process

LCDR Stephanie Griese, MD, MPH (USPHS) (CDC)
The unique considerations for special and vulnerable populations

Q&A

TRACK 2 – FEDERAL INITIATIVES AND PROGRESS

The Evolving Biosafety and Biosecurity Landscape

Session Coordinators: **Theresa Lawrence, PhD (USPHS) (ASPR)** and **Jeffrey 'Clem' Forthman, PhD (DoD)**

Susan Collar-Monarez, PhD (OSTP)
National Strategic Efforts in Biosafety and Biosecurity

June Sellers (DoD)
Biosafety and Biosecurity: A DoD Perspective

Edward You, MS (FBI)
Evolving Biosecurity Challenges

Q&A

TRACK 3 – INDUSTRY PARTNERSHIPS

Accelerating Research Transitions

Session Coordinator: **Michael Kurilla, MD, PhD (NIAID)**

David Jett, PhD (NINDS)
MCM product development support for Chemical Threats

Bert Maidment, PhD (NIAID)
MCM product development support for Rad/Nuc Threats

Michael Schaefer, PhD (NIAID)
Support for basic research and development to enable MCM product development for Biological Threats

Tina Guina, PhD (NIAID)
MCM product development support for Biological Threats

Q&A

TRACK 4 – EMERGING INFECTIOUS DISEASES AND PANDEMIC INFLUENZA

The Hits Just Keep Coming: dealing with Emerging Infectious Diseases

Session Coordinators: **Segaran Pillai PhD, MS (FDA)** and **Steve Monroe, PhD (CDC)**

Roundtable discussion

Q&A

4:00-5:30pm

Poster Session and Exhibit Hall

The 2016 Call for Abstracts will include requests for exhibit booths and posters to be available during the evening sessions on both days of the workshop.

DAY 2

8:30-11:30am

KEYNOTE ADDRESSES

Emerging Infectious Disease Responses Lessons Learned: interagency coordination to recent outbreaks

RADM Nicole Lurie, MD, MSPH (USPHS)

Assistant Secretary for Preparedness and Response

RADM Stephen Redd, MD (USPHS)

Director, Office of Public Health Preparedness, Centers for Disease Control and Prevention

Robin Robinson, PhD (ASPR/BARDA)

Director, Biomedical Advanced Research and Development Authority

11:30am-1:00pm

Lunch

1:00-2:15pm

Breakout Session III

TRACK 1 – END USER CONSIDERATIONS

Challenges with Monitoring and Assessment of Public Health Emergency (PHE) MCM's

Session Coordinator: **RADM Carmen Maher MA, BNS, RN (USPHS) (FDA)**

RADM Carmen Maher, MA, BSN, RN, (USPHS) (FDA) and **Bruce Gellin, MD, MPH (OASH)**

How do we conduct MCM data collection, post market studies, and run clinical trials during a response?

Q&A

TRACK 2 – FEDERAL INITIATIVES AND PROGRESS

Ready...Go: Science during Crisis Response

Session Coordinator: **Diane DiEuliis, PhD (NDU)**

LT Marcienne Wright, PhD (USPHS) (ASPR)

Hurricane Sandy Science Preparedness Grants

Robert Fisher, PhD (FDA)

Monitoring and Assessment

Q&A

TRACK 3 – INDUSTRY PARTNERSHIPS

Beating Back the Bugs: Combating Antibiotic Resistant Bacteria

Session Coordinator: **Christopher Houchens, PhD (ASPR/BARDA)**

Erin Reichert, PhD (DTRA); Jane Knisely, PhD

(NIAID); and **Christopher Houchens, PhD (ASPR/**

BARDA) Roundtable discussion

Q&A

TRACK 4 – FEDERAL AGENCY’S RESPONSE TO EBOLA AND OTHER EMERGING AND INFECTIOUS DISEASES

Federal response to recent threats through interactions with state, local and international partners.

Session Coordinators: **Gary Disbrow, PhD** (ASPR/BARDA) and **Jeffrey “Clem” Fortman** (DoD)

CDR Franca Jones, PhD, MS (USN) (DoD); **Peter Morris, MPS, MS** (USAID);

Melissa Harvey, RN, MSPH (ASPR); and **CAPT Inger Damon, MD, PhD** (USPHS) (CDC)

Roundtable discussion on the responses to Ebola, MERS, and H1N1

Q&A

2:15-2:30pm

Break

2:30-4:00pm

Breakout Session IV

TRACK 1 – END USER CONSIDERATIONS

The Strategic National Stockpile – the Right Stuff at the Right Time to the Right People

Session Coordinator: **Susan Gorman, PharmD, MS** (CDC)

Susan Gorman, PharmD, MS, DABAT, FAACT (DSNS/CDC)

SNS Assets and SNS Formulary Review

Scott Drexler (DSNS/CDC)

SNS Training

Rocco Casagrande, PhD (Gryphon Scientific - supporting DHS)

DHS/CDC Risk Formulary Assessment

Q&A

TRACK 2 – FEDERAL INITIATIVES AND PROGRESS

A Focus on At-Risk Populations – the National Advisory Committee on Children and Disasters (NACCD) and the National Preparedness and Response Science Board (NPRSB)

Session Coordinator: **Charlotte Spires (ASPR), LCDR Evelyn Seel, MPH** (USPHS) (ASPR)

Dr. Anne Zajicek, MD, Pharm.D. (NACCD)

Overview of the NACCD and reports to the ASPR

Dr. John S. Bradley, MD, FAAP, FIDSA (NPRSB)

Overview of the NPRSB and reports to the ASPR focusing on At-Risk Populations

Q&A

TRACK 3 – INDUSTRY PARTNERSHIPS

Past, Present and Future of the MCM Initiative at FDA Session Coordinator: **Rebecca Lipsitz, PhD** (FDA)

Robert Fisher, PhD (FDA)

Linking the Scientific and Regulatory Environments for PHEMCE Stakeholders: MCMi Regulatory Science

Drusilla Burns, PhD (FDA)

CBER MCM Research and a Case Study: Prolonging Anthrax Vaccine Shelf Life

Kevin Krudys, PhD (FDA)

Determining the Dose of MCM products in Special Populations

Heike Sichtig, PhD (FDA)

Regulatory Perspective for Infectious Disease Diagnostics and FDA-ARGOS Database

Q&A

TRACK 4 – EMERGING INFECTIOUS DISEASES AND PANDEMIC INFLUENZA

Influenza and Respiratory Pathogens Update

Session Coordinators: **Rick Bright, PhD (ASPR/BARDA)** and **Jonathan Ban (ASPR/OPP)**

Rick Bright, PhD (ASPR/BARDA)

Update on Pandemic influenza vaccine capacity and response → new initiative towards more effective influenza vaccines with universal potential

Lisa Koonin, DrPH, MN, MPH (CDC)

Update on pandemic influenza preparedness and response capabilities

Jonathan Ban (ASPR/OPP)

An Update of the HHS Pandemic Influenza Plan: Where do we need to go over the next 10 years?

Armen Donabedian, PhD (ASPR/BARDA)

Seasonal Influenza Vaccine Improvement Initiative

Q&A

4:00-4:30pm

Closing Session: Report-outs from Breakout Sessions and Closing Remarks

George Korch, PhD (ASPR)

Senior Advisor, Office of the Assistant Secretary for Preparedness and Response

4:30-5:30pm

Poster Session and Exhibit Hall

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