CURRENT EFFORTS IN CBRN PRODUCT DEVELOPMENT AND BEYOND

George W. Korch
Senior Science Advisor
August 5, 2016

Resilient People. Healthy Communities. A Nation Prepared.
ASPR Roles

- Medical Countermeasure Development
- National Disaster Medical System Response
- Coordination of ESF 8 for National Response Framework
- International Coordination
- National Health Security Strategy
- National Science Response to Disaster
All-Hazards Approach

Seasonal & Pandemic Influenza Preparedness

All Hazards Preparedness

CBRN Preparedness

Emerging Diseases Preparedness
Vision

The right medical product to the right person in the right location at the right time
“Biodefense” Expenditures by Agency 2005-2014 ($B)

- HHS, 51,698
- DOD, 9,471
- DHS, 11,628
- USDA, 1,927
- EPA, 1,737
- DOC, 1,188
- State, 905
- NSF, 265
- VA, 7

Funding figures extracted from Center for Health Security
Development is Expensive, Lengthy and Risky

**PHASES**
- Discovery
- Preclinical Development
- Phase I
- Phase II
- Phase III
- Licensure
- Production & Delivery

**PRODUCT PIPELINE**
- NIH & DoD
- PBS $4.3B*
- BARDA ARD $3.1B*

**PROBABILITY OF SUCCESS TO LICENSURE**
- 1-3%: 5-17%
- 10-25%
- 18-35%
- 45-70%
- 90%

**TIME**
- 3-7 yr
- 0.5-2 yr
- 1-2 yr
- 2-3.5 yr
- 2.5-4 yr
- 1-2 yrs

**PIPELINE PHASE COST**
- $100M-130M
- $60-70M
- $70M-100M
- $130M-160M
- $190M-220M
- $18M-20M

*Represents $1.8B transferred from PBS to support ARD FY09-13, $415M FY14, FY15

*1.8B transferred to ARD, $255M FY14, FY15
No Single Entity Leads the Entire MCM Development Portfolio

Civilian Programs
- NIH
- CDC

Military Programs
- DARPA
- DTRA-JSTO/AMC-RDECOM-ECBC/MEDCOM-MRMC
- JPEO- JPM MCS

ASPR
- BARDA
- OEM

ASPR-OEM
- FDA

• In Vitro & Animal Models
• Animal Testing
• Lab-Scale Production

• Human & Animal Efficacy, Dose, & Safety Testing
• Formulation
• Production of Clin. Supplies

• Regulatory Submission
• Manufacturing Scale-Up

• Full-Scale Production
• Safety Follow-Up

• Warm base production

Basic Research
Preclinical Development
Clinical/ Non-clinical Development
Filing & Launch preparation
Commercialization & Procurement
Readiness & Stockpiling
High-Priority Threats

- Bacillus anthracis (anthrax)*
- Clostridium botulinum toxin (botulism)*
- Cyanide
- Emerging infectious diseases
  - Pandemic influenza
- Gram negative organisms
  - Francisella tularensis (tularemia)
  - Yersinia pestis (plague)
  - Burkholderia mallei (glanders) and B. pseudomallei (meliodosis)
  - Rickettsia prowazekii (typhus)
- Multi-drug resistant Bacillus anthracis (MDR anthrax)

The PHEMCE will continue to address medical countermeasure needs to protect against high priority threats which have been determined by the Secretary of Homeland Security to pose a material threat sufficient to affect national security and/or which have the potential to seriously threaten national health security

- Nerve agents
- Radiological agents (e.g., radiological dispersal devices)
- Nuclear devices
- Variola virus (smallpox)*
- Viral Hemorrhagic Fevers
  - Marburg
  - Ebola
### 2007 PHEMCE Implementation Plan:
Priority Medical Countermeasure Acquisitions

**Near-Term**  
**FY 2007-2008**
- Broad-Spectrum Antibiotics
- Anthrax Vaccines
- Smallpox Vaccines
- Therapeutic Drugs for Acute Radiation Injury

**Mid-Term**  
**FY 2009-13**
- Broad-Spectrum Antibiotics
- Diagnostics
- Anthrax Antitoxins
- Filovirus MCMs
- Smallpox Antivirals
- MCMs for ARS and DEARE
- Radionuclide-Specific MCMs
- Rad/Nuc: Biodosimetry/Bioassays
- Enterprise CHEMPACKS

**Long-Term**  
**Beyond 2013**
- Broad-Spectrum Antivirals
- Volatile Nerve Agent Antidotes

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An Enterprise Approach

Strategic attributes for enterprise success:

- Products and capabilities that address clearly defined current requirements
- Multi-use technologies and platforms for future unknown threats
- Increase investment in FDA regulatory science
- Expand core services for industry partners
- More unified governance structure
- Establish a multi-year budget perspective
- Full Life Cycle Management
- Focus on “Final Mile”
PHEMCE Lead Roles

Key
- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

Acronyms
- PHEMCE: Public Health Emergency Medical Countermeasure Enterprise
- DHS: Department of Homeland Security
- DoD: Department of Defense
- USDA: U.S. Department of Agriculture
- VA: Department of Veterans’ Affairs
- HHS: Department of Health and Human Services
- ASPR: Assistant Secretary for Preparedness and Response
- BARDA: Biomedical Advanced Research & Development Authority
- CDC: Centers for Disease Control and Prevention
- FDA: Food and Drug Administration
- NIH: National Institutes of Health

Logos and symbols for various agencies and organizations.
Six Operating Principles

- Public-private partnerships
- Platform and enabling technologies
- Multipurpose products
- Control of total lifecycle costs
- Rigorous portfolio management
- Coordinated effort
PHEMCE MCM Life-cycle Architecture

What is the threat?  
Material Threat Assessment:

What is the Public Health Impact?  
What are the critical MCMs?  
Needs Analysis:

How many MCMs can we effectively use?  
Capabilities Assessment:

What should the MCM look like?  
Product Specific Requirements

How many should we buy for stockpile?  
Policy Recommendation:

What are the final operational plans?  
Response Integration:

How effective was the MCM?  
Monitoring and Assessment:
Scope of SNS Inventory

- $6.5 billion in material
- Approximately 900 individual line items
- Volume of six super WalMarts
- Unique kitted configurations
- Detailed physical location data
A re-look at Requirements

Did we have the best approach?

Department of Homeland Security
Overview of Material Threat Assessment 2.0

MTA 2.0 provides:
- A systematic, actor capabilities-based analyses of the plausibility of a set of scenarios
- The unmitigated consequences of this set of scenarios
- A smaller set of ‘consensus scenarios’
  - Concurred by PHEMCE-partners
  - Includes unclassified descriptors
  - Available for preparedness and requirements planning

MTA 2.0 does not provide:
- Medical consequence analyses (e.g., mitigated consequences)
- Recommendations on stockpiling
- Answers to MCM policy questions (e.g., multiple attacks)
Main Result: MTA 2.0 Plausibility Matrices

- One matrix per adversary capability
  - Low, medium, high

- Multi-factorial output seen in one glance:
  - Scenarios of weapon use
  - Numbers of people exposed
  - Adversary capability
  - Plausibility of successful execution

- Methodology permits this matrix to be updated easily if new info arrives
MTA 2.0 Status

- Anthrax – delivery imminent
- Smallpox
- Radiological Dispersal Devices
- Pharmaceutical Based Agents
## Advanced Development (AD) and Procurement Priorities

<table>
<thead>
<tr>
<th>Medical Countermeasure Category</th>
<th>AD Priorities Through FY17¹</th>
<th>Current HHS Holdings²</th>
<th>Procurements Programmed Through FY13³</th>
<th>Additional Procurements Projected Through FY17⁴</th>
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<td></td>
<td>SRF⁵</td>
<td>TBD⁶</td>
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¹ These priorities include new products coming through the advanced development pipeline, as well as enhancements to current products in the SNS.
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⁸ This includes antimicrobials for the following threat agents: anthrax, plague, tularemia, typhus, and secondary infections resulting from radiological and nuclear agents or pandemic influenza.
⁹ Advanced development of this MCM class is not expected until the long-term, but early stage research is ongoing.
BARDA’s Efforts
Stockpiled MCM’s from Project BioShield

- Smallpox
- Anthrax
- Radiation
- Chemical
- Botulism
- Thermal Burns 2015
BARDA Supported FDA Approved Products

Cell-based Influenza Vaccine
- Novartis
- Flucelvax

Influenza IV Antiviral Drug
- BioCryst Pharmaceuticals, Inc.

Recombinant-based Influenza Vaccine
- Protein Sciences Corp.

H1N1 & H5N1 Vaccines w/ Adjuvant
- GlaxoSmithKline

Botulinum Antitoxin
- Cangene

Anthrax Antitoxins
- HGS/GSK
- Emergent

Next-Generation Portable Ventilators
- Covidian

Flu/RSV POC Diagnostic
- Amgen
- 3M/Focus

Amgen

ASPR
Assistant Secretary for Preparedness and Response
Products Stockpiled under Project BioShield – New in FY 2015

**Burn MCMs**

- Silver Impregnated Bandages

**Enzymatic Debridement**

**Cell-based Skin Substitutes**

**Autograft-Sparing Technologies**
Create Robust & Innovative MCM Development Pipeline

• ~ 200 MCM product candidates in development

![Graph showing the development pipeline over time with categories such as PBS, H5N1, PAHPA, H1N1, MCM Review, PAHPRA, H7N9, Ebola, MERS-CoV, and color-coded bars for EID, FLU, and CBRN.]
FDA-approved BARDA products

- FDA has approved 15 MCMs supported by BARDA with 4-5 more approvals expected in near-future
Major Accomplishments

- Approved nine MCM new requirements for viral hemorrhagic fevers; smallpox; chemical threats; pandemic influenza; and botulism.
- Greatly accelerated MCM’s for Ebola, now Zika
- Made 2 Project BioShield Procurements for SNS (anthrax antitoxin, smallpox vaccine)
- Received FDA approval for CBRN & influenza products
  - Anthrasil, Neupogen (ARS), Cipro (plague), moxifloxicin (plague)
  - Flucelvax® and Rapivab® approved, FluBlØk® expanded indication
- Demonstrated effective reduced dose schedule for anthrax vaccine
- Data and final report submitted Neulasta for neutropenia due to radiation
New Products Projected for SNS 2016-2019

- Artificial skin replacement therapy for definitive care treatment of thermal and radiation burns
- Antimicrobial drug-impregnated mesh dressings for point-of-care treatment of thermal and radiation burns
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biothreats
- Gene expression- and other technology-based biodosimetry devices for quantitative measurement of ionizing radiation exposure in affected persons following a nuclear event
- Chemical antidotes for cyanide poisoning and highly-volatile nerve agents
- Next-generation anthrax vaccine and adjuvanted enhancement to the current anthrax vaccine
- New lyophilized MVA smallpox vaccine for “at-risk” individuals which will provide a significant lifecycle costs savings
- Second smallpox antiviral drug
- Therapeutics and vaccines for Ebola
- Zika Diagnostics and Vaccine
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9 Advanced development of this MCM class is not expected until the long-term, but early stage research is ongoing.
More Major Accomplishments

- CDC published four Guidance Documents
  - Expert Panel Meetings on Prevention and Treatment of Anthrax in Adults” (*Emerging Infectious Diseases*)
  - “Special Considerations for Prophylaxis and Treatment of Anthrax in Pregnant and Postpartum Women” (*Emerging Infectious Diseases*)
  - "Pediatric Anthrax Clinical Management” (*Pediatrics*)
  - “Clinical Guidance for Smallpox Vaccine Use in a Postevent Vaccination Program” (*MMWR*)
Antimicrobial Resistance Threat

- 2M infections per year caused by AMR pathogens
- 23,000 deaths annually in US
- Estimated economic burden of $20-35B annually
- Categorizes AMR pathogens in terms of public health threat: Urgent, Serious, or Concerning
- FQ resistance in *E. coli* now greater than 50%, untreatedable GC now detected in 11 countries.
The Antibiotic Development Gap

No New Classes to Treat Gram Negative Bacilli For 4 Decades
GOAL 4: Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines

4.1 Conduct research to enhance understanding of environmental factors that facilitate the development of antibiotic resistance and the spread of resistance genes that are common to animals and humans.

4.2 Increase research focused on understanding the nature of microbial communities, how antibiotics affect them, and how they can be harnessed to prevent disease.

4.3 Intensify research and development of new therapeutics and vaccines, first-in-class drugs, and new combination therapies for treatment of bacterial infections.

4.4 Develop non-traditional therapeutics and innovative strategies to minimize outbreaks caused by resistant bacteria in human and animal populations.

4.5 Expand ongoing efforts to provide key data and materials to support the development of promising antibacterial drug candidates.

4.6 Enhance opportunities for public-private partnerships to accelerate research on new antibiotics and other tools to combat resistant bacteria.

4.7 Create a biopharmaceutical incubator—a consortium of academic, biotechnology and pharmaceutical industry partners—to promote innovation and increase the number of antibiotics in the drug-development pipeline.
# BARDA’s Antimicrobial Portfolio

## BARDA’s BSA Supported Product Pipeline

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Compound</th>
<th>Development</th>
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</thead>
<tbody>
<tr>
<td>Achaogen</td>
<td>Plazomicin (ACHN-490)</td>
<td><strong>Preclinical</strong>: Next-generation aminoglycoside: Broad Spectrum plague, tularemia and carbapenem resistant Enterobacteriaceae (CRE)</td>
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<tr>
<td></td>
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<td><strong>Phase I</strong>: A novel fully synthetic tetracycline: Broad Spectrum plague, tularemia, complicated intra-abdominal and urinary tract infections (cIAI, cUTI)</td>
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<td>Cempra</td>
<td>Solithromycin (CEM-101)</td>
<td><strong>Preclinical</strong>: Next-generation fluoroketolide: Broad Spectrum anthrax, tularemia, gonorrhea and community-acquired bacterial pneumonia (CABP)</td>
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<td>Rempex</td>
<td>Carbazavance™ (meropenem/ RPX7009)</td>
<td><strong>Preclinical</strong>: Carbapenem/β-lactamase inhibitor: Broad Spectrum CRE, cUTI, hospital-acquired pneumonia /ventilator-associated pneumonia (HAP)/(VAP), melioidosis, glanders</td>
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**Disclaimer:** The above projects are supported by BARDA’s BSA Program utilizing non-dilutive funding via a contract and/or agreement. The stage of development is approximate as of July 2015 (please refer to the sponsors site for updated information). The table represents the compounds most advanced commercial indication being pursued by the developer.
Partnership for Antibacterial Drug Development

Use of Other Transactional Authorities

- Five year $200M public:private partnership in May 2013
- Development of multiple antibiotic candidates
- Fluidity in activities and resources to adapt to technical risk and programmatic priorities
- Governance is through a BARDA:GSK Joint Oversight Committee
- Allows for external partnerships through co-development or in-licensing agreements
More Success

• 2nd Other Transaction Authority Use Negotiated
• Portfolio of antibacterial candidates, the lead of which is aztreonam-avibactam (ATM-AVI)
• Strategic decisions will be made by a BARDA-AZ Joint Oversight Committee
• Fulfills requirement in CARB National Plan for ASPR/BARDA
  o Create at least one additional portfolio partnership with a pharmaceutical or biotechnology company by March 2016 to accelerate development of new antibacterial drugs
• Establishes international collaboration between BARDA and the EU’s Innovative Medicines Initiative (IMI)
  • Both entities will provide support for ATM-AVI pivotal trials
CARB Accelerator (CARB-X)

• Robust early stage R&D environment and pipeline of antimicrobial products to counter the increasing threat of antimicrobial resistant infections
  • rapidly develop and commercialize new antibacterial products

• NIAID and BARDA collaboration to fund a Biopharmaceutical Accelerators (s) to identify, assemble, and accelerate a portfolio of innovative early antibacterial products

• Formally Announced on July 28th
Award Information

- Cooperative Agreement
- Anticipated # of awards: 1
- Anticipated Project Period: 5 years
- Five one (1) year budget periods
- First Year Anticipated Budget Funding (FY16): $30M
- Total Anticipated Project Funding (subject to availability of funds): $250M
- Total Anticipated Match: $275M
BARDA will provide funding to a third party.

Together, NIH and BARDA will set strategic goals for the third party and monitor progress in meeting those goals.

Third party could be a nonprofit, Evergreen fund, existing incubator, etc.

Funding will be used to conduct R&D studies that will advance a candidate drug in development.
Building Advanced Research and Development Capacity for the Future
Change from Threat to Capability Focus

- Build facilities and strategy to adapt to rapidly identified threats
- Centers for innovative Advanced Development and Manufacturing (BARDA)
- Fill and Finish network (BARDA)
- Animal Model Network and Services (BARDA, NIH)
- Clinical Trials Network and Training Programs (BARDA and NIH)
- NIH diagnostics, sequencing facilities, reagent manufacturing, epitope mapping, biosafety lab support, and computational biology.
BARDA Core Services Assistance Program

CIADMs

Fill Finish Mfg. Network

Focus on Manufacturing capabilities

Regulatory & Quality Affairs

2006

ADS Modeling Hub

2009

Clinical Studies Network

2014

2012

2011

2013

Medical Countermeasures: 2016 and beyond
- Flexible-by-design, multi-product, multi-technology architecture
- Accommodate all “best of breed” flexible bioprocess technologies
- Personalized therapeutics to moderate scale bioreactors (1,000 L)
- Lower initial capital outlay by ~5X and reduces operational costs
- Focus: Phase 1, Phase 2, and Phase 3 transition studies
- Supports workforce training with dedicated mock cGMP lab space
- Multiple projects conducted simultaneously in fully contained modular clean rooms (MCRs)
- Conducting work on Process Development & Validation Plans
- Originally funded by a $50 million competitive award from the State of Texas Emerging Technology Fund (January 27, 2009)
Flexing the “Capability Muscle”
Ebola & International Efforts
Ebola Epidemic
Therapeutic Programs

Discovery
- AMGEN
- Defyus
- Bill & Melinda Gates Foundation

Preclinical
- Gilead
- Tekmira
- Staffetta Therapeutics
- BioCryst Pharmaceuticals, Inc.
- Regeneron
- Genentech
- Emergent Biosolutions
- Genetech, a Member of the Roche Group
- Dupont
- Trichoderma platform
- hZMapp mAbs

Phase I
- GS-5734
- AVI-7530
- BCX4430
- REGN3477-70-71

Phase II
- TKM-100802
- Zmab mAbs
- Brincidofovir for CMV/Adno
- Mil-77
- ZMapp™ mAbs
- Convalescent Sera
- Favipiravir for influenza

Other Ebola mAbs
- Pichia platform
- Fraunhofer, USA
- Medicago

Current Snapshot
November 2015
Ebola Epidemic
Vaccine Programs

Discovery
- USAMRIID VRP
- USAMRIID VLP
- RNA vaccine
- Russian Flu ΔNS1 Vector
- Protein Sciences

Preclinical
- Profectus BioSciences, Inc. rVSVN4CT1
- VAXART HuAd6 EBOV
- NOVAVAX EBOV GP Nanoparticle
- Emergent biosolutions™ MVA for boost

Phase I

Phase II
- gsk ChAd3 EBOV
- xΔG EBOV

Phase III
- NewLink Genetics
- Merck

Current Snapshot
November 2015

FOR OFFICIAL USE ONLY
Moving Fast from Bench to Bedside

- Successful rapid testing for Phase I safety (NIH, DOD)
- Accelerated development of Common Master Protocol for adaptive randomized clinical trial design (NIH and others)
- Accelerated Manufacturing Schedule for vaccines (BARDA and Industry)

Vaccines

- Clinical Trial Designs
  - ChAd3 EBOV Vaccine (NIH/VRC & GSK) – RCT in Liberia
  - rVSV-ZEBOV GP vaccine (CDC, Merck) – Randomized clustered step wedge in Sierra Leone

- Providing CRO, logistical plans, & clinical oversight for clinical trial in W. Africa
  - rVSV-ZEBOV GP vaccine (CDC, BARDA) – Randomized clustered step wedge in Sierra Leone

Therapeutics

- ZMapp monoclonal antibody therapeutic (BARDA and Industry)
- Clinical Trial Design
- Partnership with WHO – on-site liaison on clinical studies for Ebola therapeutics
Results for STRIVE

- 7 clinical sites
- 3 data entry hubs
- Web based data system
- 8678 participants enrolled
- 453 safety sub-study participants enrolled
- 527 immunogenicity study participants enrolled
What we have learned from the PHEMCE can be leveraged for new diseases

- Epidemiology and clinical characterization of the disease are foundational for informed choices about MCM development

- Diagnostics need to move closer to the patient

- Governments have key roles in supporting developers—especially for novel diseases
  - e.g. access to samples, development of validation panels

- Consider the full scope of possible countermeasures including diagnostics, vaccines, therapeutics, and other approaches
  - Prioritizing most appropriate candidates for development and testing requires early engagement across MCM Enterprise and with end users

- Distribution and acceptability are critical factors to address up front
Spread of ZIKA Virus 1947-2016
BARDA will work with PHEMCE partners to address medical countermeasure needs for the Zika response both domestically and globally.

- **Prevent** Zika virus infection through new vaccines
- **Detect** acute and previous Zika virus infections through new rapid diagnostics
- **Ensure** a blood supply safe from Zika virus through use of screening tests for donated blood and virus inactivation in blood products
- **Activate** our National Medical Countermeasure Response Infrastructure to help medical countermeasure developers
Prevent Zika Infection

- NIH/DOD/BARDA collaboration for USG-developed, manufactured, and evaluated Zika virus vaccine
- NIH and BARDA to support private sector development of vaccine through federal funding opportunities
- HHS to support international collaborations, including vaccine production at the Butantan Institute in Brazil
Vaccines in Development

2016
CYQ1 Q2 Q3 Q4
DNA (VRC)
Preclinical & Mfg
Phase 1 with long term follow up (VTEU)
Phase 2/2b with long term follow up (VTEU)

2017
Q1 Q2 Q3 Q4
PIV (WRAIR)
Preclinical & Mfg
Phase 1 (VTEU)
Phase 1 (WRAIR)
Phase 1 (Commercial Partner?)

2018
Q1 Q2 Q3 Q4
PIV (CIADMs)
Preclinical Development & Mfg
Phase 1/2 (CSN)

PIV (Company 1)
Preclinical Development & Mfg
Phase 1 (CSN)

mRNA (Company 2)
Preclinical & Mfg
Phase 1 (Company 2)
Phase 2/3 (Company 2)

PIV (Butantan)
Preclinical Development & Mfg
Phase 1 (TBD)

NIH funded
BARDA funded
BARDA unfunded
Where might a global MCM development effort have a role?

**Neglected Diseases of Public Health Significance**
- For neglected diseases with sporadic outbreaks, global coordination and prioritization of MCMs makes sense.

**Emerging/Re-Emerging Diseases**
- Emerging and re-emerging diseases require global collaboration in order to speed MCM development.

**Combatting Antibiotic Resistance**
- Global coordination on prioritization, clinical research networks, and regulatory policy could help develop new antimicrobials faster.

**Science Preparedness**
- We must ensure that we learn and institutionalize the important clinical, public health, and research lessons during international public health emergencies so we are better prepared next time.
Key MCM R&D Challenges

Ebola
- Licensure of vaccines(s), Rx clinical studies, & Survivor transmission

Pandemic and Seasonal Influenza
- Antigenic drift & and seasonal influenza vaccine mismatch

Antibiotic Drug Resistance
- New drug R&D: conventional & unconventional
- Global networks for clinical studies

MERS-CoV
- Complete the MERS-CoV basic and translational R&D towards MCM development & approval & clinical study infrastructure in Middle East
- Rx & vaccine licensure pathways? Mass vaccination campaigns occur? Stockpiles? What about camel vaccines?

Zika Virus
- Diagnostics for Pregnant Population, Vector Control, Vaccines
Assuring State/Local Readiness
CDC’s Commitment

- Measures state/local ability to plan and execute a large-scale MCM response (2015/2016 initiative)
  - Baseline data for 433 jurisdictions by July 2016
- Identifies operational gaps and develops solutions
- Aligns with PHEMCE methodology for assessing federal operational readiness for an MCM event
- GOAL: By 2022, all 62 PHEP jurisdictions will have achieved a “satisfactory” status level on the CDC MCM assessment
## Prioritizing Work for Full Preparedness

<table>
<thead>
<tr>
<th>Determinant</th>
<th>Initiatives</th>
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| Research and Development     | • Develop pre-Emergency Use Authorization (EUA) packages  
• Evaluate data collection strategies during a public health emergency response  
• Continue R&D for novel next-generation therapeutics  
• Provide coverage for additional populations (e.g., under 2 years) |
| Manufacturing                | • Assess production surge capacity and/or market availability for “just in time” procurements |
| Procurement and Stockpiling  | • Procure new and additional MCMs for the Strategic National Stockpile (SNS)  
• Evaluate options for extending lifecycle of MCMs in the SNS |
| Response Planning and Guidance| • Develop MCM response strategies  
• Develop and publish clinical and medical management guidelines  
• Develop tiered response strategies |
| Operational Capacity         | • Explore alternatives to expand national ability to utilize IV products in an emergency setting  
• Continue efforts to plan for federal resource support to jurisdictions  
• Better leverage CDC/DSLBR’s Operational Readiness Review evaluation process |
Special Populations

- Pediatric
- Geriatric
- Pregnant/Lactating
- Immunocompromised
- Disabled
- Institutionalized
- Transportation Disadvantaged
- Chronic Illness
- Pharmacological Dependency
- Obesity
- Communication (non-English)
The Evolution of PHEMCE Planning and Capabilities

2010

2012

2012

2014
Looking Forward

- Greater emphasis needed on Operational Capacity
- "Right-sizing" the portfolio
- Needed attention to SNS Sustainability
- Need continued regulatory research investments
- Better communication with External Stakeholders
- Re-looking at the approaches to unidentified future threats via basic research initiatives