PRODUCT LIFE CYCLE MANAGEMENT AND THE PHEMCE

George W. Korch
Senior Science Advisor
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Resilient People. Healthy Communities. A Nation Prepared.
Response: A series of Policies track after Events

POLICY

- Bioterrorism Act
- Project BioShield
- National Health Security Strategy
- MCM Enterprise Review
- PHEMCE Strategy & Implementation Plan
- PAHPA Reauthorized

EVENTS

- 9/11 and Anthrax
- Re-emerging H5N1
- Katrina, Rita, Wilma
- Ike, Gustav
- H1N1 Pandemic
- Deepwater Horizon and Tornadoes
- Hurricanes Isaac and Sandy
- Japan Earthquake Nuclear Event
- Ebola MERS Chikungunya
- Boston bombings
- Zika

Policies:
- Pandemic & All Hazards Preparedness Act
- BioShield
- Pandemic & All Hazards Preparedness Act

Years:
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
Vision

The right medical product to the right person in the right location at the right time
Vaccine & Drug Development is still Expensive, Risky and Lengthy

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

BARDA ARD

Valley of Death

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
No Single Entity Leads the Entire MCM Development Portfolio

- **Basic Research**: In Vitro & Animal Models, Animal Testing, Lab-Scale Production
- **Preclinical Development**: Human & Animal Efficacy, Dose, & Safety Testing, Formulation, Production of Clin. Supplies
- **Filing & Launch preparation**: Regulatory Submission, Manufacturing Scale-Up
- **Commercialization & Procurement**: Full-Scale Production, Safety Follow-Up
- **Readiness & Stockpiling**: Warm base production

**Civilian Programs**

- NIH
- ASPR-BARDA
- ASPR-OEM
- CDC

**Military Programs**

- DARPA
- CBDP
- DTRA-JSTO/AMC-RDECOM-ECBC/MEDCOM-MRMC
- JPEO- JPM MCS
- Individual Services

**Government Agencies**

- FDA
- CDC
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

<table>
<thead>
<tr>
<th>Near-Term (FY 2007-2008)</th>
<th>Mid-Term (FY 2009-13)</th>
<th>Long-Term (Beyond 2013)</th>
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<tr>
<td>• Broad-Spectrum Antibiotics</td>
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## Advanced Development (AD) and Procurement Priorities

### Medical Countermeasure Category

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Product Types in Portfolio

- Vaccines
- Drugs
  - Antibiotics, antitoxins, burn treatment, radiation treatment
- Diagnostic assays and equipment
- Devices
  - Ventilators, respiratory protection
- Ancillary supplies
  - Needles, syringes, I.V., etc.
- Information and Guidance
The 2010 Review
MCM Enterprise Vision

“Our Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease”

If a product fails, it should only be the result of failure of the product to achieve the desired safety or efficacy thresholds, and not as a function of our inability to provide the proper support from a technical, business and regulatory perspective.
The 2010 MCME Review
Key strategic attributes for transformation

- Invest in products and capabilities that address clearly defined current threats
- Embrace nimble, multi-use technologies and platforms for future unknown threats
- Increase investment in FDA regulatory science
- Expand core services for industry partners
- Be more creative in helping incubating and nurturing multi-use and needed technologies from discovery through advanced development
- Integrate activities and governance structure into a more unified approach
- Establish a multi-year budget perspective
All-Hazards Principle

Seasonal & Pandemic Influenza Preparedness

All Hazards Preparedness

Emerging Diseases Preparedness

CBRN Preparedness
The Evolution of PHEMCE Planning and Capabilities

2010

2012

2014

PHEMCE Multiyear Budget
Fiscal Years 2014-2018
PHEMCE Prioritization Framework

All Actions in PHEMCE are based on Two Core Principles
- Limit adverse health impact
- Stewardship of resources that create an enduring capability

Product decisions will be judged against these criteria:
- Focused on key threats
- Potential for multi-functional product
- Forecasts operational capacity
- Addresses needs of at-risk population needs
- Optimizes cost and time for product development / use
**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
- **BARDÁ**: Biomedical Advanced Research & Development Authority
- **CDC**: Centers for Disease Control and Prevention
- **FDA**: Food and Drug Administration
- **NIH**: National Institutes of Health
Six Operating Principles

- Public-private partnerships
- Platform and enabling technologies
- Multipurpose products
- Control of total lifecycle costs
- Rigorous portfolio management
- Coordinated effort
PHEMCE Governance Structure

October 2016

Enterprise Senior Council (ESC)
Policy and Strategy (Chair: Dr. Lurie)

Enterprise Executive Committee (EEC)
Coordination and Communication (Co-chairs: Drs. George Korch and Sally Phillips)

Project Coordination Teams (PCTs)
Acquisition and Advanced Development

Integrated Program Teams (IPTs)
End-to-End Portfolio Vision

Portfolio Advisory Committee (PAC)
HHS – DOD Portfolio Planning

Requirements Working Groups

Dr. Nicole Lurie, ASPR
Dr. Tony Fauci, NIAID
Dr. Robert Califf, FDA
Dr. Tom Frieden, CDC
Dr. Tom Hopkins, DoD
Dr. Kathy Brinsfield, DHS
Integrated Program Teams (IPTs)

- Anthrax
- Botulism
- Broad Spectrum Antimicrobial (BSA)
- Chemical
- Diagnostics
- Pediatric and Obstetric (PedsOB)
- Radiological/Nuclear (Rad/Nuc)
- Smallpox
- Viral Hemorrhagic Fever (VHF)
- Product Monitoring and Assessment

Working Groups

- Respiratory Protection Devices
- Emerging Infectious Diseases
- PREP

Zika Vaccine WG
# PHEMCE Requirements Process

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Outputs</th>
<th>Key Deliverables</th>
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<tbody>
<tr>
<td><strong>DHS-led</strong></td>
<td><strong>HHS-led:</strong> ASPR MCSR &amp; PHEMCE IPT</td>
<td><strong>HHS-led:</strong> BARDA &amp; CDC/SNS</td>
</tr>
<tr>
<td>Intel assessment &amp; scenario assumptions</td>
<td>Medical mitigation parameters &amp; assumptions</td>
<td>Public health &amp; medical capacity (space, staff, supplies)</td>
</tr>
<tr>
<td><strong>Public Health and Medical Consequence Analyses</strong></td>
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</tr>
<tr>
<td><strong>What is the threat?</strong></td>
<td><strong>What are the critical MCMs?</strong></td>
<td><strong>How many MCMs can we use?</strong></td>
</tr>
<tr>
<td></td>
<td><strong>How many MCMs do we need?</strong></td>
<td><strong>How many should we stockpile?</strong></td>
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<tr>
<td><strong>Consensus Scenarios</strong></td>
<td><strong>Mitigated consequences</strong></td>
<td><strong>Operational Quantity</strong></td>
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<tr>
<td><strong>Unmitigated consequences</strong></td>
<td><strong>Need-based Quantities (NBQ)</strong></td>
<td><strong>Potential Gap Solutions</strong></td>
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**KEY DELIVERABLES**

- Material Threat Assessment (MTA 2.0)
- Scenario Based Analysis (SBA)
- Integrated Capabilities Document (ICD)
- Product Specific Requirements (PSR)
- Acquisition Strategies & Plans
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:
Approved, Documented and Sequential Process

- Material Threat Assessments
- Material Threat Determination
- Public Health Consequence Assessment
- Scenario-Based Requirement
- Product Specific Requirement
- Acquisition Plan (R&D)
- In Process Review of Products
- Procurement Plan
- Operational Plans Documents
- Clinical Guidance Documents
- Portfolio Review and High Priority Actions Items
- Annual Strategic National Stockpile Review
- Multiyear (5 year) Budget Projection
Key MTA 2.0 Features

- A range of scenarios provide a consistent method to compare scenarios across threats
  - Includes scenarios with a range of consequences
  - Provides a set of consensus scenarios for PHEMCE to use to assess current and target capabilities

- Increased visibility on intelligence elicitation, agent selection, and modeling decisions/processes
  - DHS conducts intelligence elicitation
  - DHS produces exposure profiles
  - HHS produces estimates of the unmitigated medical consequences
MTA 2.0 Rationale

Rather than trying to assume that we know how an adversary might carry out a single attack scenario and the number of people who might be impacted, the goal was to examine a range of scenarios/impacts and what different adversaries might need to do to accomplish the different scenarios.
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
DART 2.0
Influenza Tool Kit
Scenario-Based Analyses (SBAs)*

- Results of medical and public health consequence modeling (with assumptions)
- Brief description of scenario(s) on which modeling is based
- At-risk population considerations
- Medically relevant timeframe
- Anticipated operations of incident response
- Consideration of currently available MCMs (pharmaceutical and non-pharmaceutical)
- Evaluation of MCM by type and quantity and non-medical countermeasures/supportive care
- Need-based quantities for each MCM class, focused on critical (days to weeks) needs
- Description of military needs/requirements (if applicable)

* Scenario-Based Analyses (SBAs) were formerly called Scenario-Based Requirements (SBRs)
Ongoing PHEMCE Activities

- Strategy and Implementation Plan (SIP)
- Strategic National Stockpile Annual Review (SNS AR)
- Portfolio Reviews
- Multi-Year Budgeting
- Portfolio Tracking Tool
- Preparedness Assessments
Create Robust & Innovative MCM Development Pipeline

- ~ 200 MCM product candidates in development

ASPR/BARDA ERA

![Graph showing the development pipeline with years 2004 to 2015 and various MCMs such as PAHPA, Ebola, and MERS-CoV]
FDA-approved BARDA Products

- FDA has approved 15 MCMs supported by BARDA with 4-5 more approvals expected in near-future.
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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
Clinical Guidance Documents

- CDC published these Guidance Documents
  - Clinical Framework and Medical Countermeasure Use During an Anthrax Mass-Casualty Incident
  - 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*)
  - Working now on Botulinum and Nuclear Guidance
Preparedness Goal Determinants

- Research and Development ("develop")
- Manufacturing Capacity ("make")
- Procurement and Stockpiling ("access")
- Response Planning and Guidance ("plan")
- Operational Capacity ("use")
Visualizing Preparedness for a given product
The Final Mile

The Right Product(s) for the Right Patients at the Right Time and Place
Special Populations

- Pediatric
- Geriatric
- Pregnant/Lactating
- Immunocompromised
- Disabled
- Institutionalized
- Transportation Disadvantaged
- Chronic Illness
- Pharmacological Dependency
- Obesity
- Communication (non-English)
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
CDC’s Public Health Emergency Preparedness Program

Division of State and Local Readiness (DSLR)

- Develops guidance,
- Provides technical assistance
- Assigns field staff
- Translates science preparedness into practice

CDC awarded $612 million in PHEP funding to 62 awardees in FY 2015, including $53 million in dedicated MCM funding (Cities Readiness Initiative)

- Specific needs for dispensing and distribution of MCMs
- Develop state and local MCM plans and capabilities
- Test, train, exercise, and develop improvement plans
- Identify operational gaps
### CDC’s MCM-Related Impact Since 9/11

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<th>Public Health Preparedness Capability</th>
<th>Before 9/11</th>
<th>Current Status</th>
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<tr>
<td>Medical Countermeasures: Sufficient storage/distribution capability</td>
<td>0%</td>
<td>98%</td>
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<tr>
<td>Medical Countermeasures: Inventory management system</td>
<td>2%</td>
<td>92%</td>
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<td>Medical Countermeasures: Pre-identified points of dispensing sites</td>
<td>2%</td>
<td>100%</td>
</tr>
<tr>
<td>Medical Countermeasure: Plans developed</td>
<td>2%</td>
<td>100%</td>
</tr>
</tbody>
</table>
The “Ideal” MCM for Emergency Needs

- Appropriate for mass dispensing settings (a nonmedical model)
  - Effective and safe
  - Oral dispensing preferred
  - Packaged for “unit of use”
  - Licensed for Specific Indication
  - Licensed for entire population
  - No requirement for monitoring after dispensing
  - No requirement for cold-chain management, mixing, or compounding
  - Long, stable shelf life
  - Inexpensive
  - Easy Instructions
  - One time delivery
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
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.
The Future for ASPR and PHEMCE

We continue to face serious public health threats – whether man-made or from mother nature

We must invest in:

– Building sustainable partnerships with industry
– Building resilient communities
– Modernizing the medical countermeasures enterprise
– Strengthening health care coalitions and the emergency response system

And commit to:

– Innovation
– Strengthening the day to day PH capacity
– Evidence-based decision making
– Continuous improvement
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
Herding Cats

It CAN be done
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