Federal Support for Medical Countermeasure Development and Delivery for Your Community

2014 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan

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Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

• Federal coordinating body, led by HHS, that protects the U.S. civilian population from national health security threats through the use of medical countermeasures (MCMs)
  – Chemical, biological, radiological, and nuclear (CBRN) agents
  – Emerging infectious diseases (including influenza)
  – Member agencies include:
    ○ HHS: ASPR (including BARDA), CDC, FDA, and NIH
    ○ DoD, DHS, VA, and USDA

• Develops, produces and makes available medical countermeasures that limit adverse health impacts
  – Medical countermeasures are medicines, devices, or other medical interventions that can lessen the harmful effects of these threats
Overview of 2014 PHEMCE Strategy and Implementation Plan (SIP)

• **2014 PHEMCE SIP** sets the course for federal medical countermeasure (MCM) activities for next five years
  
  — [http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx](http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx)

• **2014 PHEMCE SIP** articulates
  
  — Mission, scope, goals, and objectives
  
  — Prioritized activities to pursue goals and objectives within available resources

• **Process**
  
  — PHEMCE SIP issued annually per PAHPRA* requirements
  
  — 2014 SIP includes major revisions to IP (every 2 years thereafter)
  
  — Major re-evaluation of goals/objectives (as needed) in 2018 (every 4 years thereafter)

* Pandemic All Hazards Preparedness Reauthorization Act*
**PHEMCE High Priority Threats**

- *Bacillus anthracis* (anthrax)
- *Clostridium botulinum* toxin (botulism)
- Cyanide
- Emerging infectious diseases
- Gram negative organisms
  - *Burkholderia mallei* (glanders)
  - *Burkholderia pseudomallei* (melioidosis)
  - *Francisella tularensis* (tularemia)
  - *Rickettsia prowazekii* (typhus)
  - *Yersinia pestis* (plague)
- Multi-drug resistant *Bacillus anthracis* (MDR anthrax)
- Nerve agents
- Nuclear agents
- Pandemic influenza
- Radiological agents
- Variola virus (smallpox)
- Viral Hemorrhagic Fevers
  - Marburg
  - Ebola

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.
PHEMCE Mission Components

• Requirements Setting
• Early Stage Research
• Advanced Development / Manufacturing
• Regulatory Science Management
• Procurement / Inventory Management / Stockpiling
• Response Planning, Policy, Guidance and Communication
• Deployment / Distribution / Dispensing / Administration
• Monitoring / Evaluation / Assessment
PHEMCE Lead Roles

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

Acronyms

PHEMCE: Public Health Emergency Medical Countermeasures 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
2014 PHEMCE Strategic Goals

Goal 1 • Identify, create, develop, manufacture and procure critical medical countermeasures

Goal 2 • Establish and communicate clear regulatory pathways to facilitate MCM development and use

Goal 3 • Develop logistics and operational plans for optimized use of medical countermeasures at all levels of response

Goal 4 • Address medical countermeasure gaps for all sectors of the American civilian population
PHEMCE Prioritization Framework

• Two Core Principles
  – Limit adverse health impacts
  – Fiscal responsibility to be prudent with resources

• Primary Criteria
  – **Threat:** Address high-priority threats that pose greatest threat to national health security for which sufficient MCM capabilities do not exist
  – **Multi-functionality:** Prioritize investments that address multiple threats, have routine public health uses, and/or leverage commercial markets
  – **Operational Capacity:** Degree to which a product is operationally and logistically practical and acceptable to its end-users

• Moderating Criteria
  – **At-Risk Population Needs:** Address the needs of all segments of the U.S. civilian population, including at-risk populations*
  – **Time:** Balance between rapid returns on investment, and significant gains in capabilities possible through longer sustained efforts.
  – **Cost:** Consider lifecycle costs (development, acquisition, and sustainment)

*At-risk individuals have needs in one or more of the following functional areas: communication, medical care, maintaining independence, supervision, and transportation. See http://www.phe.gov/preparedness/planning/abc/pages/default.aspx
## Advanced Development (AD) and Procurement Priorities

<table>
<thead>
<tr>
<th>Medical Countermeasure Category</th>
<th>AD Priorities Through FY18¹</th>
<th>Current HHS Holdings²</th>
<th>Procurements Programmed Through FY14³</th>
<th>Additional Procurements Projected Through FY18⁴</th>
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### Footnotes:

¹ These priorities include new products coming through the research and development pipelines, as well as enhancements to current products in the SNS.

² Includes inventory held in both the SNS and alternative stockpiles.

³ Contingent upon existing resources.

⁴ Assuming appropriations are available to maintain currently stockpiled and programmed levels.

⁵ Solicitations are ongoing to maintain existing preparedness levels and manufacturing capacity established under previous contracts.

⁶ Purchase of MCMs using the SRF between FY15 and FY18 are planned pending annual appropriations.

⁷ DSNS refers to the Division of Strategic National Stockpile, the CDC division responsible for managing the SNS, whose mission is to deliver critical medical assets to the site of a national emergency.

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.
GOAL 3: MCM Utilization

• Comprehensive Action Plan for monitoring the safety and clinical benefit of MCMs during public health emergencies developed and a new IPT is being established to implement

• Anthrax vaccine prioritization guidance completed (April 2013)

• CDC updated guidance for MCM dispensing models to meet the diverse needs of communities entitled “Receiving, Distributing, and Dispensing, Strategic National Stockpile Assets: A Guide for Preparedness”

• Developed and implemented a policy framework for responding to international requests for sharing MCMs

• Clinical practice guidelines published for glanders and melioidosis, and anthrax MCMs for general population and under mass casualty conditions

GOAL 4: At-Risk Population Needs

• Clinical practice guidelines for anthrax medical countermeasures for pediatrics and pregnant women

• Development and promulgation of various online educational and training materials to support managing children’s needs in times of disasters
• Planning guidance for patient decontamination in a mass exposure chemical incident (FY15)

• Assessment of state and local capacity to utilize cytokines for ARS-associated neutropenia following use of an improvised nuclear device (FY15)

• National response strategies for anthrax (FY15), botulism, glanders and melioidosis, and smallpox (FY16)

• Clinical practice guidelines for MCMs to address chemical agents, smallpox, anthrax, and botulism (FY15-16) and ARS-associated neutropenia (FY17-18)

• CONOPs for MCMs to address neutropenia (FY17-18), glanders and melioidosis (FY17-18), and botulism (FY19)
Regulatory Mechanisms to Support Medical Countermeasure Use

- FDA established multidisciplinary Public Health and Security Action Teams (Action Teams) to resolve regulatory and scientific challenges for high-priority MCMs and related technologies

- PAHPRA amended the FD&C Act to clarify FDA’s EUA authority and to allow for certain preparedness activities and rapid deployment of certain FDA-approved MCMs, without having to issue an EUA

- FDA will provide guidance on recommendations and procedures for issuance of EUAs concordant with authorities made by PAHPRA

- FDA will continue to provide policy assistance for relevant partners as necessary
  - First responders’ ready access to and use of MCMs;
  - MCM development challenges that are unique to the warfighter;
  - Expiration dating as it pertains uniquely to stockpiled MCMs;
  - Data collection during a public health emergency;
  - Guidance development;
  - MCM import and export during emergency responses
Utilization Planning for At-Risk Population Needs

- Provide clinicians with dosing and use guidance for using stockpiled MCMs in pediatric populations during an emergency (e.g., under an EUA)

- Ensure public health and medical information takes into account the range of communication and other functional needs of recipients

- Leverage relationships with the American Academy of Pediatrics and other clinical organizations to inform MCM strategies and policies

- ASPR will support the development of pediatric-specific training curriculum guidance for managing children’s needs in times of disasters (coordinating with the Federal Education and Training Interagency Group and the National Center for Disaster Medicine and Public Health)

- Integrate operational considerations and resources targeting the needs of pediatric and other at-risk populations into HHS All-Hazards Plan and threat-specific annexes
• Provide guidance to SLTT partners on receiving and effectively utilizing (i.e., deploying, distributing, and dispensing) MCMs provided by the Strategic National Stockpile
  – Promote exercises of these capabilities at the community, SLTT, and federal levels to include regional emergency planning alliances and healthcare coalition participation

• Build medical countermeasure delivery and utilization capabilities at the state and regional level
  – State and local distribution and dispensing plans
  – Federal assistance to states and localities
    ▪ Hospital Preparedness Program
    ▪ Federal assets to augment state and local plans

• Develop regional MCM annexes to complement and supplement the MCM dispensing plans developed by the 10 largest Urban Areas Security Initiative areas under the Cities Readiness Initiative program

• Enhance coordination on preparedness among regional HHS partners by developing a consistent national framework for the regional coordination of prevention, mitigation, preparedness, response, and recovery activities, including those required for effective MCM utilization
Support for SLTT Response Efforts (cont.)

- Ensure effective communications to both responders and the public before, during and after a public health emergency
  - Test effectiveness of public health communication materials
  - Disseminate best practices for regional coordination

- Ensure SLTT public health officials and designated hospital authorities have sufficient knowledge of the contents and dispensing policies associated with the materiel from the SNS

- Implement and maintain training programs in risk communication to train government leaders and partners in risk communications through the Crisis and Emergency Risk Communication (CERC) program

- Provide training for the response and recovery workforce on the use of MCMs against all hazards, including making available just-in-time advanced training for MCMs targeting particular threat agents
• Town Hall session at 2015 Public Health Preparedness Summit (April 14-17; Atlanta, GA) on PHEMCE engagement with state and local partners
  — “From Bench to Bloodstream – Federal Priorities for Medical Countermeasure Development and Use in Public Health Emergencies”
  — Many other sessions by PHEMCE partners

• Panelists will include
  — ASPR Office of Policy and Planning
  — CDC Office of Public Health Preparedness and Response, Division of the Strategic National Stockpile
  — ASPR Office of Emergency Management

• April 15 (10:30 AM - 12:00 PM)
PHEMCE on the web

http://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx

Public Health Emergency Medical Countermeasures Enterprise

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS interagency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA).

PHEMCE Highlights

2014 HHS PHEMCE Strategy and Implementation Plan

2010 PHEMCE Review

The vision to combat emerging infectious diseases, pandemics, and bioterrorism is simple: our nation must have the nimble, flexible capability to produce MCMs rapidly. In the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional. Learn More >>

PHEMCE Mission Components

The PHEMCE coordinates medical countermeasure-related efforts within HHS and in cooperation with PHEMCE interagency partners. This is a complex mission space and many Federal agencies have responsibilities that are critical to its success. Learn More >>

PHEMCE Governance

Questions

• How/where have you looked in the past for Federal MCM policies and guidance? Have they been incorporated into your plans?

• How do you communicate MCM questions and issues to Federal partners?

• What additional information does your organization need to support medical countermeasure response planning?

• What are the biggest challenges to your organization being able to use MCMs in a public health emergency?
Backup Slides
Goal 1: Identify, create, develop, manufacture and procure critical medical countermeasures

Objectives:

1.1 Develop a strategic framework to prioritize PHEMCE resources and investments.

1.2 Utilize consistent approaches for medical consequence and public health response assessments and medical countermeasure requirement setting that include consideration of effective production, storage, deployment and administration strategies.

1.3 Ensure a robust and sustainable product pipeline for medical countermeasures that emphasizes multi-functional capabilities rather than stand alone outcomes (e.g., platform technologies, host-based innovations, broad-spectrum medical countermeasures) and includes consideration of viable commercial markets and/or routine public health applicability.

1.4 Promote effective domestic and international partnerships with developers and manufacturers and support core services.
Objectives:

2.1 Identify scientific and regulatory issues that challenge medical countermeasure development or use during public health emergencies and coordinate activities among PHEMCE partners to address those challenges.

2.2 Assist medical countermeasure developers in working interactively with FDA during product development and regulatory review.
Objectives:

3.1 Promote innovative approaches to inventory management to enable a sustainable preparedness infrastructure.

3.2 Develop and communicate medical countermeasure utilization policy, guidance and response strategies, including FDA regulatory frameworks, that are responsive to end-user needs and that are integrated with regional, state, local, tribal, territorial, and private sector response plans, and when possible international partners, and that ensure timely, safe, and effective medical countermeasure distribution and utilization.

3.3 Develop and provide medical countermeasure communications, training, and education information to inform all stakeholders.

3.4 Develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance during and after a public health emergency response.
Goal 4: Address medical countermeasure gaps for all sectors of the American civilian population

Objectives:

4.1 Develop medical consequence and public health response assessments and requirements setting for at-risk individuals.

4.2 Support medical countermeasure advanced development and procurement for at-risk individuals.

4.3 Develop and implement strategies, policies, and guidance to support the appropriate use of medical countermeasures in all civilian populations during an emergency.