



*United States Department of*

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



# **PHEMCE Partner Efforts in Support of Goal 4 of the 2012 PHEMCE Strategy**

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**BARDA Industry Day**  
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# Presentation Outline



1. 2012 PHEMCE Strategy – Goal 4
2. Pediatric and Obstetric Integrated Program Team  
(PedsOB IPT)
3. PHEMCE Partner Efforts in Support of Goal 4



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# 2012 PHEMCE Strategy: Goal 4



## *Address medical countermeasure gaps for all sectors of the American civilian population.*

- **Objective 4.1** – Develop medical consequence and public health response assessments and requirements setting for at-risk individuals.
- **Objective 4.2** – Support medical countermeasure advanced development and procurement for at-risk individuals.
- **Objective 4.3** – Develop and implement strategies, policies, and guidance to support the appropriate use of medical countermeasures in all civilian populations during an emergency.



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# PedsOB IPT: Purpose (1)



- Established in October of 2011.
- Advises the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) with strategies for identifying, developing, acquiring, deploying, and using high priority medical countermeasures for children and pregnant women in public health emergencies.
- Agencies represented: ASPR (BARDA, NDMS, Policy), CDC, DHS, FDA, NIH, NVPO, and VA.



## PedsOB IPT: Purpose (2)



The PedsOB IPT accomplishes its purpose by:

- Supporting the threat-based PHEMCE IPTs
- Prioritizing issues and recommending solutions for identified MCM gaps for obstetric and pediatric populations
- Providing input on requirements setting, research needs, the Annual Review of the Strategic National Stockpile (SNS), and other matters determined by the PHEMCE
- Engaging stakeholder feedback as needed and appropriate



# PedsOB IPT: Presentations and Requests



The IPT has met 13 times since its inception and has prepared and/or considered 17 presentations or requests; some examples:

1. Review of NBSB pediatric anthrax study recommendations
2. Considerations for MCM development in children (AAP)
3. Dysphagia: data and implications for the SNS
4. Auto-injectors for children; 2-PAM and midazolam
5. Review of pediatric ancillary supplies for the SNS
6. Ventilator requirements for the pediatric population
7. Analysis of regulatory gaps for pediatric/OB MCMs in the SNS
8. Discussion of inclusion of uterotonic medications in the SNS



# PedsOB IPT: Outputs



- Responded to the Anthrax IPT request to review the requirement for anthrax antimicrobial PEP for young children.
- Responded to the Rad-Nuc IPT request to make formulation recommendations on the supply of tablet and liquid KI in the SNS.
- Participated in the 2012 SNS Annual Review.
  - Prioritized and made recommendations around 13 MCMs using five criteria: criticality, flexibility, performance, sustainability, usability.



# PedsOB IPT: Future Plans



- Prioritize “closing the gaps” for use of pediatric and obstetric MCMs: IND to EUA, and EUA to labeling.
- Facilitate appropriate dosing and utilization of pediatric and obstetric medical countermeasures.



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# PHEMCE Partner Efforts (1)



- The **Children's HHS Interagency Leadership on Disasters (CHILD) Working Group**, co-chaired by ASPR and ACF, prioritized three additional areas of focus for 2012:
  1. Children with special health care needs and other sub-populations of children traditionally under-represented in planning efforts
  2. Pregnant/breastfeeding women and neonates (including subsection specific to medical countermeasures)
  3. Enhancing interdepartmental and NGO collaboration
- Public summary of 2011 report available at [www.phe.gov/abc](http://www.phe.gov/abc).



## PHEMCE Partner Efforts (2)



- BARDA includes options for studies to support development of pediatric and geriatric indications and formulations of MCMs in all late-stage development and procurement contracts.
  - BARDA is supporting the development of safe and effective pediatric formulations of Radiogardase (Prussian Blue) for children less than two years of age for treatment after radiation poisoning (i.e., radioactive cesium and/or radioactive or non-radioactive thallium).



## PHEMCE Partner Efforts (3)



- The **National Biodefense Science Board (NBSB)** benefits from five members with expertise in pediatric emergency medicine, infectious disease, epidemiology, and child psychiatry.
- The FDA established a **Pediatric and Maternal Public Health and Security Action Team** through its Medical Countermeasures Initiative (MCMi).
  - Among its activities, this group worked with CDC to complete an inventory of the SNS to identify data gaps that could inhibit the effective use of stockpiled MCMs in children and other at-risk populations.



## PHEMCE Partner Efforts (4)



- FDA and NICHD manage the implementation of the **Best Pharmaceuticals for Children Act (BPCA)** and the **Pediatric Research Equity Act (PREA)**, which:
  - Address obstacles that hinder the adequate study and labeling of drugs and devices for the pediatric population.
  - Identify and prioritize drugs needing study, and develop study requests in collaboration with NIH and FDA.
  - Offer an additional six months of patent exclusivity for on-patent drugs being tested for pediatric use.
  - As a result, more than 425 drug labels have been revised with important pediatric information.



## PHEMCE Partner Efforts (5)



- CDC's **Children's Preparedness Initiative** champions the needs of children in disaster planning and response efforts through cultivating and collaborating with partners, building technical expertise, integrating children's needs, and increasing awareness. Examples include:
  - Working with the American Academy of Pediatrics to formalize clinical guidance for the treatment and prophylaxis of children against anthrax.
  - Developing an instructional video in English and Spanish about pill crushing (e.g., doxycycline) for in-home use.



# PHEMCE Partner Efforts (6)



- **NICHD: Pediatric Trials Network (PTN)**
  - Established in 2010 to create an infrastructure to study critical drugs and diagnostic devices in children to improve labeling for pediatric use.
  - Plans to conduct 16 trials over the next five years that might enhance pediatric labeling.
  
- **NIAID**
  - Vaccine trials in special populations for pandemic and seasonal influenza.
  - Therapeutic trials for antivirals for multiple special populations
    - Neonates, solid tumor transplant patients, immunosuppressed.
  - Approval through the Animal Rule of therapeutic modalities for all populations.



# PHEMCE Partner Efforts



- Thank you for your attention.
- Any questions?