



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness & Response (ASPR)
Biomedical Advanced Research & Development Authority (BARDA)



Medical Counter Measures: What about the Children?

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Medical Counter Measures for Children



IMPORTANT CHALLENGE FOR HHS/ASPR/BARDA IS THE CONSIDERATION OF SPECIAL POPULATIONS IN RELATION TO MEDICAL COUNTERMEASURES

- **Estimated proportion of Americans that are in special populations:**
 - Children: *26% of the U.S. population are 0-17 years of age*
 - 8% are 0-5 years of age
 - 14% are < 12 years of age
 - Elderly: *13% of U.S. citizens are 65 years or older*
 - Pregnant women: *At least 2.1% of all women at any one time are pregnant*
 - Neuromuscular impairment: *? % associated with swallowing difficulty*
 - *Includes strokes, cerebral palsy, trauma, tumors, muscle disease, neurologic disease, etc.*
 - Immunocompromised: *3.6% of U.S. citizens*



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Exposure of children to biomedical, chemical or radiological/nuclear threats could occur virtually everywhere:

- Any public gathering event:
- Shopping malls
- Mass transportation
- Inhabitants of target cities
- Public water supply
- Contaminated food
- Nosocomial infections in medical centers



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BARDA can procure and store pediatric medical counter measures for the Strategic National Stockpile

if:

➤ **The counter measure is approved for use in children by the FDA.**

Or

➤ **Enough information is available for it to be used under an IND or Emergency Use Authorization (EUA).**



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Barriers to the development of new medical counter measures for children and other populations:

- Ethical concerns
- Economic barriers
- Logistics
- Technical Challenges
- Formulation



There has been progress:

- **Best Pharmaceuticals for Children Act (BPCA) passed in 2002**
- **Pediatric Research Equity Act (PREA) passed in 2003**
- **We still need more momentum to push for pediatric medical counter measures**



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BARDA has undertaken numerous efforts to address the needs of children for MCM:

- **Since the passage of the Pandemic All-Hazard Preparedness Act (PAHPA) in 2006, all BARDA procurement contracts have included options to expand label indications to include special populations once the product is approved for adults.**
- **BARDA will be including development of MCMs for children as part of their base contracts moving forward.**
- **BARDA is an active partner in NBSB evaluation of pediatric counter measures. Most recently is coordinating multiagency input for anthrax post-exposure prophylaxis.**



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Examples of pediatric considerations involving CBRN MCM Efforts:

- Smallpox anti-viral formulation in the base contract.
- Heptavalent botulinum antitoxin developed under a BARDA contract has been used in children from 10 days to 15 years of age.
- SNS has pediatric formulations (liquid) of antibiotics for anthrax.
- Contract for a pediatric formulation of Prussian Blue to decorporation of radioactive nuclides.
- Supporting NIAID to develop an oral formulation for DTPA (chelator for radioactive nuclides).
- New contracts to include pediatric formulations of broad spectrum antibiotics against plague, tularemia, and anthrax.
- Funding a palatability study to support crushing ciprofloxacin or doxycycline for pediatric dosing for an anthrax attack.
- Co-funding a study to support approval for the use midazolam as a pediatric countermeasure for a neurochemical threat.



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Examples of pediatric considerations for Influenza MCM Efforts

- Pediatric H5N1 adjuvanted vaccine study.
- Multiple Pandemic monovalent H1N1 vaccine pediatric studies in 2009
- Funded pediatric syringes for inactivated and sprayers for live attenuated influenza vaccine during H1N1 response.
- Oral and oral suspension oseltamivir was purchased for SNS to use in children during H1N1 response.
- Inhaled Zanamivir was purchased for the SNS
- IV peramivir was made available for children under an EUA



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Examples of pediatric considerations for Influenza MCM Efforts

➤ Respirators:

- Currently supporting the development of a portable ventilator that can be used in all populations, from neonates to adults. If cleared by the FDA, there is the capability to manufacture 10,000 ventilators within 6 months.
- New Influenza BAA looking for the next generation of portable ventilators that would include infants and children.

➤ Diagnostics:

- Rapid influenza tests – BARDA continues to support improvements and assessments of these tests along with information and data that can lead to improved guidance and testing practices.
- BARDA continues to fund projects to detect multiple respiratory pathogens, recognizing the need for improved understanding of the significance of co-detection of multiple pathogens has been associated with more severe illness in children.



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BARDA's New Division of Clinical Studies (DCS)

- **The DCS is aware of needs of MCM for special populations including but not limited to pregnant women, the elderly and children.**
- **Presently, the DCS has three physicians with considerable experience in clinical studies and who have provided medical care for special populations.**
 - Including a Pediatrician with 21 years experience in primary care and pediatric infectious diseases.
- **One of the key objectives of the DCS to be sure BARDA project team members are aware of the needs of special populations during all phases of program development.**



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Questions for Dr. Krug or Dr. King?

