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?

James King M.D.
Contractor
Division of Clinical Studies
BARDA/ASPR/HHS
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
Medical Counter Measures for Children

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
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).
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
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.
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.
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
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 date 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.
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.
Medical Counter Measures for Children

Questions for Dr. Krug or Dr. King?