



The Risks of Cough/Cold Preparations to Young Children

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OUTLINE

- **Principles of Pediatric Drug Safety**
 - **Relevance to cough/cold preparations**
- Sources of Data
- Categories of adverse drug events (ADE) associated with cough/cold preparation use in children
- Range of Toxicity

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Principles of Pediatric Drug Safety

- Extrapolation of adult data to create pediatric doses is fraught with danger
- Passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act have been important
- The time is now for FDA to begin evaluating agents previously designated “Generally Regarded as Safe”

Toxicity of Cough/Cold Preparations

Sources of Data

- Poison Centers
- Medical Examiner reports
- Published Case Reports
- FDA
- CDC
- State and local agencies

Toxicity of Cough/Cold Preparations

Sources of Data

- **Poison Centers**

- Data from 2001 through 2005

- 328,441 calls to poison centers about children exposed to cough/cold preparations
- Includes overdose, interactions and unexpected toxicities

- **Medical Examiner**

- 10 deaths in Ohio (J Anal Tox, 2005)

- 8 infant deaths from 1999-2005 (J For Sci 2007)

Toxicity of Cough/Cold Preparations

Sources of Data

- **Published case reports**
 - More than 10 published reports of toxicity to young children
 - Several fatalities
 - Adverse events included hallucinations, agitation, seizures, and cardiac arrest

Toxicity of Cough/Cold Preparations

Sources of Data

- **Public health authorities**
 - **FDA**
 - 27-year analysis of AERS
 - 401 serious adverse events and 123 deaths
 - **CDC**
 - Reviewed 3 infant deaths in two states (MMWR, Jan 2007)
 - Over 2 years, 1519 children sent to emergency departments
 - **State and local agencies**
 - 900 calls about children < 5 in one year (Maryland, 2004)
 - 4 deaths in children under 4 in Baltimore

Categories of Adverse Drug Events

- Acute, single overdose
 - By child
 - By parent
- Chronic overmedication (by parent)
- “Therapeutic misadventures” (by parent)
 - Drug-host interactions
 - Drug-drug interactions

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Range of Toxicity

- Cardiovascular
 - Hypertension
 - Tachyarrhythmias
 - Cardiomyopathy
 - Cardiac Arrest
- Neurologic
 - Neurobehavioral (hallucinations, agitation, psychosis)
 - Seizures
- Metabolic
 - Metabolic acidosis
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Conclusions

- **When a treatment is ineffective, its risks - if not zero - will always exceed its benefits**