Pediatric Cough & Cold Products: Analysis of American Association of Poison Control (AAPCC) Data, 2011-2016

Office of Surveillance and Epidemiology (OSE)
Division of Epidemiology-1 (DEPI-1)

Sara Karami, PhD
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Disclosure Statement

This document contains proprietary data from the American Association of Poison Control Centers obtained by FDA under contract.

The opinions in this presentation are my own and do not necessary reflect the views and policies of the FDA.

Outline

- Background
- Purpose of the Investigation
- Study Methods
- Study Results
- Study Limitations
- Summary of Findings

Background

- CDC report indicates that drug overdose deaths among adolescents 15–19 years in the United States has increased from 2014 to 2015
- Autopsy/toxicology reports can identify molecules (e.g., hydrocodone), but not specific products (e.g., analgesics or cough syrups)
- Hospitalization codes do not have product details; would need chart review
- Calls to poison control centers often provide more detailed reports on specific products/drug classes

Source: NCHS Data Brief No. 282, August 2017

Purpose

- Calculate rates of exposure to opioid and non-opioid containing cough & cold products in pediatric patients in calls to poison control centers

- Examine reason for exposure

Methods

- Retrospective analysis of aggregate data obtained from National Poison Data System (NPDS), maintained by the American Association of Poison Control Centers (AAPCC)
- Exposure data captured via phone call from patient or healthcare professional
- January 1, 2011 - December 31, 2016
- Human exposure calls
  - Hydrocodone, codeine, benzonatate and dextromethorphan cough & cold products
  - Children and adolescents <18 years
  - Single-substance exposure calls (calls involving one product)

Methods (continued)

AAPCC codes all calls by the underlying reason for which the exposure occurred

- **Adverse Reaction-** unwanted effects due to an allergic reaction, hypersensitivity, or idiosyncratic responses to an ingredient when exposure involves normal, prescribed, labeled or recommended use
- **Unintentional**- unintended exposure resulting from the wrong dose, incorrect route of administration, administration to the wrong person or administration of the wrong substance
- **Intentional**- intentional improper or incorrect use of a substance; may include use of a substance to attempt to gain a high, euphoric effect, psychotropic effect, or to do self-harm

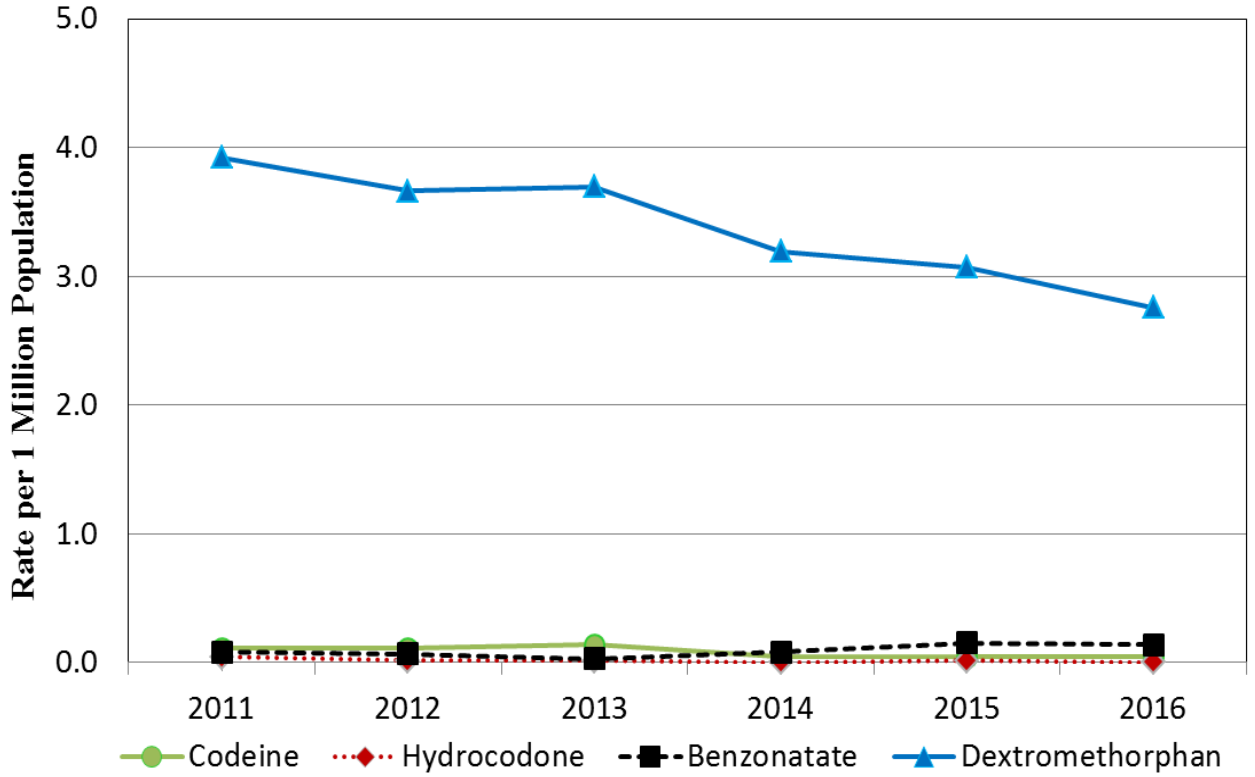
Methods (continued)

- We calculated age-specific annual call rates per 1 million population using age-specific population estimates from the US Census Bureau

- No statistical evaluation of trends, just descriptive analysis

Results

Annual Population-Adjusted Call Rates to Poison Control Centers Involving **Adverse Reaction** to Cough & Cold Products, Ages < 18 Years



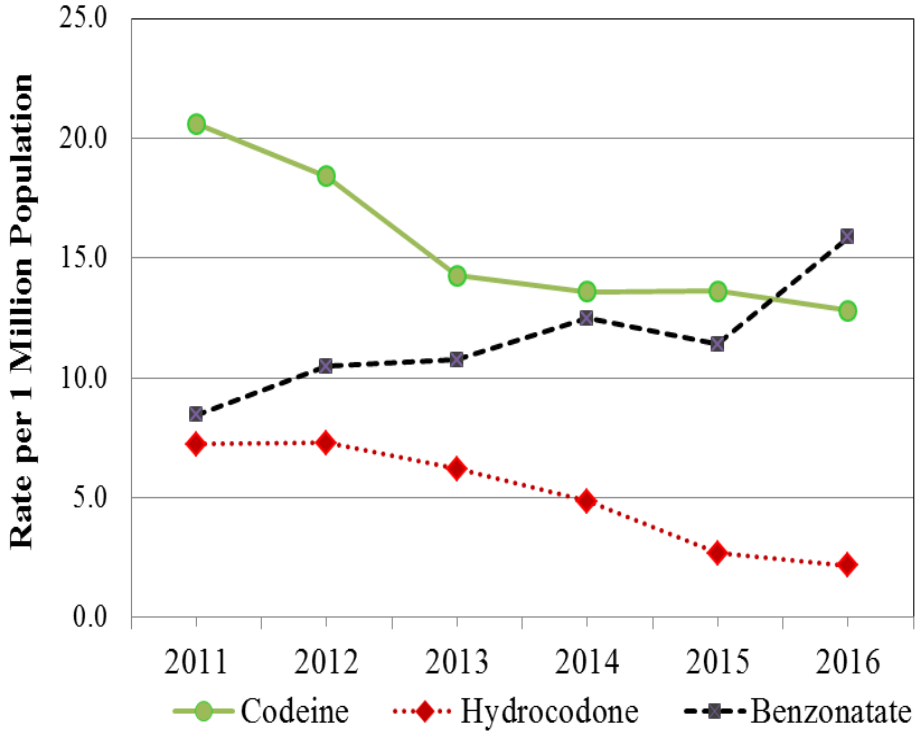
Mean Call Rate per Million Population	**0.08**	**0.01**	**0.09**	**3.38**

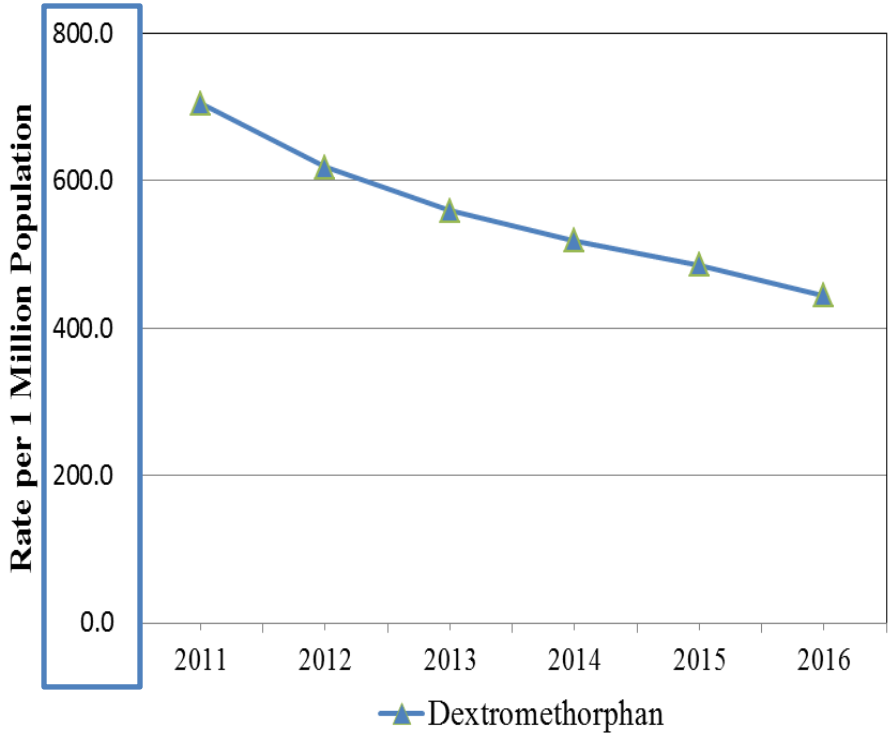
Adverse reactions are unwanted effects involving normal, prescribed, labeled or recommended use

Source: AAPCC_NPDS

Results (continued)

Annual Population-Adjusted Call Rate to Poison Control Centers Involving **Unintentional Exposure** to Cough & Cold Products, Ages <6 Years





Mean Call Rate per Million Population :
15.5 5.1 11.6

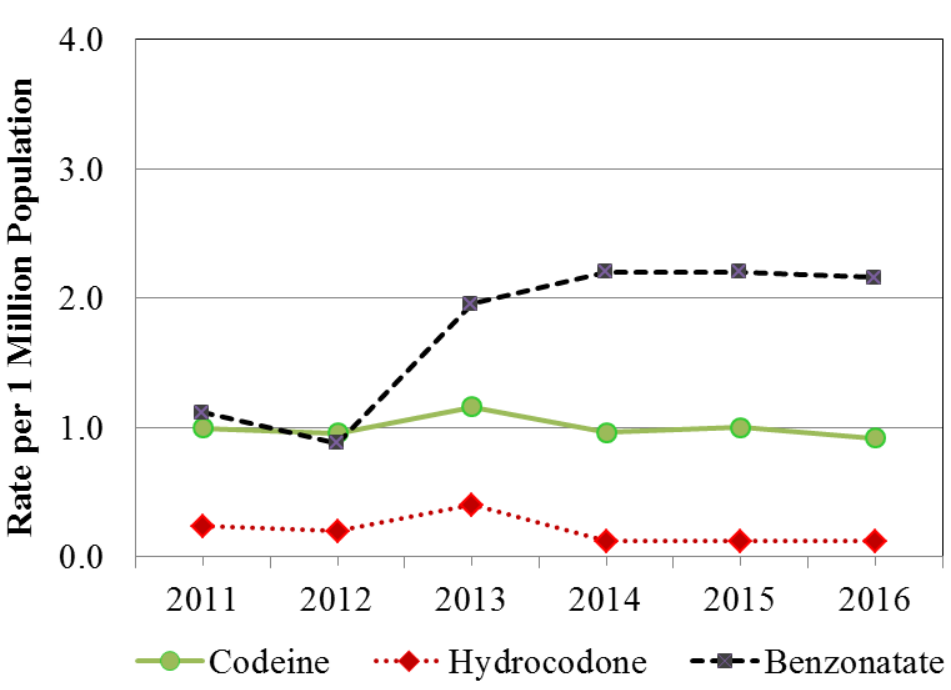
Mean Call Rate per Million Pop: 555.2

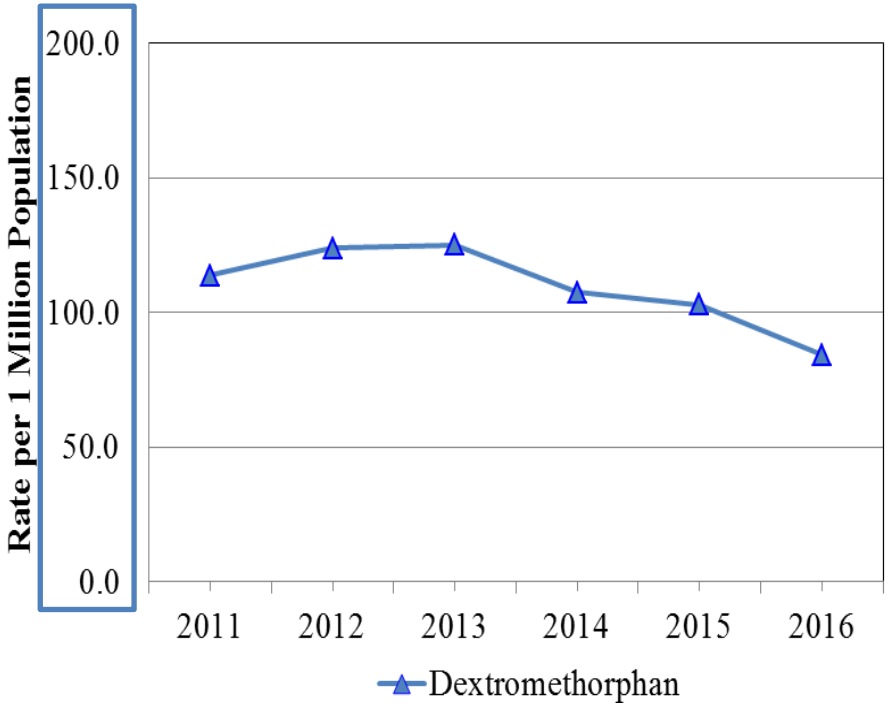
Unintended exposures result from incorrect dose, person, substance or route of administration

Source: AAPCC_NPDS

Results (continued)

Annual Population-Adjusted Call Rates to Poison Control Centers Involving **Intentional Exposure** to Cough & Cold Products, Ages 12-17 Years





Mean Call Rate per Million Population :
1.0 0.2 1.8

Mean Call Rate per Million Pop: 109.6

Intentional exposures result from improper or incorrect use of a substance; may include use of a substance to gain a high, euphoric or psychotropic effect, or to do self-harm

Source: AAPCC_NPDS

AAPCC Data Limitations

- Data do not represent the complete incidence of national exposures to any substance
- Data only capture events if exposure resulted in a call to a poison control center (PCC)
- PCC call data rely on information electively shared by patients and healthcare personnel
- Changes in rates may reflect changes in public and professional awareness of risks associated with specific drugs and/or awareness of abuse potential
- Call rate may be influenced by general changes to PCCs over time as number of call have declined during the past 10 years
- No statistical evaluation of trends, just descriptive analysis

Summary

Annual call rates for codeine and hydrocodone cough & cold products

- Decreased since 2011 for unintentional exposures in children < 6 years
- Steady since 2011 for intentional exposures in adolescents 12-17 years

Annual call rates for benzonatate cough & cold products

- Slowly increase for unintentional exposures in children <6 years
- Slight increase in 2012-13 and steady thereafter for intentional exposures in adolescents 12-17 years

For dextromethorphan cough & cold products the annual call rates

- Decrease in recent years for all age groups
- Largest proportion of cough & cold exposure calls

Reason for Exposure

- Intentional exposures much greater for adolescents 12-17 years
- Unintentional exposures much greater for children <6 years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