Lessons from Product Safety Changes to Reduce Pediatric Medication Errors to Acetaminophen

Poison Center Analyses

November 15, 2024

Kate M. Reynolds, MPH

Director of Research
Rocky Mountain Poison & Drug Safety (RMPDS)
– Denver Health & Hospital Authority

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH™
est. 1860
FOR LIFE'S JOURNEY

Objectives

- Outline pediatric acetaminophen safety changes
- Describe impact of safety changes on medication errors reported to poison center data
- Describe associated contributing factors to medication errors

Disclaimer

- RMPDS – Denver Health received an Investigator Initiated Study (IIS) award funding from Johnson & Johnson Consumer Inc. (now Kenvue) to conduct research described
- RMPDS – Denver Health has research, clinical and consulting contracts with Kenvue
- Study authors were employed by RMPDS – Denver Health and received only their salary for work on the described studies

Pediatric Liquid Acetaminophen Safety Changes

- Poison centers: **analgesics** are second most common type of exposure in children <6 years old[1]

- 2011: start of product safety changes to liquid acetaminophen
  - Flow restrictors
  - Standardization of concentration to 160 mg/5 mL
  - mL only as dosing units (no tsp)
  - In-pack standardized dosing device
  - Other best practices regarding dosing instructions

2023

- 58,196 (67%) **unintentional exposures**
- 25,559 (29%) **medication errors**
  - 51% single ingredient ibuprofen, 41% single ingredient acetaminophen
  - 1% of single ingredient acetaminophen and ibuprofen medication errors admitted to healthcare facility

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH est. 1860 FOR LIFE'S JOURNEY

Poison Center Studies to Evaluate Impact of Product Safety Changes

- **Purpose:** Determine if safety changes affected rate of **medication errors** and unintentional exposure reported to poison centers[2]
- Examined data from 2007 to 2016
- Children <12 years of age
- Exposures with reason of unintentional therapeutic error*

About Poison Center Data

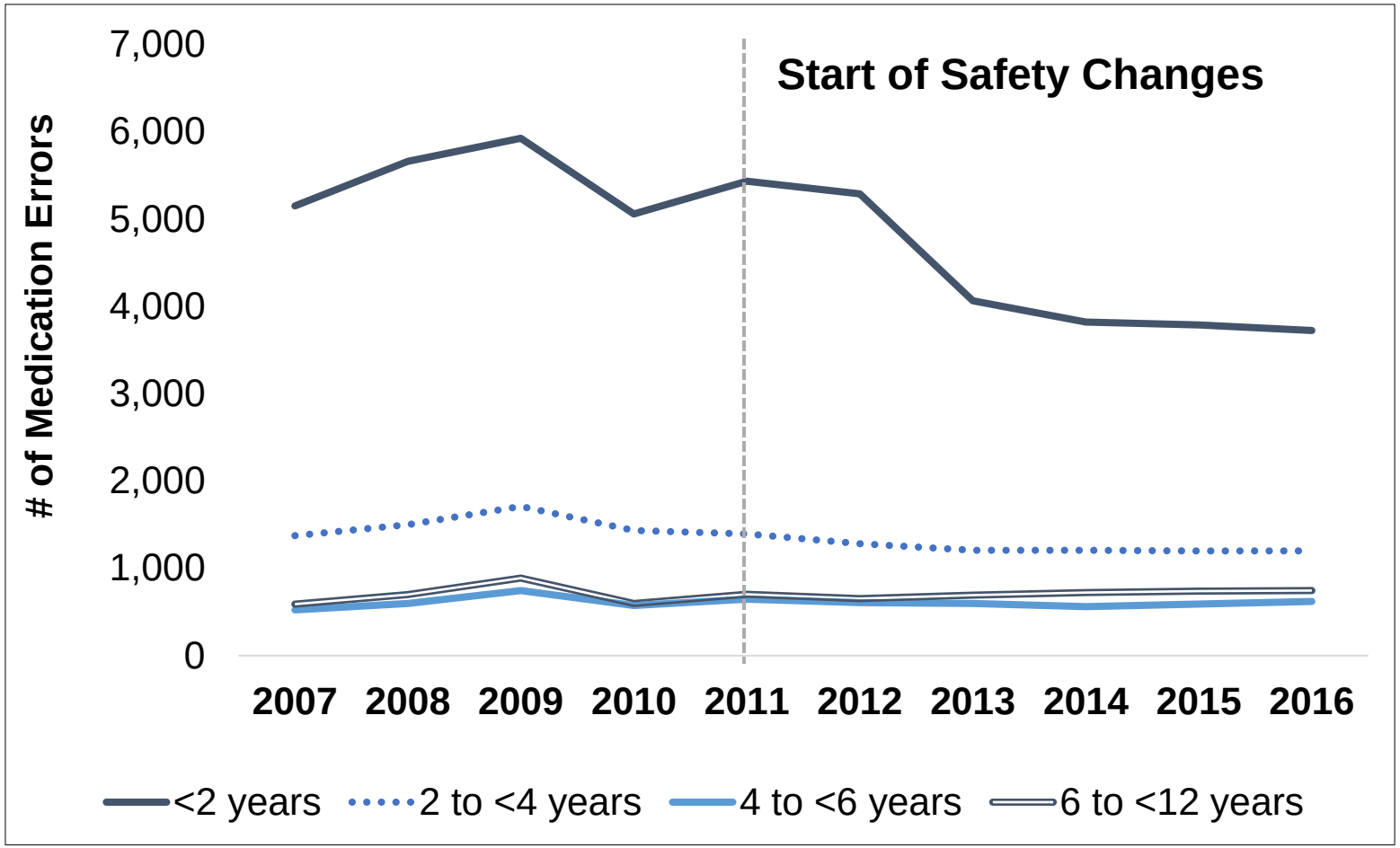
- 55 US poison centers provide free medical information to poisoned patients and their healthcare providers
- 1 call to a poison center represents 1 exposure or case
- Exposure is any contact with a substance regardless of toxicity

*Unintentional therapeutic error is deviation from a proper therapeutic regimen that results in the wrong dose, route, patient or substance.

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH
est. 1860
FOR LIFE'S JOURNEY

Change in Medication Error Exposures to Acetaminophen in Children <12 Years of Age, 2007 to 2016[2]

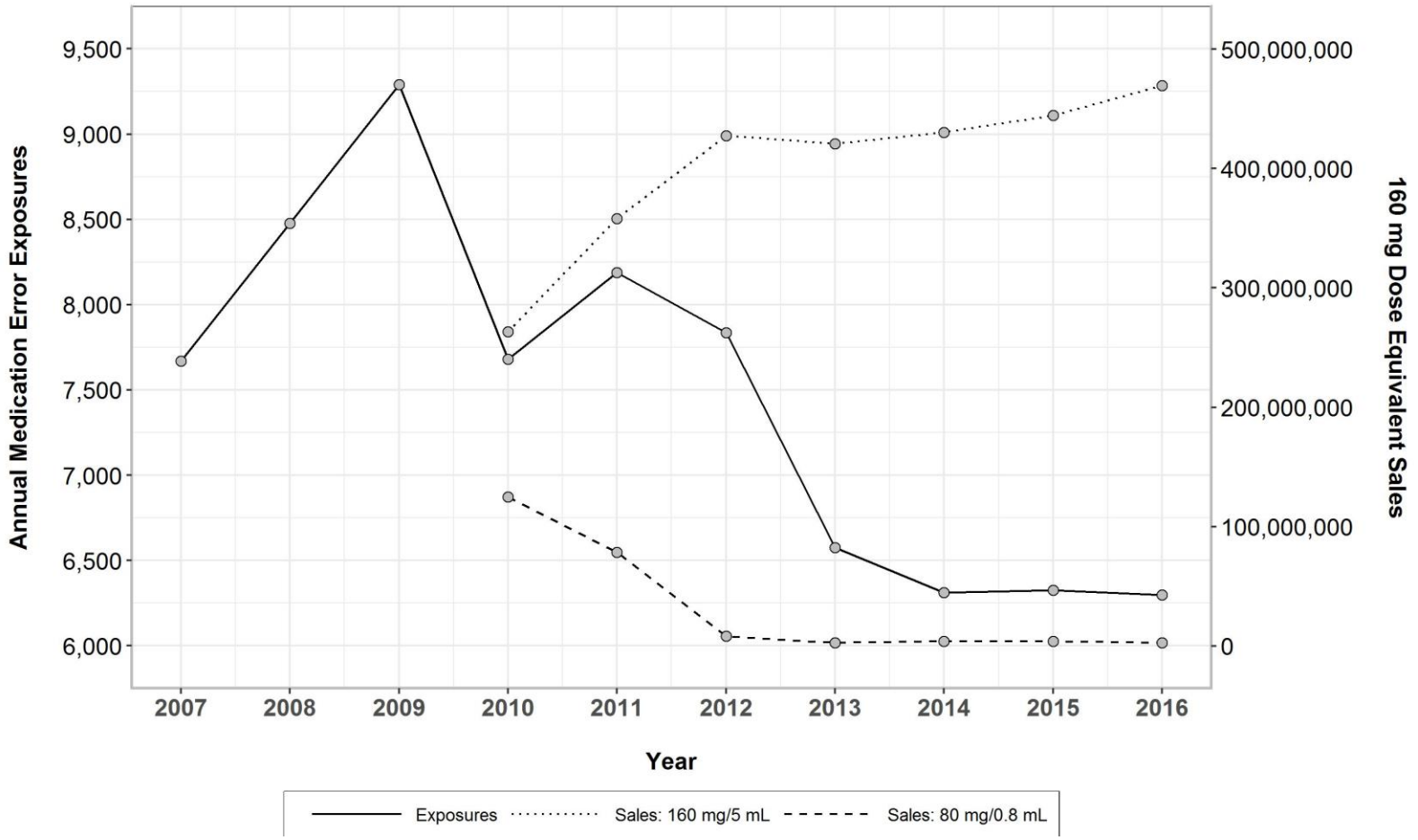


- **19% decrease in overall medication errors**
- Largest decrease (24%) in medication errors in children <2 years old

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH
est. 1860
FOR LIFE'S JOURNEY

Medication Error Exposures and Sales by Acetaminophen Concentrations, 2007 to 2016[2]



- Medication errors decreased in correlation to decreased sales of 80 mg/0.8 mL product and increase in sales of standard concentration 160 mg/5mL

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH est. 1860 FOR LIFE'S JOURNEY

Follow Up Surveys to Determine Contributing Factors to Medication Errors

Outstanding question: What preventable factors contribute to pediatric medication errors involving acetaminophen?

Study Design[2,3]

- Follow up survey at 6 regional poison centers
- Phone survey ~15 min in length
- Surveys conducted August 1, 2013 – December 31, 2019
- Single ingredient acetaminophen only (no combination products)
- Calls from caregivers only (no healthcare providers)
- n=2,294 completed medication error surveys
  - 95.6% involved liquids

Follow Up Surveys to Determine Contributing Factors to Medication Errors

Top Contributing Factors[3]:

- 26.5% more than one caregiver gave dose
- 18.9% gave doses too close together
- 11.6% misread instructions
- 10.1% confused units of measure (ml vs. tsp)
- 4.3% gave the wrong medicine (2.6% mixed up ibuprofen and acetaminophen)
- 2.2% used non-dosing device to measure medicine
- 2.1% gave too many medicines with acetaminophen

Summary

- **Medication error lessons:**
  - Removal of multiple concentrations associated with reduction in poison center calls for medication errors
  - Contributing factors to medication errors include:
    - Dosing interval errors
    - Errors interpreting label or dosing instructions
    - Units of measure
    - Using wrong dosing device
    - Mixing up medications
  - Medication errors involving ibuprofen and acetaminophen not associated with clinically significant outcomes in children

Limitations

- Spontaneous poison center reports
- Do not have baseline data for some research questions
- No measure of denominator

References

1. Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C. 2022 Annual Report of the National Poison Data System® (NPDS) from America's Poison Centers®: 40th Annual Report. Clin Toxicol (Phila). 2023 Oct;61(10):717-939. doi: 10.1080/15563650.2023.2268981.
2. Brass EP, Reynolds KM, Burnham RI, Green JL. Medication Errors With Pediatric Liquid Acetaminophen After Standardization of Concentration and Packaging Improvements. Acad Pediatr. 2018 Jul;18(5):563-568. doi: 10.1016/j.acap.2018.03.001.
3. Reynolds KM. 2020. Monitoring the Impact of Interventions Involving Pediatric Formulations of Acetaminophen: A Multi System Surveillance Program (MAPS), 01 August 2013 – 31 December 2019. Unpublished report, Denver Health & Hospital Authority, RMPDS.