

Pediatric ingestions of gummy-formulated medications

Suzanne Doyon, MD, MPH, FACMT

Medical Director, Connecticut Poison Control Center

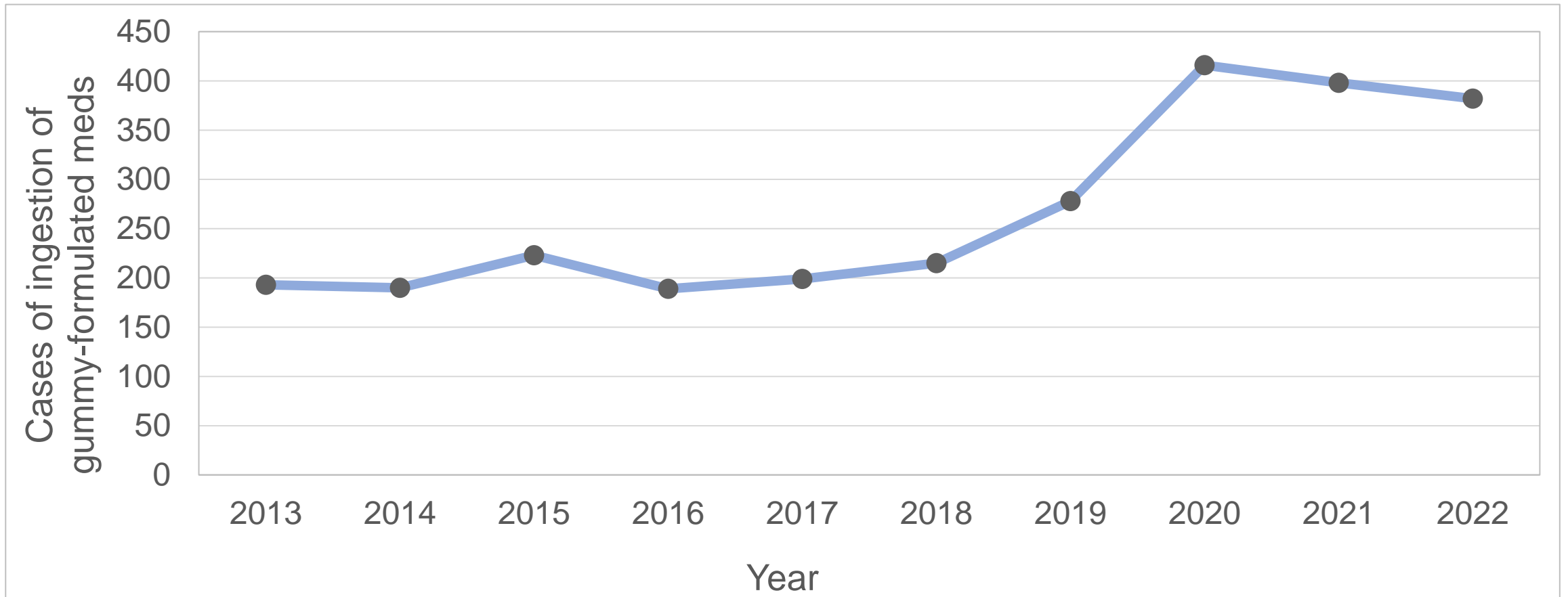
Associate Professor, School of Medicine UConn

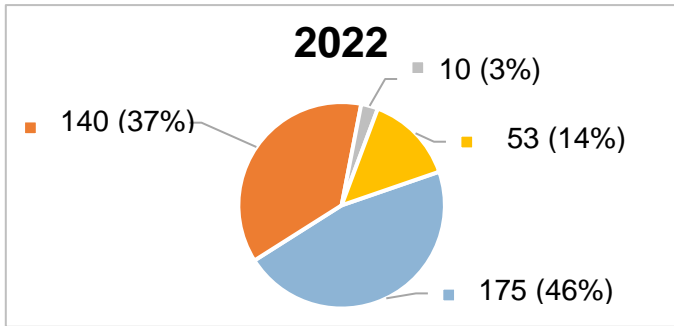
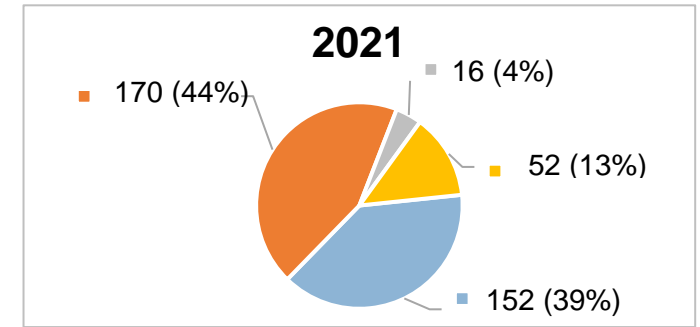
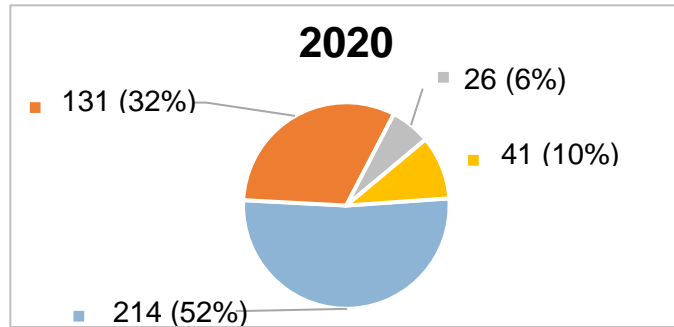
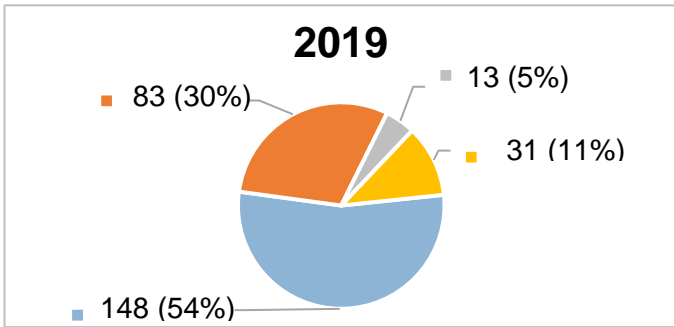
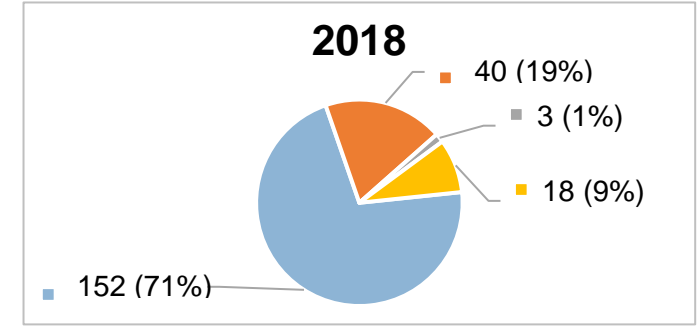
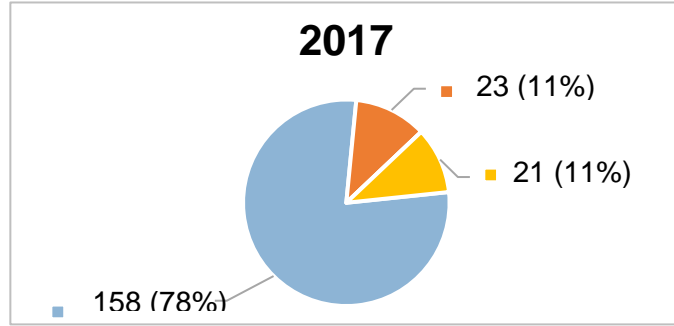
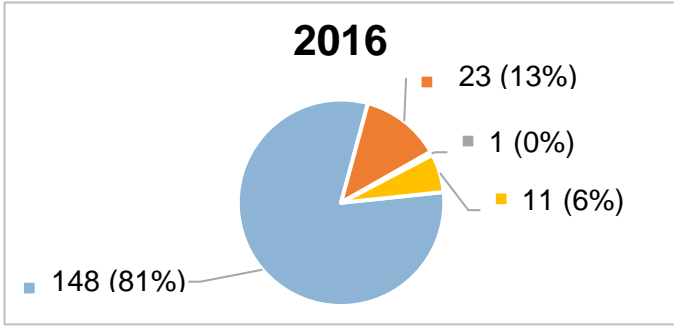
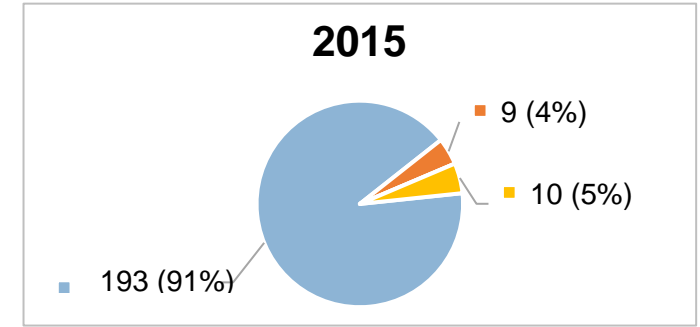
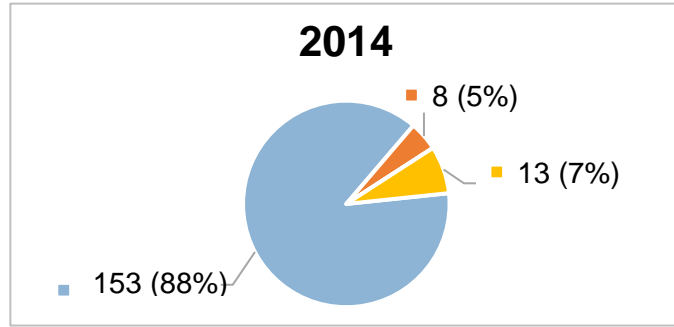
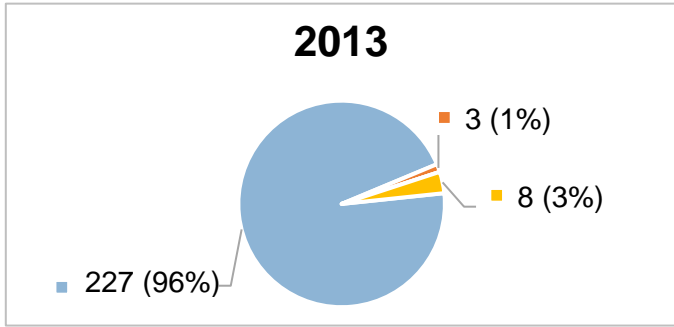
Objectives

- Scenarios
 - Unsupervised ingestions
 - Play
 - Imitating adults
- Poison center data
- NEISS data
- Medical literature
- Imprint/embossing



Poison center- Regional (CT)





■ Vitamins

■ Melatonin

■ Elderberry

■ Others

Poison center data-National

The screenshot shows a web browser window with the following elements:

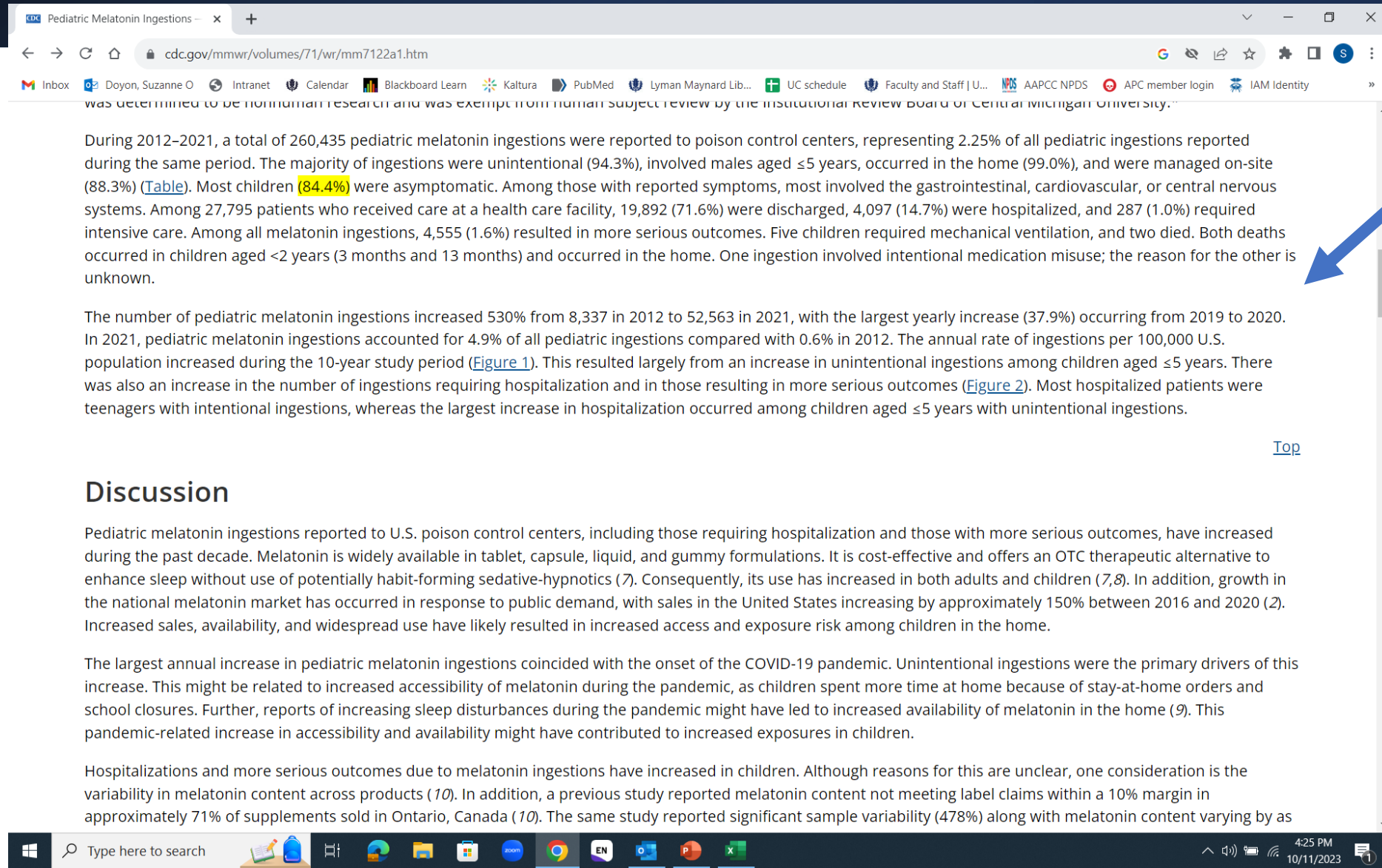
- Browser Tab:** Pediatric Melatonin Ingestions - x
- Address Bar:** cdc.gov/mmwr/volumes/71/wr/mm7122a1.htm
- Navigation Bar:** Includes icons for Gmail, Doyon, Suzanne O, Intranet, Calendar, Blackboard Learn, Kaltura, PubMed, Lyman Maynard Lib..., UC schedule, Faculty and Staff | U..., AAPCC NPDS, APC member login, and IAM Identity.
- CDC Logo:** Centers for Disease Control and Prevention, CDC 24/7: Saving Lives, Protecting People™
- Search Bar:** A search box with the text "Search" and a magnifying glass icon.
- Section Header:** Morbidity and Mortality Weekly Report (MMWR)
- Article Title:** Pediatric Melatonin Ingestions — United States, 2012–2021
- Metadata:** Weekly / June 3, 2022 / 71(22);725–729
- Note:** Please note: This report has been corrected. An [erratum](#) has been published.
- Authors:** Karima Lelak, MD¹; Varun Vohra, PharmD²; Mark I. Neuman, MD³; Michael S. Toce, MD³; Usha Sethuraman, MD^{1,4} ([VIEW AUTHOR AFFILIATIONS](#))
- Citation:** [View suggested citation](#)
- Summary Section:**
 - What is already known about this topic?**

Melatonin is regulated by the Food and Drug Administration as a dietary supplement and is a widely available over-the-counter sleep aid for adults and children.
 - What is added by this report?**

During 2012–2021, the annual number of pediatric ingestions of melatonin increased 530% with a total of 260,435 ingestions reported. Pediatric hospitalizations and more serious outcomes also increased, primarily because of an increase in unintentional melatonin ingestions in children aged ≤5 years.
 - What are the implications for public health practice?**

Increasing use of over-the-counter melatonin might place children at risk for potential adverse events. Public health initiatives should focus on raising awareness of increasing melatonin ingestions among children and on preventive
- Article Metrics Section:**
 - Altmetric:** A donut chart showing 3608 total mentions. The legend includes: News (450), Blogs (14), Twitter (210), Facebook (2), Reddit (2), Video (3), and Mendeley (26).
 - Citations:** 16
 - Views:** 45,319 (Views equals page views plus PDF downloads)
- Taskbar:** Windows taskbar at the bottom with search bar, task view, and various application icons. System tray shows 4:23 PM on 10/11/2023.

Poison center--National data



was determined to be nonhuman research and was exempt from human subject review by the Institutional Review Board of Central Michigan University.

During 2012–2021, a total of 260,435 pediatric melatonin ingestions were reported to poison control centers, representing 2.25% of all pediatric ingestions reported during the same period. The majority of ingestions were unintentional (94.3%), involved males aged ≤ 5 years, occurred in the home (99.0%), and were managed on-site (88.3%) ([Table](#)). Most children (84.4%) were asymptomatic. Among those with reported symptoms, most involved the gastrointestinal, cardiovascular, or central nervous systems. Among 27,795 patients who received care at a health care facility, 19,892 (71.6%) were discharged, 4,097 (14.7%) were hospitalized, and 287 (1.0%) required intensive care. Among all melatonin ingestions, 4,555 (1.6%) resulted in more serious outcomes. Five children required mechanical ventilation, and two died. Both deaths occurred in children aged < 2 years (3 months and 13 months) and occurred in the home. One ingestion involved intentional medication misuse; the reason for the other is unknown.

The number of pediatric melatonin ingestions increased 530% from 8,337 in 2012 to 52,563 in 2021, with the largest yearly increase (37.9%) occurring from 2019 to 2020. In 2021, pediatric melatonin ingestions accounted for 4.9% of all pediatric ingestions compared with 0.6% in 2012. The annual rate of ingestions per 100,000 U.S. population increased during the 10-year study period ([Figure 1](#)). This resulted largely from an increase in unintentional ingestions among children aged ≤ 5 years. There was also an increase in the number of ingestions requiring hospitalization and in those resulting in more serious outcomes ([Figure 2](#)). Most hospitalized patients were teenagers with intentional ingestions, whereas the largest increase in hospitalization occurred among children aged ≤ 5 years with unintentional ingestions.

[Top](#)

Discussion

Pediatric melatonin ingestions reported to U.S. poison control centers, including those requiring hospitalization and those with more serious outcomes, have increased during the past decade. Melatonin is widely available in tablet, capsule, liquid, and gummy formulations. It is cost-effective and offers an OTC therapeutic alternative to enhance sleep without use of potentially habit-forming sedative-hypnotics (7). Consequently, its use has increased in both adults and children (7,8). In addition, growth in the national melatonin market has occurred in response to public demand, with sales in the United States increasing by approximately 150% between 2016 and 2020 (2). Increased sales, availability, and widespread use have likely resulted in increased access and exposure risk among children in the home.

The largest annual increase in pediatric melatonin ingestions coincided with the onset of the COVID-19 pandemic. Unintentional ingestions were the primary drivers of this increase. This might be related to increased accessibility of melatonin during the pandemic, as children spent more time at home because of stay-at-home orders and school closures. Further, reports of increasing sleep disturbances during the pandemic might have led to increased availability of melatonin in the home (9). This pandemic-related increase in accessibility and availability might have contributed to increased exposures in children.

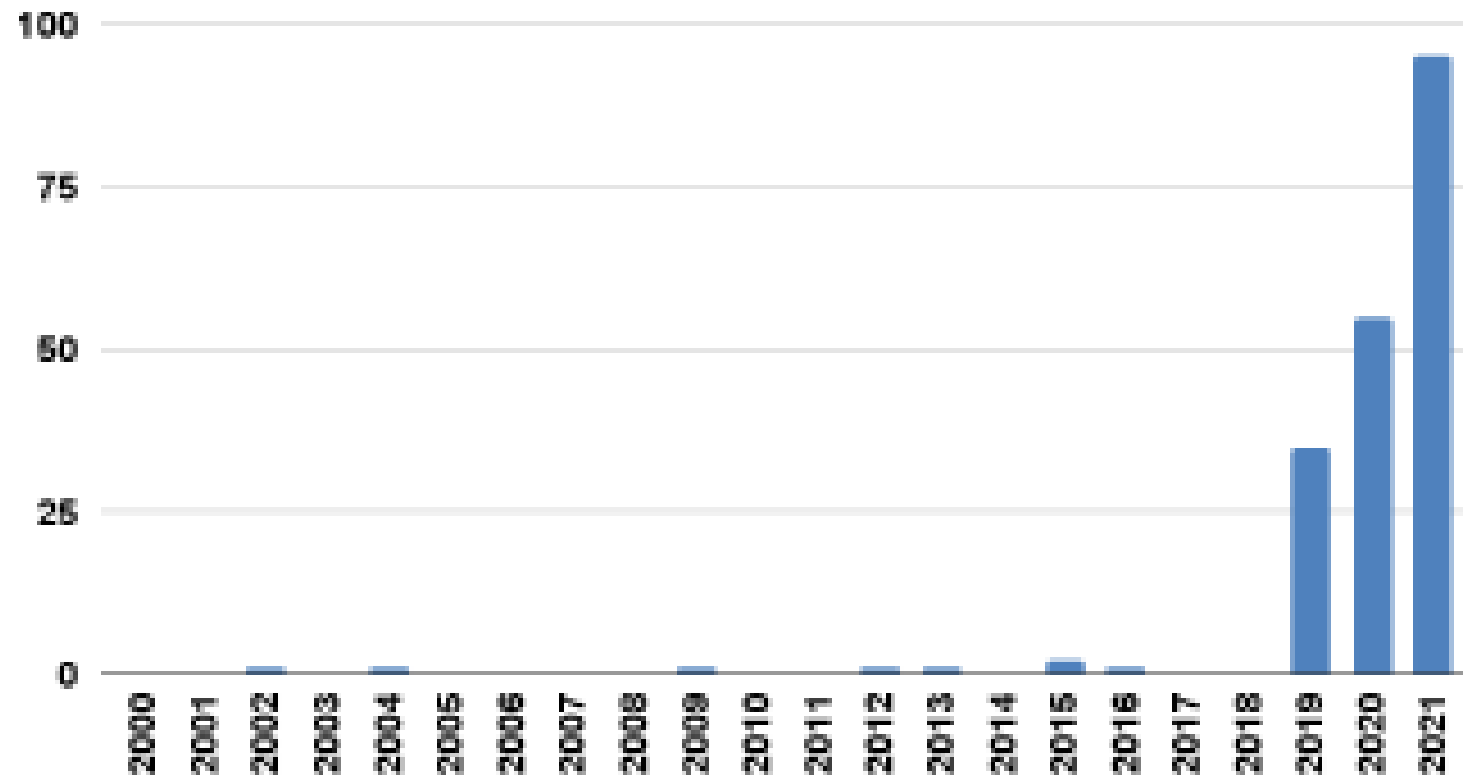
Hospitalizations and more serious outcomes due to melatonin ingestions have increased in children. Although reasons for this are unclear, one consideration is the variability in melatonin content across products (10). In addition, a previous study reported melatonin content not meeting label claims within a 10% margin in approximately 71% of supplements sold in Ontario, Canada (10). The same study reported significant sample variability (478%) along with melatonin content varying by as

NEISS data

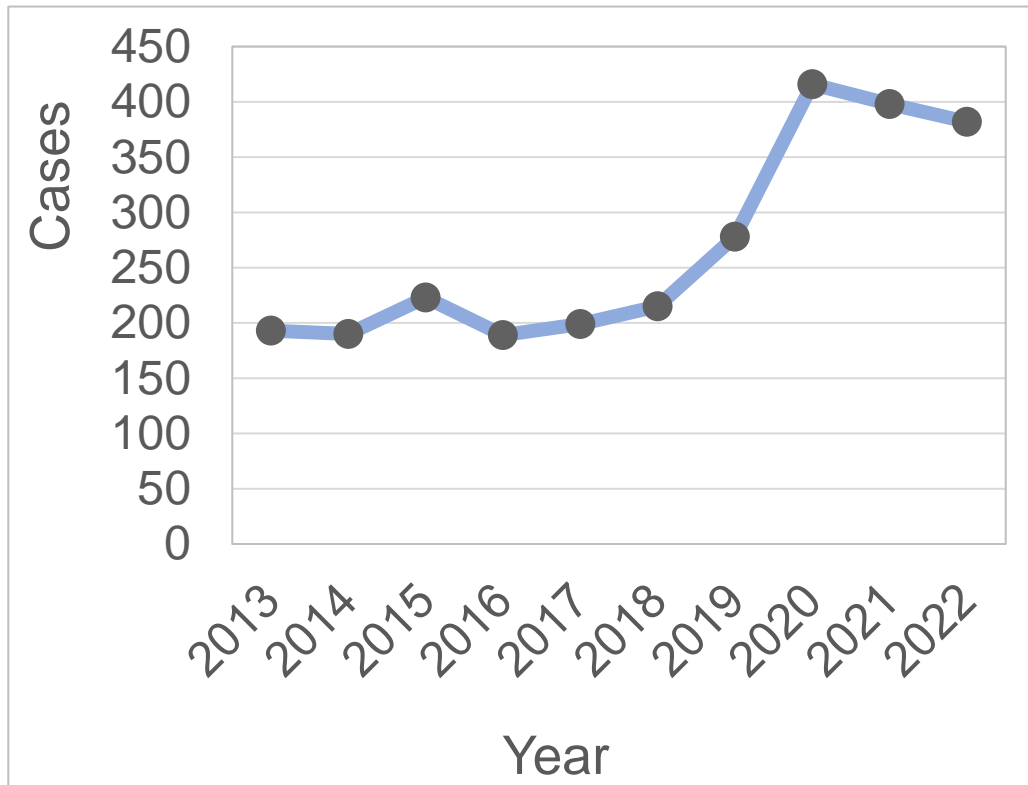
- National sample of 100 Emergency Departments (5000)
- Publicly available
- Coded and narrative data
- Narratives queried
- 22 years (2000-2021)
- Children under 4 yo
- Results: 193 cases total over 22 years

NEISS data

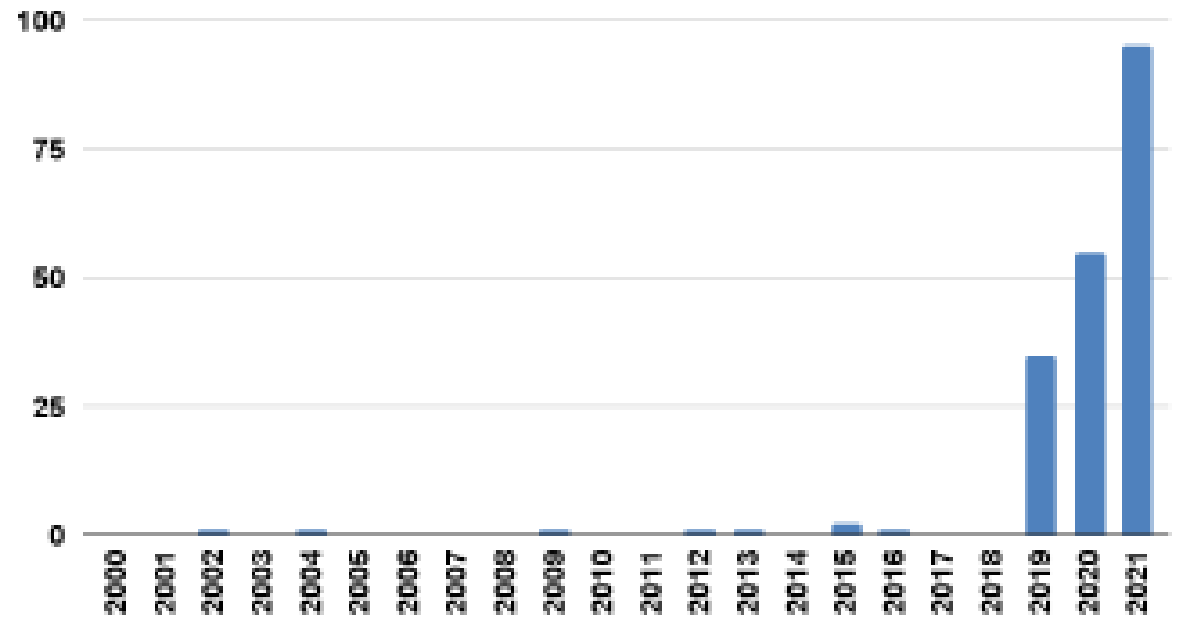
Cases per year



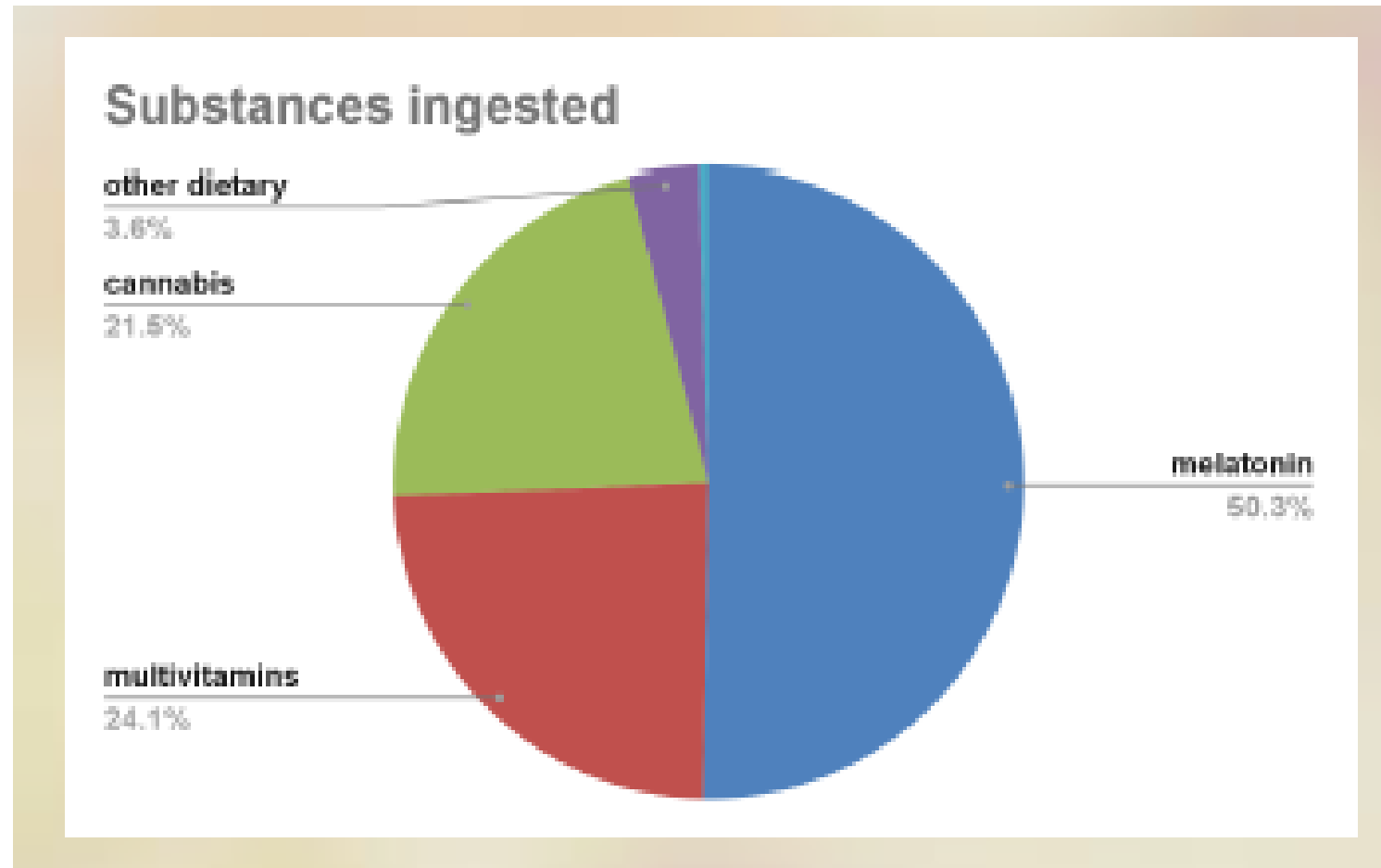
Connecticut vs NEISS data



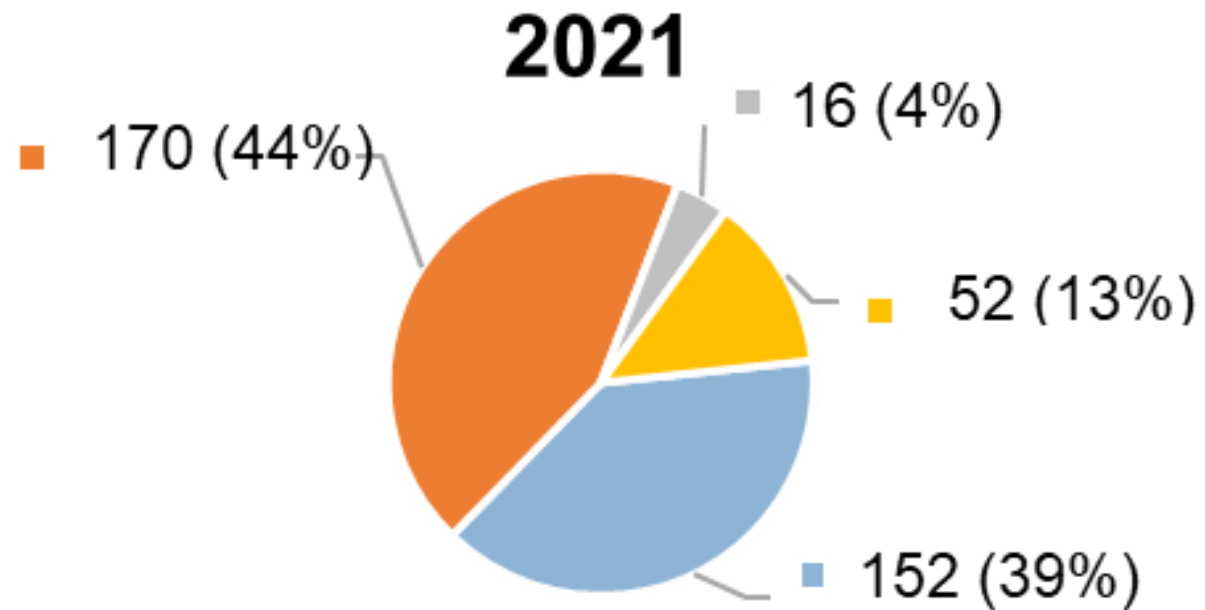
Cases per year



NEISS data

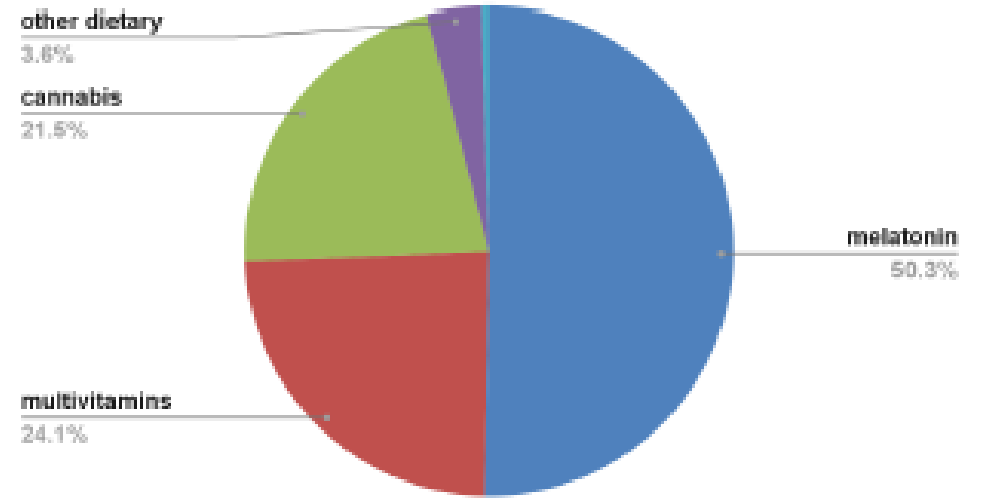


Connecticut vs NEISS data



■ Vitamins ■ Melatonin ■ Elderberry ■ Others

Substances ingested



Pivot---Medical literature



Unit-Dose Packaging of Iron Supplements and Reduction of Iron Poisoning in Young Children

Milton Tenenbein, MD 2005

Conclusions: These are the first data that show a decrease in the incidence of nonintentional ingestion of a specific drug by young children and a decrease in mortality from poisoning by this drug after the introduction of unit-dose packaging. There was a decrease in the in-

Unit-Dose Packaging and Unintentional Buprenorphine-Naloxone Exposures

George Sam Wang, MD,^{a,b} S. Geoffrey Severtson, PhD,^b Gabrielle E. Bau, MS,^b
Richard C. Dart, MD, PhD,^{b,c} Jody L. Green, PhD^{b,d} 2018

CONCLUSIONS: The shift from non-UDP to UDP in over 80% of buprenorphine-naloxone products was associated with a significant decrease in unintentional pediatric exposures reported to poison centers. Packaging controls should be a mainstay in the approach to the prevention of unintentional buprenorphine pediatric exposures as well as exposures to other prescription opioids.

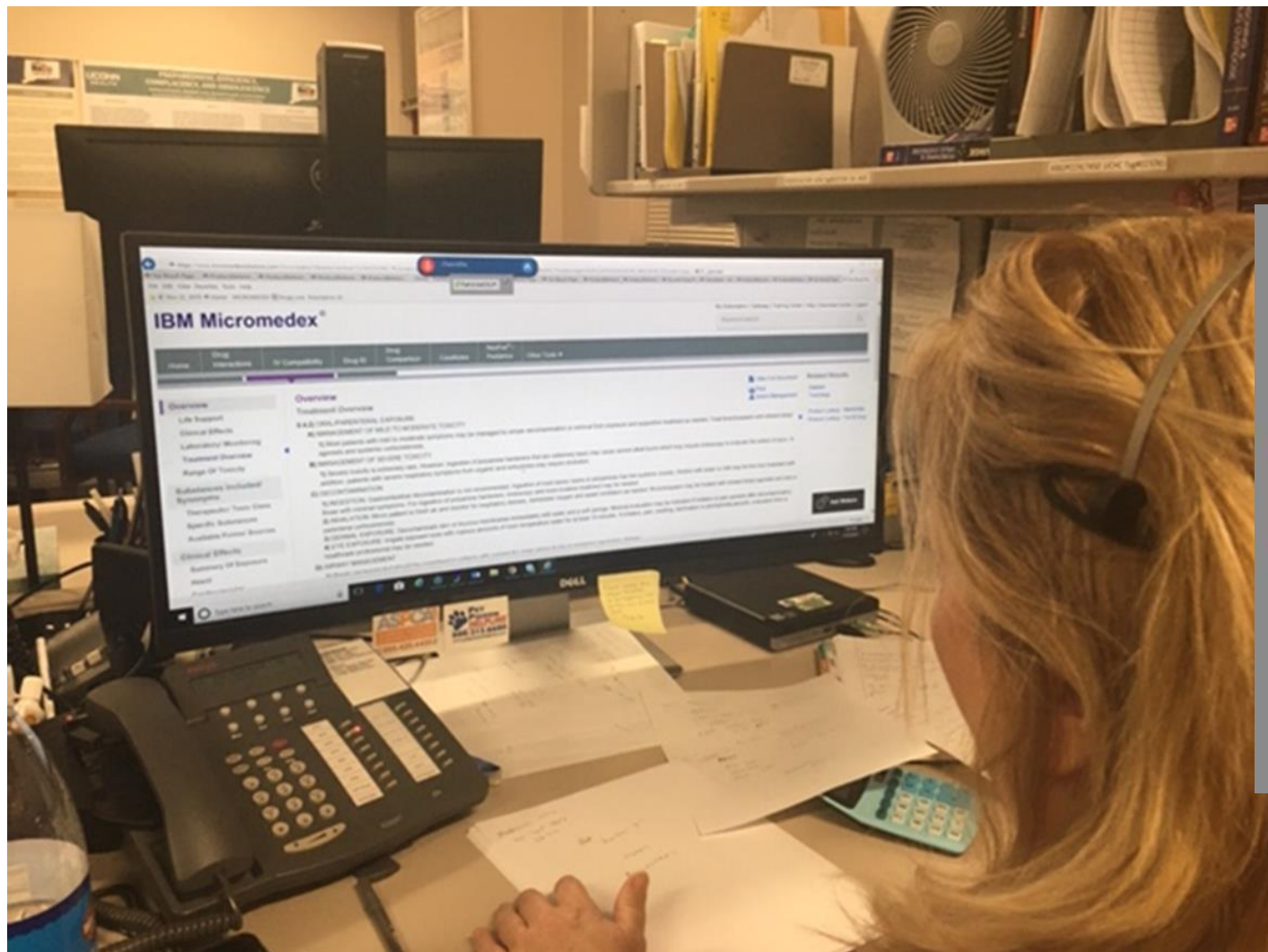
Effects of legislation restricting pack sizes of paracetamol and salicylate on self poisoning in the United Kingdom: before and after study

Keith Hawton, Ellen Townsend, Jonathan Deeks, Louis Appleby, David Gunnell, Olive Bennewith, Jayne Cooper 2001

On 16 September 1998 legislation was introduced in the United Kingdom limiting pack sizes of paracetamol, salicylates, and their compounds sold over the counter (box).⁷ At the same time nearly all preparations became available only in blister packs. The justification for the

Conclusion Legislation restricting pack sizes of paracetamol and salicylates in the United Kingdom has had substantial beneficial effects on mortality and morbidity associated with self poisoning using these drugs.

Tablet imprint/embossing



Conclusions

- Pediatric ingestions of gummy-formulated medications are on the rise
- Multivitamins and melatonin
- Child-resistant packaging works!
- Unit dose packaging works!
- Tablet imprint/embossing

