

AJPM FOCUS

INCLUSIVITY IN PEOPLE, METHODS, AND OUTCOMES

PILOT DATA ANALYSIS

A Pilot Study Assessing Common Medication Organizers for Child-Resistant Features



Lilai Teum, PharmD,^{1,2} Fallon Gokhman, PharmD,^{1,3} Sophia Park, PharmD,^{1,4} Daniel S. Budnitz, MD, MPH,^{1,5} Joseph W. Aquilina, MD,¹ Edwin K. Kuffner, MD¹

Introduction: Prescription and most over-the-counter medicines are required to have child-resistant packaging and/or labeled with instructions “Keep out of reach of children.” Although medication organizers are not required to have such design features or instructions, these could help prevent unsupervised ingestions by children. Commonly purchased medication organizers were evaluated for child-resistant design features and instructions for safe use to prevent unsupervised ingestions.

Methods: The 29 best-selling medication organizers on Amazon.com were identified, and product identifiers, design characteristics, and safety characteristics were recorded using a standardized instrument.

Results: Of the 29 medication organizers, none claimed to be child resistant. Only 31% provided a specific warning that the organizer was not child resistant on the packaging; only 41% communicated “Keep out of reach of children.” Most organizers (59%) provided neither a warning that the organizer was not child resistant nor instructions to store out of reach of children. The majority of organizers (79%) shared the following characteristics: plastic construction, rectangular shape, non-electronic flip-top opening mechanisms, and 7-day usage.

Conclusions: Opportunities exist for manufacturers of medication organizers to improve child-resistant product design, provide information to help prevent unsupervised ingestions (directions to keep the device out of the reach of children), and help to reduce unsupervised ingestions.

AJPM Focus 2024;3(4):100232. © 2024 Johnson & Johnson Consumer Inc. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

INTRODUCTION

Approximately 15% of all adults aged 40–59 years and 35% of adults aged >65 years regularly take 5 or more medications each month.^{1–3} Many of these adults use medication organizers to help simplify the daily administration of multiple medications.^{4–6} Medication organizers are also employed when taking medicines away from home (e.g., at work or when traveling), when the transport of larger medication containers is not practical but medications still must be accessible.

Unfortunately, when medications are easily accessible, it is more likely for young children to find and ingest them. Poison centers received nearly 890,000 calls in

2020 for medication exposures, and more than 40,000 young children are brought to emergency departments for unsupervised medication exposures annually.^{7,8} In over 50% of calls to poison centers involving prescription pills and over 20% of calls involving over-the-counter (OTC) pills, children ingested pills that had

From the ¹Global Product Safety, Johnson & Johnson Consumer, Skillman, New Jersey; ²Janssen Pharmaceuticals, Raritan, New Jersey; ³Bristol Myers Squibb, Princeton, New Jersey; ⁴Genmab US, Plainsboro, New Jersey; and ⁵Johnson & Johnson Consumer, Skillman, New Jersey

Address correspondence to: Lilai Teum, PharmD, Janssen Pharmaceuticals, 1000 US-202, Raritan NJ 08869. E-mail: lteum@its.jnj.com.

2773-0654/\$36.00

<https://doi.org/10.1016/j.focus.2024.100232>

been removed from their original bottles or packaging and put in other containers or left out.⁹

However, unlike the original packaging of prescription and most OTC medicines, medication organizers and other containers advertised to hold medications are not required to be child resistant (CR). Therefore, this study sought to identify the key characteristics of commonly purchased medication organizers and assess whether they have CR features and instructions for safe use in the presence of young children.

METHODS

On September 17, 2019, at 12:00PM, the 25 most frequently purchased medication organizers from Amazon.com were identified using website's top 100 best sellers search feature and were purchased. When reviewing the top 100 list, it was observed that organizers with unique characteristics were not included, or some did not have enough representation. Four additional medication organizers were purchased, including 1 circular organizer to ensure that at least 5 organizers were circular, one 30-day organizer to ensure that at least 5 organizers had a maximum duration of 30-days of use, and 2 electronic organizers, which was a design feature not seen in the top 25 list. Product identifiers, design characteristics, and safety characteristics were recorded independently by 2 authors for each product using a standardized instrument in 2020 (Appendix Table 1, available online). Frequency and proportion of each design and safety characteristics were calculated in 2021–2022.

RESULTS

Of the 29 medication organizers evaluated, the most common design characteristics observed were plastic materials (100%), flip-top openings for pill compartments (97%), no electronic mechanisms (93%), rectangular shape (83%), and 7-day usage (83%) (Table 1). Most medication organizers (79%) had all 5 characteristics. A minority had detachable compartments (41%) and compartments for dosing multiple times per day (15%).

None of the purchased medication organizers were labeled as CR containers (Table 2). A minority of organizers had safety information written on the packaging, including instructions to store the organizer out of the reach of children (41%) and/or warning that the organizer was not CR (34%). Most organizers (17 of 29, 59%) provided neither a warning that the organizer was not CR nor instructions to store out of reach of children. One organizer required multiple steps to access the

Table 1. Structural Characteristics of Common Medication Organizers

Characteristic	n (%)
Shape	
Rectangular	24 (83%)
Circular	5 (17%)
Maximum duration of use	
7 days	24 (83%)
30 days	5 (17%)
Dosage frequency	
Once daily	14 (48%)
2 or more times daily	15 (52%)
Electronic mechanism	
Yes	2 (7%)
No	27 (93%)
Opening mechanism	
Flip-top	28 (97%)
Key	1 (3%)
Material	
Plastic	29 (100%)
Metallic	0 (0%)
Detachable compartments	
Yes	12 (41%)
No	17 (59%)

medication compartment, but the organizer was not labeled as a CR container (Figure 1).

The average price of the 29 organizers was \$12.91 (U.S. currency), median of \$9.99, with prices ranging from \$2.49 to \$79.95 (IQR=\$4.84–\$11.93). Average cost of medication organizers increased with duration of use and dosage frequency supported. Two electronic organizers were the costliest (\$63.71 and \$79.95); both shared features, including an alarm, clock, and battery level display. The most expensive model offered a locking mechanism that required a physical key to open.

Table 2. Safety Characteristics of 29 Commonly Purchased Medication Organizers

Characteristic	n (%)
Labeled as a child-resistant medication organizer	0 (0%)
Instructions on how to open compartment(s)	11 (38%)
Safe storage instructions provided (keep out of reach of children)	12 (41%)
Warning provided that the organizer was not child resistant	9 (31%)
Manufacturer phone number provided	12 (41%)
Multiple steps required to access medication compartment	1 (3%)



Figure 1. Single medication organizer observed with 2-step flip-top opening. User must press down plastic bar before opening each individual compartment.

DISCUSSION

None of medication organizers most commonly sold by the most popular online retailer in the U.S. were identified to be CR. On one hand, this finding should not be surprising, given that the Poison Prevention Packaging Act (PPPA) requirements for CR testing for the primary packaging of medicines do not apply to medication organizers. On the other hand, this finding is quite concerning because when consumers take prescription or OTC medicines from CR containers or packaging and place them into non-CR medication organizers, there is an increased risk of unsupervised ingestions (UIs).⁹ Moreover, medication organizers are not required to display any specific instructions to help minimize UIs such as a warning to “Keep out of reach of young children.” Indeed, nearly 60% of the top-selling organizers purchased do not include instructions to store out of reach of children nor identify their lack of CR.

Although there are no mandatory or even voluntary standards regarding CR features and warnings on medication organizers to help prevent UIs, there are short-term and longer-term opportunities that can help keep young children safe. First, all medication organizers and their carton labeling should clearly state that the container should be kept out of reach and sight of young children at all times. This is especially important when medication organizers are used in environments where young children may be present. Second, manufacturers could begin to produce organizers that have CR features, such as 2-step mechanisms, that are tested in a manner similar to PPPA protocols.^{10,11}

A single medication organizer evaluated in this study had a 2-step opening mechanism (plastic bar extending behind individual pouches needed to be depressed to open pouches) that may make the device more difficult for children to access (Figure 1). Labeling on this organizer appropriately indicated that this product was not

tested to be CR because, currently, there are no CR testing standards for medication organizers. Until a methodology is developed to address this gap in safety standards, such as the voluntary testing protocols for flow restriction for liquid medications, there is no standardized way to assess the ease or difficulty at which young children can self-access the contents of medication organizers. As noted earlier, manufacturers could volunteer to test medication organizers using methods available in PPPA protocols.^{10,11}

Limitations

Strengths of this evaluation included standardized identification of medication organizer design characteristics and representation of the variety of medication organizers available. On the other hand, assessing the top-selling organizers from a single, albeit the largest, online retailer may not have been representative of all organizers available because models sold only in retail pharmacies and grocery chains may not have been included.

CONCLUSIONS

Few medication organizers evaluated alerted users, who may be taking treatment or OTC medicines from containers and packaging that are CR, that the medication organizer they are putting individual doses into does not provide a similar type of protection against UIs. Opportunities exist for manufacturers to improve product design and incorporate features, such as 2-step mechanisms, which have been demonstrated to decrease access by curious young children and provide instructions to “Keep out of reach of children” that incorporate prevention strategies. Innovation research, including developing a testing methodology, could support introduction of features or lock mechanisms on medication organizers designed to limit access by young children and decrease risk for unsupervised ingestions by children.

ACKNOWLEDGMENTS

We thank the personnel at Johnson & Johnson Consumer Health who purchased the medication organizers and provided revisions for this study's publication and original presentation at the 2019 Centers for Disease Control and Prevention PROTECT Initiative (Ankur Patel, PharmD, Manager of Medical Information and Knowledge Integration; Stacey Ross, RPh, Director of Medical Affairs; Amisha Parikh-Das, PhD, Associate Director of Clinical Research; Evren Atillasoy, MD, Senior Director of Clinical Research; and Tammi Schaeffer, DO, Associate Medical Safety Officer). The authors would like to acknowledge Kathleen E. Boyle of 4 Learning Group, LLC for editorial and publication management support.

This work was supported by Johnson & Johnson Consumer, Inc. The authors were employees of Johnson & Johnson Consumer, Inc, at the time the research was conducted.

CREDIT AUTHOR STATEMENT

Lilai Teum: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization. Fallon Gokhman: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization. Sophia Park: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization. Daniel S. Budnitz: Formal analysis, Writing – review & editing, Visualization. Joseph W. Aquilina: Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Visualization, Supervision. Edwin K. Kuffner: Conceptualization, Methodology, Writing – review & editing, Visualization, Supervision, Funding acquisition.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.focus.2024.100232](https://doi.org/10.1016/j.focus.2024.100232).

REFERENCES

- Hales CM, Servais J, Martin CB, Kohen D. Prescription drug use among adults aged 40–79 in the United States and Canada. *NCHS Data Brief*. 2019;347:1–8. Accessed at 7 April 2024 <https://www.cdc.gov/nchs/products/databriefs/db347.htm>.
- Young EH, Pan S, Yap AG, Reveles KR, Bhakta K. Polypharmacy prevalence in older adults seen in United States physician offices from 2009 to 2016. *PLOS ONE*. 2021;16(8):e0255642. <https://doi.org/10.1371/journal.pone.0255642>.
- Charlesworth CJ, Smit E, Lee DS, Alramadhan F, Odden MC. Polypharmacy among adults aged 65 years and older in the United States: 1988–2010. *J Gerontol A Biol Sci Med Sci*. 2015;70(8):989–995. <https://doi.org/10.1093/gerona/glv013>.
- Choudhry NK, Krumme AA, Ercole PM, et al. Effect of reminder devices on medication adherence: The REMIND Randomized Clinical Trial. *JAMA Intern Med*. 2017;177(5):624–631. <https://doi.org/10.1001/jamainternmed.2016.9627>.
- Conn VS, Ruppert TM, Chan KC, Dunbar-Jacob J, Pepper GA, De Geest S. Packaging interventions to increase medication adherence: systematic review and meta-analysis. *Curr Med Res Opin*. 2015;31(1):145–160. <https://doi.org/10.1185/03007995.2014.978939>.
- Faisal S, Ivo J, Patel T. A review of features and characteristics of smart medication adherence products. *Can Pharm J (Ott)*. 2021;154(5):312–323. <https://doi.org/10.1177/17151635211034198>.
- Gummin DD, Mowry JB, Beuhler MC, et al. Annual report of the American Association of Poison Control Centers' National Poison Data System (NPDS) [38th Annual Report]. *Clin Toxicol (Phila)*. 2021;59(12):1282–1501. <https://doi.org/10.1080/15563650.2021.1989785>.
- Budnitz DS, Lovegrove MC, Geller RJ. Prevention of unintentional medication overdose among children: time for the promise of the Poison Prevention Packaging Act to come to fruition. *JAMA*. 2020;324(6):550–551. <https://doi.org/10.1001/jama.2020.2152>.
- Agarwal M, Lovegrove MC, Geller RJ, et al. Circumstances involved in unsupervised solid dose medication exposures among young children. *J Pediatr*. 2020;219:188–195.e6. <https://doi.org/10.1016/j.jpeds.2019.12.027>.
- Child resistant packaging: ASTM index type. United States Consumer Product Safety Commission. <https://www.cpsc.gov/Regulations-Laws-Standards/Statutes/Poison-Prevention-Packaging-Act/CRP-ASTM-Type>. Updated June 29, 2017. Accessed April 4, 2024.
- Title 16 Chapter II Subchapter E Part 1700 § 1700.20. 38 FR 21247, August 7, 1973, as amended at 60 FR 37735, 37738, July 22, 1995. Code of Federal Regulations. <https://www.ecfr.gov/current/title-16/chapter-II/subchapter-E/part-1700/section-1700.20>. Updated May 13, 2024. Accessed May 15, 2024.