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Review Article

Child-resistant and tamper-resistant packaging: A systematic review to inform tobacco packaging regulation



Catherine L. Jo ^a, Anita Ambs ^{b,*}, Carolyn M. Dresler ^b, Cathy L. Backinger ^b

- ^a Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC, United States
- b Office of Science, Center for Tobacco Products (CTP), Food and Drug Administration (FDA), Rockville, MD, United States

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ABSTRACT

Objective. We aimed to investigate the effects of special packaging (child-resistant, adult-friendly) and tamper-resistant packaging on health and behavioral outcomes in order to identify research gaps and implications for packaging standards for tobacco products.

Methods. We searched seven databases for keywords related to special and tamper-resistant packaging, consulted experts, and reviewed citations of potentially relevant studies. 733 unique papers were identified. Two coders independently screened each title and abstract for eligibility. They then reviewed the full text of the remaining papers for a second round of eligibility screening. Included studies investigated a causal relationship between type of packaging or packaging regulation and behavioral or health outcomes and had a study population composed of consumers. Studies were excluded on the basis of publication type, if they were not peer-reviewed, and if they had low external validity. Two reviewers independently coded each paper for study and methodological characteristics and limitations. Discrepancies were discussed and resolved.

Results. The review included eight studies: four assessing people's ability to access the contents of different packaging types and four evaluating the impact of packaging requirements on health-related outcomes. Child-resistant packaging was generally more difficult to open than non-child-resistant packaging. Child-resistant packaging requirements have been associated with reductions in child mortality.

Conclusions. Child-resistant packaging holds the expectation to reduce tobacco product poisonings among children under six.

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E-mail address: anita.ambs@fda.hhs.gov (A. Ambs).

^{*} Corresponding author at: Office of Science, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Building 71, G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, United States.

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1. Introduction

Every year in the United States there are an average of 50,000 cases of unintentional poisonings among children under age six years (Centers for Disease Control and Prevention, 2013), and a significant proportion of these poisonings are related to tobacco products. From 2006 through 2008, the National Poison Data System reported 13,705 cases of tobacco product ingestion by children under six (Connolly et al., 2010). During these years, ingested tobacco products included cigarettes, smokeless tobacco (chewing tobacco and snuff), and cigars (Connolly et al., 2010).

The marketplace of tobacco products is ever changing, and novel tobacco products such as dissolvables, snus, and electronic cigarettes (ecigarettes or ENDS – electronic nicotine delivery devices) have raised new concerns about poisoning, given their potential appeal to children.

Some dissolvable products, like Camel Orbs®, have a candy-like appearance and come in flavors like mint and cinnamon (Wilson, 2010). Snus, another oral tobacco product, is available in flavors like "frost" and "winterchill" (TobaccoProducts.Org, 2010). Snus is a traditional Swedish smokeless tobacco product made from moist, finely ground tobacco and sold in small sachets or in loose form (National Cancer Institute, 2014). E-liquids, or the liquids used in e-cigarette devices, are offered in fruit and sweet flavors (e.g., strawberry banana smoothie, pink lemonade, caramel apple fritter) (Popular E-Liquid, 2016). These tobacco products have all been linked to poisonings in children (Connolly et al., 2010; Forrester, 2015; Vakkalanka et al., 2014).

E-liquids and other e-cigarette components have received particular attention, given the growing popularity of e-cigarettes (Arrazola et al., 2015; Pepper and Brewer, 2014), the April 2015 U.S. death of a toddler due to e-liquid ingestion (Clukey, 2015), and the rapid increase in poisoning cases due to e-cigarette exposure (Forrester, 2015; Vakkalanka et al., 2014; Chatham-Stephens et al., 2014). Chatham-Stephens et al. (2014) analyzed e-cigarette and cigarette-related calls made to U.S. poison centers from 2010 to 2014. E-cigarette exposures represented a growing proportion of these calls, from 0.3% in September 2010 to about 42% in 2014. Most e-cigarette exposures have been reported as ingestions (Forrester, 2015; Durmowicz, 2014) and for children under six years (Vakkalanka et al., 2014; Chatham-Stephens et al., 2014; Ordonez et al., 2015). Negative health effects associated with e-cigarette exposure have included vomiting, nausea, eye irritation, headaches, and dizziness (Chatham-Stephens et al., 2014; Ordonez et al., 2015). The U.S. Food and Drug Administration's adverse event database, which includes consumers' complaints associated with e-cigarettes, has also reported the death of an infant due to choking on an e-cigarette cartridge (Durmowicz, 2014).

In response to this public health threat, some manufacturers of ecigarettes, dissolvables, and snus have voluntarily packaged their products in child-resistant containers (Wilson, 2010; Buettner-Schmidt et al., 2016; Nikitin et al., 2016; Rosetta, 2009). E-cigarette liquids have been reported to include press-and-turn closures resembling those used for aspirin (Buettner-Schmidt et al., 2016; Nikitin et al., 2016). At least one tobacco product manufacturer has claimed that its dissolvable packaging is child-resistant (Connolly et al., 2010). In general though, e-liquids have been sold in containers that are not considered child-resistant (Chatham-Stephens et al., 2016; Kamboj et al., 2016).

Policymakers at the local, state, federal, and global levels have also begun implementing legislation requiring child-resistant packaging for liquids and occasionally gels, cartridges, or other e-cigarette paraphernalia (114th Congress, 2015; Frey and Tilburg, 2016; Bear River Board

of Health, 2014; European Parliament and the Council of the European Union, 2014). In July 2015 the U.S. Food and Drug Administration issued an Advance Notice of Proposed Rulemaking soliciting information to guide regulatory development around child-resistant packaging for nicotine liquid and other tobacco products (e.g., gels, dissolvables) (U.S. Department of Health and Human Services, 2015). In January 2016 *special packaging* standards, which had been in place for household substances, were expanded to include liquid nicotine through the Child Nicotine Poisoning Prevention Act (114th Congress, 2015). Special packaging is defined as packaging that is "significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly" (Code of Federal Regulations, 1973)

Another dimension of packaging distinct from special packaging but potentially relevant to packaging standards for tobacco products is resistance to tampering. Tamper-resistant packaging, which is required for over-the-counter drugs, aims to prevent the post-manufacture altering of products and to enable consumers to determine easily whether or not their product may have been altered (e.g., seal is missing from medication container) (Code of Federal Regulations, 2016). In contrast to special packaging, tamper-resistant packaging, to our knowledge, has not been mentioned in news stories or policies related to tobacco products. However, given the poor quality control exhibited by some e-cigarette manufacturers (Cobb et al., 2010; Lisko et al., 2015), policymakers may want to consider including tamper-resistant design features as one way to address quality control in packaging.

To help inform ongoing and future legislative and regulatory efforts, we conducted a systematic review to investigate the effects of special and tamper-resistant packaging on the health and behavioral outcomes of individuals. We aimed to identify research gaps and implications for packaging standards for tobacco products. For the purpose of this review, we use the terms "child-resistant" and "special packaging" interchangeably.

2. Methods

2.1. Search strategy

We developed two search strings, one containing keywords related to special packaging and one containing words related to tamper-resistant packaging. Through an iterative process, we analyzed the results generated by each string and added to and refined the strings to capture relevant articles and to reduce the number of irrelevant articles. We used and adapted, as necessary, the search strings to search for literature in seven databases: Academic Search Complete, Business Source Complete, CINAHL Plus with Full Text, Embase, PubMed, SciFinder, and Web of Science. The search strings for each database and the overall review protocol are available from the corresponding author. An example of a final PubMed search string is ((Child-resistant[TIAB] OR "child resistant"[TIAB] OR child-proof[TIAB] OR childproof[TIAB] OR "child proof"[TIAB] OR "safety packaging"[TIAB] OR "special packaging"[TIAB] OR "safety caps" [TIAB] OR "safety cap" [TIAB]) AND ("Poisoning/prevention and control" [MH] OR "drug packaging" [TIAB] OR "packaging materials" [TIAB] OR "abuse deterrent" [TIAB] OR "abuse liability" [TIAB] OR abuse-deterrent[TIAB] OR "Drug Packaging" [MH] OR "Consumer Product Safety" [MH] OR "consumer product safety" [TIAB] OR "Product Packaging" [MH] OR "product packaging" [TIAB] OR "Poison Prevention Packaging Act" [TIAB] OR "Food Packaging" [MH] OR "food packaging" [TIAB]

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