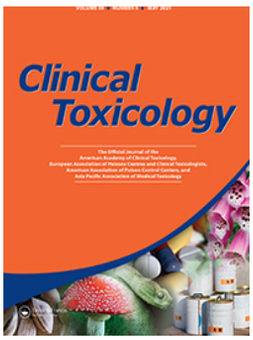

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Impact of product safety changes on accidental exposures to liquid laundry packets in children

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ABSTRACT

Objectives: To evaluate the impact of the ASTM International (formerly American Society of Testing Materials) safety standard and associated product safety changes on accidental exposures to liquid laundry packets (LLPs) in children.

Methods: The National Poison Data System was queried for reports of accidental exposures to LLPs in children <6 years old received from 01 July 2012 to 31 December 2018. In 2014, ASTM International began developing a standard specifying voluntary product changes to reduce the risk of LLP exposures in young children. Product changes were made between 2013 and 2016. Exposures were grouped into baseline, transition, and post periods based on the timing of the standard's implementation. Exposure counts and sales adjusted rates were compared between the baseline and post period for all exposures and exposures involving healthcare facility (HCF) evaluation, HCF admission, and major medical outcomes.

Results: A total of 73,942 accidental exposures in children <6 years old were reported (baseline: 10,229, 13.8%; transition: 43,507, 58.8%; post: 20,206, 27.3%). The percentage of exposures involving HCF evaluation (41.5% to 33.8%), HCF admission (4.5% to 1.9%), and major medical outcomes (0.6% to 0.1%) decreased from the baseline to post period. Sales adjusted rates of all exposures decreased 57.4% (4.920–2.094 exposures/1 million packets sold). Decreases also occurred in HCF evaluations (65.0% decrease; 2.026–0.708 exposures/1 million packets sold), HCF admissions (81.4% decrease; 0.218–0.041 exposures/1 million packets sold), and major medical outcomes (90.9% decrease; 0.030–0.003 exposures/1 million packets sold).

Conclusions: The morbidity of accidental exposures to LLPs in children decreased substantially following implementation of the ASTM International safety standard. Ongoing monitoring should be performed to determine if additional safety measures are required.

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Poison center; ASTM International safety standard; liquid laundry packets

Introduction

Liquid laundry packets (LLPs) are single-load laundry packets containing highly concentrated detergent that became available to US consumers in early 2012. In May of that year, the American Association of Poison Control Centers (AAPCC) issued a news release with a summary of 3 children exposed to LLPs and a warning to the public to keep these products locked up and out of reach of children [1]. In October 2012, Centers for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report describing poison center cases of LLP exposures, which were associated with vomiting, mental status changes, and respiratory distress in several children [2]. The report further stated that pediatric exposures to LLPs were an emerging public health hazard and that LLPs were more commonly ingested by children than traditional laundry detergents [2]. The US Consumer Product Safety Commission (CPSC) also published a safety alert in 2012 warning parents to not let children handle LLPs and to keep LLPs locked up and out of sight of children due to concerns about potential harm. [3]

Following the publication of these warnings, several other case reports and retrospective studies of poison center and emergency department (ED) cases characterized these exposures further and reported the rates of injury associated with LLPs [4–24]. These reports described symptoms and injuries associated with LLP exposure in children including vomiting/gastrointestinal distress, esophageal injury, respiratory distress, progressive central nervous system depression, ocular and dermal burns, and even death [4,7,24]. An analysis of poison center exposures in 2013 and 2014 showed that the odds of admission to a healthcare facility (HCF) was 5 times greater with LLPs compared to traditional non-packet laundry detergents and the odds of a serious medical outcome was 8 times greater with LLPs compared to traditional non-packet laundry detergents. [7]

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In response to concerns about LLP safety, ASTM International (formerly American Society of Testing Materials) began developing a voluntary standard in 2014 to reduce the risk of accidental LLP exposure in young children through product, packaging, and labeling requirements. The outer films used for the packets are required to contain an aversive agent (unpleasantly flavored substance), to withstand a minimum compression strength, and to dissolve only after a specified length of time. Product packaging is required to be opaque to limit the visibility of its contents, and the standard specifies options to ensure that the container is difficult for children to open. Labeling must also clearly communicate the hazard associated with the products to the consumer [25]. The final standard was issued in December 2015. This study evaluates the impact of the implementation of the ASTM safety standard on accidental exposures to LLPs in children <6 years old through 2018.

Methods

This retrospective study queried the National Poison Data System (NPDS) for LLP exposures. NPDS is the national database of exposures reported to regional poison centers (RPCs) covering the entire US. RPC staff are trained healthcare professionals that take calls from the public and healthcare providers to manage patients potentially exposed to pharmaceutical and non-pharmaceutical substances. Using standardized data collection systems, each RPC records information about the exposed patient, the substances involved, the clinical effects and therapies, the level of HCF care provided, and the medical outcome. The AAPCC Annual Report provides definitions of these NPDS variables [26]. A common product database containing over 400,000 substances (Micromedex Poisindex® System, IBM Watson Health, Greenwood Village, CO) is used to standardize the collection of substance information. RPC staff follow up on cases that require medical management. Medical outcome (e.g., minor effect) is recorded after follow up is complete, if follow up is determined to not be required due to the low risk of the exposure, or if follow up cannot be completed [26]. After completion of follow up, the RPC closes the case. RPCs upload case data to NPDS automatically on a pre-determined interval.

This study included cases received by RPCs from 01 July 2012 to 31 December 2018 and involved a LLP, accidental exposure (exposure reason code: unintentional-general), and a child <6 years old. The unique codes used to identify LLPs were introduced into the product database in June 2012 with 01 July 2012 being the earliest date that exposures involving LLPs can be identified in NPDS. Confirmed non-exposures were excluded.

Sales data (number of LLPs sold) were obtained from Nielsen Strategic Planner Service using their proprietary source of Total US Expanded All Outlets Combined channel which includes Food, Drug, Mass Merchandise, Club, Dollar and Military/Deca and Convenience for the four week interval beginning 22 July 2012 through the four week interval ending 30 December 2018. Nielsen samples point of sales data from multiple channels and projects national sales estimates.

Exposures were divided into 3 periods based on case received date: Baseline (before ASTM standard implementation; 01 July 2012–30 June 2013), Transition (implementation of some ASTM standard components; 01 July 2013–31 December 2016), and Post (after full implementation of ASTM standard; 01 January 2017–31 December 2018). Though the development of the ASTM safety standard began in 2014, manufacturers began making safety changes in 2013 prior to the formal ASTM efforts. As of June 2013, approximately 60% of all LLPs on store shelves had implemented either opaque packaging, revised safety labeling, or both components of the eventual final ASTM standard (Richard Sedlak, email communication, 2019). Thus, 01 July 2013 was set as the start of the transition period to align with the availability of LLP products with only some components of the ASTM standard. The 01 July 2013 start date also permitted a complete calendar year for the baseline period, which was important due to the seasonality of exposures. The final ASTM standard was issued in December 2015 and by December 2016, 99% of the products on store shelves complied with all standard requirements (Richard Sedlak, email communication, 2019). Thus, the end of the transition period was set as 31 December 2016. Exposures beginning 01 January 2017 through 31 December 2018 were included for the post period.

Descriptive statistics were used to describe exposure characteristics by period. Primary outcome variables were counts and sales adjusted rates of all exposures and clinically significant exposures. Clinically significant exposures were defined as those involving the following subcategories of exposures: HCF evaluation (treated/evaluated and released or HCF admission), HCF admission (admitted to non-critical care unit, critical care unit, or to a psychiatric care facility), and major medical outcomes (major effect or death) [26]. These categories were not mutually exclusive (e.g., an exposure in the HCF admission category was also counted in the HCF evaluation category).

Counts and sales adjusted rates of the primary outcome groups were tabulated cumulatively and over time. As sales data did not align perfectly with the study period calendar dates (01 July 2012–31 December 2018), counts and sales adjusted rates of exposures over time were calculated using the four week data interval beginning 22 July 2012 and ending 30 December 2018. Exposure rates per 1 million packets sold were calculated for each time point with corresponding 95% confidence intervals. Cumulative rates per 1 million packets sold were calculated for the baseline and post period. A log-linear Poisson regression model of the cumulative rates was used to estimate a percent change in rate from baseline to post period (with corresponding 95% confidence intervals). Additionally, an iterative fitting technique of a single breakpoint harmonic regression (which accounts for seasonality) was performed for all exposures and exposures involving HCF evaluation. Akaike information criterion (AIC) values were compared among all possible breakpoints within the range of data and the lowest model AIC value

determined the optimal 4 week interval breakpoint. The best fitting model with the single breakpoint provides a suggested transition time point for the exposures over time for the study period, where exposures prior to the breakpoint were increasing significantly and exposures after the breakpoint were significantly decreasing. All analyses were conducted using SAS (version 9.4, Cary, NC).

In alignment with the Colorado Multiple Institutional Review Board's Policies and Procedures for the Protection of Human Subjects, the Principal Investigator determined that analysis of NPDS data for this study does not meet the criteria for human subject's research per 45 CFR 46.102(f)(2) and no institutional review board approval was necessary.

Results

From 01 July 2012 to 31 December 2018, NPDS received 73,942 accidental exposures to LLPs in children <6 years old. Most exposures occurred in children <2 years old (39.5%) or 2 to <4 years old (49.4%). Approximately half (52.4%) involved male children. Most (87.0%) cases were ingestions, but ocular and dermal exposures also occurred. A total of 37.7% received HCF evaluation, with 3.3% involving admission and major medical outcomes occurring in 0.3% of cases (Table 1).

A total of 10,229 (13.8%) exposures were received during the baseline period, 43,507 (58.8%) during the transition period, and 20,206 (27.3%) during the post period. The percentage of exposures involving children <2 years old decreased from baseline (41.3%) to post (32.0%) period, while the percentage involving children 2 to <4 years old (baseline: 48.2%; post: 54.4%) and children 4 to <6 years old (baseline: 10.2%; post: 13.4%) both increased. From baseline to post period, the percentage of exposures involving ingestion (baseline: 90.4%; post: 81.9%) decreased, while ocular (baseline: 13.3%; post: 22.7%) and dermal (baseline: 10.2%; post: 17.0%) exposures both increased. The percentage of exposures involving HCF evaluation decreased from 41.5% in the baseline to 33.8% in the post period, while admissions decreased from 4.5% to 1.9% and major medical outcomes decreased from 0.6% to 0.1% (Table 1). There were 3 deaths; one death occurred in the baseline period, two deaths occurred during the transition period, and no deaths occurred in the post period. The most common clinical effects among major medical outcome cases were vomiting (70.3%), cough/choke (25.0%), and drowsiness/lethargy (43.8%) in the baseline period and vomiting (46.2%), ocular irritation/pain (46.2%), red eye/conjunctivitis (26.9%), and cough/choke (26.9%) in the post period.

All exposures were received by RPCs in a seasonal pattern with peaks in the summer months and decreases during the winter. Overall, exposures increased through 2015 and decreased thereafter (Figure 1). Exposures that received HCF evaluation followed a similar pattern (Figure 1). Breakpoint analysis established a breakpoint for all exposures in December 2015 and in February 2016 for exposures involving HCF evaluation. Exposures involving HCF admission remained fairly constant through 2014 and decreased thereafter (Figure 1). Exposures involving major medical outcomes began decreasing in 2014 (Figure 1). Sales of LLPs increased steadily over the study period (Figure 2). Sales adjusted rates of all exposures, exposures that involved HCF evaluation, HCF admission, and major medical outcomes decreased consistently over the study period (Figure 3).

Cumulative sales adjusted rates of all exposures decreased 57.4% from the baseline to post period. The rate of

Table 1. Demographics, exposure characteristics, level of care and medical outcome of all accidental exposures to liquid laundry packets by period of ASTM safety standard implementation.

	Baseline period exposures 01 July 2012–30 June 2013 ($n = 10,229$)	Transition period exposures 01 July 2013–31 December 2016 ($n = 43,507$)	Post period exposures 01 January 2017–31 December 2018 ($n = 20,206$)	All exposures 01 July 2012–31 December 2018 ($n = 73,942$)
Age (categorical)				
<2 years	4227 (41.3%)	18,541 (42.6%)	6467 (32.0%)	29,235 (39.5%)
2 to <4 years	4930 (48.2%)	20,633 (47.4%)	10,985 (54.4%)	36,548 (49.4%)
4 to <6 years	1047 (10.2%)	4231 (9.7%)	2712 (13.4%)	7990 (10.8%)
≤5 years (estimated age[a])	25 (0.2%)	102 (0.2%)	42 (0.2%)	169 (0.2%)
Gender				
Male	5307 (51.9%)	22,600 (51.9%)	10,807 (53.5%)	38,714 (52.4%)
Route of exposure[b]				
Ingestion	9248 (90.4%)	38,560 (88.6%)	16,555 (81.9%)	64,363 (87.0%)
Ocular	1357 (13.3%)	6626 (15.2%)	4589 (22.7%)	12,572 (17.0%)
Dermal	1047 (10.2%)	5191 (11.9%)	3437 (17.0%)	9675 (13.1%)
Other or unknown	33 (0.3%)	184 (0.4%)	106 (0.5%)	323 (0.4%)
Aspiration (with ingestion)	45 (0.4%)	146 (0.3%)	46 (0.2%)	237 (0.3%)
Level of HCF care and outcomes[c]				
Received HCF evaluation	4241 (41.5%)	16,830 (38.7%)	6835 (33.8%)	27,906 (37.7%)
Admitted to HCF	458 (4.5%)	1621 (3.7%)	394 (1.9%)	2473 (3.3%)
Major medical outcome[d]	64 (0.6%)	130 (0.3%)	26 (0.1%)	220 (0.3%)
Death	1 (<0.1%)	2 (<0.1%)	0 (0.0%)	3 (<0.1%)
Major effect	63 (0.6%)	128 (0.3%)	26 (0.1%)	217 (0.3%)

[a]≤5 years is an estimated age category in National Poison Data System used when specific age cannot be recorded.
[b]Multiple routes can be reported for each case.
[c]Clinically significant outcome categories of HCF Evaluation, HCF Admission, and Major Medical Outcome were not mutually exclusive.
[d]Major medical outcome included exposures resulting in major effect or death.
HCF: healthcare facility.

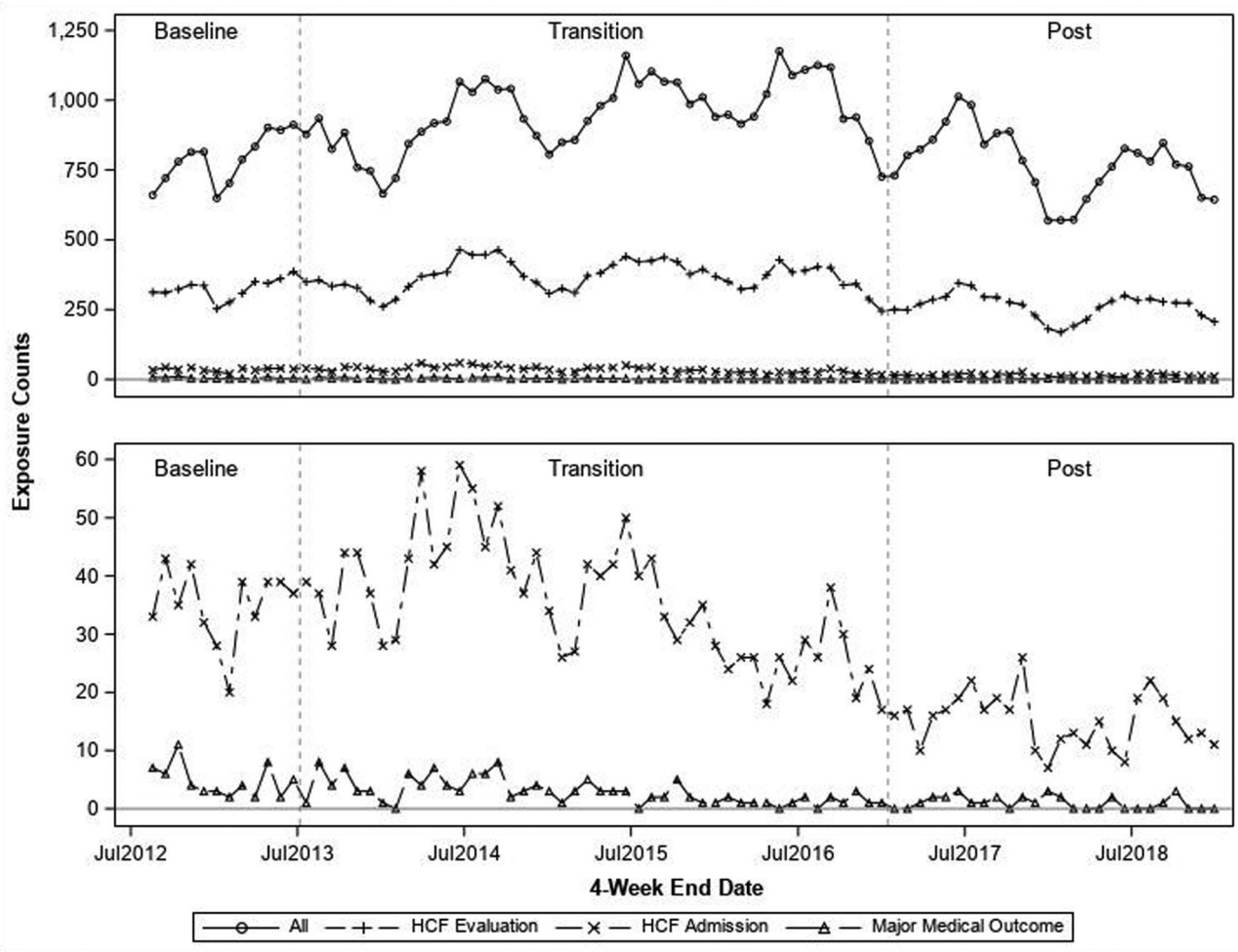

Figure 1. Frequency of all accidental exposures to Liquid Laundry Packets by level of severity. *HCF: healthcare facility; Clinically significant outcome categories of HCF Evaluation, HCF Admission, and Major Medical Outcome were not mutually exclusive. Each horizontal line represents exposures with a different level of severity category. The vertical lines represent the start/stop of the baseline, transition, and post periods. The lower panel represents a subset of the top panel, displaying only HCF admissions and major medical outcomes.

exposures involving HCF evaluation decreased 65.0% from the baseline to post period. Exposure rates involving HCF admission decreased 81.4% from the baseline to post period. Exposures involving major medical outcomes decreased 90.9% from the baseline to post period (Table 2).

Discussion

We found that the absolute count of accidental poison center exposures to LLPs in children <6 years old did not change significantly after implementation of an ASTM standard to prevent accidental exposures. However, units of LLPs sold increased threefold during the same period, which was not accompanied by an increase in exposures. The proportion of patients that were admitted to a HCF or had a major medical outcome decreased substantially. While these findings cannot establish causality, the temporal relationship shows that the implementation of the ASTM safety standard was followed by a reduction in injuries from accidental exposures involving LLPs in young children.

The lack of an absolute decrease in cases has prompted some authors to conclude that these measures were ineffective. However, the use of sales data shows that availability of these products in the home increased greatly over the study period. Accordingly, the exposure and outcome rates adjusted for the number of LLPs sold decreased substantially. Since exposures in young children are well known to be related to the number of households in which a product is present, one would expect a substantial increase in exposures due to the marked increase in LLP availability. The use of an "availability" denominator is well established in the evaluation of drug safety [27,28].

Both the absolute number of cases and the rate of exposure based on availability are needed when developing public policy. The absolute number of poison center exposures provides an assessment of the public health impact of the problem. In other words, we know that the number of children affected stayed roughly the same over the entire period although the severity of their exposures decreased. One conclusion based solely on these data could be that these public health interventions were ineffective. However, the interventions were intended to not only reduce access to the product (measured by number of exposures), but to also reduce the amount accessed (measured by severity of exposure). In this instance, while the absolute number of exposures did not change, the severity of the exposures was significantly

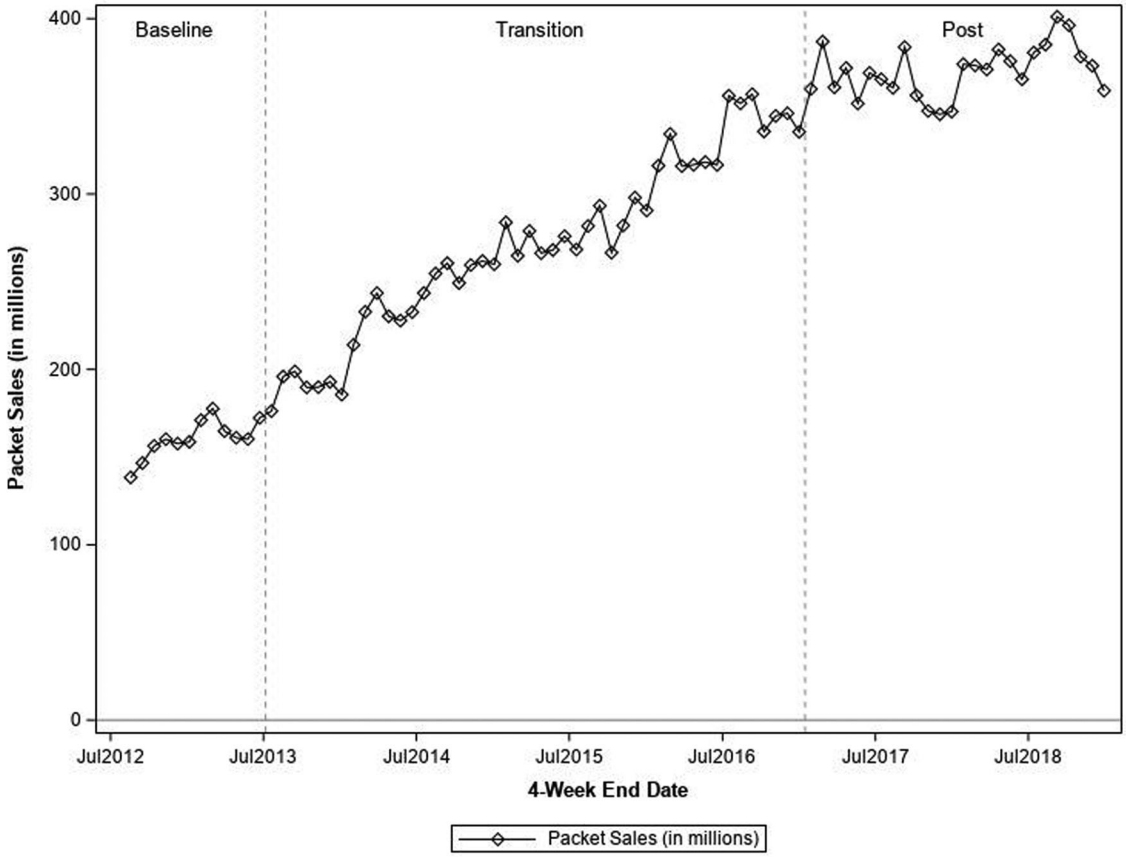

Figure 2. Liquid laundry packet sales. The vertical lines represent the start/stop of the baseline, transition, and post periods.

reduced. The fact that sales of these products increased threefold during the study period suggest that the number of exposures as a proportion of exposure opportunity was also significantly reduced.

Our findings are complemented by the National Electronic Injury Surveillance System (NEISS) data estimates of nationwide ED visits for consumer products [29,30]. This analysis compared the number and sales adjusted rates of ED visits from accidental exposure to LLPs in children <6 years old in the baseline and post periods. The number of ED visits due to LLPs was roughly equivalent in the baseline and post periods, but the sales adjusted rates of ED visits decreased significantly from 74 to 32 ED visits per 1 million LLPs sold. Furthermore, the percentage of cases involving admission decreased from 11% in the baseline period to 3% in the post period [29]. The authors concluded that the voluntary ASTM standard was associated with a 49.4–61.6% reduction in the rate of child injury from LLPs [30]. A smaller study of data collected by 12 poison centers through early 2016 found a similar pattern of results [22].

A more recent study also evaluated changes in counts of accidental LLP exposures reported to NPDS and showed modest decreases in the number of exposures in children <6 years old [31]. Gaw et al. found decreases in exposures, HCF use, HCF admission, and serious outcomes in children <6 years old, but also reported increased exposures in older children and adults. Unfortunately, they did not evaluate changes in the context of product sales. They concluded that both the ASTM safety standard and the concurrent public awareness campaigns likely contributed to decreases in exposures. Taken together, the decreases observed among exposures in the age group targeted by the ASTM standard, decreases in severity, and decreases despite increased product sales strengthen the suggestion that the product-based changes of the ASTM standard contributed to reduced injuries associated with LLP exposure in children [28].

Like Gaw et al. [31], our study found an increase in the percentage of exposures that involved ocular routes. This result was also seen in the NEISS data, where the estimated number of ED visits involving ocular routes nearly doubled [29]. Both our study and the NEISS study also found increases in dermal exposures, but the counts were too low to make meaningful comparisons [29]. None of these studies examined sales adjusted rates of or the outcomes associated with ocular and dermal exposures. Such an analysis, combined with a root cause evaluation of how ocular and dermal exposures occur, could provide valuable information to target the prevention of exposures not addressed by the ASTM standard. This type of analysis could also be useful in addressing why exposures in the post period involved fewer children <2 years old, while exposure counts in older children were unaffected.

Accidental exposures to LLPs have also been reported in Europe [32]. European case reports and retrospective studies of poison center data described symptoms similar to US reports [33–37]. In 2012, some European LLP manufacturers

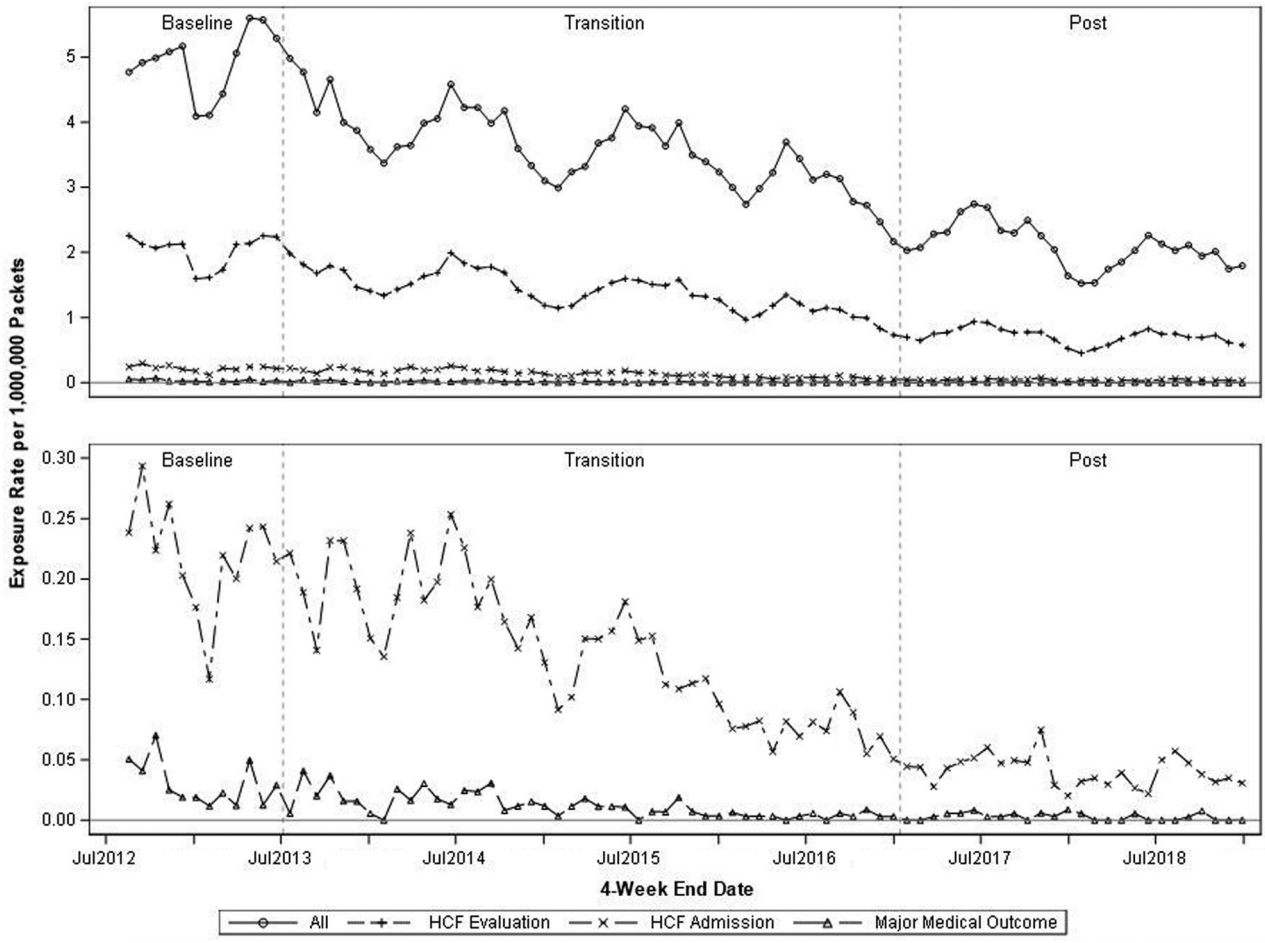

Figure 3. Sales adjusted rates of all accidental exposures to liquid laundry packets by level of severity. *HCF: healthcare facility; Clinically significant outcome categories of HCF Evaluation, HCF Admission, and Major Medical Outcome were not mutually exclusive. Each horizontal line represents sales adjusted exposures with a different level of severity category. The vertical lines represent the start/stop of the baseline, transition, and post periods. The lower panel represents a subset of the top panel, displaying only HCF admissions and major medical outcomes.

Table 2. Cumulative sales adjusted rates of all accidental exposures to liquid laundry packets in children <6 years old by period of ASTM safety standard implementation.

	Baseline period Cumulative rate per 1,000,000 packets sold	Post period Cumulative rate per 1,000,000 packets sold	% Change (95% CI)
All exposures	4.920	2.094	−57.4% (−58.5%, −56.4%)
HCF evaluation	2.026	0.708	−65.0% (−66.4%, −63.6%)
HCF admission	0.218	0.041	−81.4% (−83.8%, −78.7%)
Major medical outcomes[a]	0.030	0.003	−90.9% (−94.3%, −85.5%)

[a]Major medical outcomes included exposures resulting in major effect or death.
HCF: healthcare facility; CI: confidence interval.

entered into a voluntary International Association for Soaps, Detergents, and Maintenance Products (AISE) initiative to reduce accidental exposures in children through product and packaging changes and the promotion of safe use and storage [38]. Systematic evaluations of the AISE initiative describe mixed results in terms of its impact and refinement and evaluation of the initiative are ongoing [39–43].

NPDS data are limited by the voluntary, self-reported nature of poison center cases, and not all exposures are reported to RPCs. Though data have been consistently collected by NPDS over time, reports to RPCs have fluctuated and media attention and public awareness campaigns can impact rates of reporting [26]. The focus on LLP exposures with clinically meaningful outcomes was done to minimize this bias, as clinically meaningful outcomes are most equivalent to actual injuries and are most likely to be captured regardless of reporting fluctuation. However, as the proportion of exposures that were not followed to a known outcome increased from the baseline to post-period, it is possible that not all clinically significant exposures were captured. Additionally, while unique codes were used to identify LLP exposures, the accuracy of product coding by RPCs may result in LLP exposures being underreported. RPCs have also likely improved their management of LLP exposures, which may have reduced rates of referral to HCFs. Furthermore, we were not able to calculate product-specific rates due to

limitations in both the NPDS and sales data. This also prevented our evaluation of individual components of the ASTM standard or the timing of their introduction. We also cannot rule out the impact that public education campaigns may have had on the observed decreases, which may explain why exposures continue to decrease. The proportion of LLP sales to consumers with children <6 years old is unknown, thus the sales data used for this analysis are not a perfect denominator. However, the frequency of events in the context of product availability for relatively new products like LLPs remains important when considering the rate of exposure over time. The analysis was also limited by a short baseline period and a long transition period due to the timing of when safety changes were made and the lack of product-specific rates. This may underestimate the harms during the baseline period and removes a large proportion of the data reported during the transition period from the rate evaluation. Safety changes that were made prior to the end of the baseline may have further underestimated harms during the baseline. These limitations prevent a precise estimate of the specific impact of the ASTM standard implementation.

Conclusions

The introduction of the ASTM safety standard was temporally associated with a substantial decrease in the morbidity of US poison center exposures involving accidental exposure to LLPs in children <6 years old. Despite this improvement, over 9000 LLP exposures in children were received by US poison centers in 2018, including nearly 200 admissions to a HCF. This suggests that while improvements were seen following the implementation of the ASTM safety standard, pediatric accidental LLP exposures still occur. At a minimum, ongoing surveillance of poison center and other data sources are needed to understand the long term impact of the ASTM safety standard and to determine if the maximum benefit of the standard has been achieved.

Disclaimers

The AAPCC maintains the NPDS, which houses de-identified case records of self-reported information collected from callers during exposure management and poison information calls managed by the country's poison control centers (PCCs). NPDS data do not reflect the entire universe of exposures to a particular substance as additional exposures may go unreported to PCCs; accordingly, NPDS data should not be construed to represent the complete incidence of US exposures to any substance(s). Exposures do not necessarily represent a poisoning or overdose and AAPCC is not able to completely verify the accuracy of every report. Findings based on NPDS data do not necessarily reflect the opinions of AAPCC.

Conclusions drawn from use of the Nielsen data do not reflect the views of Nielsen.

Disclosure statement

The authors report grants from the American Cleaning Institute during the conduct of the study.

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Data availability statement

The data used for this analysis are available from the American Association of Poison Control Centers.

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