Reporting Rates of Liquid Laundry Detergent Packet Exposures Reported to the National Poison Data System (NPDS): Baseline Period Data Surveillance

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EXECUTIVE SUMMARY

Key Findings:
During the period prior to implementation of the American Society for Testing and Materials (ASTM) standards (baseline; 01 July 2012 to 30 June 2013), 10,229 unintentional-general exposures in children <6 years of age involving liquid laundry detergent packets were reported to the National Poison Data System (NPDS).

- Most (89.5%) exposures involved children <4 years of age (41.3% in children <2 years of age; 48.2% in children 2 to <4 years of age).
- Stratifications were done by level of severity to explore factors associated with clinically significant outcomes:
  - 41.5% of exposures involved healthcare facility (HCF) treatment, 4.5% involved HCF admission, and 0.6% involved severe medical outcomes (major effect or death).
- The vast majority (90.4%) of exposures involved oral route of ingestion, but exposures resulting in severe medical outcomes more commonly reported aspiration (14.1% in severe medical outcomes; 0.4% in all exposures) of the liquid laundry detergent packet.
- Contributing factors (scenarios) associated with exposures most commonly referred to improper storage of the liquid laundry detergent packet.
- Cumulative rates and trends over time were explored using both population and sales data adjusted rates and are summarized in the following table.

Type of Exposure Rate	Cumulative Population-Adjusted Rate[a]	Population-Adjusted Rate[a] Range	Cumulative Sales-Adjusted Rate[b]	Sales-Adjusted Rate[b] Range
All Exposures	**42.499** (CI 41.684, 43.331)	**9.619** (CI 9.232, 10.015) to **12.210** (CI 11.772, 12.656)	**4.920** (CI 4.822, 5.020)	**4.770** (CI 4.413, 5.141) to **5.291** (CI 4.953, 5.640)
Healthcare Facility Treatment	**17.620** (CI 17.098, 18.159)	**4.322** (CI 4.064, 4.589) to **4.957** (CI 4.680, 5.243)	**2.026** (CI 1.963, 2.090)	**2.255** (CI 2.012, 2.512) to **2.240** (CI 2.022, 2.468)
Healthcare Facility Admission	**1.903** (CI 1.736, 2.085)	**0.489** (CI 0.405, 0.582) to **0.529** (CI 0.441, 0.625)	**0.218** (CI 0.198, 0.240)	**0.239** (CI 0.164, 0.327) to **0.215** (CI 0.151, 0.289)
Severe Medical Outcome	**0.266** (CI 0.208, 0.340)	**0.108** (CI 0.070, 0.153) to **0.062** (CI 0.035, 0.098)	**0.030** (CI 0.023, 0.038)	**0.051** (CI 0.020, 0.094) to **0.029** (CI 0.009, 0.059)

[a]Rate per 100,000 US children <6 years of age and 95% Confidence Interval (CI).
[b]Rate per 1,000,000 packets sold and 95% Confidence Interval (CI).

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BACKGROUND

In late 2015, voluntary standards were created by the American Society for Testing and Materials (ASTM) to help reduce unintentional exposures to liquid laundry detergent packets in children. These changes included requirements for an aversive agent, opaque packaging, packaging that is difficult to open by children, warning statements about the dangers of putting liquid laundry detergent packets in the mouth, and that liquid laundry detergent packets should be kept away from children[1]. As with all safety interventions, it is important to measure the impact of effectiveness of such changes. An evaluation model has been proposed by comparing characteristics and rates of National Poison Data System (NPDS) exposures to liquid laundry detergent packets in the period prior to the implementation of ASTM standards (baseline) to the period after full implementation of the standards. This report describes characteristics and rates of NPDS exposures reported in the period before full adoption of the ASTM standards.

OBJECTIVE

To describe exposures to liquid laundry detergent packets reported to the National Poison Data System (NPDS) between 01 July 2012 and 30 June 2013 to establish a safety profile of the baseline period prior to the implementation of the voluntary ASTM standards:

1) Describe demographics, exposure characteristics, and associated outcomes of NPDS exposures to liquid laundry detergent packets.
2) Describe cumulative rates of all liquid laundry detergent packet exposures and liquid laundry detergent packet exposures associated with clinically significant outcomes.
3) Describe trends over time in rates of all liquid laundry detergent packet exposures and liquid laundry detergent packet exposures associated with clinically significant outcomes.

METHODS

Through work with the ASTM Laundry Packets Data team, the baseline period was defined as 01 July 2012 through 30 June 2013. This period was determined based on the availability of data and in relation to the period before the ASTM standards were implemented.

Data Sources

National Poison Data System (NPDS)

The National Poison Data System (NPDS) is the data repository for the regional poison centers of the American Association of Poison Control Centers (AAPCC). AAPCC member centers offer coverage for the entire United States, providing free medical management services to both healthcare professionals and the general public. Exposure information is collected using a standardized coding system and database. These patient data are auto-uploaded in real time from the member poison centers to the NPDS. An exposure is defined as an actual or suspected contact with any substance which has been ingested, inhaled, absorbed, applied to, or injected into the body, regardless of toxicity or clinical manifestation. For the purposes of this report an exposure represents one unique case.

The NPDS database consists of categorical variables, which capture patient demographics, exposure details (including exposure reason, chronicity, and products involved), medical outcome, clinical effects, therapies, and scenario information. The NPDS definitions associated with these variables are outlined in Appendix A.

The NPDS was searched to identify human exposures from 01 July 2012 through 30 June 2013 to liquid laundry detergent packets. Cases that were confirmed later to be non-exposures and non-human exposures were excluded. Exposures involving children <6 years of age with the NPDS exposure reason of unintentional-general were included. The exposure reason of unintentional-general is the reason code reserved for unintended exposures to substances not for a specific reason[2].

US Census Data

Quarterly population counts for children <6 years of age were obtained to generate population-adjusted rates of exposures[3] for the quarter corresponding to the start of the baseline period. The 2017 model of the US Census Bureau's monthly postcensal resident population estimates were averaged for each quarter to generate estimates. For the cumulative population, the

monthly estimates were averaged over the entire time period to produce an overall population estimate.

Nielsen Sales Data

Sales data reported by Nielsen through its Strategic Planner Service for the Liquid Laundry Packs category for four week intervals were obtained to generate sales-adjusted exposure rates. Because numerator data (NPDS exposure counts) were only available for the period of 01 July 2012 to 30 June 2013, the four week interval beginning 22 July 2012 was selected as the start period and the four week interval ending 22 June 2013 was selected as the end period for the rate analysis.

Data Analysis

National Poison Data System Summary

Descriptive statistics were used to describe the variables of interest for all unintentional-general exposures in children <6 years of age. Variables described included demographics, exposure characteristics, level of healthcare facility treatment, medical outcome, clinical effects, therapies, and scenarios (Appendix A). For this summary, related clinical effects and performed therapies were described.

Additional subanalyses were performed for exposures involving clinically significant outcomes: healthcare facility (HCF) treatment (level of HCF treatment: treated/evaluated and released, admitted to non-critical care unit, admitted to critical care unit, admitted to psychiatric care facility), exposures involving HCF admission (level of HCF treatment: admitted to non-critical care unit, admitted to critical care unit, admitted to psychiatric care facility), and exposures with severe medical outcomes (medical outcome: moderate effect and death). Importantly, these stratifications are not mutually exclusive as they are composite groupings of progressing levels of severity of treatment and/or medical outcome, and a single case may exist in all or just one of the stratifications.

National Poison Data System Fatality Summary

Fatalities for direct deaths are summarized in aggregate and on a case level. Each direct death fatality abstract was evaluated and summarized on a case-level for year, age, gender, reason for exposure, substances involved, relative contribution of the liquid laundry detergent packet to the fatality (Appendix B), cause rank of each substance (if applicable), autopsy results, and other relative details reported in the case record narratives.[2]

Cumulative and Trends Over Time Rates Summary

US Census data were used to calculate population-adjusted rates of exposures per 100,000 children <6 years of age. Nielsen sales data were used to calculate reported exposure rates per 1 million units (i.e., packets) sold. Exposure rates and corresponding 95% confidence intervals were calculated utilizing a log-linear Poisson regression model.

Rates were calculated both cumulatively for the entire baseline period and for each time point. For all rate calculations, the average of the monthly population estimates was used and the total of sales was used. For population-adjusted rates, cumulative and quarterly rates were generated corresponding to the calendar dates of the baseline period (01 July 2012 to 30 June 2013) in accordance with the availability of US Census data. Sales-adjusted rates were calculated cumulatively for the period of 22 July 2012 to 22 June 2013 and by four week

intervals in accordance with the availability of the Nielsen sales data. All calculations and analyses were done in SAS, version 9.4 (SAS Institute,
Cary, NC, USA).

RESULTS

National Poison Data System (NPDS) Summary

A total of 10,229 unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age were reported to the National Poison Data System (NPDS) from 01 July 2012 to 30 June 2013. The median age of patients was 2.0 years, with 89.5% involving a child <4 years of age. The slight majority (51.9%) of patients were male (Table 1).

Stratifications were also done by the level of treatment and medical outcome involved, with 41.5% (n=4,241) of exposures involving HCF treatment, 4.5% (n=458) involving HCF admission, and 0.6% (n=64) involving a severe medical outcome (major effect or death). The median age of patients did not differ greatly by level of treatment and medical outcome, but the percentage of exposures involving children <2 years of age increased with increasing severity of exposures (all exposures (41.3%); exposures involving HCF treatment (48.1%); exposures involving HCF admission (64.4%); exposures with severe medical outcomes (68.8%); Table 1). Exposures with severe medical outcomes were also more likely to involve male children (65.6%) compared to the other levels of treatment and medical outcome stratifications (all exposures (51.9%); exposures involving HCF treatment (52.0%); exposures involving HCF admission (55.5%); Table 1).

Table 1. Demographics and Exposure Characteristics of All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Characteristics	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Age				
Mean (SD), years	2.1 (1.00)	2.0 (1.00)	1.6 (0.83)	1.6 (0.79)
Median, years	2.0	2.0	1.5	1.4
Age (categorical)				
<2 years	4,227 (41.3%)	2,039 (48.1%)	295 (64.4%)	44 (68.8%)
2 to <4 years	4,930 (48.2%)	1,812 (42.7%)	143 (31.2%)	17 (26.6%)
4 to <6 years	1,047 (10.2%)	384 (9.1%)	20 (4.4%)	3 (4.7%)
≤5 years	25 (0.2%)	6 (0.1%)	0 (0.0%)	0 (0.0%)
Gender				
Female	4,899 (47.9%)	2,033 (47.9%)	204 (44.5%)	22 (34.4%)
Male	5,307 (51.9%)	2,204 (52.0%)	254 (55.5%)	42 (65.6%)
Unknown	23 (0.2%)	4 (0.1%)	0 (0.0%)	0 (0.0%)

[a]*All exposures includes unintentional-general exposures in patients <6 years of age.*

The majority (96.2%) of all unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age occurred at the patient's own residence, which did not differ by level of treatment or medical outcome stratification (Table 2).

Ingestion was the most common (90.4%) route of exposure followed by ocular (13.3%) and dermal (10.2%) exposures. Exposures with more severe outcomes were more likely to involve aspiration (14.1%) than the other stratifications (all exposures (0.4%); exposures involving HCF treatment (0.9%); exposures involving HCF admission (5.2%); Table 2). A greater percentage (17.7%) of exposures involving HCF treatment involved an ocular route than all exposures (13.3%), but the ocular route was reported less frequently with more severe exposures (exposures involving HCF admission (4.4%); exposures with severe medical outcomes (9.4%)). An acute exposure of 1 substance was most commonly (99.8%) reported, which did not vary by level of treatment or medical outcome stratification (Table 2).

Table 2. Exposure Characteristics of All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Characteristics	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Exposure Site				
Own Residence	9,838 (96.2%)	4,095 (96.6%)	442 (96.5%)	62 (96.9%)
Other Residence	282 (2.8%)	94 (2.2%)	9 (2.0%)	2 (3.1%)
Workplace	7 (0.1%)	6 (0.1%)	0 (0.0%)	0 (0.0%)
Health Care Facility	7 (0.1%)	6 (0.1%)	0 (0.0%)	0 (0.0%)
School	3 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Other	75 (0.7%)	31 (0.7%)	5 (1.1%)	0 (0.0%)
Unknown	17 (0.2%)	8 (0.2%)	2 (0.4%)	0 (0.0%)
Route of Exposure[b]				
Ingestions	9,248 (90.4%)	3,699 (87.2%)	447 (97.6%)	58 (90.6%)
Aspiration (with ingestion)	45 (0.4%)	39 (0.9%)	24 (5.2%)	9 (14.1%)
Inhalation/Nasal	30 (0.3%)	11 (0.3%)	4 (0.9%)	1 (1.6%)
Ocular	1,357 (13.3%)	749 (17.7%)	20 (4.4%)	6 (9.4%)
Dermal	1,047 (10.2%)	364 (8.6%)	28 (6.1%)	5 (7.8%)
Parenteral	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	1 (<0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown	2 (<0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Characteristics	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Chronicity				
Acute	10,213 (99.8%)	4,233 (99.8%)	458 (100.0%)	63 (98.4%)
Acute-on-chronic	13 (0.1%)	7 (0.2%)	0 (0.0%)	1 (1.6%)
Chronic	2 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Unknown	1 (<0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of Substances				
Mean (SD)	1.0 (0.17)	1.0 (0.17)	1.0 (0.21)	1.1 (0.36)
Median	1.0	1.0	1.0	1.0

[a] *All exposures includes unintentional-general exposures in patients <6 years of age.*
[b] *A single exposure may involve more than one route.*

Approximately half (46.9%) of all unintentional-general exposures involving liquid laundry detergent packets in children <6 years of age were recommended to or received HCF treatment. Of those that received HCF treatment (n=4,241), 89.2% were treated without being admitted, while 10.8% were admitted (Table 3). Of those exposures that resulted in a severe medical outcome, all (100.0%) of them were managed in a HCF and approximately 79.7% were admitted to a HCF (Table 3).

Table 3. Level of Healthcare Facility (HCF) Treatment of All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Characteristics	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Recommended to or Received HCF Treatment				
Yes	4,795 (46.9%)	4,241 (100.0%)	458 (100.0%)	64 (100.0%)
No	5,298 (51.8%)	---	---	0 (0.0%)
Unknown	136 (1.3%)	---	---	0 (0.0%)
Level of Treatment[b]				
Treated/evaluated and released	3,783 (78.9%)	3,783 (89.2%)	---	12 (18.8%)
Admitted to non-critical care unit	251 (5.2%)	251 (5.9%)	251 (54.8%)	2 (3.1%)
Admitted to critical care unit	207 (4.3%)	207 (4.9%)	207 (45.2%)	49 (76.6%)
Admitted to psychiatric care facility	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patient refused referral/did not arrive at HCF	168 (3.5%)	---	---	0 (0.0%)
Patient lost to follow-up/left AMA	386 (8.1%)	---	---	1 (1.6%)

[a] *All exposures includes unintentional-general exposures in patients <6 years of age.*
[b] *Denominator is the number of exposures that were recommended to or received healthcare facility treatment.*

The majority (77.3%) of all unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age were followed to a known outcome. Just over half (51.5%) of the exposures followed to a known outcome involved a minor effect, followed by no or an unrelated effect (18.0%), moderate effect (7.2%), and major effect (0.6%; Table 4). One death (<0.1%) was reported and is summarized in a subsequent section. As would be expected, more severe medical outcomes were associated with a greater percentage of exposures involving HCF treatment and admission (Table 4).

Table 4. Medical Outcome of All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Medical Outcome	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Followed to a Known Outcome	**7,908 (77.3%)**	**3,963 (93.4%)**	**443 (96.7%)**	**64 (100.0%)**
Death	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	1 (1.6%)
Major Effect	63 (0.6%)	62 (1.5%)	50 (10.9%)	63 (98.4%)
Moderate Effect	740 (7.2%)	651 (15.4%)	196 (42.8%)	---
Minor Effect	5,267 (51.5%)	2,829 (66.7%)	177 (38.6%)	---
No Effect or Unrelated Effect	1,837 (18.0%)	420 (9.9%)	19 (4.1%)	---
Not Followed to Known Outcome	**2,321 (22.7%)**	**278 (6.6%)**	**15 (3.3%)**	**---**
Unable to follow, potentially toxic	464 (4.5%)	40 (0.9%)	10 (2.2%)	---
Not followed, Non-toxic	147 (1.4%)	12 (0.3%)	0 (0.0%)	---
Not followed, minimal clinical effects expected	1,710 (16.7%)	226 (5.3%)	5 (1.1%)	---

[a]*All exposures includes unintentional-general exposures in patients <6 years of age.*

The most common related clinical effects are presented in Table 5 (full listing of related clinical effects presented in Appendix C). Vomiting was the most commonly (48.1%) reported clinical effect among all unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age. Vomiting was also the most common clinical effect among exposures involving HCF treatment (61.6%), HCF admission (76.6%), and severe medical outcomes (70.3%). Drowsiness/lethargy, dyspnea, tachycardia, and respiratory depression were each reported in ≤5% of all exposures, but increased in frequency with increasing severity of exposures and were each reported in more than 20% of exposures involving severe medical outcomes.

Table 5: Most Common Related Clinical Effects[a] Among All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Related Clinical Effects	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Vomiting	4,917 (48.1%)	2,613 (61.6%)	351 (76.6%)	45 (70.3%)
Cough/choke	1,328 (13.0%)	744 (17.5%)	154 (33.6%)	16 (25.0%)
Ocular - Irritation/pain	1,105 (10.8%)	634 (14.9%)	18 (3.9%)	6 (9.4%)
Red eye/conjunctivitis	679 (6.6%)	401 (9.5%)	11 (2.4%)	3 (4.7%)
Drowsiness/lethargy	517 (5.1%)	414 (9.8%)	118 (25.8%)	28 (43.8%)
Nausea	467 (4.6%)	245 (5.8%)	40 (8.7%)	8 (12.5%)
Other	436 (4.3%)	302 (7.1%)	102 (22.3%)	17 (26.6%)
Oral irritation	362 (3.5%)	165 (3.9%)	29 (6.3%)	6 (9.4%)
Throat irritation	243 (2.4%)	138 (3.3%)	47 (10.3%)	9 (14.1%)
Erythema/flushed	203 (2.0%)	92 (2.2%)	15 (3.3%)	2 (3.1%)
Edema	173 (1.7%)	126 (3.0%)	7 (1.5%)	1 (1.6%)
Excess secretions	167 (1.6%)	130 (3.1%)	56 (12.2%)	11 (17.2%)
Corneal abrasion	154 (1.5%)	149 (3.5%)	7 (1.5%)	5 (7.8%)
Dermal - Irritation/pain	152 (1.5%)	78 (1.8%)	5 (1.1%)	0 (0.0%)
Diarrhea	147 (1.4%)	88 (2.1%)	20 (4.4%)	1 (1.6%)
Lacrimation	147 (1.4%)	96 (2.3%)	2 (0.4%)	2 (3.1%)
Dyspnea	130 (1.3%)	120 (2.8%)	65 (14.2%)	22 (34.4%)
Rash	114 (1.1%)	56 (1.3%)	9 (2.0%)	0 (0.0%)
Abdominal Pain	88 (0.9%)	53 (1.2%)	5 (1.1%)	1 (1.6%)
Bronchospasm	83 (0.8%)	78 (1.8%)	43 (9.4%)	8 (12.5%)
Agitated/irritable	77 (0.8%)	57 (1.3%)	18 (3.9%)	6 (9.4%)
Tachycardia	62 (0.6%)	59 (1.4%)	37 (8.1%)	13 (20.3%)

Related Clinical Effects	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
X-ray findings(+)	60 (0.6%)	60 (1.4%)	45 (9.8%)	11 (17.2%)
Hyperventilation/tachypnea	46 (0.4%)	43 (1.0%)	29 (6.3%)	8 (12.5%)
Burns	41 (0.4%)	38 (0.9%)	4 (0.9%)	2 (3.1%)
Respiratory depression	39 (0.4%)	37 (0.9%)	30 (6.6%)	18 (28.1%)
Pallor	36 (0.4%)	31 (0.7%)	7 (1.5%)	3 (4.7%)
Dysphagia	29 (0.3%)	25 (0.6%)	9 (2.0%)	1 (1.6%)
Photophobia	26 (0.3%)	24 (0.6%)	0 (0.0%)	0 (0.0%)
Acidosis	25 (0.2%)	25 (0.6%)	22 (4.8%)	9 (14.1%)
Burns (superficial)	24 (0.2%)	20 (0.5%)	2 (0.4%)	0 (0.0%)
Pneumonitis	24 (0.2%)	24 (0.6%)	19 (4.1%)	7 (10.9%)
Fever/hyperthermia	21 (0.2%)	19 (0.4%)	14 (3.1%)	5 (7.8%)
Oropharyngeal edema	21 (0.2%)	19 (0.4%)	14 (3.1%)	6 (9.4%)
Oral burns (including lips)	20 (0.2%)	16 (0.4%)	9 (2.0%)	2 (3.1%)
Coma	17 (0.2%)	16 (0.4%)	14 (3.1%)	9 (14.1%)

[a]*More than one related clinical effect can be reported per exposure.*
[b]*All exposures included unintentional-general exposures in patients <6 years of age.*

Dilute/irrigate/wash (76.0%) and food/snack (10.6%) were the most common therapies performed among all unintentional-general exposures involving liquid laundry detergent packets in children <6 years of age. Dilute/irrigate/wash was also the most common therapy performed in exposures involving HCF treatment (68.6%) and HCF admission (53.7%). Fluids, IV (33.2%) and oxygen (20.1%) were also commonly performed among exposures involving HCF admission. Among exposures resulting in severe medical outcomes, the most commonly performed therapies were oxygen (70.3%), fluids, IV (60.9%), intubation (60.9%), ventilator (57.8%), sedation (other; 37.5%), and bronchodilators (21.9%; Table 6).

Table 6: Therapies Performed[a] Among All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Performed Therapies	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Dilute/irrigate/wash	7,776 (76.0%)	2,909 (68.6%)	246 (53.7%)	26 (40.6%)
Food/snack	1,088 (10.6%)	308 (7.3%)	30 (6.6%)	7 (10.9%)
Other	713 (7.0%)	411 (9.7%)	97 (21.2%)	22 (34.4%)
Antibiotics	243 (2.4%)	231 (5.4%)	30 (6.6%)	7 (10.9%)
Fluids, IV	224 (2.2%)	220 (5.2%)	152 (33.2%)	39 (60.9%)
Antiemetics	137 (1.3%)	134 (3.2%)	32 (7.0%)	3 (4.7%)
Other emetic	123 (1.2%)	53 (1.2%)	10 (2.2%)	2 (3.1%)
Oxygen	115 (1.1%)	111 (2.6%)	92 (20.1%)	45 (70.3%)
Bronchodilators	104 (1.0%)	101 (2.4%)	64 (14.0%)	14 (21.9%)
Steroids	97 (0.9%)	91 (2.1%)	49 (10.7%)	12 (18.8%)
Intubation	63 (0.6%)	61 (1.4%)	59 (12.9%)	39 (60.9%)
Ventilator	60 (0.6%)	59 (1.4%)	57 (12.4%)	37 (57.8%)
Antihistamines	47 (0.5%)	31 (0.7%)	10 (2.2%)	2 (3.1%)
Sedation (other)	42 (0.4%)	40 (0.9%)	35 (7.6%)	24 (37.5%)
Calcium	39 (0.4%)	5 (0.1%)	1 (0.2%)	0 (0.0%)
Benzodiazepines	18 (0.2%)	17 (0.4%)	17 (3.7%)	10 (15.6%)
Neuromuscular blocker	6 (0.1%)	6 (0.1%)	6 (1.3%)	3 (4.7%)
Charcoal, single dose	5 (<0.1%)	4 (0.1%)	2 (0.4%)	0 (0.0%)
Naloxone	5 (<0.1%)	5 (0.1%)	4 (0.9%)	3 (4.7%)
Fresh air	4 (<0.1%)	2 (<0.1%)	0 (0.0%)	0 (0.0%)
Ipecac	4 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Vasopressors	3 (<0.1%)	3 (0.1%)	1 (0.2%)	1 (1.6%)
Alkalinization	2 (<0.1%)	2 (<0.1%)	2 (0.4%)	1 (1.6%)

Performed Therapies	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Anticonvulsants	2 (<0.1%)	2 (<0.1%)	2 (0.4%)	2 (3.1%)
Atropine	2 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
CPR	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	1 (1.6%)

[a]*More than one performed therapy can be reported per exposure.*
[b]*All exposures included unintentional-general exposures in patients <6 years of age.*

Table 7 describes the scenarios, or factors that contributed to the event, among unintentional-general exposures involving liquid laundry detergent packets in children <6 years of age. Six percent (5.5%) of all exposures reported one or more scenarios, with the majority involving storage within sight of the child (34.3%), followed by other (unspecified; 29.7%), the product temporarily open because it was in use (10.3%), and product stored inappropriately (8.7%). A slightly higher percentage (8.5%) of exposures involving HCF admission reported one or more scenarios than the other level of treatment and medical outcome stratifications (all exposures (5.5%); exposures involving HCF treatment (6.5%); exposures with severe medical outcomes (3.1%); Table 5)). Among all level of treatment and medical outcome stratifications, stored within sight of child, other, product temporarily open because product was in use, and product stored inappropriately were the most common scenarios reported.

Table 7. National Poison Data System (NPDS) Scenario of All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Scenario	All Exposures[a] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Was a Scenario Reported?				
No	9,667 (94.5%)	3,964 (93.5%)	419 (91.5%)	62 (96.9%)
Yes	562 (5.5%)	277 (6.5%)	39 (8.5%)	2 (3.1%)
Scenario[b]				
Stored within sight of child	193 (34.3%)	86 (31.0%)	9 (23.1%)	2 (100%)
Other	167 (29.7%)	101 (36.5%)	16 (41.0%)	0 (0.0%)
Product temporarily open because product was in use	58 (10.3%)	23 (8.3%)	8 (20.5%)	0 (0.0%)
Product stored inappropriately (other than above)	49 (8.7%)	27 (9.7%)	4 (10.3%)	0 (0.0%)
Product always left out	38 (6.8%)	19 (6.9%)	1 (2.6%)	0 (0.0%)
Stored in unlocked, low cabinet in kitchen or bathroom	23 (4.1%)	8 (2.9%)	1 (2.6%)	1 (50.0%)
Scenario unknown (not allowed with other options)	14 (2.5%)	4 (1.4%)	1 (2.6%)	0 (0.0%)
Child caused exposure (gave to sibling or pet, etc)	12 (2.1%)	7 (2.5%)	0 (0.0%)	0 (0.0%)
Container transfer involved	6 (1.1%)	2 (0.7%)	0 (0.0%)	0 (0.0%)
Inadequate decontamination after product use	4 (0.7%)	2 (0.7%)	0 (0.0%)	0 (0.0%)
Patient confused or mentally incompetent	3 (0.5%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
Child or pet accessed medication/product from suitcase	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patient has illness of unknown etiology	2 (0.4%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
Child or pet accessed medication/product from purse	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exposure was the result of a dare or similar behavior	1 (0.2%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
Unknown CRC Status	1 (0.2%)	1 (0.4%)	0 (0.0%)	0 (0.0%)

[a]*All exposures includes unintentional-general exposures in patients <6 years of age.*
[b]*A single exposure may involve more than one scenario.*

National Poison Data System (NPDS) Fatality Summary

One fatality involving a liquid laundry detergent packet was reported between 01 July 2012 and 30 June 2013. The fatality involved a 6 month old male child. The reason for exposure was unintentional-general. The exposure was determined to be clearly not responsible for the fatality. There was no history of a witnessed liquid laundry detergent packet ingestion, but the child's mother thought she saw a laundry packet next to the child and was concerned it may have been related (Table 8).

Table 8: Case Characteristics of Fatalities Involving Liquid Laundry Detergent Packets

Year	Age, Gender	Exposure Reason	Chronicity	Products or Substances Involved (Cause Rank, if applicable)	Relative Contribution of Exposure to Fatality	Autopsy Findings (if applicable) and Other Details Reported	Additional Information Reported in Case Notes
2012	6 Month, Male	Unintentional-general	Acute	Laundry Detergents: Liquids (unit dose)	Clearly not responsible	*Autopsy findings not available*	• Had one episode of emesis followed by 2 seizures • Family was living in a shelter; was watched by non-primary caretaker for 2 days prior to death • No history of witnessed ingestion

Cumulative Rates Summary

Cumulative Population- and Sales-Adjusted Rates of All Exposures

The population-adjusted rate of reported unintentional-general exposures involving a liquid laundry detergent packet from 01 July 2012 to 30 June 2013 was 42.499 exposures per 100,000 US children <6 years of age (CI 41.684, 43.331; Table 9). This equates to one exposure per every 2,353 children <6 years of age in the US.

Though the baseline period was 01 July 2012 to 30 June 2013, sales-adjusted rates were calculated using the four week intervals beginning 22 July 2012 to the four week interval ending 22 June 2013 based on sales data availability. The sales-adjusted rate of reported exposures to a liquid laundry detergent packet for this period was 4.920 exposures per 1 million units sold (CI 4.822, 5.020; Table 9). This equates to one exposure per 0.203 million units (i.e., packets) sold.

Table 9. Cumulative Population- and Sales-Adjusted Rates of All Exposures

POPULATION-ADJUSTED Rates of Exposures (All Exposures)	
Exposure Counts[a]	10,229
Total Population	24,068,591
Rate of All Exposures per 100,000 Children <6 Years of Age (95% CI)	**42.499 (41.684, 43.331)**
SALES-ADJUSTED Rates of Exposure (All Exposures)	
Exposure Counts[b]	9,471
Total Sales	1,924,858,481
Rate of All Exposures per 1,000,000 Packets Sold (95% CI)	**4.920 (4.822, 5.020)**

[a]Exposure counts for population based rates include exposures from 01 July 2012 to 30 June 2013.
[b]Exposure counts for sales-adjusted rates are subset to match the four week intervals in the Neilson sales data and include exposures from 22 July 2012 to 22 June 2013.

Cumulative Population- and Sales-Adjusted Rates of Exposures with Clinically Significant Outcomes

The population-adjusted rate of reported exposures to a liquid laundry detergent packet that involved HCF treatment during the baseline period was 17.620 per 100,000 US children <6 years of age (CI 17.098, 18.159). This equates to one HCF treatment per every 5,675 children <6 years of age in the US. The population-adjusted rate of reported exposures to a liquid laundry detergent packet that involved HCF admission during the baseline period was 1.903 per 100,000 US children <6 years of age (CI 1.736, 2.085). This equates to one HCF admission per every 52,549 children <6 years of age in the US. The population-adjusted rate of reported exposures to a liquid laundry detergent packet involving severe medical outcomes during the baseline period was 0.266 per 100,000 US children <6 years of age (CI 0.208, 0.340). This equates to one severe medical outcome per every 375,940 children <6 years of age in the US (Table 10).

Table 10. Cumulative Population-Adjusted Rates of Exposures with Clinically Significant Outcomes

POPULATION-ADJUSTED Rates of Exposures with Severe Outcomes	
Total Population (Count)	24,068,591
Exposures Involving HCF Treatment (Counts)	4,241
Rate of Exposures Involving HCF Treatment per 100,000 Children <6 Years of Age (95% CI)	**17.620 (17.098, 18.159)**
Exposures Involving HCF Admission (Counts)	458
Rate of Exposures Involving HCF Admission per 100,000 Children <6 Years of Age (95% CI)	**1.903 (1.736, 2.085)**
Exposures with Severe Medical Outcomes (Counts)	64
Rate of Exposures with Severe Medical Outcomes per 100,000 Children <6 Years of Age (95% CI)	**0.266 (0.208, 0.340)**

The sales-adjusted rate of reported exposures to a liquid laundry detergent packet that involved HCF treatment during the baseline period was 2.026 per 1 million units sold (CI 1.963, 2.090). This equates to one HCF treatment per 0.494 million units (i.e., packets) sold. The sales-adjusted rate of reported exposures to a liquid laundry detergent packet involving HCF admission during the baseline period was 0.218 per 1 million units sold (CI 0.198, 0.240). This equates to one HCF admission per 4.587 million units (i.e., packets) sold. The sales-adjusted rate of reported exposures to a liquid laundry detergent packet involving severe medical outcomes during the baseline period was 0.030 per 1 million units sold (CI 0.023, 0.038; Table 11). This equates to one severe medical outcome per 33.333 million units (i.e., packets) sold.

Table 11. Cumulative Sales-Adjusted Rates of Exposures with Clinically Significant Outcomes

SALES-ADJUSTED Rates of Exposures with Severe Outcomes	
Total Sales (Count)	1,924,858,481
Exposures Involving HCF Treatment (Counts)	3,899
Rate of Exposures Involving HCF Treatment per 1,000,000 Packets Sold (95% CI)	**2.026 (1.963, 2.090)**
Exposures Involving HCF Admission (Counts)	420
Rate of Exposures Involving HCF Admission per 1,000,000 Packets Sold (95% CI)	**0.218 (0.198, 0.240)**
Exposures with Severe Medical Outcomes (Counts)	57
Rate of Exposures with Severe Medical Outcomes per 1,000,000 Packets Sold (95% CI)	**0.030 (0.023, 0.038)**

Trends-Over-Time Rates Summary

Population- and Sales-Adjusted Rates of All Exposures Over Time
Over time, counts of unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age fluctuated seasonally with decreases in the winter months (first quarter). During the same time period the total population of children <6 years of age increased steadily each quarter (Table 12; Figure 1).

The population-adjusted rate of reported unintentional-general exposures involving a liquid laundry detergent packet in children <6 years of age increased significantly from a rate of 9.619 per 100,000 US children <6 years of age (CI 9.232, 10.015) in third quarter 2012 to a peak rate of 12.210 per 100,000 US children <6 years of age (CI 11.772, 12.656) in second quarter 2013 (Table 12; Figure 2).

Table 12. Population-Adjusted Rates of All Exposures by Quarter (01 July 2012 to 30 June 2013)

Quarter	Exposure Count	Total Population Count	Rates of All Exposures per 100,000 Children <6 Years of Age (95% CI)
2012Q3 (01 July 2012 to 30 September 2012)	2,319	24,108,094	9.619 (9.232, 10.015)
2012Q4 (01 October 2012 to 31 December 2012)	2,514	24,095,846	10.433 (10.029, 10.845)
2013Q1 (01 January 2013 to 31 March 2013)	2,465	24,064,871	10.243 (9.843, 10.651)
2013Q2 (01 April 2013 to 30 June 2013)	2,931	24,005,552	12.210 (11.772, 12.656)

Figure 1. All Exposures and Population Counts by Quarter (01 July 2012 to 30 June 2013)

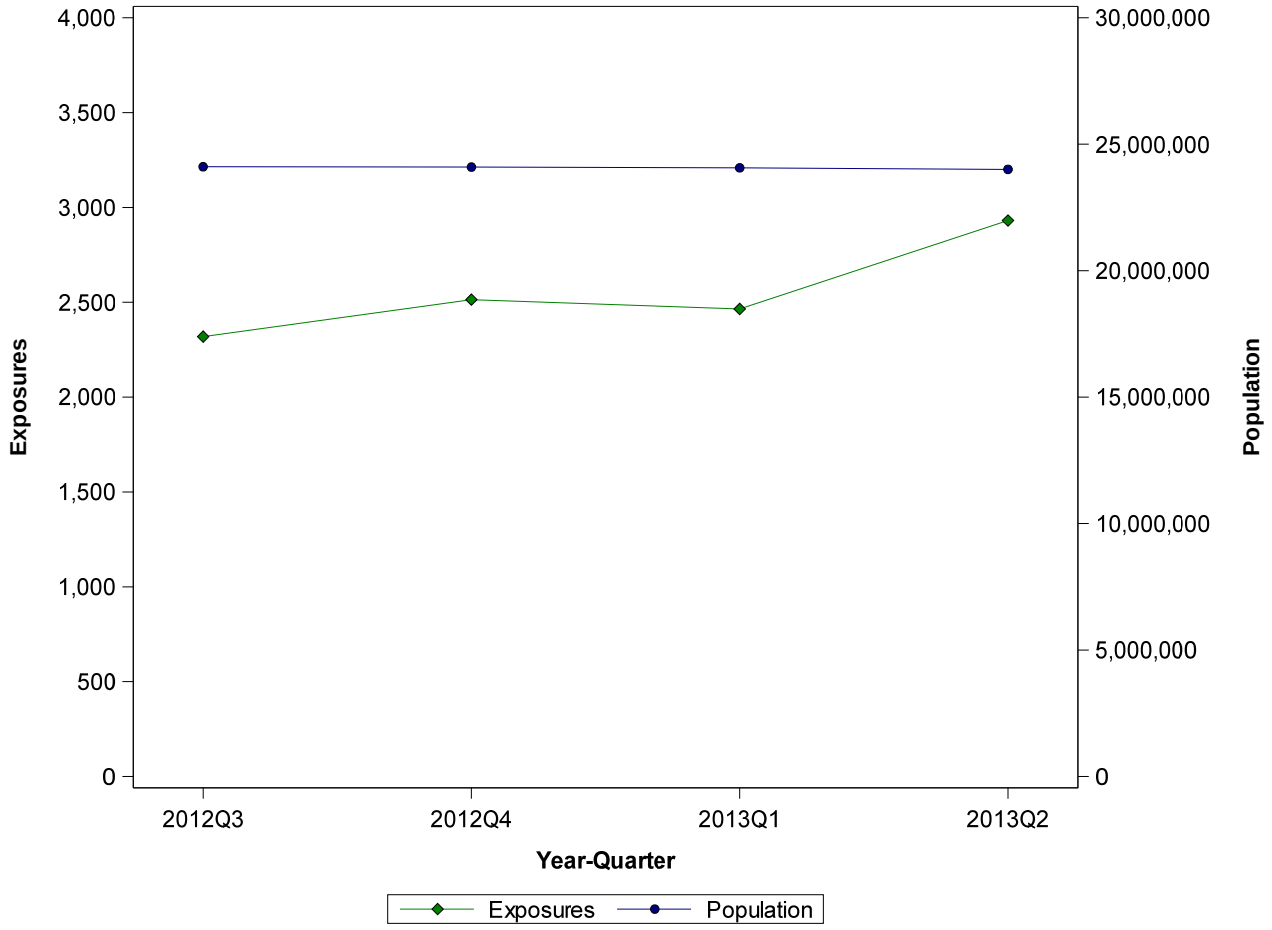
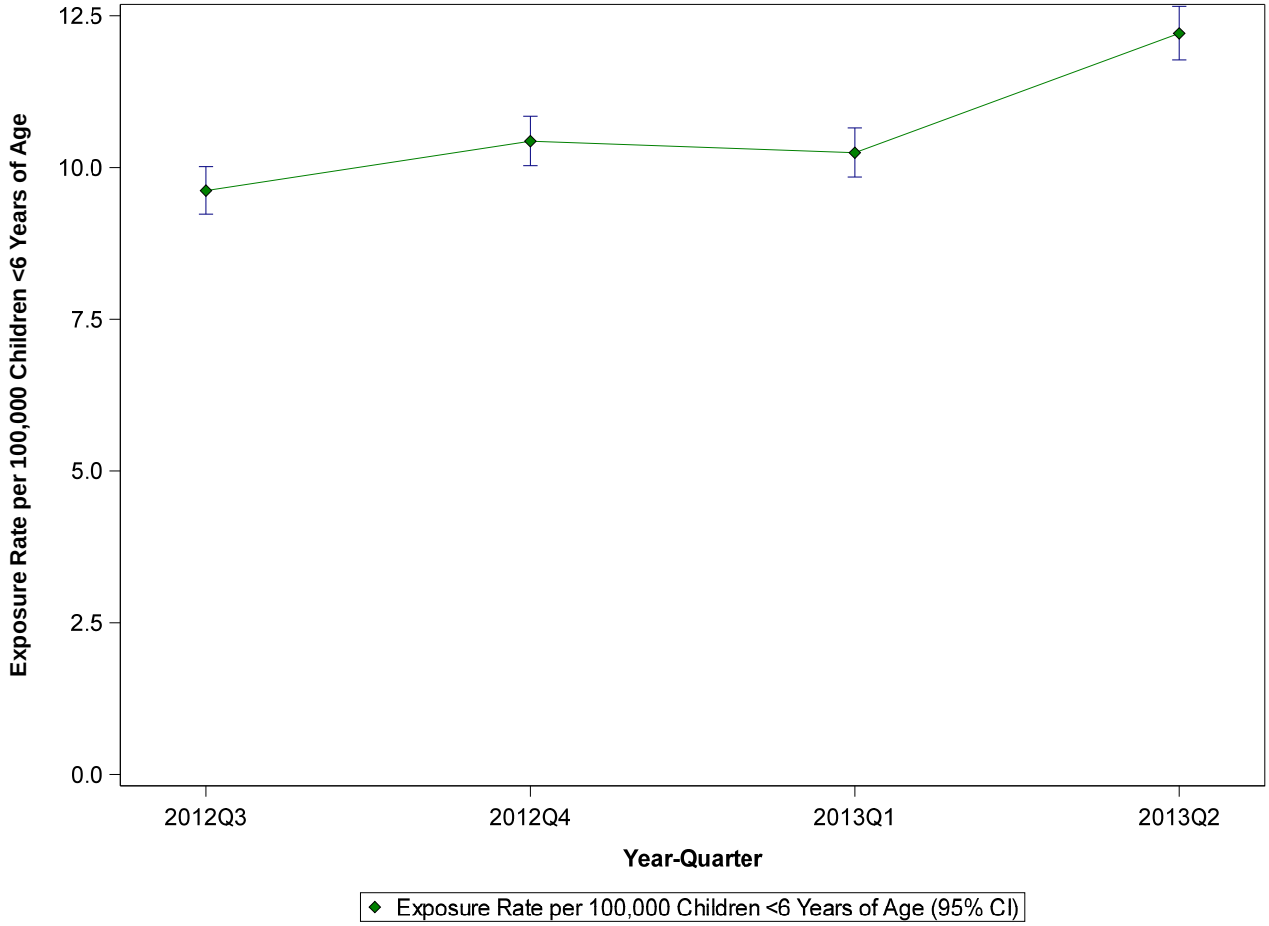


Figure 2. Population-Adjusted Rates of All Exposures by Quarter (01 July 2012 to 30 June 2013)



When examined by four week intervals corresponding to sales periods, counts of unintentional-general exposures involving a liquid laundry detergent packets in children <6 years of age fluctuated seasonally with increases from August through November then decreases through January and increases thereafter. During the same time period the total sales in children <6 years of age fluctuated slightly with a steady increase over time (Table 13; Figure 3).

The sales-adjusted rates of reported unintentional-general exposures involving liquid laundry detergent packets in children <6 years of age fluctuated throughout the baseline period, with peaks in sales-adjusted rates of all exposures in the four week interval ending 08 December 2012 (5.169 per million units sold (CI 4.820, 5.530)) and 27 April 2013 (5.602 per million units sold (CI 5.242, 5.973)). The four week interval ending 27 April 2013 reported the highest sales-adjusted rate of exposure, which was significantly different from the initial rate of 4.770 per 1 million units sold (CI 4.413, 5.141) during the four week interval beginning 22 July 2012. Since the peak rate in April 2013, rates decreased through the four week interval ending 22 June 2013 to 5.291 per 1 million units sold (CI 4.953, 5.640; Table 13; Figure 4).

Table 13. Sales-Adjusted Rates of All Exposures by Four Week Interval (22 July 2012 to 22 June 2013)

Four Week Interval Date	Exposure Count	Total Packets Sales Count	Rate of All Exposures per 1,000,000 Packets Sold (95% CI)
22 July 2012 to 18 August 2012	660	138,355,958	4.770 (4.413, 5.141)
19 August 2012 to 15 September 2012	721	146,612,045	4.918 (4.565, 5.283)
16 September 2012 to 13 October 2012	780	156,369,907	4.988 (4.644, 5.344)
14 October 2012 to 10 November 2012	814	160,177,007	5.082 (4.739, 5.437)
11 November 2012 to 08 December 2012	815	157,666,057	5.169 (4.820, 5.530)
09 December 2012 to 05 January 2013	649	158,606,062	4.092 (3.783, 4.413)
06 January 2013 to 02 February 2013	703	171,063,002	4.110 (3.811, 4.419)
03 February 2013 to 02 March 2013	788	177,595,380	4.437 (4.133, 4.752)
03 March 2013 to 30 March 2013	834	164,788,263	5.061 (4.723, 5.410)
31 March 2013 to 27 April 2013	902	161,022,945	5.602 (5.242, 5.973)
28 April 2013 to 25 May 2013	893	160,244,796	5.573 (5.213, 5.944)
26 May 2013 to 22 June 2013	912	172,357,060	5.291 (4.953, 5.640)

Figure 3. All Exposures and Sales Counts by Four Week Interval (22 July 2012 to 22 June 2013)

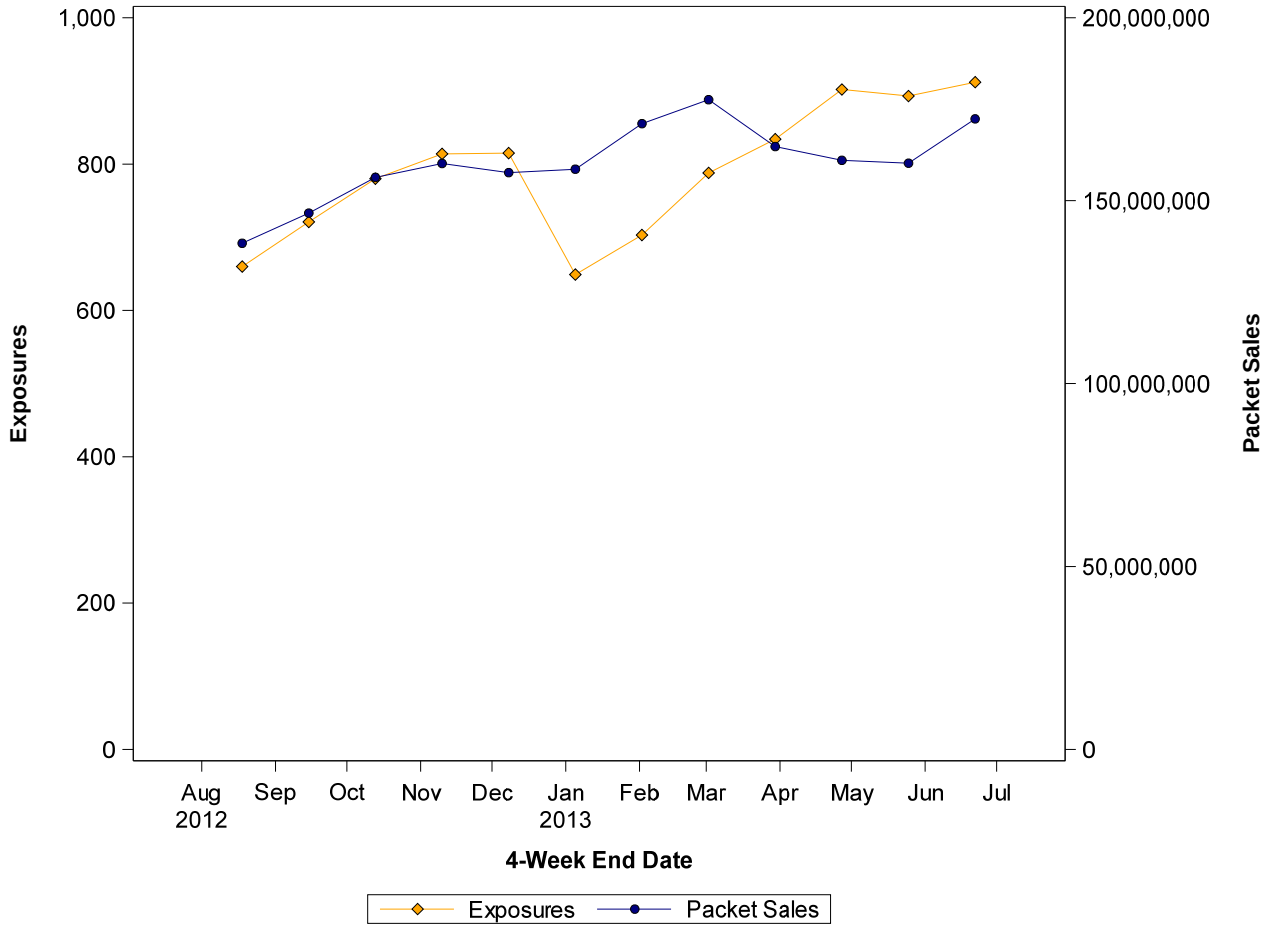
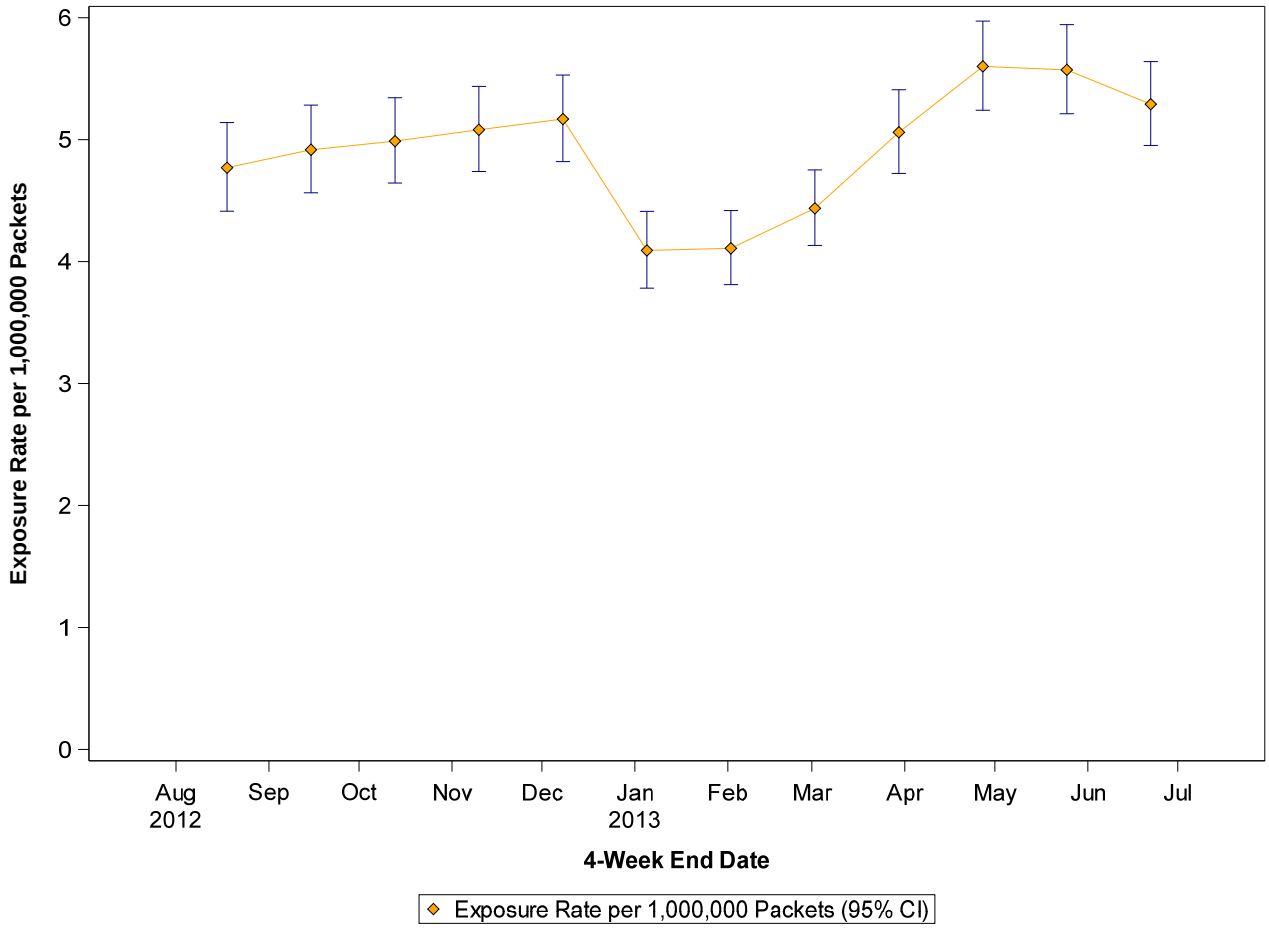


Figure 4. Sales-Adjusted Rates of All Exposures by Four Week Interval (22 July 2012 to 22 June 2013)



Population- and Sales-Adjusted Rates of Exposures with Clinically Significant Outcomes Over Time

Over time, counts of exposures involving HCF treatment fluctuated seasonally in the same pattern as all exposures with decreases in first quarter. During the same time period the total population in children <6 years of age increased steadily each quarter (Table 14; Figure 5).

The population-adjusted rate of reported exposures involving liquid laundry detergent packets in children <6 years of age decreased from a rate of 4.322 per 100,000 US children <6 years of age (CI 4.064, 4.589) in third quarter 2012 to a rate of 4.089 per 100,000 US children <6 years of age (CI 3.837, 4.348) in first quarter 2013 then increased to a peak rate of 4.957 per 100,000 US children <6 years of age (CI 4.680, 5.243) in second quarter 2013. The population-adjusted rate of exposures involving HCF treatment in second quarter 2013 was statistically different than the rate in second quarter 2013 during the baseline period (Table 14, Figure 6).

Table 14. Population-Adjusted Rates of Exposures Involving Healthcare Facility Treatment by Quarter (01 July 2014 to 30 June 2013)

Quarter	Exposure Count	Total Population Count	Rate of Exposures Involving HCF Treatment per 100,000 Children <6 Years of Age (95% CI)
2012Q3 (01 July 2012 to 30 September 2012)	1,042	24,108,094	4.322 (4.064, 4.589)
2012Q4 (01 October 2012 to 31 December 2012)	1,025	24,095,846	4.254 (3.997, 4.518)
2013Q1 (01 January 2013 to 31 March 2013)	984	24,064,871	4.089 (3.837, 4.348)
2013Q2 (01 April 2013 to 30 June 2013)	1,190	24,005,552	4.957 (4.680, 5.243)

Figure 5. Exposures Involving Healthcare Facility Treatment and Population Counts by Quarter (01 July 2014 to 30 June 2013)

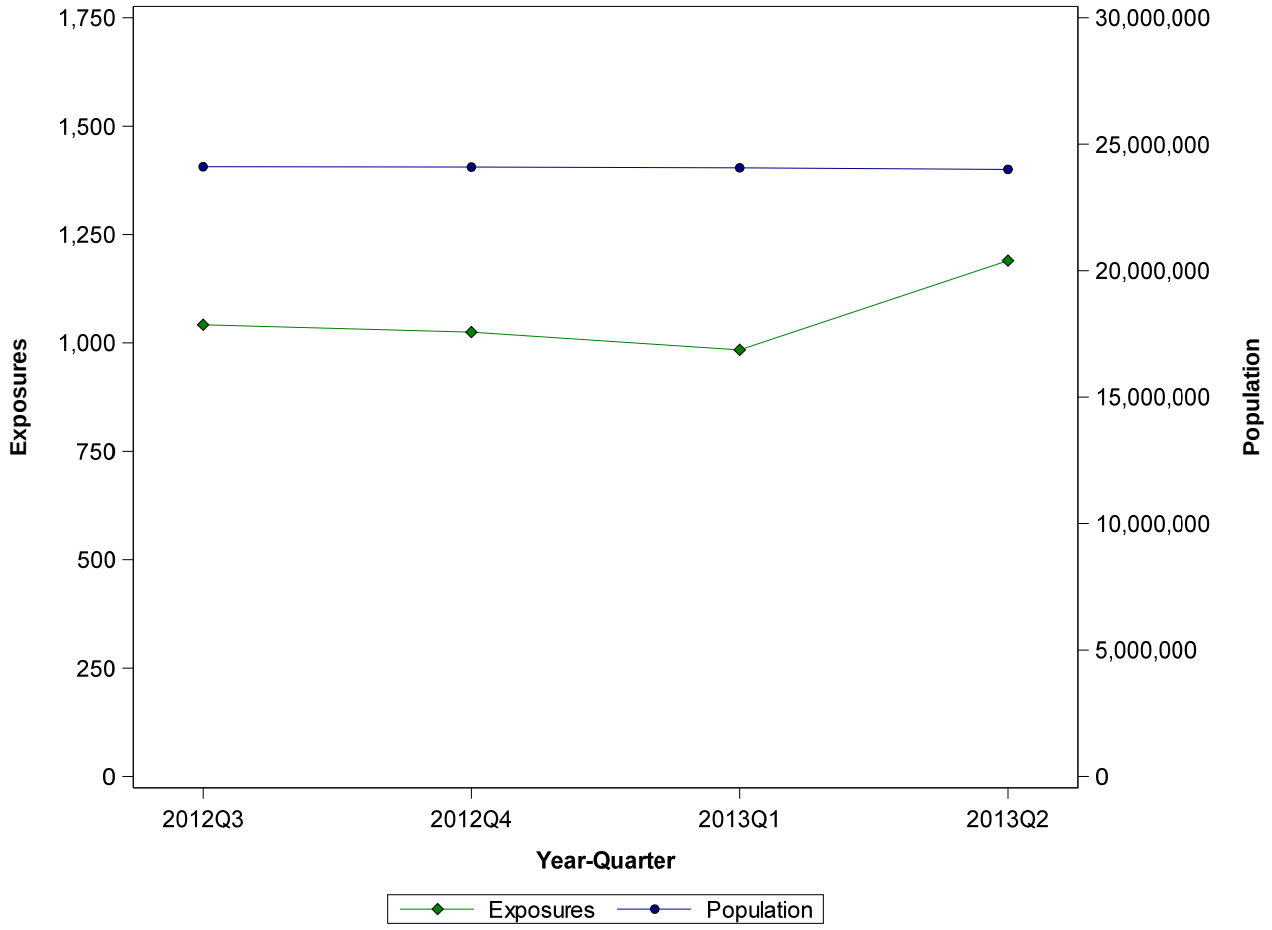
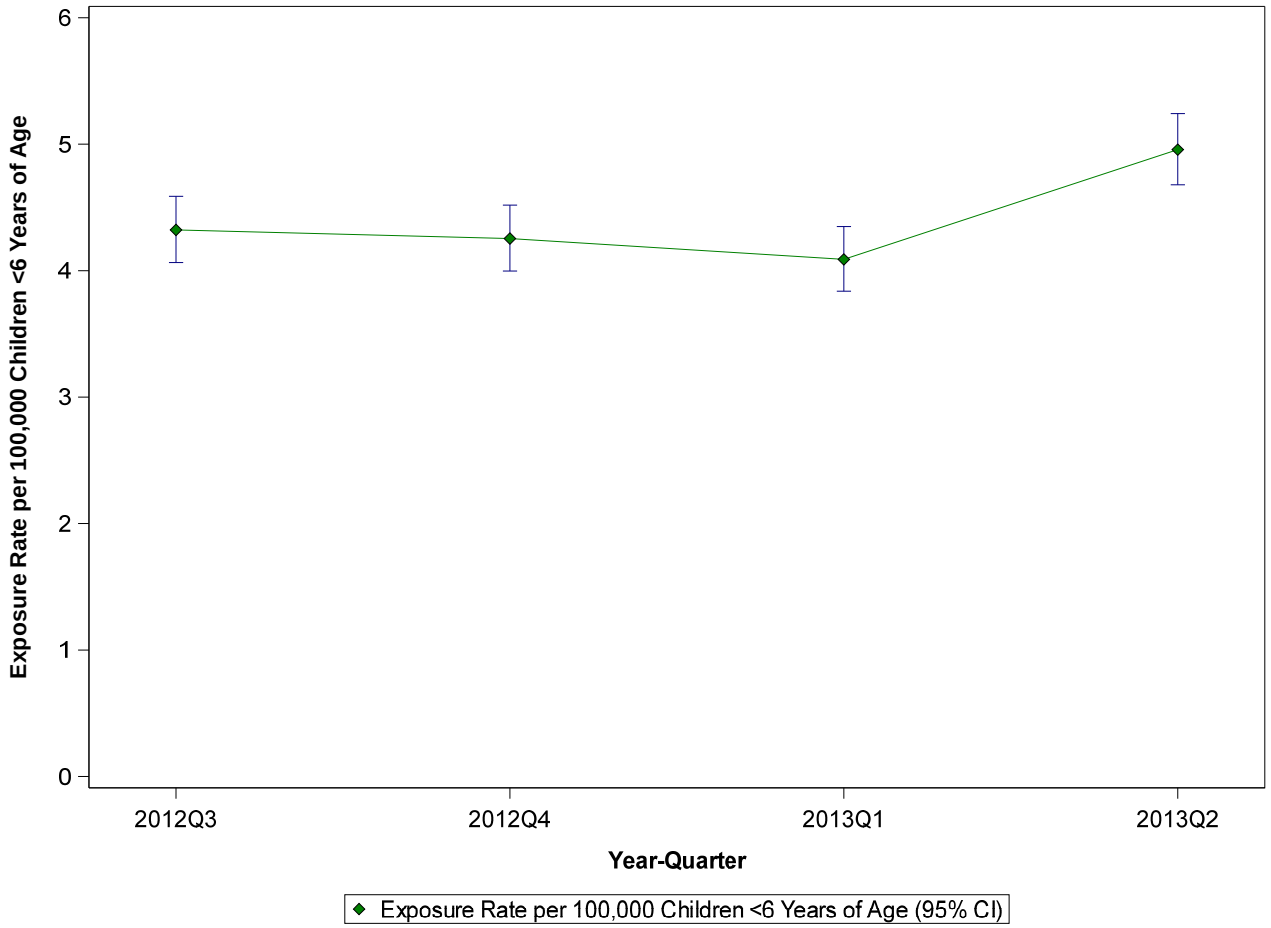


Figure 6. Population-Adjusted Rates of Exposures Involving Healthcare Facility Treatment by Quarter (01 July 2014 to 30 June 2013)



When examined by four week intervals corresponding to sales, counts of exposures involving HCF treatment fluctuated seasonally in the same pattern as all exposures with decreases from October to December and increases thereafter. During the same time period the total sales in children <6 years of age fluctuated slightly with a steady increase over time (Table 15; Figure 7).

The sales-adjusted rate of reported unintentional-general exposures to a liquid laundry detergent packet involving treatment in a HCF decreased gradually from a rate of 2.255 per 1 million units sold (CI 2.012, 2.512) in August 2012 to 1.613 per 1 million units sold (CI 1.429, 1.809) in February 2013 and then gradually increased to a rate of 2.240 per 1 million units sold (CI 2.022, 2.468) in June 2013 (Table 15; Figure 8).

Table 15. Sales-Adjusted Rates of Exposures Involving Healthcare Facility Treatment by Four Week Interval (22 July 2012 to 22 June 2013)

Four Week Interval Date	Exposure Count	Total Packets Sales Count	Rate of Exposures Involving HCF Treatment per 1,000,000 Packets Sold (95% CI)
22 July 2012 to 18 August 2012	312	138,355,958	2.255 (2.012, 2.512)
19 August 2012 to 15 September 2012	311	146,612,045	2.121 (1.892, 2.363)
16 September 2012 to 13 October 2012	323	156,369,907	2.066 (1.846, 2.297)
14 October 2012 to 10 November 2012	339	160,177,007	2.116 (1.897, 2.348)
11 November 2012 to 08 December 2012	336	157,666,057	2.131 (1.909, 2.365)
09 December 2012 to 05 January 2013	253	158,606,062	1.595 (1.405, 1.798)
06 January 2013 to 02 February 2013	276	171,063,002	1.613 (1.429, 1.809)
03 February 2013 to 02 March 2013	308	177,595,380	1.734 (1.546, 1.933)
03 March 2013 to 30 March 2013	350	164,788,263	2.124 (1.907, 2.352)
31 March 2013 to 27 April 2013	344	161,022,945	2.136 (1.917, 2.368)
28 April 2013 to 25 May 2013	361	160,244,796	2.253 (2.026, 2.491)
26 May 2013 to 22 June 2013	386	172,357,060	2.240 (2.022, 2.468)

Figure 7. Exposure Involving Healthcare Facility Treatment and Sales Counts by Four Week Interval (22 July 2012 to 22 June 2013)

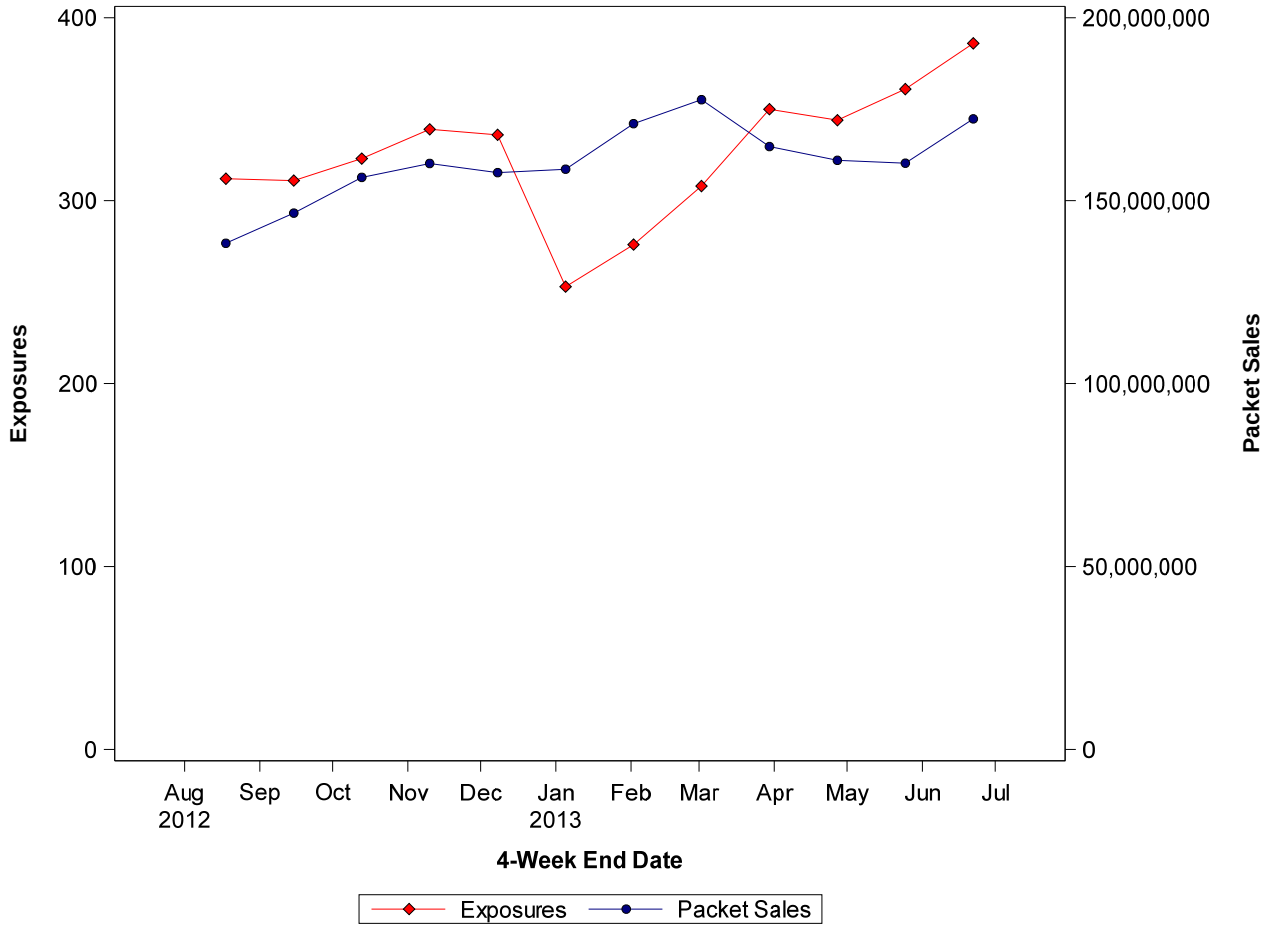
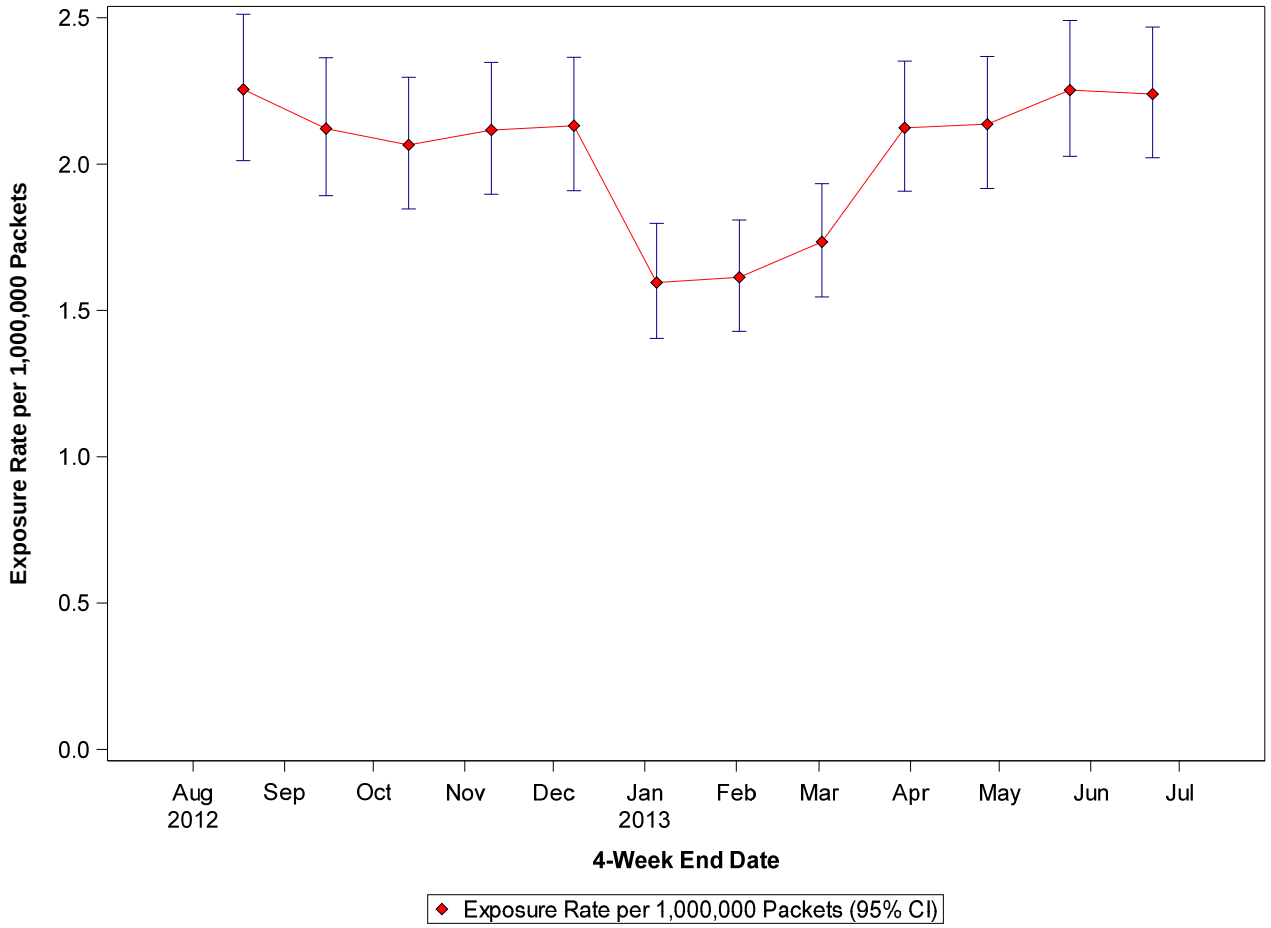


Figure 8. Sales-Adjusted Rates of Exposure Involving Healthcare Facility Treatment by Four Week Interval (22 July 2012 to 22 June 2013)



Over time, counts of exposures involving HCF admission fluctuated seasonally in the same pattern as all exposures with decreases in first quarter. During the same time period the total population in children <6 years of age increased steadily each quarter (Table 16; Figure 9).

The population-adjusted rate of reported exposures involving liquid laundry detergent packets in children <6 years of age decreased from a rate of 0.489 per 100,000 US children <6 years of age (CI 0.405, 0.582) in third quarter 2012 to a rate of 0.395 per 100,000 US children <6 years of age (CI 0.319, 0.478) in first quarter 2013 then increased to a peak rate of 0.529 per 100,000 US children <6 years of age (CI 0.441, 0.625) in second quarter 2013 (Table 16, Figure 10).

Table 16. Population-Adjusted Rates of Exposures Involving Healthcare Facility Admission by Quarter (01 July 2012 to 30 July 2013)

Quarter	Exposure Count	Total Population Count	Rate of Exposures Involving HCF Admission per 100,000 Children <6 Years of Age (95% CI)
2012Q3 (01 July 2012 to 30 September 2012)	118	24,108,094	0.489 (0.405, 0.582)
2012Q4 (01 October 2012 to 31 December 2012)	118	24,095,846	0.490 (0.405, 0.582)
2013Q1 (01 January 2013 to 31 March 2013)	95	24,064,871	0.395 (0.319, 0.478)
2013Q2 (01 April 2013 to 30 June 2013)	127	24,005,552	0.529 (0.441, 0.625)

Figure 9. Exposures Involving Healthcare Facility Admission and Population Counts by Quarter (01 July 2012 to 30 July 2013)

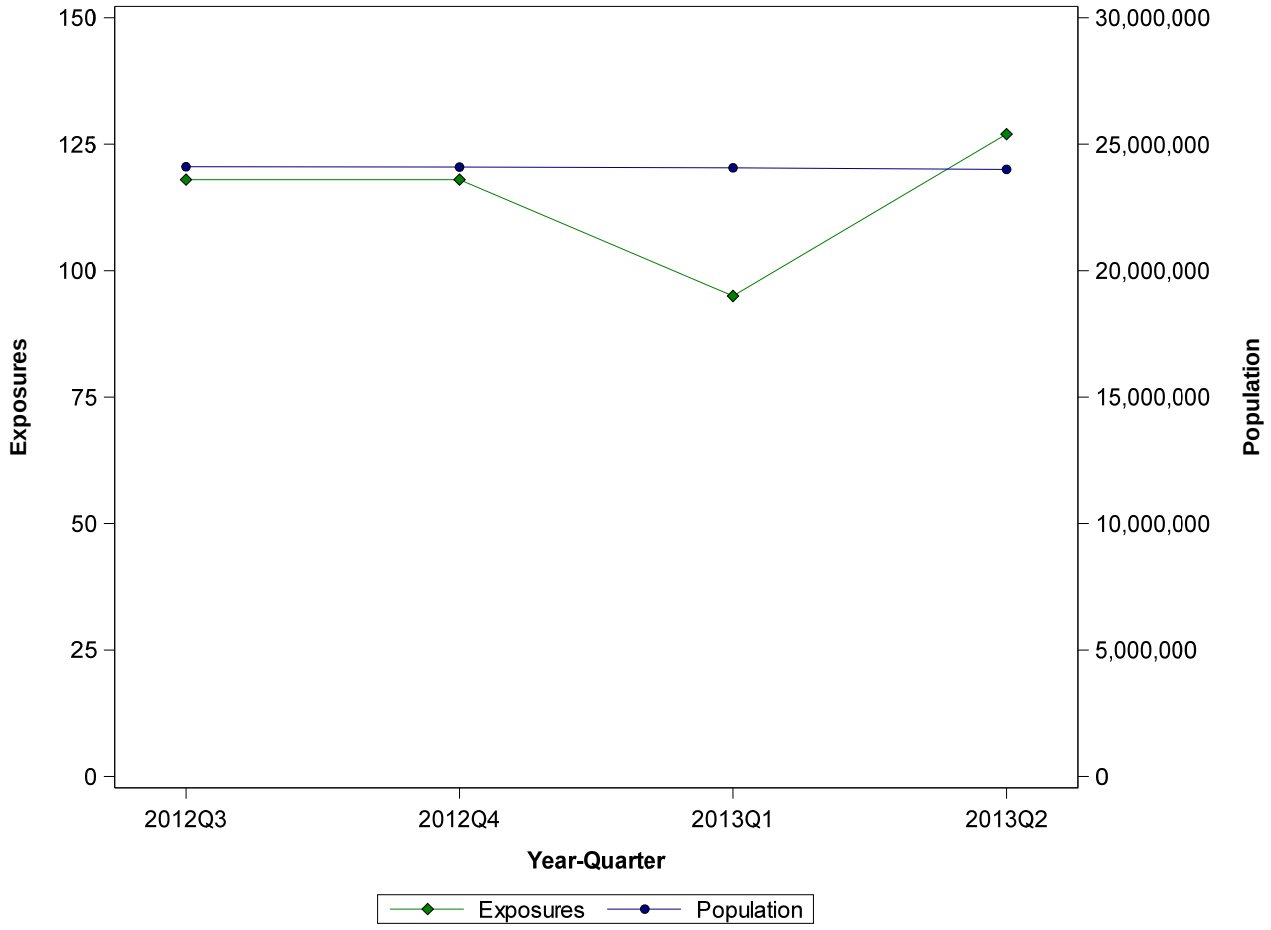
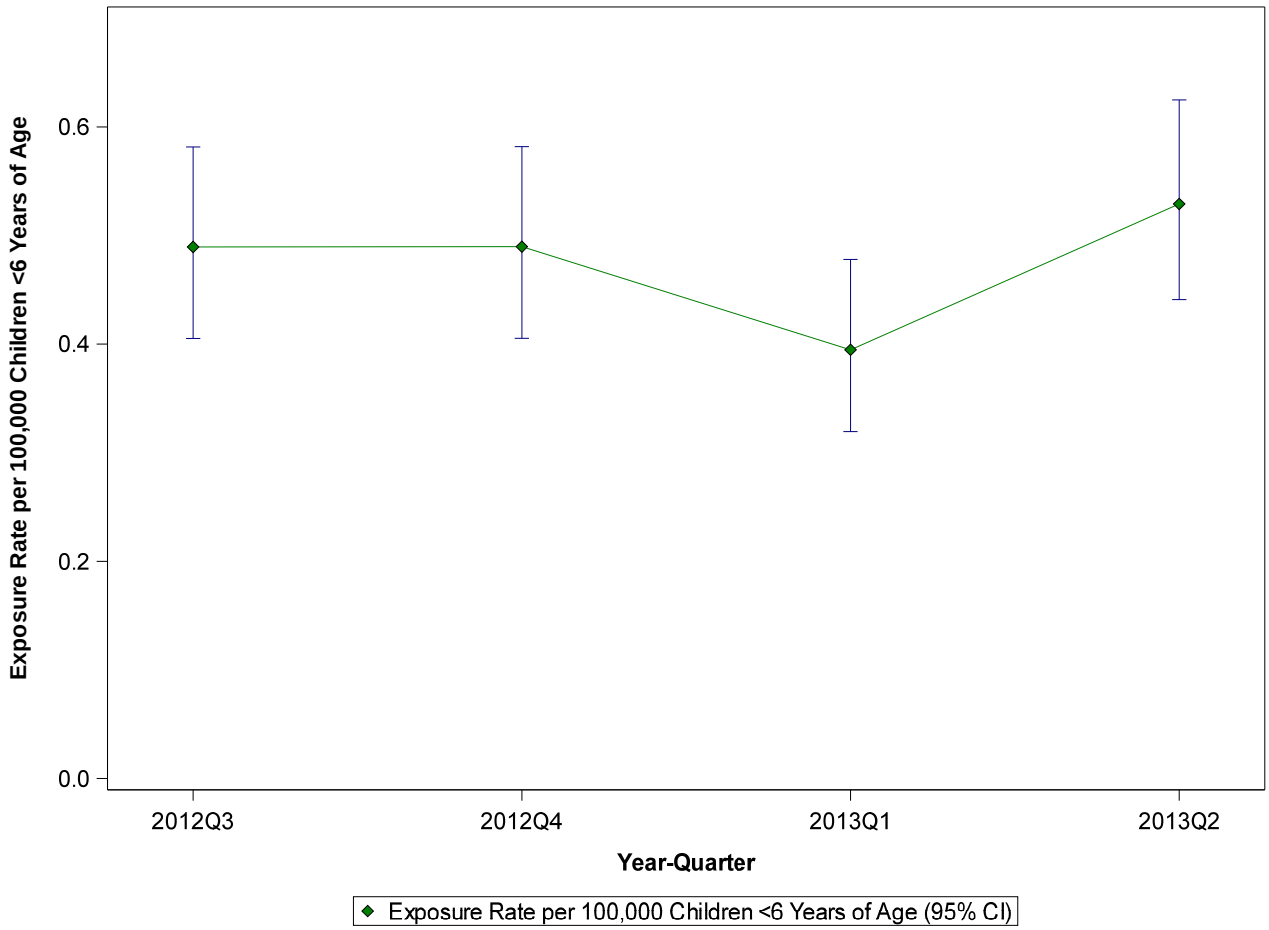


Figure 10. Population-Adjusted Rates of Exposures Involving Healthcare Facility Admission by Quarter (01 July 2012 to 30 July 2013)



When examined by four week intervals corresponding to sales, counts of exposures involving HCF admission fluctuated seasonally in a similar pattern as all exposures with decreases from October to January. During the same time period the total sales in children <6 years of age fluctuated slightly with a steady increase over time (Table 17; Figure 11).

The sales-adjusted rate of reported unintentional-general exposures to a liquid laundry detergent packet involving an admission to a HCF decreased from a rate of 0.239 per 1 million units sold (CI 0.164, 0.327) in August 2012 to 0.117 per 1 million units sold (CI 0.071, 0.173) in February 2013 and then increased to a rate of 0.215 per 1 million units sold (CI 0.151, 0.289) in June 2013 (Table 17; Figure 12).

Table 17. Sales-Adjusted Rates of Exposures Involving Healthcare Facility Admission by Four Week Interval (22 July 2012 to 22 June 2013)

Four Week Interval Date	Exposure Count	Total Packets Sales Count	Rate of Exposures Involving HCF Admission per 1,000,000 Packets Sold (95% CI)
22 July 2012 to 18 August 2012	33	138,355,958	0.239 (0.164, 0.327)
19 August 2012 to 15 September 2012	43	146,612,045	0.293 (0.212, 0.387)
16 September 2012 to 13 October 2012	35	156,369,907	0.224 (0.156, 0.304)
14 October 2012 to 10 November 2012	42	160,177,007	0.262 (0.189, 0.347)
11 November 2012 to 08 December 2012	32	157,666,057	0.203 (0.139, 0.279)
09 December 2012 to 05 January 2013	28	158,606,062	0.177 (0.117, 0.248)
06 January 2013 to 02 February 2013	20	171,063,002	0.117 (0.071, 0.173)
03 February 2013 to 02 March 2013	39	177,595,380	0.220 (0.156, 0.294)
03 March 2013 to 30 March 2013	33	164,788,263	0.200 (0.138, 0.274)
31 March 2013 to 27 April 2013	39	161,022,945	0.242 (0.172, 0.324)
28 April 2013 to 25 May 2013	39	160,244,796	0.243 (0.173, 0.325)
26 May 2013 to 22 June 2013	37	172,357,060	0.215 (0.151, 0.289)

Figure 11. Exposures Involving Healthcare Facility Admission and Sales Counts by Four Week Interval (22 July 2012 to 22 June 2013)

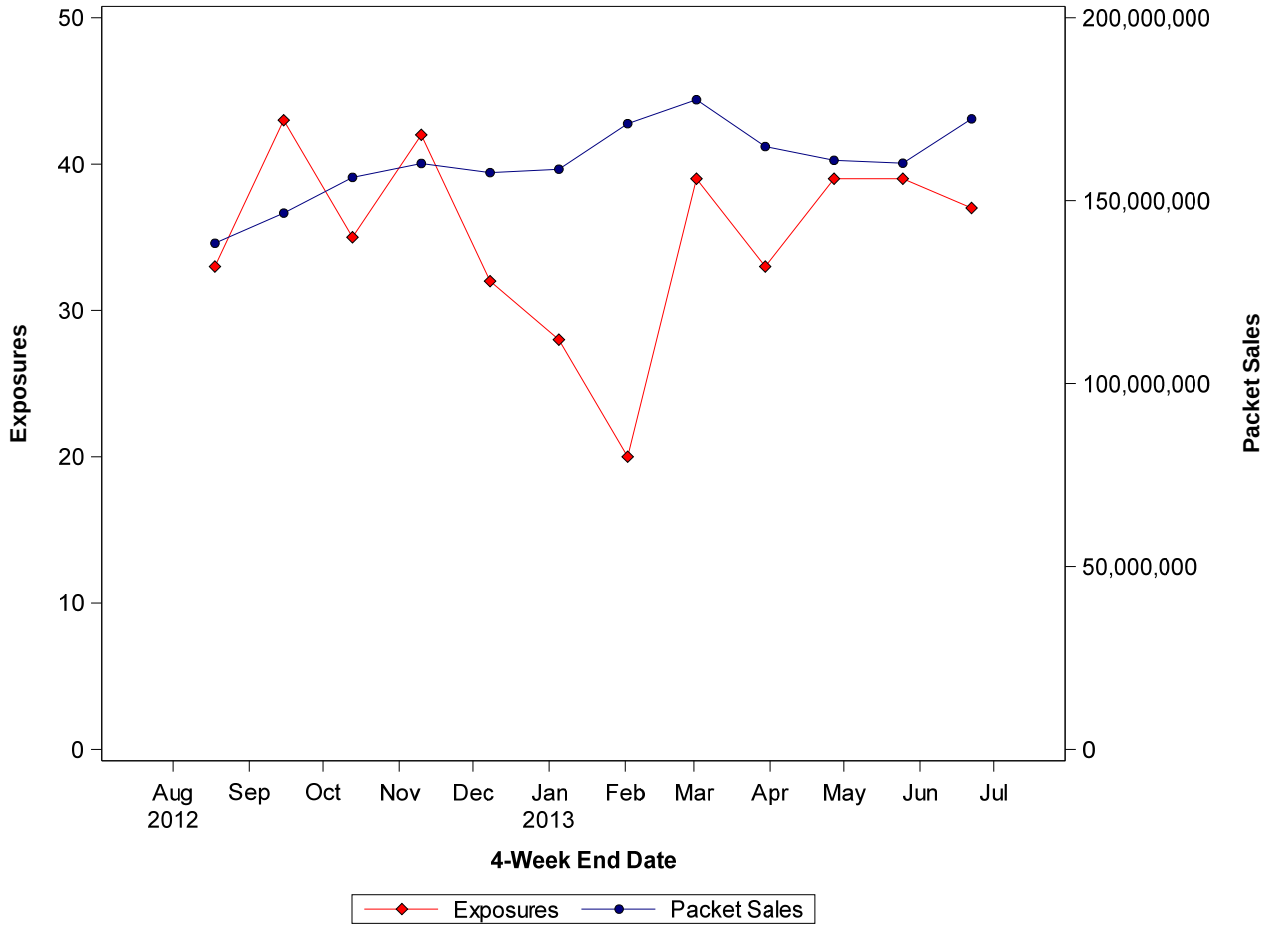
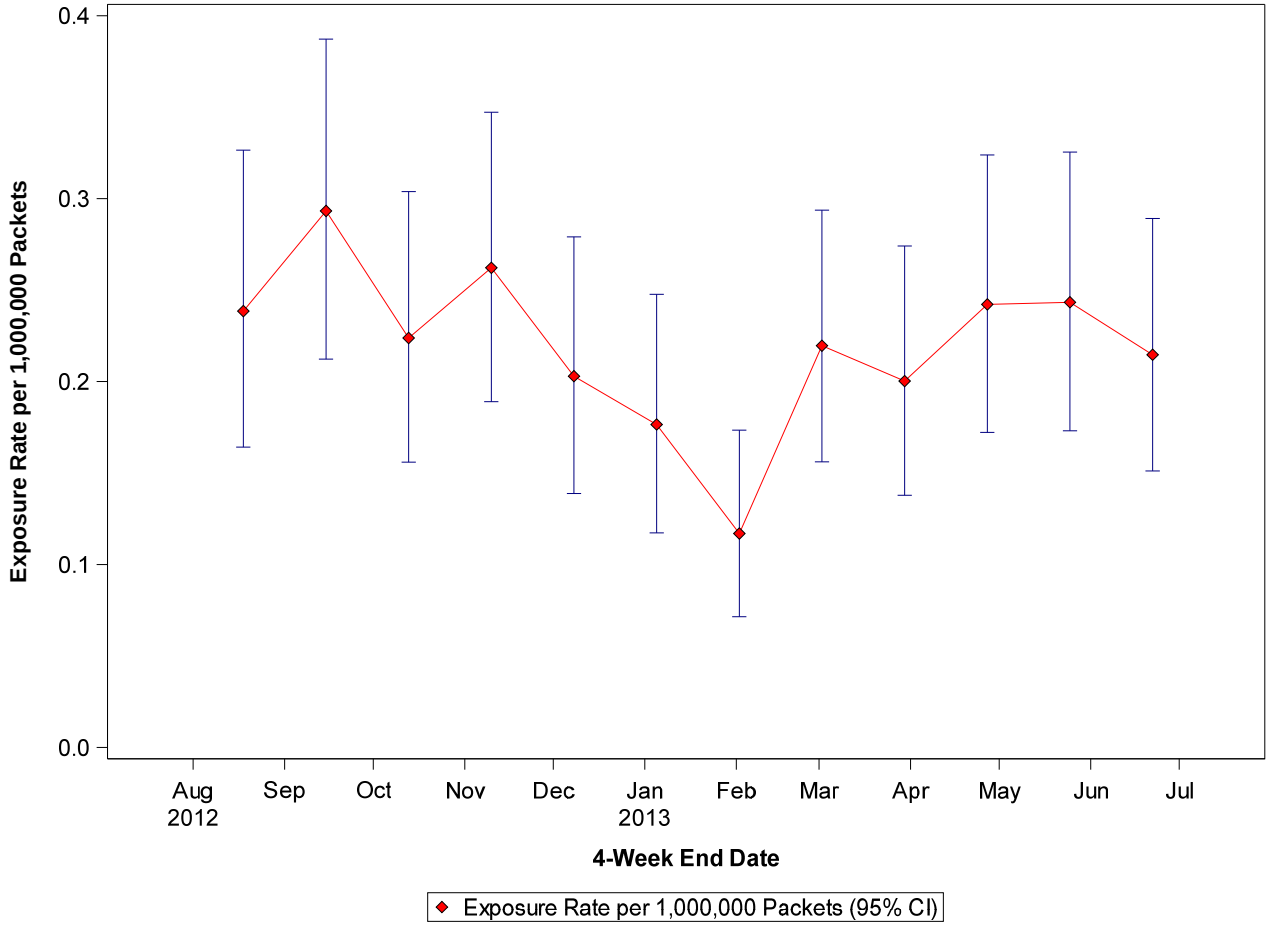


Figure 12. Sales-Adjusted Rates of Exposures Involving Healthcare Facility Admission by Four Week Interval (22 July 2012 to 22 June 2013)



Over time, counts of exposures involving severe medical outcomes fluctuated seasonally in the same pattern as all exposures with decreases in first quarter. During the same time period the total population in children <6 years of age increased steadily each quarter (Table 18; Figure 13).

The population-adjusted rate of reported exposures involving liquid laundry detergent packets in children <6 years of age decreased from a rate of 0.108 per 100,000 US children <6 years of age (CI 0.070, 0.153) in third quarter 2012 to a rate of 0.033 per 100,000 US children <6 years of age (CI 0.014, 0.060) in first quarter 2013 then increased to a rate of 0.062 per 100,000 US children <6 years of age (CI 0.035, 0.098) in second quarter 2013 (Table 18, Figure 14).

Table 18. Population-Adjusted Rates of Exposures Resulting in Severe Medical Outcomes by Quarter (01 July 2012 to 30 June 2013)

Quarter	Exposure Count	Total Population Count	Rate of Exposures Resulting in Severe Medical Outcomes per 100,000 Children <6 Years of Age (95% CI)
2012Q3 (01 July 2012 to 30 September 2012)	26	24,108,094	0.108 (0.070, 0.153)
2012Q4 (01 October 2012 to 31 December 2012)	15	24,095,846	0.062 (0.035, 0.097)
2013Q1 (01 January 2013 to 31 March 2013)	8	24,064,871	0.033 (0.014, 0.060)
2013Q2 (01 April 2013 to 30 June 2013)	15	24,005,552	0.062 (0.035, 0.098)

Figure 13. Exposures Resulting in Severe Medical Outcomes and Population Counts by Quarter (01 July 2012 to 30 June 2013)

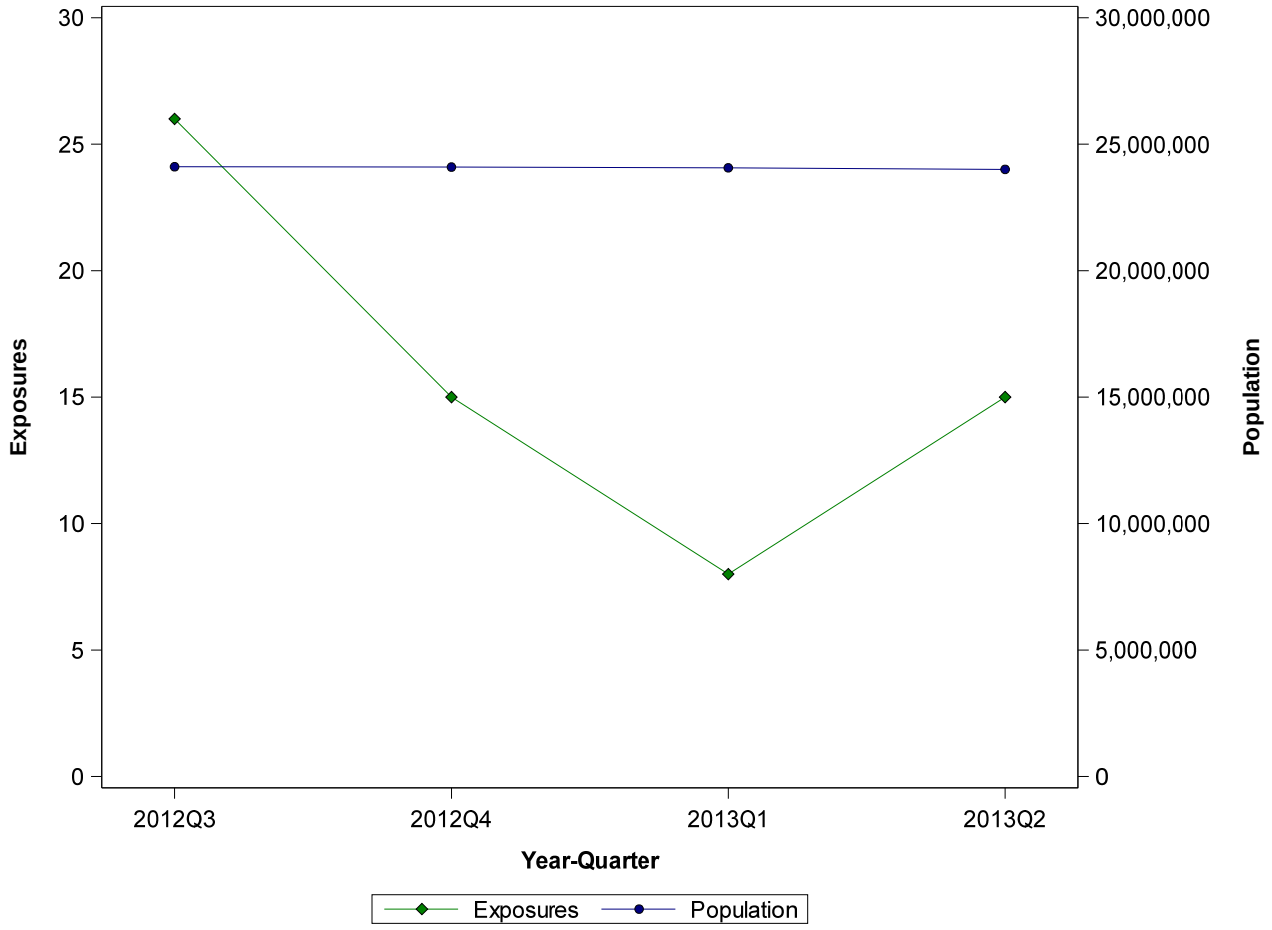
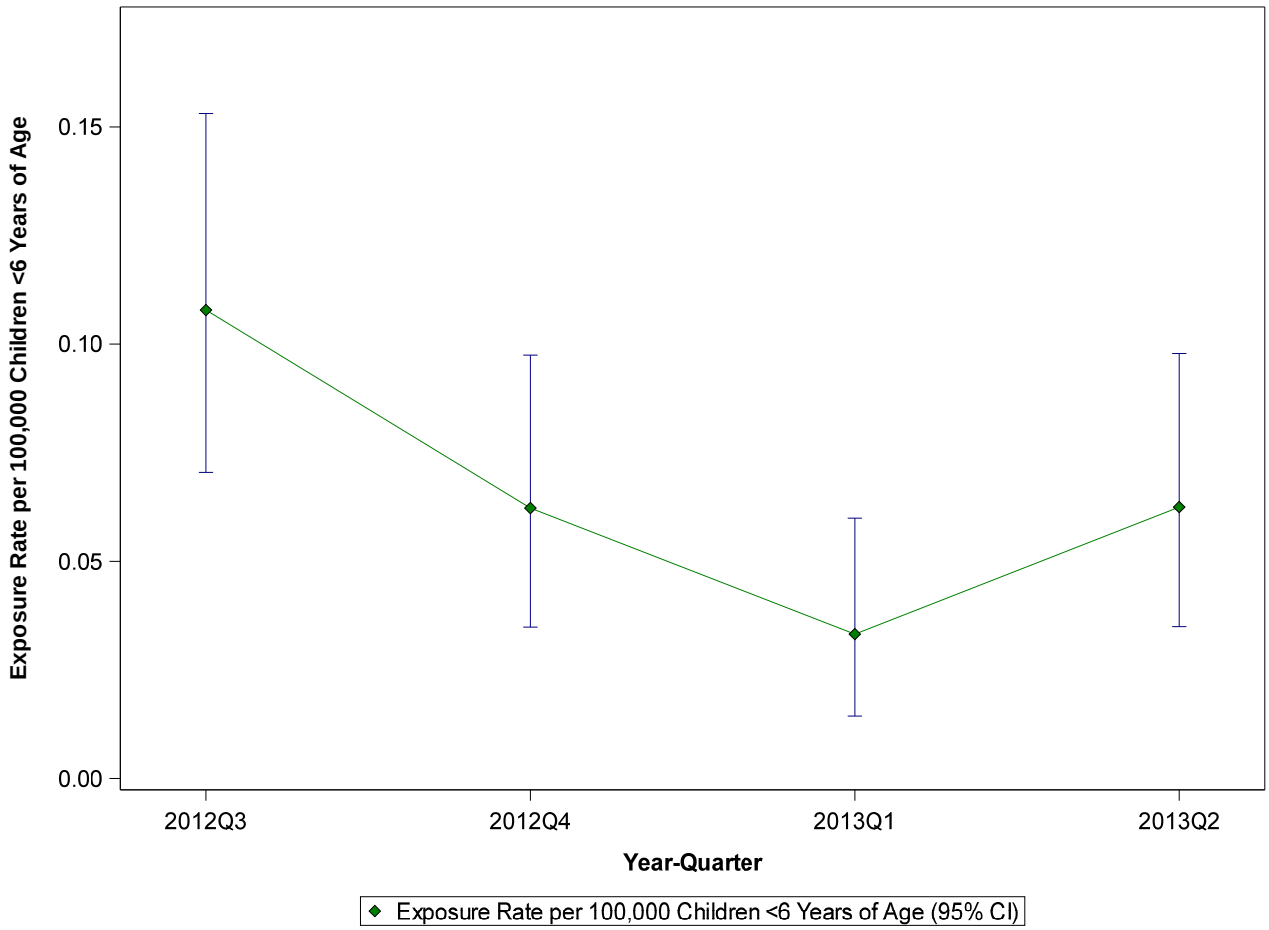


Figure 14. Population-Adjusted Rates of Exposures Resulting in Severe Medical Outcomes by Quarter (01 July 2012 to 30 June 2013)



When examined by 4-week intervals corresponding to sales, counts of exposures involving severe medical outcomes fluctuated seasonally in a similar pattern as all exposures with decreases from September to January and increases thereafter. During the same time period the total sales in children <6 years of age fluctuated slightly with a steady increase over time (Table 19; Figure 15).

The sales-adjusted rate of reported unintentional-general exposures to a liquid laundry detergent packet involving a severe medical outcome fluctuated from a rate of 0.051 per 1 million units sold (CI 0.020, 0.094) in August 2012 to a low of 0.012 per 1 million units sold (CI 0.001, 0.033) in February 2013, March 2013, and May 2013 and then increased to 0.029 per 1 million units (CI 0.009, 0.059) in June 2013 (Table 19; Figure 16).

Table 19. Sales-Adjusted Rates of Exposures Resulting in Severe Medical Outcomes by Four Week Interval (22 July 2012 to 22 June 2013)

Four Week Interval Date	Exposure Count	Total Packets Sales Count	Rate of Exposures Resulting in Severe Medical Outcomes per 1,000,000 Packets Sold (95% CI)
22 July 2012 to 18 August 2012	7	138,355,958	0.051 (0.020, 0.094)
19 August 2012 to 15 September 2012	6	146,612,045	0.041 (0.015, 0.080)
16 September 2012 to 13 October 2012	11	156,369,907	0.070 (0.035, 0.118)
14 October 2012 to 10 November 2012	4	160,177,007	0.025 (0.007, 0.055)
11 November 2012 to 08 December 2012	3	157,666,057	0.019 (0.004, 0.046)
09 December 2012 to 05 January 2013	3	158,606,062	0.019 (0.004, 0.046)
06 January 2013 to 02 February 2013	2	171,063,002	0.012 (0.001, 0.033)
03 February 2013 to 02 March 2013	4	177,595,380	0.023 (0.006, 0.049)
03 March 2013 to 30 March 2013	2	164,788,263	0.012 (0.001, 0.034)
31 March 2013 to 27 April 2013	8	161,022,945	0.050 (0.021, 0.090)
28 April 2013 to 25 May 2013	2	160,244,796	0.012 (0.002, 0.035)
26 May 2013 to 22 June 2013	5	172,357,060	0.029 (0.009, 0.059)

Figure 15. Exposures Resulting in Severe Medical Outcomes and Sales Counts by Four Week Interval (22 July 2012 to 22 June 2013)

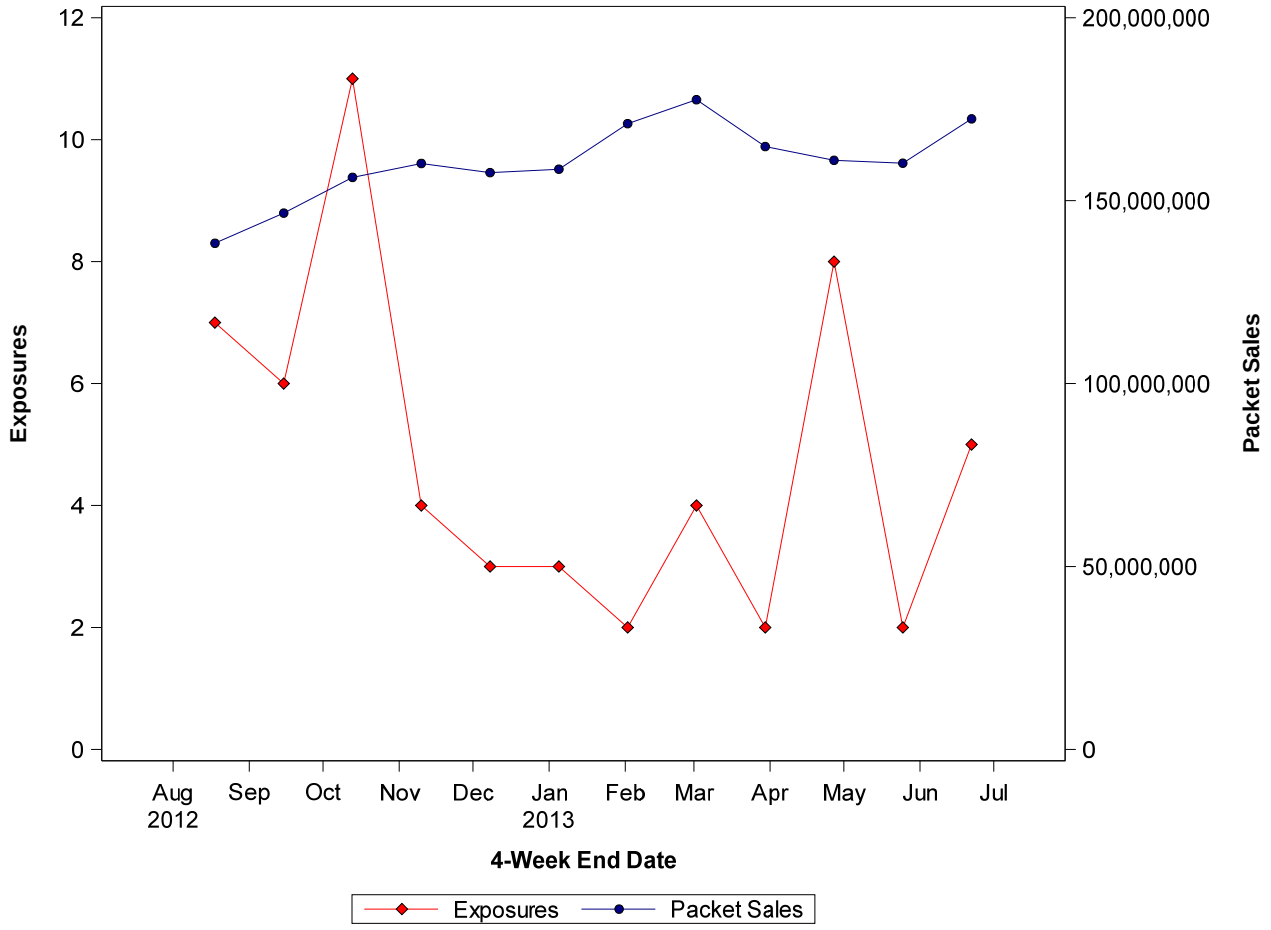
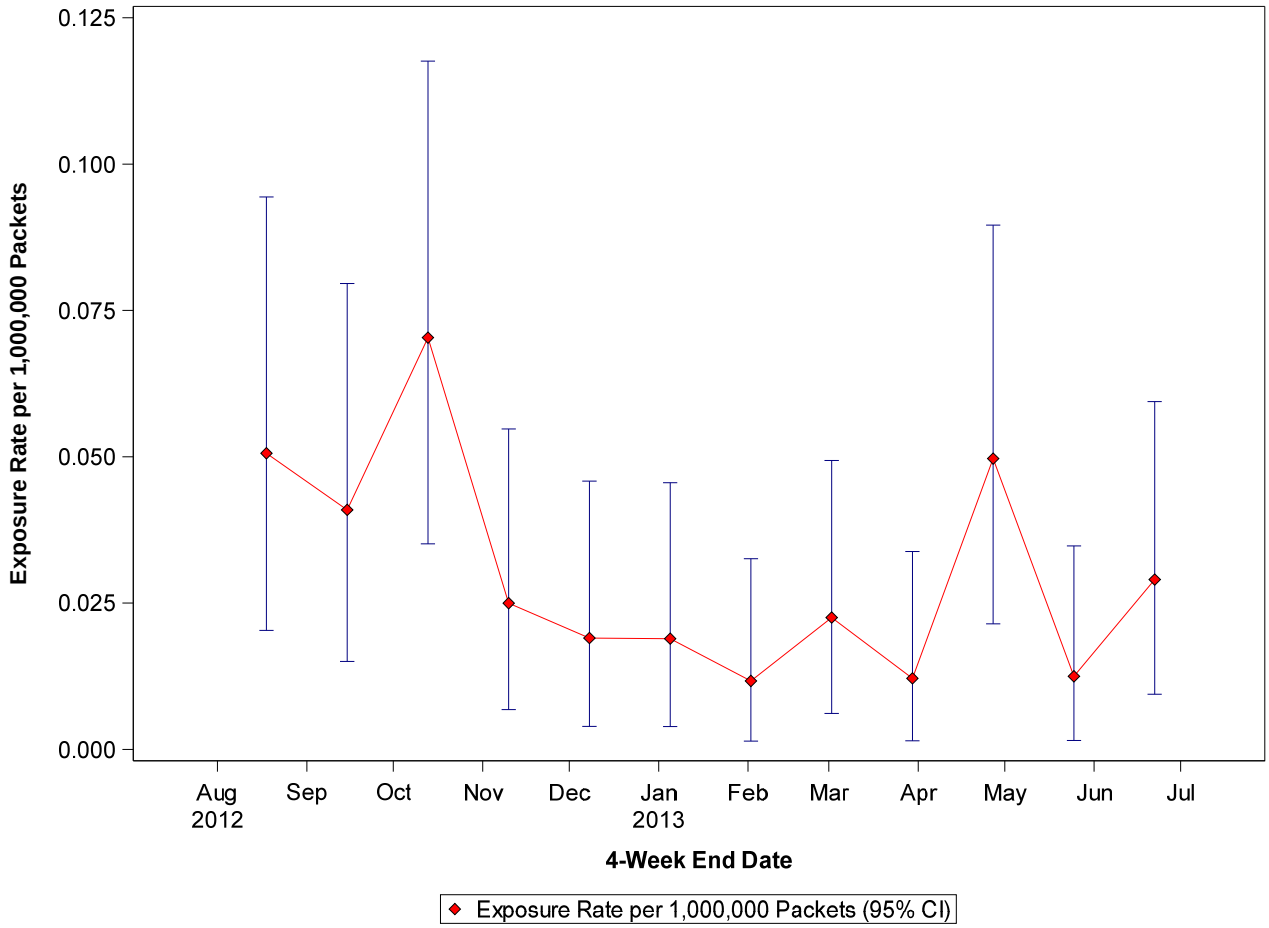


Figure 16. Sales-Adjusted Rates of Exposures Resulting in Severe Medical Outcomes by Four Week Interval (22 July 2012 to 22 June 2013)



SUMMARY

This baseline surveillance report describes the 10,229 unintentional-general exposures to liquid laundry detergent packets in children <6 years of age reported to the National Poison Data System (NPDS) between 01 July 2012 and 30 June 2013. Most of these exposures involved children <4 years of age. Approximately half of all liquid laundry detergent packet exposures involved healthcare facility (HCF) treatment, with over three-quarters of exposures that received HCF treatment being released without admission. In total, less than 10% of exposures resulted in HCF admission. Most exposures were followed to a known outcome, with minor effects being reported in approximately half of all exposures. Severe medical outcomes (major effect n=63, death n=1) were reported in 0.6% (n=64) of all exposures.

Exposures involving children <2 years of age were associated with higher percentages of HCF admission and severe medical outcomes. While the most common route of exposure to a liquid laundry detergent packet was ingestion, aspiration was associated with more severe medical outcomes. Regardless of severity of the outcome, product storage was most commonly cited as a contributing factor to the exposure. The single fatality reported during the baseline period was determined to be clearly not responsible for the death, so limited contributory details could be extracted from this exposure.

Rates were evaluated cumulatively and over time using the US population <6 years of age and sales data for all exposures, exposures involving HCF treatment, exposures involving HCF admission, and severe medical outcomes. These rates are summarized in Table 20. Rates of exposures calculated by adjusting for the US population indicate that approximately 42 children per 100,000 US children <6 years of age were exposed to a liquid laundry detergent packet during the baseline period. When the rate of exposure was adjusted for product sales, approximately 5 exposures occurred for every 1,000,000 packets sold. Rates of exposures resulting in severe medical outcomes (major effect or death) adjusted for the population and for product sales were approximately 27 exposures per 10 million US children <6 years of age and 3 exposures per every 100,000,000 million packets sold. Over time, exposure counts fluctuated seasonally with peaks in July or second quarter and low points in January or first quarter of each year. As sales increased steadily over the period, rates corresponded to trends in exposures with peak rates occurring in July or second quarter and the lowest rates occurring in January or first quarter of each year.

Table 20. Summary of Population-Adjusted and Sales-Adjusted

Type of Exposure Rate	Cumulative Population-Adjusted Rate[a]	Population-Adjusted Rate[a] Range	Cumulative Sales-Adjusted Rate[b]	Sales-Adjusted Rate[b] Range
All Exposures	**42.499** (CI 41.684, 43.331)	**9.619** (CI 9.232, 10.015) to **12.210** (CI 11.772, 12.656)	**4.920** (CI 4.822, 5.020)	**4.770** (CI 4.413, 5.141) to **5.291** (CI 4.953, 5.640)
Healthcare Facility Treatment	**17.620** (CI 17.098, 18.159)	**4.322** (CI 4.064, 4.589) to **4.957** (CI 4.680, 5.243)	**2.026** (CI 1.963, 2.090)	**2.255** (CI 2.012, 2.512) to **2.240** (CI 2.022, 2.468)
Healthcare Facility Admission	**1.903** (CI 1.736, 2.085)	**0.489** (CI 0.405, 0.582) to **0.529** (CI 0.441, 0.625)	**0.218** (CI 0.198, 0.240)	**0.239** (CI 0.164, 0.327) to **0.215** (CI 0.151, 0.289)
Severe Medical Outcome	**0.266** (CI 0.208, 0.340)	**0.108** (CI 0.070, 0.153) to **0.062** (CI 0.035, 0.098)	**0.030** (CI 0.023, 0.038)	**0.051** (CI 0.020, 0.094) to **0.029** (CI 0.009, 0.059)

[a]Rate per 100,000 US children <6 years of age and 95% Confidence Interval (CI).
[b]Rate per 1,000,000 packets and 95% Confidence Interval (CI).

Interpretation of NPDS data are limited in that exposures are reported by caregivers who self-select to contact a poison center. Furthermore, as the primary purpose of poison centers is to manage exposures, exposures may be both underreported and have some variation in quality and completeness. However, though sales data are not a perfect measure of product availability, analysis of sales-adjusted rates of exposure can normalize reporting rates in the context of product availability. Population-adjusted rates provide additional context for changes in trends over time.

These analyses show that rates of exposure increased over the baseline period, but more severe medical outcomes remained infrequent. Certain characteristics appeared to contribute to the exposure and were associated with severe medical outcomes, including exposures in children <2 years of age and aspiration of the product. As with many accidental exposures, improper product storage was identified as the primary contributor to exposure. Comparison of these characteristics along with rates of exposure and trends in outcome during the baseline and post-ASTM standard implementation periods should be encouraged to evaluate the impact of the safety standards.

DISCLAIMERS

American Association of Poison Control Centers
The American Association of Poison Control Centers (AAPCC; http://www.aapcc.org) maintains the national database of information logged by the country's regional poison centers (PCs) serving all 50 United States, Puerto Rico, and the District of Columbia. Case records in this database are from self-reported calls: they reflect only information provided when the public or health care professionals report an actual or potential exposure to a substance (e.g., an ingestion, inhalation, or topical exposure), or request information/educational materials. Exposures do not necessarily represent a poisoning or overdose. The AAPCC is not able to completely verify the accuracy of every report made to member centers. Additional exposures may go unreported to PCs and data referenced from the AAPCC should not be construed to represent the complete incidence of national exposures to any substance(s).

Nielsen
The analyses performed in this report are based in part on data reported by Nielsen through its Strategic Planner Service for the Liquid Laundry Packs category for four week intervals from 22 July 2012 through 22 June 2013, for the Total US market for Nielsen's Expanded All Outlets Combined channel which includes Food, Drug, Mass Merchandise, Club, Dollar, and Military/Deca. Conclusions drawn from the use of Nielsen data do not reflect the views of Nielsen.

REFERENCES

1. ASTM International. Standard Safety Specification for Liquid Laundry Packets. West Conshohocken, PA: ASTM International; 2015:1-16. doi:10.1520/F3159-15E01.
2. Mowry JB, Spyker DA, Brooks DE, Zimmerman A, Schauben JL. 2015 Annual report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 33rd Annual report. *Clin. Toxicol.* 2016; 54(10): 924-1109. DOI: 10.1080/15563650.2016.1245421.
3. 2010 Census Data. U.S. Census Bureau website. https://www.census.gov/2010census/data/. Accessed September 25, 2017.

APPENDICES

Appendix A: National Poison Data System (NPDS) Definitions

EXPOSURE
Actual or suspected contact with any substance which has been ingested, inhaled, absorbed, applied to, or injected into the body, regardless of toxicity or clinical manifestation.

REASON FOR EXPOSURE
Unintentional Exposure
An unintentional exposure results from an unforeseen or unplanned event. Includes all subtypes: unintentional general, environmental, occupational, therapeutic error, misuse, bite/sting, food poisoning and unintentional unknown.

1) **Unintentional-General**: All unintended exposures that are not specifically defined below. Most unintentional exposures in children should be coded here. Never use this code if there is another code that fits the case.

CHRONICITY
Chronicity of the exposure.

Acute: A single, repeated or continuous exposure occurring over a period of eight hours or less.

Acute-on-Chronic: A single exposure that was preceded by a continuous, repeated, or intermittent exposure occurring over a period exceeding eight hours.

Chronic: A continuous, repeated, or intermittent exposure to the same substance lasting longer than eight hours.

Unknown: It is not possible to determine whether the exposure is acute, acute-on-chronic, or chronic.

MEDICAL OUTCOME
Case followed to known outcome:
A response is appropriate in this area only if follow-up continues until medical outcome can be documented with reasonable certainty.

Unrelated effect: Based upon all the information available, the exposure was probably not responsible for the effect(s).

No effect: The patient developed no symptoms as a result of the exposure. Follow-up is required to make this determination unless the initial poison center call occurs sufficiently long after the exposure that you are reasonably certain no effects will occur.

Minor effect: The patient exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient. The symptoms usually resolve rapidly and usually involve skin or mucous membrane manifestations. The patient has returned to a pre-exposure state of wellbeing and has no residual disability or disfigurement.

Moderate effect: The patient exhibited symptoms as a result of the exposure which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually some form of treatment is or would have been indicated. Symptoms were not

life-threatening and the patient has returned to a pre-exposure state of well-being with no residual disability or disfigurement.

Major effect: The patient has exhibited symptoms as a result of the exposure which were life-threatening or resulted in significant residual disability or disfigurement.

Death: The patient died as a result of the exposure or as a direct complication of the exposure where the complication was unlikely to have occurred had the toxic exposure not preceded the complication. Only includes deaths which are probably or undoubtedly related to the exposure.

Case <u>not</u> followed to a known outcome:
In some circumstances it is not appropriate or possible to follow a patient to a reasonably certain medical outcome.

Not followed, judged as nontoxic exposure. The patient was not followed because in the clinical judgment of the specialist in poison information, the exposure was likely to be nontoxic because:

- the agent involved was nontoxic
- the amount implicated in the exposure was insignificant (nontoxic), and/or
- the route of exposure was unlikely to result in a clinical effect

Not followed, minimal clinical effects possible. The patient was not followed because, in the clinical judgment of the specialist in poison information, the exposure was likely to result in only minimal toxicity of a trivial nature. This outcome is selected only when reasonably certain, in a worst case scenario, that the patient will experience no more than a minor effect. This also includes cases that refused follow-up if the exposure would possibly result in minimal clinical effects and would cause no more than a minor effect.

Unable to follow, judged as a potentially toxic exposure. The patient was lost to follow-up (or the poison center neglected to provide follow-up) and in the judgment of the specialist in poison information the exposure was significant and may have resulted in toxic manifestations with a moderate, major or fatal outcome.

Death, indirect report: A reported fatality is coded as “indirect” if no inquiry was placed to the poison center. For example, if the case was obtained from a medical examiner who sends post mortem reports to the poison center or from a newspaper article. An inquiry to the poison center after the patient died is not necessarily indirect. For example, a medical examiner calling with a question about the cause of death or a family member calling with a question about a toxicology laboratory result is not an indirect report.

CLINICAL EFFECT
Reported signs, symptoms and clinical findings associated with an exposure, recorded by relationship to the exposure.

THERAPIES
Therapies that were recommended and/or performed in relation to the exposure reported.

SCENARIO
A description of the events that led to the reported exposure.

Appendix B: National Poison Data System (NPDS) Relative Contributions to Fatality (RCF)

Undoubtedly responsible
In the opinion of the Case Review Team (CRT) the Clinical Case Evidence establishes beyond reasonable doubt that the SUBSTANCES actually caused the death.

Probably responsible
In the opinion of the CRT the Clinical Case Evidence suggests that the SUBSTANCES caused the death, but some reasonable doubt remained.

Contributory
In the opinion of the CRT the Clinical Case Evidence establishes that the SUBSTANCES contributed to the death, but did not solely cause the death. That is, the SUBSTANCES alone would not have caused the death, but combined with other factors, were partially responsible for the death.

Probably not responsible
In the opinion of the CRT the Clinical Case Evidence establishes to a reasonable probability, but not conclusively, that the SUBSTANCES associated with the death did not cause the death.

Clearly not responsible
In the opinion of the CRT the Clinical Case Evidence established beyond a reasonable doubt that the SUBSTANCES did not cause this death.

Unknown
In the opinion of the CRT the Clinical Case Evidence is insufficient to impute or refute a causative relationship for the SUBSTANCES in this death.

APPENDIX C: All Related Clinical Effects Among All Unintentional-General Exposures to Liquid Laundry Detergent Packets by Level of Treatment and Severe Medical Outcome

Related Clinical Effects	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Vomiting	4,917 (48.1%)	2,613 (61.6%)	351 (76.6%)	45 (70.3%)
Cough/choke	1,328 (13.0%)	744 (17.5%)	154 (33.6%)	16 (25.0%)
Ocular - Irritation/pain	1,105 (10.8%)	634 (14.9%)	18 (3.9%)	6 (9.4%)
Red eye/conjunctivitis	679 (6.6%)	401 (9.5%)	11 (2.4%)	3 (4.7%)
Drowsiness/lethargy	517 (5.1%)	414 (9.8%)	118 (25.8%)	28 (43.8%)
Nausea	467 (4.6%)	245 (5.8%)	40 (8.7%)	8 (12.5%)
Other	436 (4.3%)	302 (7.1%)	102 (22.3%)	17 (26.6%)
Oral irritation	362 (3.5%)	165 (3.9%)	29 (6.3%)	6 (9.4%)
Throat irritation	243 (2.4%)	138 (3.3%)	47 (10.3%)	9 (14.1%)
Erythema/flushed	203 (2.0%)	92 (2.2%)	15 (3.3%)	2 (3.1%)
Edema	173 (1.7%)	126 (3.0%)	7 (1.5%)	1 (1.6%)
Excess secretions	167 (1.6%)	130 (3.1%)	56 (12.2%)	11 (17.2%)
Corneal abrasion	154 (1.5%)	149 (3.5%)	7 (1.5%)	5 (7.8%)
Dermal - Irritation/pain	152 (1.5%)	78 (1.8%)	5 (1.1%)	0 (0.0%)
Diarrhea	147 (1.4%)	88 (2.1%)	20 (4.4%)	1 (1.6%)
Lacrimation	147 (1.4%)	96 (2.3%)	2 (0.4%)	2 (3.1%)
Dyspnea	130 (1.3%)	120 (2.8%)	65 (14.2%)	22 (34.4%)
Rash	114 (1.1%)	56 (1.3%)	9 (2.0%)	0 (0.0%)
Abdominal Pain	88 (0.9%)	53 (1.2%)	5 (1.1%)	1 (1.6%)
Bronchospasm	83 (0.8%)	78 (1.8%)	43 (9.4%)	8 (12.5%)
Agitated/irritable	77 (0.8%)	57 (1.3%)	18 (3.9%)	6 (9.4%)
Tachycardia	62 (0.6%)	59 (1.4%)	37 (8.1%)	13 (20.3%)
X-ray findings(+)	60 (0.6%)	60 (1.4%)	45 (9.8%)	11 (17.2%)
Hyperventilation/tachypnea	46 (0.4%)	43 (1.0%)	29 (6.3%)	8 (12.5%)
Burns	41 (0.4%)	38 (0.9%)	4 (0.9%)	2 (3.1%)
Respiratory depression	39 (0.4%)	37 (0.9%)	30 (6.6%)	18 (28.1%)
Pallor	36 (0.4%)	31 (0.7%)	7 (1.5%)	3 (4.7%)

Related Clinical Effects	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Dysphagia	29 (0.3%)	25 (0.6%)	9 (2.0%)	1 (1.6%)
Photophobia	26 (0.3%)	24 (0.6%)	0 (0.0%)	0 (0.0%)
Acidosis	25 (0.2%)	25 (0.6%)	22 (4.8%)	9 (14.1%)
Burns (superficial)	24 (0.2%)	20 (0.5%)	2 (0.4%)	0 (0.0%)
Pneumonitis	24 (0.2%)	24 (0.6%)	19 (4.1%)	7 (10.9%)
Fever/hyperthermia	21 (0.2%)	19 (0.4%)	14 (3.1%)	5 (7.8%)
Oropharyngeal edema	21 (0.2%)	19 (0.4%)	14 (3.1%)	6 (9.4%)
Oral burns (including lips)	20 (0.2%)	16 (0.4%)	9 (2.0%)	2 (3.1%)
Coma	17 (0.2%)	16 (0.4%)	14 (3.1%)	9 (14.1%)
Blurred vision	12 (0.1%)	7 (0.2%)	0 (0.0%)	0 (0.0%)
Cyanosis	12 (0.1%)	9 (0.2%)	4 (0.9%)	3 (4.7%)
Ataxia	11 (0.1%)	9 (0.2%)	5 (1.1%)	1 (1.6%)
Anorexia	10 (0.1%)	7 (0.2%)	2 (0.4%)	1 (1.6%)
Pruritus	10 (0.1%)	5 (0.1%)	0 (0.0%)	0 (0.0%)
Hives/welts	9 (0.1%)	8 (0.2%)	2 (0.4%)	0 (0.0%)
ADR to treatment	8 (0.1%)	4 (0.1%)	1 (0.2%)	1 (1.6%)
Visual defect	8 (0.1%)	6 (0.1%)	0 (0.0%)	0 (0.0%)
Electrolyte abnormality	7 (0.1%)	7 (0.2%)	5 (1.1%)	2 (3.1%)
Hypertension	7 (0.1%)	7 (0.2%)	2 (0.4%)	2 (3.1%)
Burns 2 - 3 degree	6 (0.1%)	6 (0.1%)	0 (0.0%)	0 (0.0%)
Bleeding (other)	5 (<0.1%)	3 (0.1%)	0 (0.0%)	0 (0.0%)
Hematemesis	5 (<0.1%)	5 (0.1%)	5 (1.1%)	0 (0.0%)
Bradycardia	4 (<0.1%)	4 (0.1%)	3 (0.7%)	1 (1.6%)
Miosis	4 (<0.1%)	4 (0.1%)	4 (0.9%)	0 (0.0%)
Pain (not dermal, GI, ocular)	4 (<0.1%)	3 (0.1%)	1 (0.2%)	0 (0.0%)
Papilledema	4 (<0.1%)	3 (0.1%)	0 (0.0%)	2 (3.1%)
Bullae	3 (<0.1%)	2 (<0.1%)	0 (0.0%)	0 (0.0%)
Dizziness/vertigo	3 (<0.1%)	2 (<0.1%)	0 (0.0%)	0 (0.0%)
Hyperglycemia	3 (<0.1%)	3 (0.1%)	2 (0.4%)	1 (1.6%)
Muscle weakness	3 (<0.1%)	3 (0.1%)	1 (0.2%)	0 (0.0%)
Seizure (single)	3 (<0.1%)	3 (0.1%)	3 (0.7%)	2 (3.1%)
Anion gap increased	2 (<0.1%)	2 (<0.1%)	1 (0.2%)	0 (0.0%)

Related Clinical Effects	All Exposures[b] (N=10,229)	Exposures Involving HCF Treatment (N=4,241)	Exposures Involving HCF Admission (N=458)	Exposures with Severe Medical Outcomes (N=64)
Chest pain (including noncardiac)	2 (<0.1%)	2 (<0.1%)	0 (0.0%)	1 (1.6%)
Diaphoresis	2 (<0.1%)	2 (<0.1%)	0 (0.0%)	0 (0.0%)
Hypotension	2 (<0.1%)	2 (<0.1%)	1 (0.2%)	1 (1.6%)
Pulmonary edema	2 (<0.1%)	2 (<0.1%)	2 (0.4%)	1 (1.6%)
Blood per rectum (other)	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	0 (0.0%)
Cardiac arrest	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	1 (1.6%)
Confusion	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Creatinine increased	1 (<0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastric burns	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	1 (1.6%)
Nystagmus	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Oliguria/anuria	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Puncture wound/sting	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Respiratory arrest	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	1 (1.6%)
Slurred speech	1 (<0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Syncope	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Tinnitus	1 (<0.1%)	1 (<0.1%)	0 (0.0%)	0 (0.0%)
Urinary incontinence	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	0 (0.0%)