SURVEILLANCE OF PEDIATRIC EXPOSURES TO LAUNDRY DETERGENTS IN ITALY: COMPARISON BETWEEN CASES EXPOSED TO LIQUID CAPSULES AND TRADITIONAL PRODUCTS

Presented by Laura Settimi

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Italian National Institute of Health: Study design and statistical analyses. L. Settimi, L. Lauria

La Sapienza University: Data quality control and editing, statistical analyses. F. Giordano
Liquid laundry detergent capsules (LLDCs) are unit dose fabric washing products consisting of about 32-35 mL of highly concentrated liquid detergent wrapped in a water-soluble membrane.
In mid-July 2010 LLDCs are launched in Italy by a major company (MC)
In mid-August 2011, other companies (OCs) start marketing LLDCs
Immediately after the LLDCs launch the National Poison Control Centre in Milan (NPCCCM) observes an increasing number of cases exposed to laundry detergents.

- **MC-LLDCs**: OCs-LLDCs

- **LLDCs average**: 1.35 cases of exposure/day

- **TLDs average**: 0.80 cases of exposure/day

- **All laundry detergents average**: 2.2 cases of exposure/day
Most of cases exposed to the newly marketed products are symptomatic.

Unexpected eye and skin injuries and oropharyngeal effects of moderate severity are immediately observed in association with LLDCs exposure.

Most of cases exposed to LLDCs are children aged <5 years
Actions promptly undertaken by MPCC:

- **Notification to the Industry and Ministry of Health of LLDCs-related cases of injuries/poisonings**
- **Ad hoc surveillance in collaboration with the Italian National Institute of Health**

Informative support for evidence-based preventive measures and legislative acts

Monitoring occurrence of laundry detergents exposures, main characteristics of cases, and severity of the associated clinical effects
Preventive measures undertaken in Italy

**January 2011**
Voluntary action (MC)
«Keep out of reach of children» more prominent safety icon on the lid, along with an educational campaign.

**January 2012**
Voluntary action (MC)
Use of additional opening and closing latch requiring opening with two hands

**August 2012**
Voluntary action (MC)
MC-LLDCs are introduced into the market in opaque outer-packaging

**June 2013**
Ministry decree:
LLDCs to be commercialized in opaque packaging with child-impeding closure, safety icons and warnings

**December 2013**
Ministry decree:
LLDCs in transparent outer packaging are withdrawn from the Italian market
AIM OF THE PRESENT STUDY

to compare the main characteristics of cases aged <5 years exposed to LLDCs and traditional laundry detergents (TLDs) between September 2010 and July 2015

METHODS

The distribution of the main characteristics of cases exposed to LLDCs and TLDs were compared using Pearson’s $X^2$ test or Fisher’s exact test.

Changes in the occurrence of cases of exposure to different types of laundry detergents per month were monitored using the Change Point Analysis and linear regression analysis.

The association between different types of laundry detergents and severity of poisonings were estimated by logistic regression models taking in to account exposure period.
RESULTS:
CASES IDENTIFIED BETWEEN SEPTEMBER 2010 AND JULY 2015

2799 cases exposed to laundry detergents and aged <5 years

1649 cases exposed to LLDCs
- 1188 cases exposed to MC-LLDCs
- 461 cases exposed to OCs-LLDCs

1150 cases exposed to TLDs
RESULTS: COMPARISON BETWEEN THE MAIN CHARACTERISTICS OF CASES AGED <5 YEARS EXPOSED TO LLDCs (N. 1649) AND TLDs (N. 1150).
ITALY, SEPTEMBER 2010-JULY 2015

<table>
<thead>
<tr>
<th>Origination of request for assistance</th>
<th>Hospital</th>
<th>68% (N. 1,123) vs 40% (N. 477)</th>
<th>Non-hospital</th>
<th>32% (N. 566) vs 60% (N. 755)</th>
</tr>
</thead>
</table>

| age class (years), p<0.001 | <1 | 6% (N. 95) vs 5% (N. 52) | 1 | 38% (N. 621) vs 43% (N. 489) | 2 | 29% (N. 484) vs 36% (N. 415) | 3 | 18% (N. 289) vs 12% (N. 135) | 4 | 10% (N. 160) vs 5% (N. 59) |

| route of exposure, p<0.001 | Single route | 88% (N. 1452) vs 93% (N. 1072) | Multiple routes | 12% (N. 197) vs 7% (N. 73) |
RESULTS: COMPARISON BETWEEN THE MAIN CHARACTERISTICS OF CASES AGED <5 YEARS EXPOSED TO LLDCs (N. 1649) AND TLDs (N. 1150) ITALY, SEPTEMBER 2010-JULY 2015

**Clinical signs/symptoms, p<0.0001**

- None/not associated: 25% (N. 416) vs 78% (N. 900)
- Associated (at least one): 75% (N. 1233) vs 22% (N. 250)
RESULTS: COMPARISON BETWEEN THE MAIN CHARACTERISTICS OF CASES AGED <5 YEARS EXPOSED TO LLDCs (N. 1649) AND TLDs (N. 1.150).

ITALY, SEPTEMBER 2010-JULY 2015

Poisoning severity*, p<0.0001

<table>
<thead>
<tr>
<th>Level</th>
<th>LLDCs (N. 1649)</th>
<th>TLDs (N. 1.150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>87% (N. 1076)</td>
<td>99% (N. 249)</td>
</tr>
<tr>
<td>Moderate</td>
<td>12% (N. 147)</td>
<td>0.1% (N. 1)</td>
</tr>
<tr>
<td>High</td>
<td>1% (N. 10)</td>
<td>0.0% (N. 0)</td>
</tr>
</tbody>
</table>

*Assessed according to Poisoning Severity Score, Persson et al, J. Toxicol Clin Toxicol, 1998
RESULTS: CLINICAL EFFECTS OBSERVED ONLY AMONG CASES EXPOSED TO LLDCs (N. 1649) IN ITALY BETWEEN SEPTEMBER 2010 AND JULY 2015

### OROPHARYNGEAL

<table>
<thead>
<tr>
<th>Effect</th>
<th>Count (N)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lips/oral cavity oedema</td>
<td>7</td>
<td>0.6%</td>
</tr>
<tr>
<td>Lips/oral cavity disepithelisation</td>
<td>7</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

### RESPIRATORY

<table>
<thead>
<tr>
<th>Effect</th>
<th>Count (N)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laryngospasm/bronchospasm</td>
<td>19</td>
<td>1.5%</td>
</tr>
<tr>
<td>Breath sounds</td>
<td>15</td>
<td>1.2%</td>
</tr>
<tr>
<td>Bronchial hypersecretion</td>
<td>11</td>
<td>0.9%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>11</td>
<td>0.9%</td>
</tr>
<tr>
<td>Stridor</td>
<td>5</td>
<td>0.4%</td>
</tr>
<tr>
<td>Edema of glottis</td>
<td>3</td>
<td>0.4%</td>
</tr>
<tr>
<td>Chemical pneumonia</td>
<td>3</td>
<td>0.4%</td>
</tr>
</tbody>
</table>
RESULTS: CLINICAL EFFECTS OBSERVED ONLY AMONG CASES EXPOSED TO LLDCs (N. 1649) BETWEEN SEPTEMBER 2010 AND JULY 2015

<table>
<thead>
<tr>
<th></th>
<th>Ocular</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal abrasion</td>
<td>N. 22 (1.8%)</td>
<td>Edema</td>
</tr>
<tr>
<td>Ptosis</td>
<td>N. 19 (1.5%)</td>
<td>N. 20 (1.6%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rush</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N. 8 (0.6%)</td>
</tr>
</tbody>
</table>
RESULTS: OCCURRENCE TREND AND CHANGES AMONG CHILDREN AGED <5 YEARS EXPOSED TO LLDCs (N. 1649) AND TLDs (N. 1150).

ITALY, SEPTEMBER 2010-JULY 2015

January 2011: On the lid
January 2012: Double latch
August 2012: Obscure container
June 2013: Ministry decree: All newly marketed LLDCs
December 2013: Ministry decree: Withdrawn

Estimated averages (cases/day) in pre- and post-change point periods:

- LLDCs = 1.26 cases/day (Pre-change)
- LLDCs = 0.65 cases/day (Post-change)
- TLDs = 0.68 cases/day (Pre-change)
- TLDs = 0.63 cases/day (Post-change)
RESULTS: OCCURRENCE TREND AND CHANGES FOR CHILDREN AGED <5 YEARS EXPOSED TO MC-LLDCs (N. 1188) AND OCs-LLDCS (N. 461).

ITALY, SEPTEMBER 2010-JULY 2015

Estimated averages (cases/day) in pre- and post-change point periods:
- **Pre-change period**
  - **MC**: 1.03 cases/day
  - **OCs**: 0.38 cases/day

- **Post-change period**
  - **MC**: 0.36 cases/day
  - **OCs**: 0.29 cases/day
RESULTS: OCCURRENCE TREND AND CHANGES FOR CHILDREN AGED <5 YEARS EXPOSED TO MC-LLDCs (N. 1188) AND OCs-LLDCS (N. 461).

ITALY, SEPTEMBER 2010-JULY 2015
in the post-change point period (four months after the introduction of opaque outer-containers) the mean number of cases exposed to MC-LLDCs was reduced by 19.6 cases/month (95% CI: -23.2; -16.1), p<0.0001 (adjusted by quantity sold)
RESULTS: MEASURING THE ASSOCIATION BETWEEN EXPOSURE TO LAUDRY DETERGENTS AND SEVERITY OF POISONING AMONG CHILDREN AGED <5 YEARS AND PRESENTING WITH CLINICAL EFFECTS, LOGISTIC REGRESSION ANALYSIS
ITALY, SEPTEMBER 2010-JULY 2015

<table>
<thead>
<tr>
<th>Type of product</th>
<th>N.</th>
<th>moderate/high severity (%)</th>
<th>Crude OR</th>
<th>Adjusted OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLDs</td>
<td>250</td>
<td>0.9</td>
<td>1</td>
<td>1</td>
<td>--</td>
</tr>
<tr>
<td>MC-LLDCs</td>
<td>839</td>
<td>15.3</td>
<td>19.9</td>
<td>22.5</td>
<td>5.5 - 91.9</td>
</tr>
<tr>
<td>OCs-LLDCs</td>
<td>461</td>
<td>10.2</td>
<td>12.6</td>
<td>12.4</td>
<td>2.9 - 52.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period</th>
<th>N.</th>
<th>moderate/high severity (%)</th>
<th>Crude OR</th>
<th>Adjusted OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-change point (Sept 2010-Nov 2012)</td>
<td>888</td>
<td>10.8</td>
<td>1</td>
<td>1</td>
<td>--</td>
</tr>
<tr>
<td>Post-change point (Dec 2012-June 2015)</td>
<td>595</td>
<td>13.5</td>
<td>1.3</td>
<td>1.6</td>
<td>1.2 - 2.3</td>
</tr>
</tbody>
</table>
CONCLUSIONS

After voluntary introduction of obscure outer-packaging by a MC, occurrence of exposure to MC-LLDCs among children aged <5 years has been halved within a four months period.

Safety icons/statements and improvement of outer packaging closure may be poorly effective if LLDCs are easily visible to young children.
CONCLUSIONS

For both MC-LLDCs and OCs-LLDCs, the association with moderate/severe poisoning was highly statistically significant and it was not lowered during the observation period.

The available observations indicate that further efforts are needed to reduce the risk of poisoning/injuries in case of exposure to these hazardous products.
Poison Control Centres play a central role to:

- identify emerging problems;
- support post marketing surveillance of products;
- provide evidence based information to support preventive measures and legislative acts and evaluate their impact.
IMPROVING PRODUCTS SAFETY

- National Public Health Institutes
- Poison Control Centres
- Industry
- European Commission
- National authorities
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