**BACKGROUND**

- Acetaminophen is safe for self-care when used as directed, but has a narrow therapeutic index.\(^1,2\)
- Acetaminophen-related overdose is currently the number one cause of acute liver failure, and is a leading cause of liver transplant in the United States.\(^3,4\)
- Appropriate labeling of the over-the-counter (OTC) Drug Facts Labels for nonprescription acetaminophen has been a primary focus of the FDA for over 46 years.\(^5\)

**PURPOSE**

- Compare consumer preferences for, and comprehension of, the current OTC Drug Facts format versus a revised format for nonprescription acetaminophen labeling, using previously published methodology.
- Compare consumer preferences for a revised cap statement versus the currently marketed cap statement on brand Tylenol (acetaminophen).

**METHODS**

- Study design: Prospective label comprehension study using design and implementation from prior published studies.\(^6\) Study approved by the UCSF Committee on Human Research.
- Revised label: Development informed by an extensive literature review, expert opinion from liver transplant and Poison Control pharmacists, and focus groups.
- Revised cap statement: Developed using information already contained on the current OTC Drug Facts label.
- Recruitment: Community center in San Francisco in September 2013. Participants received a US$5.00 gift card incentive for survey completion.
- Inclusion criteria: No history of liver damage due to acetaminophen; between 18 – 90 years of age; able to read English; able to read English in 6-point Helvetica with or without corrective lenses; consent to participate in study.
- Measures: (a) Label: ease of finding and understanding the liver warning, correct intended action after reading scenario (Table 1), usefulness and overall preference (Figure 3); (b) Cap Statement: likelihood to read label and overall preference (Figure 5).

**RESULTS**

- \(N=110\) included in final analysis: 120 participants recruited, 10 were excluded for failure to meet inclusion criteria and early drop out.
- Baseline demographics: Well-balanced between participants randomized to view the current label first versus the revised label first (\(p>0.05\)).
  - Age 20-36 years (71% vs. 55%)
  - Female (69% vs. 65%)
  - Achieved secondary education (91% vs. 81%)
  - Caucasian (85% vs. 80%)
- Past use of multiple OTC analytics (acetaminophen [78% vs. 85%], aspirin [90% vs. 75%], ibuprofen [89% vs. 85%]).

**DISCUSSION, LIMITATIONS, CONCLUSIONS**

- **Discussion:** To our knowledge, this is the first publicly available post-marketing study on the liver warning in the acetaminophen OTC Drug Facts label.
- Consumers preferred the following key revisions to the current liver warning for OTC acetaminophen: signs of overdose, re-location of directions to seek medical help after "severe liver damage," revised headings, and re-organization of information to improve usefulness.
- **Potential Limitations:** (a) sample size, although the study demographic matches a large segment of the U.S. consumer population; (b) investigators not blind to randomization although researchers were trained with a standard script and did not interfere with participants completing the survey on their own.
- **Conclusions:** Our findings indicate the proposed labeling revisions would help improve consumer awareness and action in the event of an overdose. The label comprehension model used in this study can serve as a lower cost approach with rapid turn-around for those companies interested in optimizing the likelihood that their product labels will be used to help improve medication safety.

**REFERENCES**


**DISCLOSURES**

Authors of this presentation have no possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation. Funding for this study was provided by the Vinson-Grant provided by the UCSF School of Pharmacy.

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**Figure 1:** Schematic of Study Procedure

**RESULTS (continued)**

**RESULTS (continued)**

**Figure 4. Current (A) and Revised (B) Cap Statement for Side-by-Side Comparison**

**Figure 5. Overall Increased Likelihood of Reading the Label and Preference**

**Table 1. Overdose Scenario: Individual Reviews of Actual Cartons (\(N=55\) per group)**

<table>
<thead>
<tr>
<th>Label</th>
<th>Rating Current Label (%)</th>
<th>Rating Revised Label (%)</th>
<th>(%) CI</th>
<th>(p)-value for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Label</td>
<td>51% (29)</td>
<td>64% (35)</td>
<td>54 – 61</td>
<td>0.001</td>
</tr>
<tr>
<td>Revised Label</td>
<td>63% (37)</td>
<td>73% (41)</td>
<td>66 – 80</td>
<td>0.001</td>
</tr>
</tbody>
</table>

**Figure 3. Overall Usefulness and Preference Ratings for Labels (\(N=110\), both groups)**

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