Safer Labeling of Pediatric Medications: Reducing Literacy-related Health Disparities among Chronically Ill Adolescents

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Disparities in Understanding Medication Information

Addressing health disparities is a national priority (IOM, NIH, NSF, FDA)

Low health literacy is a common driver of these disparities
- 1 in 3 adolescents has a chronic condition (Bethell 2012)
- 1 in 4 adolescents and young adults has low health literacy (Kutner 2003, Yin 2009)
- Adults with limited literacy cannot understand Medication Guides (Wolf 2012, Trivedi 2014)

FDA’s mission to improve safe medication use -- especially for vulnerable populations
- Limited literacy, English-language proficiency
- Under-represented minority (URM) status
- Geography (rural)
- Children and adolescents with chronic conditions

Little evidence exist to improve medication understanding for vulnerable populations
FDA Mission to Address Literacy-related Disparities

- Creating targeted outreach to consumers and health care practitioners serving underrepresented patient subpopulations
- Developing an FDA-specific “language access” plan to address the needs of people with limited English proficiency
- Advancing efforts to include underrepresented subpopulations in FDA’s new Patient Network and Health Professional Network
- Continuing research into health literacy and FDA safety messaging
- Increasing the use of social media platforms to support the above activities and improve awareness among underrepresented subpopulations and racial subgroups about important safety information for medical products

CERSI- Stanford & OMHHE project supports additional information in health literacy

Courtesy Christine Lee, FDA
Research Aims

1 To assess the **suitability** of medication labels commonly used by adolescents with chronic illness.

2 To gain **perspectives** about written information accompanying prescription (Rx) and over-the-counter (OTC) medications -- from chronically-ill adolescents in low-income communities.

3 To **co-design** and **test** new tools that will support informed adolescent decision making in the understanding and use of these medications.
Suitability of Medication Information

Methods: Sampled labels (sigs, black-box labels, outside package, on bottle) from medications most commonly used by children with chronic conditions (ref: Medicaid-billing analysis of >100k children*). Measure: Independent coding using the Suitability Assessment of Materials (SAM) (Doak, Doak, Root 1996)

![Graph showing mean SAM scores (SD) for medication information by type]

- OTC
- Rx - Label
- Rx - MedGuide (Old)
- Rx - MedGuide (New)
- Rx - Spanish Info Sheet

![Graph showing medication guides (old vs. updated)]

- Medication Guides
- Updated Medication Guides

* DHCS, CCS 2015

Smith MCJ, PAS, May 2016.
Adolescents’ Perspectives on Medication Information

**Methods:** Sampled parent-child dyads from Medicaid-insured population of children with chronic conditions, on ≥ 1 chronic medication. In-depth interviews to assess understanding of medication labels, including risks, indications, and recommendations for improvement.

<table>
<thead>
<tr>
<th></th>
<th>Teen</th>
<th>Parent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (range)</td>
<td>14.7 (14-18)</td>
<td>45.1 (33-57)</td>
</tr>
<tr>
<td>Sex – N (%) female</td>
<td>11 (55%)</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>Chronic meds -- median (range)</td>
<td>5 (1–48)</td>
<td>N/A</td>
</tr>
<tr>
<td>Limited English Proficiency – N (%)</td>
<td>0</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Limited Literacy – N (%)</td>
<td>3 (15%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Subspecialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Gastroenterology</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>- Endocrinology</td>
<td>11</td>
<td>N/A</td>
</tr>
<tr>
<td>- Other</td>
<td>3</td>
<td>N/A</td>
</tr>
</tbody>
</table>
“...but it doesn't really tell you what to do if you start to experience these because sometimes it's possible that these side effects will go away”

“I just put it in Google. I put in the certain medicine, and there are group forums where people just give their opinions on it”

“when I was looking up for marijuana... I found a forum, so people had their own personal experiences, which is probably not super-reliable, but at least it was hopefully going to give me a good idea”

“Did you take your ‘short’ pill today?”

Co-Design of Rx Information for Teens and Families

**Methods:** Pilot RCT. **Intervention:** Human-centered redesign of Rx Information. Iterative prototyping. **Control:** FDA Medication Information Guide. Sample: 30 parent-child dyads. **Primary outcome:** Patient understanding of safety, indications and side effects.
**Methods:** Pilot RCT.  
**Intervention:** Redesigned Rx Information Guide. **Control:** FDA Rx Information Guide.

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – mean (SD)</td>
<td>15.6 (1.8)</td>
<td>14.7 (1.7)</td>
</tr>
<tr>
<td>Sex – N (%) female</td>
<td>11 (68%)</td>
<td>6 (43%)</td>
</tr>
<tr>
<td>Low Household Income</td>
<td>10 (62%)</td>
<td>9 (64%)</td>
</tr>
<tr>
<td>Limited Literacy</td>
<td>8 (25%)</td>
<td>7 (25%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Hispanic</td>
<td>5 (31%)</td>
<td>3 (21%)</td>
</tr>
<tr>
<td>- Asian/PI</td>
<td>3 (18%)</td>
<td>2 (14%)</td>
</tr>
</tbody>
</table>

**UNDERSTANDING OF MEDICATION INDICATION AND RISKS**

![Bar chart showing understanding of various medication aspects between Intervention and Control groups.](image)

- Indications to take Medication
- Side effects
- Side effects (with alcohol)
- Contra-indications
- Safety (seeking help)
- Med-Med Interactions

* p<0.05

Next Steps: Scaling Low-Literacy Solutions

- Co-Design and Testing: OTC Medication Information
- Prototype Iteration: Natural language processing, across multiple medications
- Comparative Effectiveness Trial: Multi-site, URM communities (FQHCs)
- Design Studio: Elevating URM Youth, from Research Subjects to “Co-Investigators”
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