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MEDICINE

# **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



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# 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

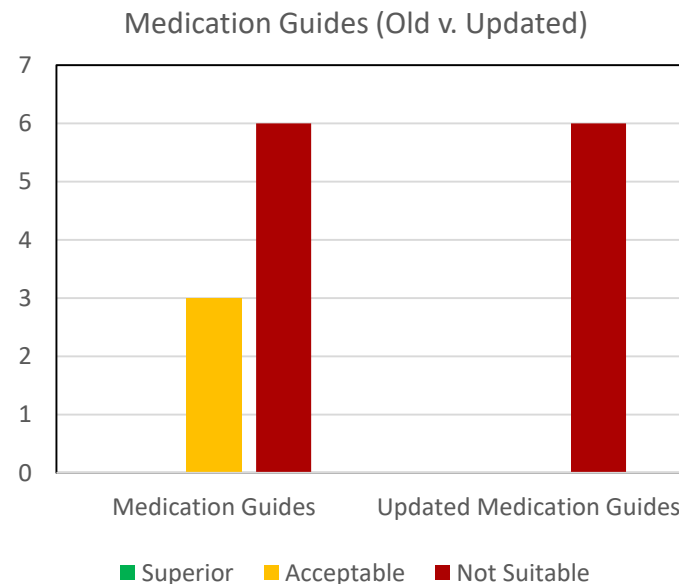
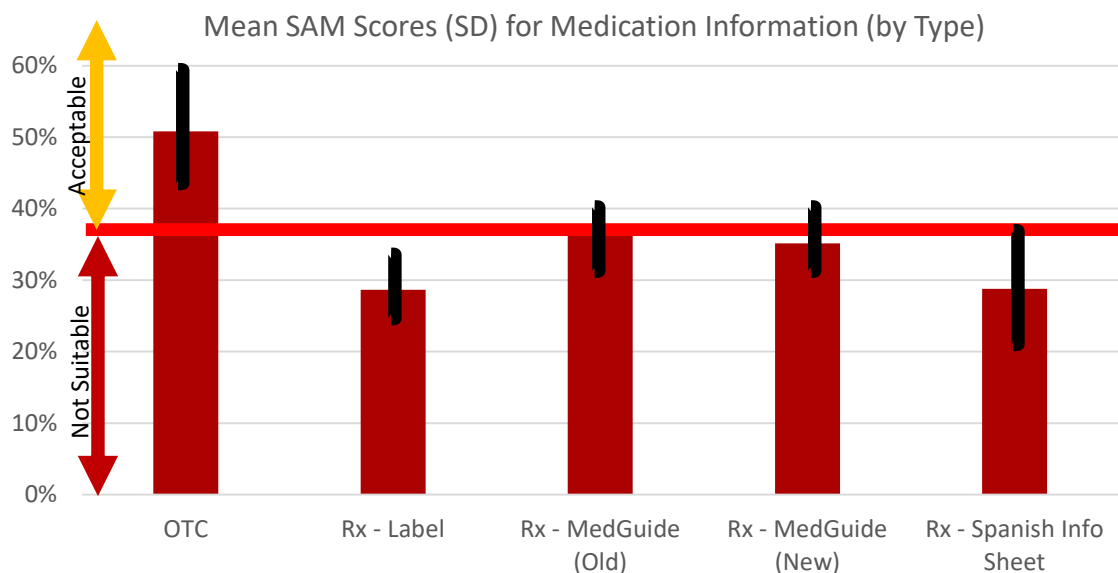
Courtesy Christine Lee, FDA

# 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)



# Adolescents' Perspectives on Medication Information

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

	Teen	Parent
Age in years (range)	14.7 (14-18)	45.1 (33-57)
Sex – N (%) female	11 (55%)	15 (75%)
Chronic meds -- median (range)	5 (1– 48)	N/A
Limited English Proficiency – N (%)	0	5 (25%)
Limited Literacy – N (%)	3 (15%)	5 (25%)
Subspecialty		
- Gastroenterology	6	N/A
- Endocrinology	11	N/A
- Other	3	N/A

# Adolescents' Perspectives on Medication Information

Information **Too Complex**

Concerns about **side effects**

*"..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"*

Desire for **prioritized side effects**, with actionable advice

Desire for authoritative, **web-accessible** information

*"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"*

Interactions between medications and **recreational drugs and alcohol**

**Social stigma** around their chronic condition and medication use

*"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.





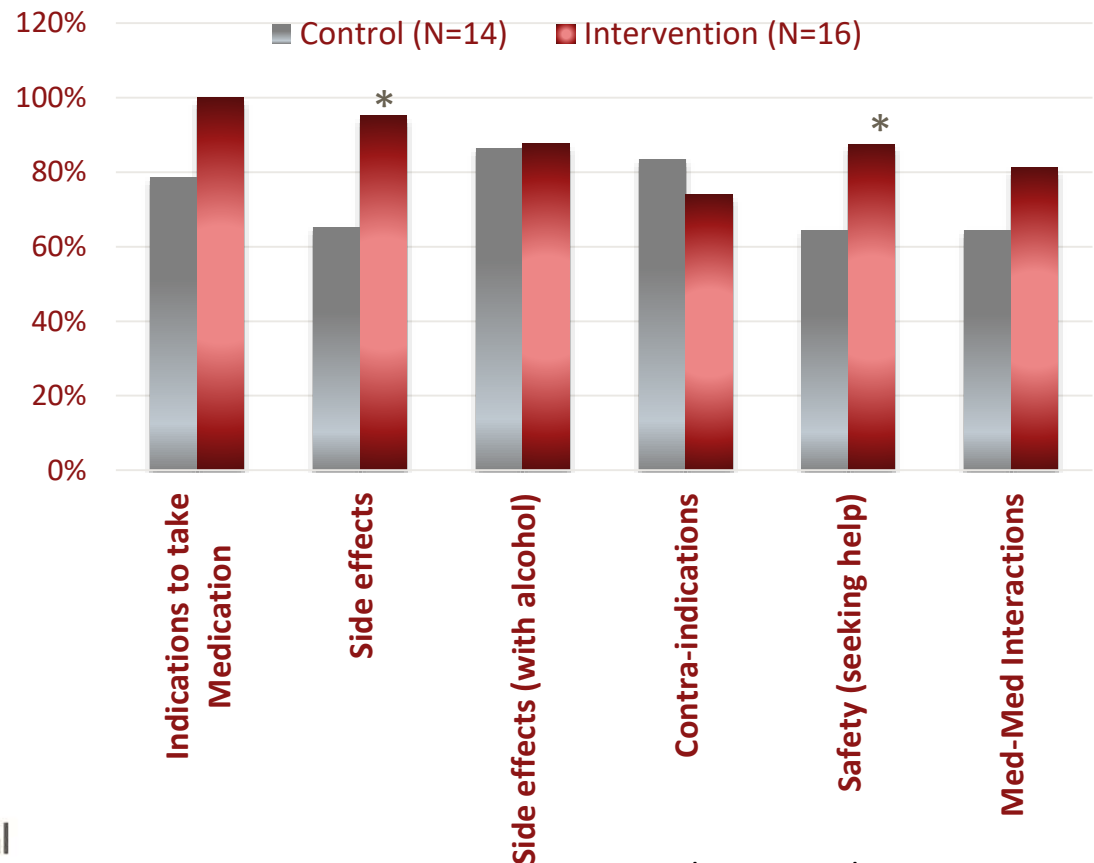
# Co-Design of Rx Information for Teens and Families

**Methods:** Pilot RCT.

**Intervention:** Redesigned Rx Information Guide. **Control:** FDA Rx Information Guide.

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

## UNDERSTANDING OF MEDICATION INDICATION AND RISKS



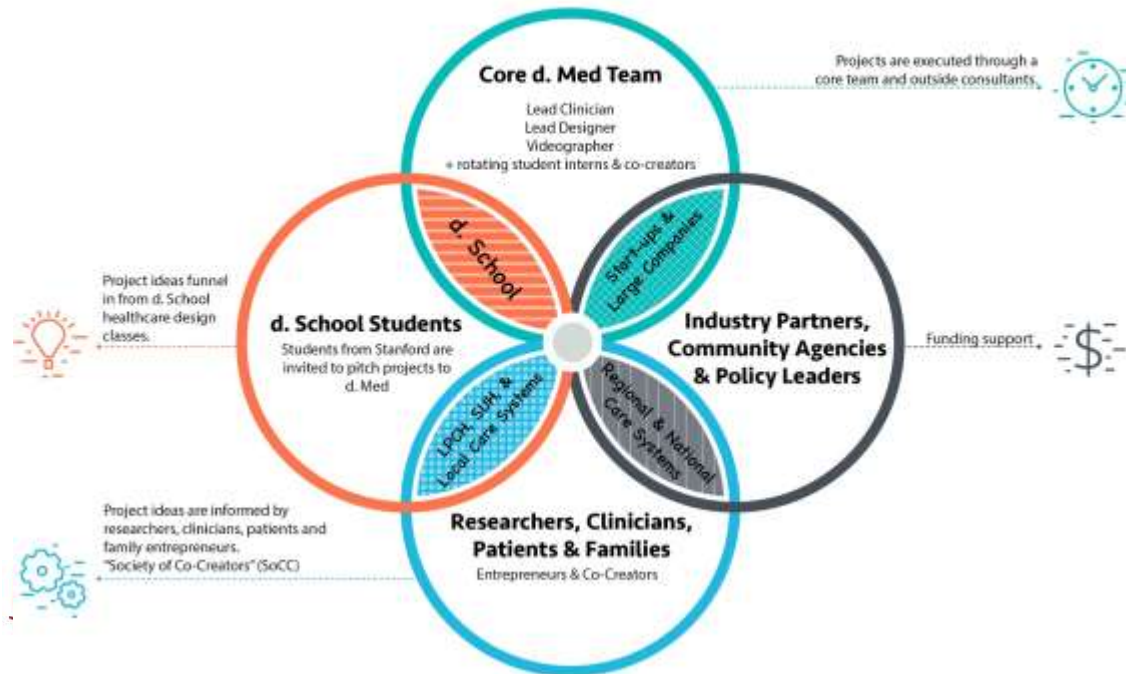
Ochoa K, et al, PAS, May 2020.

# 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”

## d. Med

### Stakeholders & Team



# Thank You



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