Effect of Redesigned Prescription Drug Labels on Medication Use: A Randomized Controlled Trial

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• Drs. Kripalani, Mohan, and Boyington are consultants to and hold equity in PictureRx, LLC.

• Mr/Ms. Riley, Trochez, Mashburn, and Jenkins were employed by PictureRx, LLC.
Background – Rx Labels

- Prescription drug labels are not well designed

- Layout is not patient-centered
  - Pharmacy info emphasized
  - Info not in logical order

- Poor typography
  - Small font
  - ALL CAPS

- Instructions not simple
  - Numbers spelled out
  - Specific times of day not given

ACP white paper to IOM, 2007
Patient Understanding of Labels

- Patients often misunderstand Rx labels
- Health literacy is associated with misunderstanding

<table>
<thead>
<tr>
<th>Instruction</th>
<th>Adequate HL</th>
<th>Marginal HL</th>
<th>Inadequate HL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take two tablets by mouth twice daily</td>
<td>10.6%</td>
<td>15.9%</td>
<td>29.3%</td>
</tr>
<tr>
<td>Take one tablet my mouth once each day</td>
<td>5.3%</td>
<td>12.4%</td>
<td>13.3%</td>
</tr>
</tbody>
</table>

- Limited English Proficiency (LEP) is also a concern
  - Labels rarely given in patients’ preferred language
  - Less understanding, more adverse drug events

# Toward More Patient-Centered Labels

## ACP / IOM Recommendations for Label Design

- Use explicit text to describe dosage / interval.
- Use a universal medication schedule (UMS) to convey and simplify dosage / use instructions.
- Organize label in a patient-centered manner.
- Include distinguishable front and back sides to the label.
- When possible, include indication for use.
- Simplify language, avoiding unfamiliar words / jargon.
- Improve typography: use larger, sans serif font.
- When applicable, use numeric instead of alphabetic characters.
- Use typographic cues (bolding and highlighting) for patient content only.
- Use horizontal text only.
- Use a standard icon system for signaling and organizing auxiliary warnings and instructions.

## California, USP Guidelines

- Emphasize info important to patients: Patient name, Drug name, strength, Clear directions for use, Drug indication
- Cluster this info in one area, occupying at least 50% of label.
- Use 10-12 point font.
- Provide in patient’s preferred language.
- Use bold text or highlighting for emphasis.
- Can use icons if shown to be well-understood.

**ACP white paper to IOM, 2007**
California, USP label standards
Traditional and More Patient-Centered Labels

California label standards
Development of PictureRx Label

- Based on published evidence, California, USP guidelines
- Additional elements
  - Image of medication
  - Icons for drug indication: 90+ icons developed and tested for comprehension cross-culturally
  - Instructions by 4 times of day (aka Universal Medication Schedule)
  - Incorporate special instructions/warnings
- Developed 9 prototypes, iteratively refined
  - Reviewed by patients, pharmacists, national expert panel
- Developed software platform to create
  - Can output English or bilingual (English/Spanish) label
Final PictureRx Label Designs

**Jonathan Cash Doe**

Hydralazine 25 mg

Take:
- 2 pills in the morning,
- 2 pills at noon,
- 2 pills in the evening,
- 2 pills at bedtime.

**For:** Blood Pressure

**Warnings**

May cause dizziness.
May cause nausea.
Take with food.

DOB: 03/19/1958
Provider: A. Mohan
NDC: 417-25529-00
Filled: 05/31/2011
Expires: 10/08/2011
Refills: 3
Rx #: 5483-3921-3345

PRXpharmacy
Phone Number: 617-665-1000
90 Frasier Ave, Chattanooga, TN 27405

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**Juan A. García Nevado**

Hydralazine 25 mg

Tome:
- 2 pastillas en la mañana,
- 2 pastillas al mediodía,
- 2 pastillas en la tarde.

(For: Blood Pressure)

(Advertencias (Warnings))

Puede causar mareos.
(May cause dizziness.)
Puede causar náuseas.
(May cause nausea.)
Tome con comida.
(Take with food.)

DOB: 03/19/1958
Proveedor: A. Mohan
NDC: 417-25529-00
Llenado (filled): 05/31/2011
Vence (expires): 10/08/2011
Refil (refill): 3 Veces
120 Pastillas (120 pills)

PRXpharmacy
Phone Number: 617-665-1000
90 Frasier Ave, Chattanooga, TN 27405

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**English only label**

**Spanish-English label**
Objective

• To test whether providing patients with a redesigned, evidence-based, illustrated medication label, improves understanding, self-efficacy, satisfaction, and adherence, compared to traditional prescription drug labels.
Study Design

• Randomized controlled trial
  • Permutated block randomization, stratified by site
  • Concealed allocation
• Sites: 5 retail pharmacies in TN and FL
• Participants:
  • Filling at least one “new” prescription
  • English or Spanish speaking
  • Provided written informed consent
• Provided PictureRx label or traditional label
• Counseling per pharmacy standard
Follow-up, Outcomes

- Telephone interview approximately 1 week later
- Medication Understanding Questionnaire (MUQ) - primary
  - Knowledge of indication, strength, dose, frequency; warnings
- Self-Efficacy for Appropriate Medication use Scale (SEAMS)
  - Confidence to take medications correctly
- Satisfaction with Information about Medications Scale (SIMS)
  - “Right amount” of info about med name, purpose, dosing, side effects
- Adherence to Refills and Medications Scale (ARMS)
  - Subscale: self-reported adherence with taking meds during last week
- Intention to treat analysis
- Independent samples t-tests
## Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Usual Care (N=255)</th>
<th>Intervention (N=245)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD)</strong></td>
<td>50.1 (16.7)</td>
<td>50.8 (16.9)</td>
</tr>
<tr>
<td><strong>Female gender, N (%)</strong></td>
<td>163 (63.9%)</td>
<td>152 (62.0%)</td>
</tr>
<tr>
<td><strong>Race:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, N (%)</td>
<td>171 (67.1%)</td>
<td>157 (64.1%)</td>
</tr>
<tr>
<td>Black</td>
<td>78 (30.6%)</td>
<td>81 (33.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (2.4%)</td>
<td>7 (2.9%)</td>
</tr>
<tr>
<td><strong>Latino ethnicity, N (%)</strong></td>
<td>85 (33.3%)</td>
<td>80 (32.7%)</td>
</tr>
<tr>
<td><strong>Years of education, mean (SD)</strong></td>
<td>11.8 (3.0)</td>
<td>11.7 (2.9)</td>
</tr>
<tr>
<td><strong>Prescription medications, mean (SD)</strong></td>
<td>4.8 (3.3)</td>
<td>4.9 (3.4)</td>
</tr>
<tr>
<td><strong>Completed follow-up, N (%)</strong></td>
<td>237 (92.9%)</td>
<td>227 (92.7%)</td>
</tr>
</tbody>
</table>
Results – Medication Understanding

* p<0.001, † p<0.05; Preliminary analysis of first 100 patients
Results

• Self-efficacy (scale 10-30)
  • Higher in the intervention group (26.6 vs 25.8, p<0.05)

• Self-reported adherence (scale 4-16)
  • No significant difference (5.9 vs 6.0)

• Satisfaction with amount of information received
  • Fewer patients said they got “little” or “no” info; not significant

• Perceptions among intervention patients
  • Overall satisfied - 99%
  • Clear and easy to read - 97%
  • Directions easy to understand - 100%
Strengths

• Multi-center
• Rigorous RCT design
• Diverse population
• High follow-up rates

Limitations

• Outcomes short-term (1 week)
• Self-reported
• Did not assess actual behavior or clinical outcomes
• Unable to control for counseling received
Conclusions

• A redesigned, evidence-based, illustrated drug label
  • Significantly improved patients’ understanding of medication instructions and drug warnings
  • Significantly improved self-efficacy (by modest amount)
  • Did not significantly improve self-reported adherence or satisfaction with the amount of information received
  • Was perceived to be clear and easy to understand

• Patient-centered labels are a promising strategy to improve medication use
• Additional research is needed to verify the benefits of patient-centered labels and translate into practice
Thank you!

What questions do you have?