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

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Acknowledgements, Disclosures

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

Instruction	Adequate HL	Marginal HL	Inadequate HL
Take two tablets by mouth twice daily	10.6%	15.9%	29.3%
Take one tablet my mouth once each day	5.3%	12.4%	13.3%

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

Davis, Wolf. Ann Intern Med 2006; Bailey. Med Care 2009; Weiss. J Urban Health 2007

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.

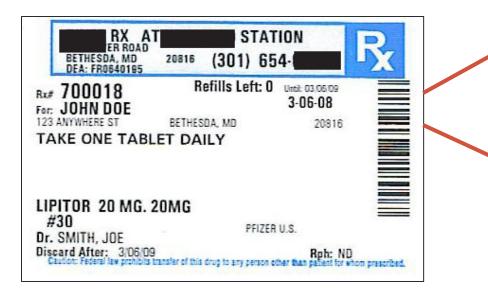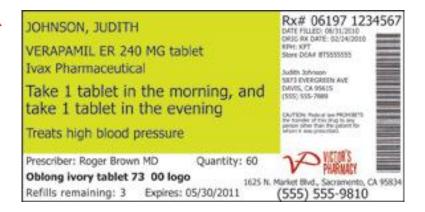| California, USP Guidelines |
| --- |
| Emphasize info important to patients:
    Patient name
    Drug name, strength
    Clear directions for use
    Drug indication |
| Cluster this info in one area, occupying at least 50% of label. |
| Use 10-12 point font. |
| Provide in patient's preferred language. |
| 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
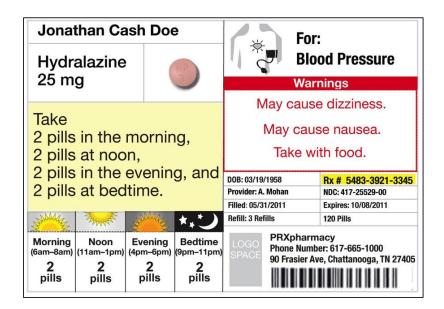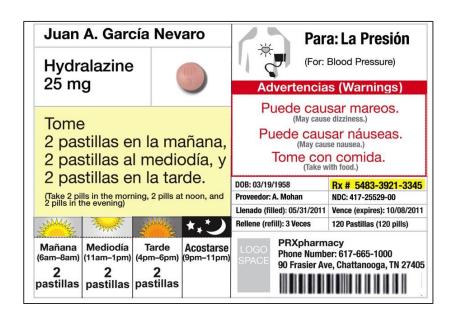

California label standards

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

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
  - Permuted 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
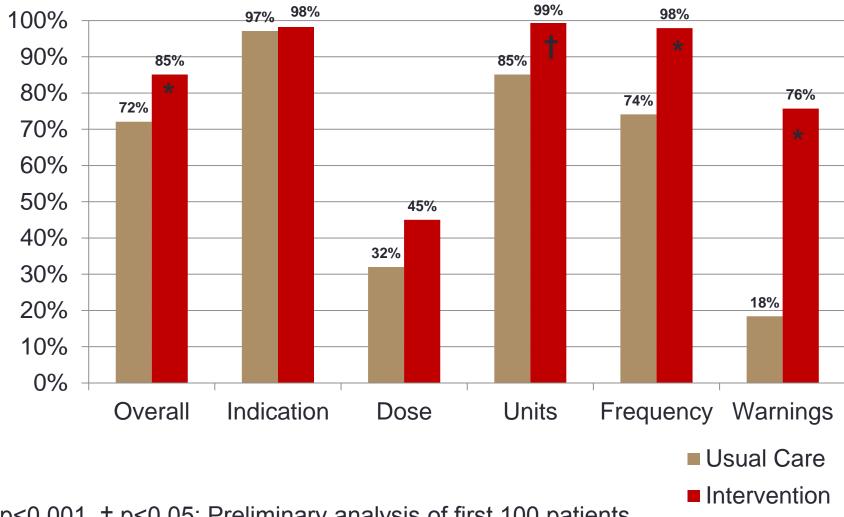- Counseling per pharmacy standard

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

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

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?