

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

RX AT [REDACTED] STATION
[REDACTED] ER ROAD
BETHESDA, MD 20816 (301) 654-[REDACTED]
DEA: FR0640195

Rx# **700018** Refills Left: **0** Util: 03/06/09
For: **JOHN DOE** 3-06-08
123 ANYWHERE ST BETHESDA, MD 20816

TAKE ONE TABLET DAILY

LIPITOR 20 MG. 20MG
#30 PFIZER U.S.
Dr. SMITH, JOE
Discard After: 3/06/09 Rph: ND
Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

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

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

RX AT STATION
ER ROAD
BETHESDA, MD 20816 (301) 654-
DEA: FR0640195

Rx# 700018 Refills Left: 0 Until: 03/06/09
For: **JOHN DOE** 3-06-08
123 ANYWHERE ST BETHESDA, MD 20816
TAKE ONE TABLET DAILY

LIPITOR 20 MG. 20MG
#30
Dr. SMITH, JOE
Discard After: 3/06/09
Pfizer U.S. Rph: ND

Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

VIC/pharmacy Rx# 1234567
Ph: (555) 555-9810 RPH: KPT
DATE FILLED: 10/31/2009
ORIG RX DATE: 02/24/2009
5873 EVERGREEN AVE
DAVIS, CA 95615 (555) 555-7889

1625 N. Market Blvd
Sacramento, CA 95834

JOHNSON, JUDY
VERAPAMIL ER 240 MG TABLET
Ivax Pharmaceutical
Take 1 tablet in the morning, and
take 1 tablet in the evening
Treats high blood pressure
Prescriber: Roger Brown, MD Quantity: 60
Oblong ivory tablet 73 00 logo
Refills remaining: 2 Expires: 05/30/2011

JOHNSON, JUDITH Rx# 06197 1234567
DATE FILLED: 08/31/2010
DRUG RX DATE: 02/24/2010
RPH: KPT
Store DEA# 8T5555555

Judith Johnson
5873 EVERGREEN AVE
DAVIS, CA 95615
(555) 555-7889

VERAPAMIL ER 240 MG tablet
Ivax Pharmaceutical
Take 1 tablet in the morning, and
take 1 tablet in the evening
Treats high blood pressure

Prescriber: Roger Brown MD Quantity: 60
Oblong ivory tablet 73 00 logo
Refills remaining: 3 Expires: 05/30/2011

VICTOR'S PHARMACY
1625 N. Market Blvd., Sacramento, CA 95834
(555) 555-9810

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				 For: Blood Pressure
Hydralazine 25 mg				
Take 2 pills in the morning, 2 pills at noon, 2 pills in the evening, and 2 pills at bedtime.				Warnings May cause dizziness. May cause nausea. Take with food.
DOB: 03/19/1958 Provider: A. Mohan Filled: 05/31/2011 Refill: 3 Refills		Rx # 5483-3921-3345 NDC: 417-25529-00 Expires: 10/08/2011 120 Pills		
 Morning (6am-8am) 2 pills	 Noon (11am-1pm) 2 pills	 Evening (4pm-6pm) 2 pills	 Bedtime (9pm-11pm) 2 pills	LOGO SPACE PRXpharmacy Phone Number: 617-665-1000 90 Frasier Ave, Chattanooga, TN 27405 

English only label

Juan A. García Nevaro				 Para: La Presión (For: Blood Pressure)
Hydralazine 25 mg				
Tome 2 pastillas en la mañana, 2 pastillas al mediodía, y 2 pastillas en la tarde.				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 Lenado (filled): 05/31/2011 Rellene (refill): 3 Veces		Rx # 5483-3921-3345 NDC: 417-25529-00 Vence (expires): 10/08/2011 120 Pastillas (120 pills)		
 Mañana (6am-8am) 2 pastillas	 Mediodía (11am-1pm) 2 pastillas	 Tarde (4pm-6pm) 2 pastillas	 Acostarse (9pm-11pm)	LOGO SPACE PRXpharmacy Phone Number: 617-665-1000 90 Frasier Ave, Chattanooga, TN 27405 

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

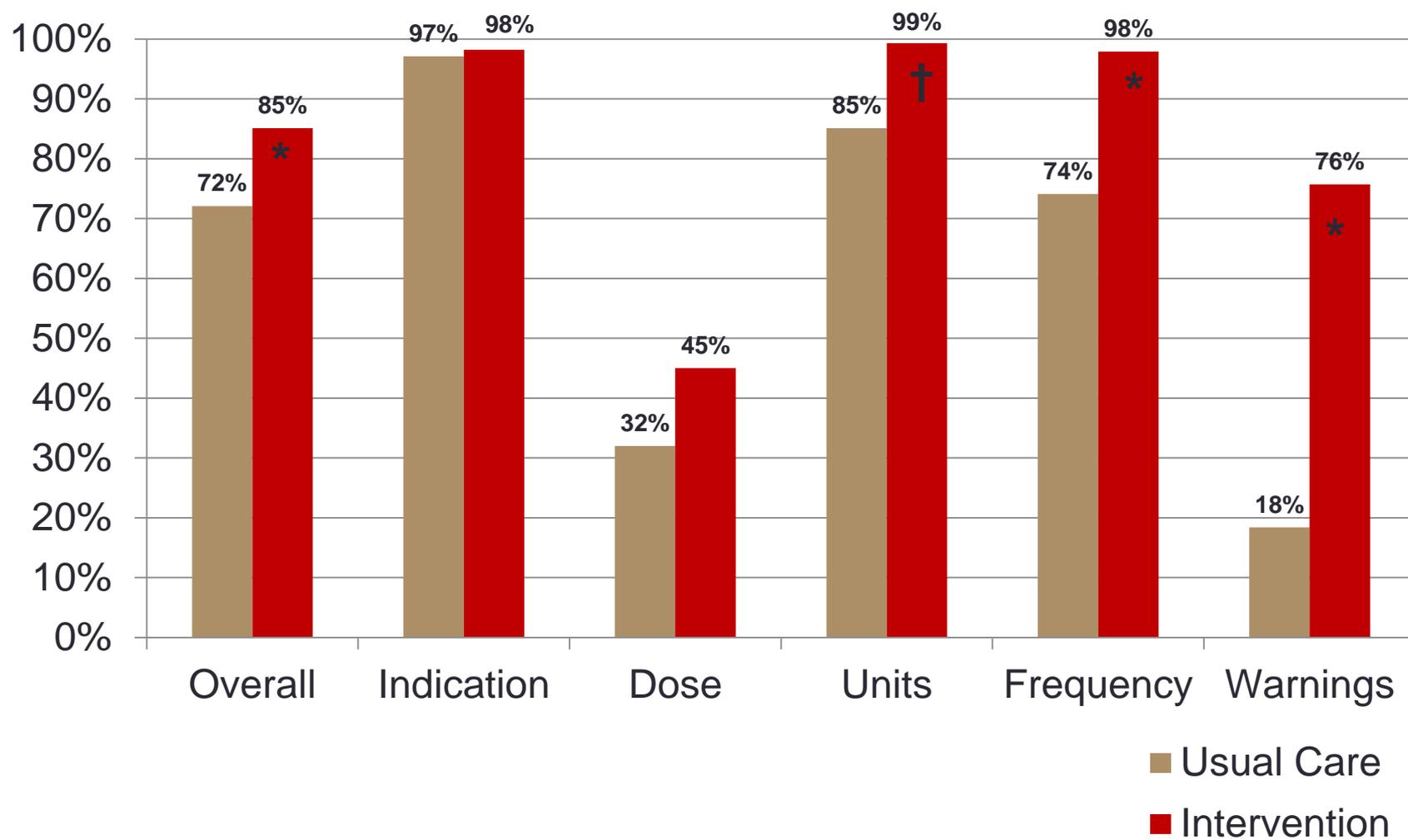
Follow-up, Outcomes

- 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 (%)	171 (67.1%)	157 (64.1%)
Black	78 (30.6%)	81 (33.1%)
Other	6 (2.4%)	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?