HEALTH POLICY

Evaluation of Language Concordant, Patient-Centered Drug Label Instructions

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BACKGROUND: Despite federal laws requiring language access in healthcare settings, most US pharmacies are unable to provide prescription (Rx) medication instructions to limited English proficient (LEP) patients in their native language.

OBJECTIVE: To evaluate the efficacy of health literacy-informed, multilingual Rx instructions (the ConcordantRx instructions) to improve Rx understanding, regimen dosing and regimen consolidation in comparison to standard, language-concordant Rx instructions.

DESIGN: Randomized, experimental evaluation.

PARTICIPANTS: Two hundred and two LEP adults speaking five non-English languages (Chinese, Korean, Russian, Spanish, Vietnamese), recruited from nine clinics and community organizations in San Francisco and Chicago.

INTERVENTION: Subjects were randomized to review Rx bottles with either ConcordantRx or standard instructions.

MAIN MEASURES: Proper demonstration of common prescription label instructions for single and multi-drug medication regimens. Regimen consolidation was assessed by determining how many times per day subjects would take medicine for a multi-drug regimen.

KEY RESULTS: Subjects receiving the ConcordantRx instructions demonstrated significantly greater Rx understanding, regimen dosing and regimen consolidation in comparison to those receiving standard instructions (incidence rate ratio [IRR]: 1.25, 95 % confidence interval [CI]: 1.06–1.48; $P=0.007$ for Rx understanding, IRR: 1.19, 95 % CI: 1.03–1.39; $P=0.02$ for regimen dosing and IRR: 0.76, 95 % CI: 0.64–0.90; $P=0.001$ for regimen consolidation). In most cases, instruction type was the sole, independent predictor of outcomes in multivariate models controlling for relevant covariates.

CONCLUSIONS: There is a need for standardized, multilingual Rx instructions that can be implemented in pharmacy practices to promote safe medication use among LEP patients. The ConcordantRx instructions represent an important step towards achieving this goal.

KEY WORDS: health literacy; prescription; medication; drug labeling; limited English proficiency.

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INTRODUCTION

Approximately 20 % of the United States population speaks a language other than English at home, and nearly 1 in 11 has limited English proficiency (LEP), defined as the ability to speak English less than ‘very well.’¹ Despite laws requiring language access in healthcare settings, research on pharmacy practice indicates that language barriers persist.^{2–6} Interpreters are rarely available to assist pharmacists in counseling LEP adults, half of pharmacies provide limited or no translation services for prescription (Rx) labels, and other print materials are seldom available in non-English languages.^{3,4,6} When Rx information is translated, it is often inaccurate or written at a reading level that is too difficult for many to understand.^{7,8}

Such language barriers constitute a serious patient safety concern.⁸ The 2006 Institute of Medicine report *Preventing Medication Errors* reported that poor comprehension of Rx instructions is a root cause of adverse drug events and other medication errors.⁹ Recently, studies among LEP adults have linked Rx misunderstanding to higher rates of adverse drug reactions, unsafe medication management and poor adherence.^{10–14}

Interventions are needed to improve comprehension of medication instructions among LEP adults and to promote language access in pharmacy. Lessons learned in the development of health literacy-informed, English-language instructions can guide this process. Wolf and colleagues previously tested the efficacy of patient-centered Rx instructions among English-speaking patients and found that more explicit instructions significantly improved comprehension, particularly among low literate patients.¹⁵ While language proficiency is a distinctly different risk factor, it is clearly associated with health literacy.¹⁶ Therefore, our team developed a set of multilingual Rx

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instructions, the ConcordantRx instructions, which incorporate the same health literacy ‘best practices’ as those used by Wolf and colleagues.¹⁷ Instructions were designed to be consistent with current pharmacy software and to comply with recent legislation requiring standardized, patient-centered labeling.

In this study, we conducted a randomized, experimental evaluation to test the efficacy of using the ConcordantRx instructions to improve comprehension among LEP individuals compared to standard instructions. As adults are increasingly taking multiple medications, we also examined the effect of the ConcordantRx instructions on regimen dosing and patients’ regimen consolidation.¹⁸

METHODS

Design Overview

A randomized, experimental evaluation was conducted in two cities (San Francisco and Chicago) among LEP adults speaking one of five languages (Chinese, Korean, Russian, Spanish and Vietnamese). For sample size calculations, we assumed a 60 % success rate for understanding standard instructions, based upon the study by Wolf et al.¹⁹ We then calculated the sample size necessary to detect a 20 % absolute difference between arms.²⁰

Study Settings

Six clinics and three community-based organizations served as recruitment sites. These organizations provided services for primarily low-income, urban populations. Multiple methods were used to recruit participants. These strategies included: 1) approaching patients in waiting rooms, 2) having healthcare professionals direct patients to a research assistant (RA) to learn more about the study and/or 3) announcing the study or distributing flyers during group classes or clinic visits. Individuals who expressed interest were screened by an RA. If eligible, the RA described the study, engaged the participant in the informed consent process and administered a one-hour interview in the participant’s language. Participants were compensated \$40. The Institutional Review Boards at Northwestern University and the University of California at San Francisco approved the study.

Participants

A total of 202 participants were recruited from August 2010 to March 2011 (n=100 in San Francisco, n=102 in Chicago; n=40 in Russian, Spanish, and Vietnamese, n=41 in Chinese and Korean). Participants were eligible if they: 1) were 18 to 85 years old, 2) spoke either Chinese (Cantonese or Mandarin), Korean, Russian, Spanish or

Vietnamese as their primary language, 3) had basic reading skills and visual acuity, demonstrated by the ability to read three kindergarten-level words aloud, 4) had taken a prescription medication in the past year and 5) were limited English proficient. Limited English proficiency was measured according to Karliner and colleagues validated criteria.²¹ Patients were asked how well they spoke English and in what language they prefer to receive their medical care. Individuals who spoke English *not well* or *not at all* were considered LEP, as well as those who spoke English *well* but preferred to receive medical care in their native language.

Randomization and Intervention

Research assistants used a random number list, created by the study team, to assign participants to receive either standard or ConcordantRx instructions. Instructions were printed on Rx labels and affixed to standard 40-dram vials.

Standard Instructions. Standard instructions were based upon those generated by a national chain pharmacy offering language assistance services. Instructions utilized typical terminology and a ‘times per day’ approach to explain when medicine should be taken (i.e. ‘TAKE TWO TABLETS TWICE DAILY’). They were written in all capitalized letters using sans serif font, as this was the standard practice for the pharmacy. In the few instances when the pharmacy system was unable to generate a translated instruction, a translator adapted the instruction by using the same terms and syntax as those used in other instructions generated by the pharmacy system.

Concordant Rx Instructions. ConcordantRx instructions were developed using health literacy ‘best practices.’ A complete description of the ConcordantRx instructions and their development has been published previously.²² In brief, the instructions ground medication-taking to four distinct time periods (i.e. morning, noon, evening, bedtime) to help patients understand when to take medicine (i.e. Take 2 pills in the morning and 2 pills at bedtime). They also utilize simpler terms (i.e. pill vs. tablet), lowercase and uppercase letters, and numeric characters (i.e. 2 vs. two). A committee-based approach was used to translate the Rx instructions.

Outcomes

Outcomes were: 1) Rx understanding, 2) regimen dosing and 3) regimen consolidation. Each was measured with a dosing tray, which consisted of 24 compartments, each labeled with one hour of the day. As some cultures use a

24 hour clock (i.e. 1400 vs. 2:00 pm) two different versions of trays were created. Participants were shown both and allowed to choose their preferred format. RAs demonstrated how to use the tray, then verified participant understanding of the tool.

To measure Rx understanding, RAs handed participants the dosing tray and a Rx bottle and stated, “Using this tray, please show me when you would take this medicine over the course of one full day.” The number of pills the participant placed in each of the 24 compartments was recorded by the RA. Participants could refer to the Rx label throughout the exercise. This process was repeated for a series of 5 individual labels. Similar procedures have been used in previous studies to assess Rx understanding.^{19,23,24}

To measure regimen dosing and consolidation, RAs handed participants five medication bottles simultaneously and asked them to imagine that they had been prescribed all five. Participants used the dosing tray to demonstrate how and when they would take all five medications on a typical day. The number of pills of each medication that the participant placed in each of the compartments was recorded by the RA.

Analysis

Rx understanding was coded dichotomously [0=incorrect, 1=correct]. Participants had to demonstrate the correct dose, frequency and spacing inferred by each instruction to be coded as ‘correct.’ Spacing criteria was developed by the research team with the assistance of two general internal medicine physicians. For medications that were dosed four times a day, doses were expected to be 3 to 7 hours apart, for medications taken three times a day, the doses were considered correct if they were 4 to 8 hours apart, and for medicines taken twice daily, the doses were expected to be 8 to 16 hours apart. A repeated measures analysis for binary data was conducted to test the hypothesis that LEP individuals will exhibit greater understanding of ConcordantRx instructions in comparison to standard. Rx understanding was modeled using a generalized linear model with a Poisson distribution and a log link function, allowing for the calculation of relative risk.

Since Rx understanding is a repeated measures factor with five levels, a generalized estimating equation approach was used to accommodate within-participant correlation. Study site, language, sex, and education were included in the model as either recruitment was stratified based upon those criteria, there was a statistically significant difference between study arms by this characteristic, or it was a variable of interest.

Regimen dosing was coded as a count variable representing the number of medications that the participant correctly dosed out of a five drug regimen. Participants had to

demonstrate the correct dose, frequency and spacing inferred by the Rx instruction. Regimen consolidation was also coded as a count variable. Its value was equivalent to the number of compartments used in the tray during the regimen dosing exercise. This was intended to represent the number of times per day that a participant would take medication.

Multivariable, negative binomial regressions were conducted to determine whether instruction type was independently associated with regimen dosing or consolidation. For consolidation, only those participants who demonstrated a correct understanding of each medication’s dosing frequency were included in analyses (n=116). This was essential to ensure that individuals would not be classified as consolidating their regimen when in fact they merely misunderstood the dosing frequency. Study site, language, sex, and education were included in the model. All analyses were performed using STATA version 10 (College Station, TX).

RESULTS

A total of 364 adults were approached or expressed interest in the study. Thirty-three were ineligible, 128 declined participation and 203 were randomized and initiated the study interview. 202 completed the entire interview and were included in analyses. Table 1 presents the sample characteristics, stratified by arm. Participants were older (mean age 63.6), from low income households and had lived in the US for over a decade. Medication use was common, with participants taking an average of 4.5 medications (median 4.0, interquartile range [IQR]: 2.0–

Table 1. Characteristics of Study Sample, Stratified by Instruction Type

Variable	All Participants (n=202)	Label Type		P
		Standard (n=100)	ConcordantRx (n=102)	
Age, Mean (SD)	63.6(0.91)	63.6(1.1)	63.5(1.4)	0.62
Male, %	37.8	31.0	44.6	0.05*
Years of Education, %				0.42
< 9	19.8	23.0	16.7	
9–11	14.4	11.0	17.7	
12 or GED	29.2	26.0	32.4	
Some College	14.9	16.0	13.7	
≥ College Graduate	21.8	24.0	19.6	
Income				0.68
< \$10,000	44.7	47.8	41.8	
\$10,000 to \$19,999	36.7	35.6	37.8	
≥\$20,000	18.6	16.7	20.4	
# Rx Drugs Taken, Mean (SD)	4.5 (0.2)	4.5(0.3)	4.6(0.4)	0.92
Years in US, Mean (SD)	17.0 (0.7)	16.9 (1.0)	17.0 (1.0)	0.91

SD = standard deviation, *p≤ 0.05

6.0). Education level varied by linguistic group; on average, Spanish-speaking participants had low levels of education while Russian-speakers were college graduates. The only statistically significant difference found between the arms in terms of participant characteristics was sex. A greater percentage of the ConcordantRx arm was male in comparison to the standard arm (44.6 %, vs. 31.0 %, $p=0.05$).

Rx Understanding

Overall, 74.7 % of Rx instructions were understood by participants. Rates of comprehension differed significantly for standard versus ConcordantRx instructions (66.0 % vs. 83.0 %, $P>0.0001$). Approximately one-third of patients understood all five instructions they were shown, another third understood four instructions, and the remaining third understood fewer than four. An examination of each Rx instruction and its common misinterpretations will be reported elsewhere. In bivariate analyses, a positive, significant association was found between education and Rx understanding ($P<0.001$; Table 2). There were no

significant differences in Rx understanding by any other variables.

In multivariable analyses, receipt of the ConcordantRx label was found to be a significant, independent predictor of Rx understanding (relative risk ratio [RR]: 1.25, 95 % confidence interval [CI]: 1.06–1.48; $P=0.007$; Table 3). No other variables predicted Rx understanding and no interaction was found between education and study arm on understanding.

Regimen Dosing

Regimen dosing ability differed significantly by study arm ($P<0.0001$); the median number of medications dosed correctly was 3.0 (IQR: 2.0–4.0) for individuals receiving the standard instructions versus 4.0 (IQR: 3.0–5.0) for individuals receiving the ConcordantRx instructions (Table 2). Overall, 24.3 % of participants dosed all five medications correctly (14.0 % in standard arm vs. 34.3 % in ConcordantRx arm, $P=0.001$). In bivariate analyses, participants

Table 2. Rx Understanding, Regimen Dosing and Consolidation by Participant Characteristics

Variable	% Correct Understanding	P	# Regimen Correct Median (IQR)	P	# Consolidate Median (IQR)	P
Label Type		<0.0001*		<0.0001*		<0.0001*
Standard	66.0		3.0 (2.0–4.0)		6.0 (5.0–9.0)	
ConcordantRx	83.1		4.0 (3.0–5.0)		4.0 (4.0–5.0)	
Education		0.001*		0.04*		0.79
< 9	62.8		3.5 (2.0–4.0)		5.0 (4.0–8.0)	
9–11	75.9		4.0 (3.0–5.0)		5.0 (4.0–7.5)	
12 or GED	76.2		4.0 (3.0–5.0)		5.0 (4.0–6.0)	
Some College	78.7		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
≥ College Graduate	79.9		4.0 (3.0–5.0)		4.5 (4.0–6.5)	
Primary Language		0.52		0.01*		0.15
Chinese	78.5		4.0 (3.0–5.0)		4.0 (4.0–5.0)	
Korean	71.2		4.0 (3.0–4.0)		5.5 (4.0–7.0)	
Russian	75.9		4.0 (3.0–5.0)		5.0 (4.0–7.0)	
Spanish	73.5		4.0 (3.0–5.0)		5.0 (4.0–8.0)	
Vietnamese	74.2		3.0 (3.0–4.0)		5.0 (4.0–6.0)	
Sex		0.19		0.80		0.005*
Female	73.2		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
Male	77.0		4.0 (3.0–5.0)		4.0 (4.0–5.0)	
Income		0.21		0.24		0.97
< \$10,000	72.7		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
\$10,000 to \$19,999	76.7		4.0 (3.0–4.0)		5.0 (4.0–6.0)	
≥\$20,000	78.9		4.0 (3.0–5.0)		4.5 (4.0–7.0)	
Study Location		0.10		0.81		0.76
Chicago	72.4		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
San Francisco	77.0		4.0 (3.0–4.5)		5.0 (4.0–6.0)	
Age		0.41		0.19		0.87
18 to 54	73.7		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
55 to 64	78.3		4.0 (3.0–5.0)		5.0 (4.0–7.0)	
65 to 74	73.4		3.5 (3.0–4.0)		5.0 (4.0–6.0)	
75 to 85	72.4		4.0 (3.0–5.0)		4.0 (4.0–6.0)	
# Rx Drugs Taken		0.15		0.51		0.58
0 to 2	78.8		4.0 (4.0–4.0)		5.0 (4.0–7.5)	
3 to 5	71.1		4.0 (3.0–4.0)		4.0 (4.0–6.0)	
6 to 9	74.5		4.0 (2.0–5.0)		5.0 (4.0–7.0)	
10 or more	73.7		4.0 (3.0–4.0)		5.0 (4.0–6.0)	
Years in US		0.09		0.62		0.46
0 to 9	80.4		4.0 (3.0–4.0)		4.0 (4.0–5.0)	
10 to 19	73.0		4.0 (3.0–4.0)		5.0 (4.0–7.0)	
20 or more	72.4		4.0 (2.0–5.0)		5.0 (4.0–7.0)	

IQR=Interquartile Range, * $p\leq0.05$

Table 3. Multivariate Model of Correct Rx Understanding

Variable	Correct Rx Understanding		
	RR	95 % CI	P
Instruction Type	—	—	—
Standard	—	—	—
ConcordantRx	1.25	(1.06–1.48)	0.007*
Site	—	—	—
San Francisco	—	—	—
Chicago	0.96	(0.82–1.13)	0.64
Language	—	—	—
Chinese	—	—	—
Korean	0.92	(0.71–1.18)	0.51
Russian	0.88	(0.66–1.18)	0.41
Spanish	0.98	(0.76–1.26)	0.85
Vietnamese	0.98	(0.76–1.25)	0.85
Education	—	—	—
< 9th grade	0.75	(0.55–1.01)	0.06
9th to 11th grade	0.86	(0.63–1.18)	0.35
12th grade or GED	0.88	(0.67–1.16)	0.36
Some College	0.96	(0.72–1.27)	0.76
College Graduate	—	—	—
Sex	—	—	—
Female	—	—	—
Male	0.99	(0.83–1.18)	0.90

RR=Relative Risk Ratio adjusted for all variables shown; CI=Confidence Interval, * $p \leq 0.05$

with lower levels of education and individuals speaking Vietnamese were significantly less likely to dose medications in the regimen correctly. There were no significant differences in regimen dosing ability by any other variables.

In multivariable analyses (Table 4), receipt of the ConcordantRx instructions and an education of less than 9th grade were the only significant, independent predictors of Rx regimen dosing ability (incidence ratio rate [IRR]: 1.19, 95 % confidence interval [CI]: 1.03–1.39; $P = 0.02$ for instruction type; IRR: 0.75, 95 % CI: 0.57–

0.99; $P = 0.04$ for less than 9th grade education). No other participant characteristics were significantly associated with the outcome.

Regimen Consolidation

Consolidation also differed significantly by study arm ($P < 0.0001$). The median number of times daily that individuals dosed medication in the regimen was 6.0 for individuals receiving the standard instructions (IQR: 5.0–9.0) versus 4.0 for individuals receiving the ConcordantRx instructions (IQR: 4.0–5.0; Table 2). Bivariate analyses show a statistically significant difference in consolidation by sex, with men being more likely to consolidate medications than women (median times dosed 4.0 vs. 5.0, respectively, $p = 0.005$). There were no significant differences in consolidation by any other variables.

In multivariable analyses, receipt of the ConcordantRx label was found to be the only significant, independent predictor of regimen consolidation (IRR: 0.76, 95 % Confidence Interval [CI]: 0.64–0.90; $P = 0.001$; Table 5).

DISCUSSION

This study sought to address the problem of poorly understood Rx instructions among LEP adults by developing and testing a set of health literacy-informed, multilingual Rx instructions. Study results found that LEP adults who received ConcordantRx instructions were significantly more likely than those who received standard instructions to

Table 4. Multivariate Model of Correct Rx Regimen Dosing

Variable	Correct Dosing		
	IRR	95 % CI	P
Instruction Type	—	—	—
Standard	—	—	—
ConcordantRx	1.19	(1.03–1.39)	0.02*
Language	—	—	—
Chinese	—	—	—
Spanish	0.91	(0.72–1.14)	0.42
Russian	0.79	(0.60–1.03)	0.08
Korean	0.93	(0.74–1.16)	0.52
Vietnamese	0.81	(0.64–1.03)	0.08
Site	—	—	—
San Francisco	—	—	—
Chicago	1.04	(0.90–1.21)	0.59
Education	—	—	—
< 9th grade	0.75	(0.57–0.99)	0.04*
9th to 11th grade	0.87	(0.65–1.16)	0.34
12th grade or GED	0.82	(0.64–1.06)	0.13
Some College	0.90	(0.69–1.17)	0.41
College Graduate	—	—	—
Sex	—	—	—
Female	—	—	—
Male	0.95	(0.81–1.12)	0.57

IRR=Incidence Rate Ratio adjusted for all variables shown; CI=Confidence Interval, * $p \leq 0.05$

Table 5. Multivariate Model of Rx Regimen Consolidation

Variable (n=116)	Regimen Consolidation		
	IRR	95 % CI	P
Instruction Type	—	—	—
Standard	—	—	—
ConcordantRx	0.76	(0.64–0.90)	0.001*
Language	—	—	—
Chinese	—	—	—
Spanish	1.26	(0.98–1.63)	0.07
Russian	1.19	(0.88–1.60)	0.26
Korean	1.17	(0.93–1.47)	0.19
Vietnamese	1.16	(0.89–1.50)	0.27
Site	—	—	—
San Francisco	—	—	—
Chicago	1.00	(0.86–1.17)	0.96
Education	—	—	—
< 9th grade	1.01	(0.74–1.38)	0.94
9th to 11th grade	1.05	(0.78–1.41)	0.74
12th grade or GED	1.02	(0.77–1.33)	0.91
Some College	0.99	(0.74–1.34)	0.96
College Graduate	—	—	—
Sex	—	—	—
Female	—	—	—
Male	0.89	(0.74–1.08)	0.24

IRR=Incidence Rate Ratio adjusted for all variables shown; CI=Confidence Interval, * $p \leq 0.05$

demonstrate how to take a single Rx medication appropriately. LEP adults who received ConcordantRx instructions were also significantly more likely to dose more medications correctly in a multi-drug regimen and to simplify medication use by consolidating when pills would be taken. Differences in understanding found in this study were remarkably similar to those found among English speakers in a previous study by Wolf and colleagues, where 69 % of standard labels were understood versus 91 % of the health-literacy informed instructions ($p < 0.001$).¹⁵

These findings could have implications for actual medication use. Patients who have a greater understanding of medication instructions may be more likely to take drugs safely, reducing the potential for preventable adverse drug events.^{9,25} Additionally, evidence suggests that patients with simplified regimens are more likely to be adherent.^{10,26} While our results may be tempered by the use of hypothetical medications during study assessments, the comprehension rates reported are for two types of Rx instructions written in participants' native language. As half of this sample (49.5 %) reported never receiving Rx labels written in their primary language for their actual medications, it is likely that our results underestimate the effect ConcordantRx instructions could have in actual use.

Despite the clear benefits of the ConcordantRx instructions, results indicate that additional interventions may be necessary to promote medication management. Only a quarter of participants were able to demonstrate correct dosing of all five medications in the regimen. This is particularly disturbing given that participants were taking an average of four drugs in actual use. This underscores the significant self-management demand associated with using prescription medications and indicates that changes in Rx instructions alone may not be sufficient. It is likely that additional patient counseling or other strategies will be necessary to help LEP adults manage complex regimens.

As the use of multiple drugs becomes increasingly common in the US, there is an imminent need for viable, policy and practice-level solutions to help patients safely take their medications.¹⁸ The ConcordantRx instructions were designed in a manner to support current pharmacy software programs with minimal disruption to practice. Results from this study provide support for the use of ConcordantRx instructions to promote comprehension of Rx directions, improve regimen dosing and increase consolidation among LEP adults. Studies are needed, however, to identify the best methods of implementing these Rx instructions in pharmacy practices. Additionally, the instructions should be evaluated in an actual use setting, to determine if their use can impact medication-taking behavior, as this study focused solely on comprehension. Currently, an Agency for Healthcare Research and Quality-funded study is being conducted to test the effect of the Spanish-language ConcordantRx instructions in actual use among Spanish-speaking patients in Northern Virginia. If successful, the other ConcordantRx instructions should also

be tested and efforts should be made to expand to other commonly spoken languages in the US.

There are limitations to this study that should be noted. Participants were recruited using convenience sampling. On average, study participants had lived in the United States for over a decade. While this affects the generalizability of our results, it is likely to be representative of those LEP adults who are older and taking multiple medications. Also, participants were not asked if a caregiver assisted them in taking medications. It is possible that individuals receiving assistance would have less difficulty taking to their own Rx drugs correctly. The standard instructions evaluated in this study were based upon those produced by one pharmacy's translation software. While it is possible that results would have differed if another pharmacy's instructions had been used, we chose this pharmacy because it could generate instructions in multiple languages, thereby producing a set of uniform directions to serve as a comparison group. Regardless, some instructions may have been poorly translated or vague, as evidence suggests is common in current pharmacy practice.^{7,27} Finally, this study only examined participant understanding and dosing of hypothetical medications; it did not examine actual medication use or behaviors.

Federal laws are in place requiring language access in healthcare settings.^{2,5} At this time, California is the first and only state to mandate that pharmacies utilize a standardized, patient-centered Rx label through a bill passed in October 2007. The California Patient Medication Safety Act enlisted the California Board of Pharmacy to create a set of requirements on the design and content of Rx labels. The purpose of this bill, implemented in 2011, was to improve comprehension of Rx instructions by ensuring that the information provided is grounded in the evidence from health literacy research. Unfortunately, language concordance was not included as a requirement. Regardless, the ConcordantRx instructions comply with the recommendations set forth in this bill in terms of patient-centered labeling and can be used to fulfill California's labeling requirements for the LEP community. The California State Board of Pharmacy has also agreed to post the ConcordantRx instructions online to promote their use in pharmacy practices throughout the state.

As demonstrated by this study, the language-concordant Rx instructions currently generated by pharmacies are suboptimal. There is a clear need for standardized, multilingual Rx instructions that can be implemented in pharmacy practice. The ConcordantRx instructions represent an important, positive step towards achieving this goal and offering a standard 'best practice' that enhances the reliability of Rx instructions and eliminates pharmacy variability in translation.

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Conflict of Interest: The authors declare that they do not have a conflict of interest.

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