

## Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency

Stacy Cooper Bailey, PhD, MPH  
Romana Hasnain-Wynia, PhD  
Alice Hm Chen, MD, MPH  
Urmimala Sarkar, MD, MPH  
Alisu Schoua-Glusberg, PhD  
Lee A. Lindquist, MD, MPH, MBA  
Dean Schillinger, MD  
Michael S. Wolf, PhD, MPH

*Summary:* This article describes the development of a set of patient-centered prescription medication instructions and their translation into Chinese, Korean, Russian, Spanish, and Vietnamese. Challenges and lessons learned from this process are reported to inform future efforts to develop easy-to-understand, multilingual materials for use in health care settings.

*Key words:* Translation, prescription, medication, cross-cultural.

**M**ore than 24 million people living in the United States have limited English proficiency (LEP), defined as the ability to speak English less than very well.<sup>1</sup> Many federal, state and local laws require language access in health care, or the ability to attain comprehensible and meaningful health services and materials in one's primary language.<sup>2,3</sup> Despite these requirements, research indicates language barriers persist in pharmacy practice.<sup>4-8</sup> Interpreters are rarely available to aid pharmacists in counseling

---

*STACY COOPER BAILEY is an Assistant Professor of Medicine in the Division of General Internal Medicine at Feinberg School of Medicine, Northwestern University (NWU). ROMANA HASNAIN-WYNIA is an Associate Professor and Director of the Center for Healthcare Equity in the Institute for Healthcare Studies at Feinberg School of Medicine, NWU. ALICE CHEN is an Assistant Professor of Medicine in the Division of General Internal Medicine at the University of California at San Francisco's (UCSF) San Francisco General Hospital. URMIMALA SARKAR is Assistant Professor of Medicine in the Division of General Internal Medicine at UCSF, and the UCSF Center for Vulnerable Populations, San Francisco General Hospital. ALISU SCHOUA-GLUSBERG is a Principal at Research Support Services Inc. LEE LINDQUIST is an Assistant Professor of Medicine in the Division of General Internal Medicine at Feinberg School of Medicine, NWU. DEAN SCHILLINGER is a Professor of Medicine in Residence, Chief of the Division of General Internal Medicine at UCSF, and the Director of the UCSF Center for Vulnerable Populations, San Francisco General Hospital. MICHAEL WOLF is an Associate Professor of Medicine and Associate Division Chief-Research in the Division of General Internal Medicine at Feinberg School of Medicine, NWU. Please address correspondence to Stacy Cooper Bailey, PhD, MPH, Assistant Professor of Medicine, Division of General Internal Medicine, Northwestern University, 750 N. Lake Shore Drive, 10th Floor, Chicago, IL 60611; stacy-bailey@northwestern.edu.*

LEP patients, prescription (Rx) medication instructions are frequently unavailable in non-English languages and Rx materials are often poorly translated into other languages.<sup>4-8</sup> These barriers may explain observed difficulties in Rx medication use among LEP patients.<sup>9-11</sup> LEP adults are significantly more likely than their English-proficient counterparts to have poorer understanding of Rx instructions and to report an adverse drug reaction due to this misunderstanding.<sup>9,10</sup> Low health literacy, along with LEP, negatively affects Rx understanding and use in this population.<sup>10,11</sup>

While research has documented poor language access in pharmacies and its associated consequences, few solutions have been offered or evaluated.<sup>4-8</sup> A first step would be to develop easy-to-understand Rx instructions in multiple languages. This is essential, as Rx labels are often the most frequently used source of Rx information for patients.<sup>12</sup> The purpose of this article is to describe the development of a set of patient-centered, multilingual Rx instructions and to report the challenges and lessons learned from this process.

## The Development Process

Through the ConcordantRx study, a project funded by The California Endowment, a set of patient-centered Rx instructions were developed for Chinese, Korean, Russian, Spanish, and Vietnamese-speaking populations in the U.S. This project was funded in response to the California Patient Medication Safety Act, which called the California Board of Pharmacy to design a standardized, easy-to-understand Rx label for all prescription drugs dispensed to patients in California.<sup>13</sup> To be *patient-centered*, our instructions took into account patient 1) literacy, 2) language, and 3) culture. The process of developing the ConcordantRx instructions in accordance with these domains is described below.

*Literacy.* The first step of the ConcordantRx study was to develop a set of Rx instructions appropriate for those with limited health literacy. LEP individuals are more likely than English-proficient adults to have low health literacy, defined as a limitation in “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”<sup>11</sup>[p.32] To address this, researchers created Rx instructions by incorporating health literacy best practices.<sup>12</sup> Specifically, Rx instructions were written in Arial (a sans-serif font), used numbers instead of the written equivalent (e.g., 2 instead of *two*), and were written in sentence format, with only the first letter capitalized. When possible, simpler terms were utilized instead of less familiar or difficult terms (e.g., *pill* instead of *tablet*).

In terms of content, the ConcordantRx instructions provided explicit guidance on when to take medications. This was accomplished by associating medication-taking with four distinct time periods (*morning, noon, evening, and bedtime*), also known as *grounding* the instructions. This recommendation is supported by prior research. Davis and colleagues found that patients were significantly more likely to understand the instruction *Take 2 pills in the morning and 2 pills in the evening* when compared with *Take two pills twice daily, Take two pills at 8:00 am and 8:00 p.m. or Take two pills every twelve hours*.<sup>14</sup> Grounded instructions were separated *via carriage returns* to improve comprehension (e.g., *Take 2 pills in the morning* is on a separate line from



<b>JANE SMITH</b> 444 MAIN ST., CHICAGO, IL 60611		<b>PHARMACY</b>  10 MAIN ST, CHICAGO, IL 60601	
<b>ZOPALINE 50MG TABLETS</b>			
<b>TAKE TWO TABLETS TWICE DAILY</b>			
RX	<b>0664978-55528</b>	YOUR DOCTOR	
DATE	07/01/10	QTY	<b>50</b>
USE BEFORE	07/01/11	ONE REFILL BEFORE 12/31/10	

Figure 1. Standard Rx label.

2 pills at bedtime). Figures 1 and 2 provide examples of standard Rx versus patient-centered Rx instructions.

*Language.* The next step was to translate the Rx instructions into Chinese, Korean, Russian, Spanish and Vietnamese *via a committee approach*. In this method, three bilingual, bicultural translators each independently translated the English-language Rx instructions into another language.<sup>15</sup> The translators then convened and discussed the instructions as a team and, with the help of a moderator, achieved consensus on the most appropriate translations. The involvement of three translators allowed for multiple viewpoints and diverse skills. The discussion provided an opportunity to identify and discuss discrepancies as a team. This process was standardized across all five study languages.

*Culture.* Beyond language, the culture of the target populations was taken into account

<b>Jane Smith</b> 444 Main St., Chicago, IL 60611		<b>PHARMACY</b>  10 MAIN ST, CHICAGO, IL 60601	
<b>Zopaline 50mg Tablets</b>			
<b>Take 2 pills in the morning and 2 pills at bedtime.</b>			
Rx	<b>0664978-55528</b>	YOUR DOCTOR	
DATE	07/01/10	Qty	<b>50</b>
USE BEFORE	07/01/11	One Refill Before 12/31/10	

Annotations:

- Sentence format: points to the instruction box.
- Numeric characters: points to the numbers '2' in the instruction.
- Simpler terms: points to the instruction.
- Grounding: points to the word 'pills'.
- Carriage return: points to the line break in the instruction.

Figure 2. Patient-centered Rx label.

when translating the ConcordantRx instructions. There were limited opportunities to culturally adapt the Rx instructions due to their necessary brevity. Nevertheless, translators raised issues related to cultural distinctions that could affect the way in which Rx instructions were understood. Translators reported that using terms such as “at breakfast” could be problematic, as many immigrants are more accustomed to eating at times that are consistent with meal times in their countries of origin, or may be adherent to religious customs that involve fasting for periods of time. Therefore, the translators suggested avoiding any mention of meals in directions..

## Challenges Encountered

Despite such efforts to address literacy, language, and culture, a number of challenges arose. These can be broadly categorized as difficulties related to 1) finding equivalent terms, 2) ensuring similar reading levels, 3) accounting for regional differences, and 4) managing changes in label spacing and formatting.

**Finding equivalent terms.** One of the most common challenges in translating Rx instructions was in determining equivalent words for the terms *morning*, *noon*, *evening*, and *bedtime*. *Evening* was a particularly difficult word to translate, as few terms exist referring exclusively to the desired time frame (approximately 4:00–6:00 p.m.). For example, the word *tarde* in Spanish was initially selected by the Spanish translators; however, during the committee discussion it was concluded that *tarde* could refer to anytime after 12:00 p.m. until nightfall. The committee ultimately selected the term *atardecer*, which refers to dusk. While the time frame referred to by this term could vary according to season, the committee felt it would be more likely to encompass the hours of 4:00–6:00 p.m.

**Ensuring similar reading levels.** As the purpose of the ConcordantRx Study was to create Rx instructions that could be easily understood by LEP patients regardless of literacy level, efforts were made to ensure that the translated Rx instructions were not written at too high a reading grade level. This was especially challenging for the Chinese translation team when attempting to translate the word *evening*. In considering various terms, the translators concluded that the term 黃昏時段, which translates into English as *the time when the sky turns a misty yellow*, was the closest to 4:00–6:00 p.m. Despite the accuracy of the term, it was ultimately discarded due to concerns about its comprehensibility for those with limited health literacy. Translators felt the term was predominantly used in literary works and would be difficult for many Chinese patients. Alternative terms were discussed, and ultimately a phrase used to refer to *the evening news* on Chinese television broadcasts was selected. As such, it was determined to be a more easily understood term for Chinese patients across literacy levels.

**Accounting for dialects and regional differences.** One language can often have a number of dialects and be spoken by people with different cultural heritages. Such diversity made it important to use words and phrases that were common across dialects. Translators from diverse backgrounds were included on the committees and each instruction was reviewed for cross-dialectal comprehensibility. The Chinese instructions posed the greatest number of challenges in terms of regional differences. While the Chinese written language is the same across all Chinese dialects, there are neverthe-

less some characters that are more commonly used in one dialect than in another.<sup>16</sup> As Mandarin and Cantonese are the most commonly spoken varieties of Chinese in the U.S., particular efforts were made to include characters that were easily understood by individuals speaking these varieties.<sup>16</sup>

**Resulting changes in label spacing and formatting.** The ConcordantRx instructions were designed to be easily implemented into current pharmacy practice. Rx instructions had to fit within the space available on labels currently used by U.S. pharmacies. This was often difficult with translated instructions as they were frequently longer than their English equivalent (e.g., *bedtime vs. la hora de acostarse*). To overcome this obstacle, a different sans-serif font was selected and font size was reduced to 10 point. While a larger font would have been preferable, this reduced font size is more common in actual practice than the font previously considered by the research team.<sup>17</sup>

## Lessons Learned

Through this process, a set of patient-centered Rx instructions were created in five languages with a focus on literacy, language and culture. The ConcordantRx Study revealed six key lessons learned that may be beneficial to future efforts to translate and culturally adapt materials.

1. *Put aside an appropriate amount of time and resources.* Accurate translations are more likely to be produced *via* an iterative process that involves the time and effort of multiple people and therefore higher costs.<sup>15</sup> Through the committee approach, multiple perspectives were incorporated into the translations of Rx instructions; coordinating times to meet, holding discussions and documenting translations took time and effort despite the brevity of the instructions themselves.
2. *Involve a diverse set of experienced translators to promote universality.* Most languages have regional variations and are associated with many diverse cultures. Including translators from different regions on a committee helps ensure that translations will be appropriate for a broad set of individuals. Translators should also be chosen based upon their language and translation skills, their ability to work as a team, and experience with the immigrant community in question.
3. *Include a moderator and subject matter expert in discussions.* Moderators are essential to keeping discussions on track and to ensuring the involvement of all translators. Including a subject matter expert, for example a health professional or researcher, can provide information on the intent of the translated text.
4. *Take a broad approach to translation instead of seeking direct English equivalence.* Finding words, terms, or phrases in non-English languages that exactly mirror those in English is frequently a challenge. Having such restrictive standards may actually diminish comprehension of the translated text. It is better to think of broad messages that need to be transmitted and to work with translators to come up with the best ways to phrase this information. Consider using colloquial terms when appropriate.
5. *Consider the final product.* The ConcordantRx instructions were designed to be implemented in current pharmacy practice. It was therefore necessary to ensure

that instructions could fit on a standard Rx label. Other projects are likely to have space parameters that should be considered during translation. Failing to recognize these limitations could result in translations that are unsuitable for the final product.

6. *Pilot-test all translations among the target population.* Even given best efforts, it is necessary to pilot-test translations among the target population. We recently interviewed 200 LEP patients in Chicago and San Francisco to evaluate the accuracy of ConcordantRx instructions. Findings will be used to refine instructions further.

**Limitations.** The methodology described above is both time- and cost-intensive. It may not be feasible for others to replicate. Given the design of our study, we elicited opinions on the ConcordantRx instructions from community members during an extensive pilot-testing phase. We believe it was essential to develop literacy-appropriate, professionally translated, culturally competent instructions prior to community member involvement, and strongly recommend iterative pilot-testing and revision. However, should others have limited opportunities for pilot-testing and revisions, they may want to involve community members earlier in the translation process.

**Conclusions.** Despite the importance of Rx labels, little attention has been placed on the process and potential pitfalls of translating Rx instructions for non-English speakers. Through a focus on language, literacy and culture, the ConcordantRx Study constitutes a first step towards developing patient-centered, multilingual Rx instructions for use within current pharmacy labeling practices. Findings from the process of improving, translating, and adapting Rx instructions can be used to better inform the development of other patient materials, within pharmacy or in other health care settings.

## Acknowledgment

Funding Source: California Endowment; Agency for Healthcare Research and Quality (AHRQ R01 HS019435; PI: Wolf)

## Notes

1. Shin HB, Kominski RA. Language use in the United States: 2007. Washington, DC: U.S. Census Bureau, 2010. Available at: <http://www.census.gov/prod/2010pubs/acs-12.pdf>.
2. Chen AH, Youdelman MK, Brooks J. The legal framework for language access in health-care settings: Title VI and beyond. *J Gen Intern Med.* 2007 Nov;22(Suppl 2):362–7.
3. Youdelman MK. The medical tongue: U.S. laws and policies on language access. *Health Aff (Millwood).* 2008 Mar–Apr;27(2):424–33.
4. Bradshaw M, Tomany-Korman S, Flores G. Language barriers to prescriptions for patients with limited English proficiency: a survey of pharmacies. *Pediatrics.* 2007 Aug; 120(2):e225–35.
5. Bailey SC, Pandit AU, Curtis L, et al. Availability of Spanish prescription labels: a multi-state pharmacy survey. *Med Care.* 2009 Jun;47(6):707–10.
6. Sharif I, Tse J. Accuracy of computer-generated, Spanish-language medicine labels. *Pediatrics.* 2010 May;125(5):960–5.

7. Muzyk AJ, Muzyk TL, Barnett CW. Counseling Spanish-speaking patients: Atlanta pharmacists' cultural sensitivity, use of language-assistance services, and attitudes. *J Amer Pharm Assoc* (2003). 2004 May-Jun;44(3):366-74.
8. Dilworth TJ, Mott D, Young H. Pharmacists' communication with Spanish-speaking patients: a review of the literature to establish an agenda for future research. *Res Social Adm Pharm*. 2009 Jun;5(2):108-20.
9. Wilson E, Chen AH, Grumbach K, et al. Effects of limited English proficiency and physician language on health care comprehension. *J Gen Intern Med*. 2005 Sep;20(9):800-6.
10. Leyva M, Sharif I, Ozuah PO. Health literacy among Spanish-speaking Latino parents with limited English proficiency. *Ambul Pediatr*. 2005 Jan-Feb;5(1):56-9.
11. Institute of Medicine. Health literacy: a prescription to end confusion. Washington, DC: National Academy Press, 2004.
12. Institute of Medicine. Standardizing medication labels: confusing patients less. Workshop summary. Washington, DC: National Academy Press, 2008.
13. California State Board of Pharmacy. Title 16-1707.5. Patient-centered labels on medication containers. Available at: [http://www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_proposed\\_text.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_proposed_text.pdf).
14. Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug instructions. *J Gen Intern Med*. 2009 Jan;24(1):57-62.
15. Harkness JA, Pennell BE, Schoua-Glusberg A. Survey questionnaire translation and assessment. In: Presser S, Rothgeb JM, Couper MP, et al., eds. *Methods for testing and evaluating survey questionnaires*. New Jersey: Wiley, 2004.
16. Tu SP, Yip MP, Chun A, et al. Development of intervention materials for individuals with limited English proficiency: lessons learned from "Colorectal Cancer Screening in Chinese Americans." *Med Care*. 2008 Sep;46(9 Suppl 1):S51-61.
17. Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. *Arch Intern Med*. 2007 Sep 10;167(16):1760-5.