Improving Medication Understanding Among Latinos Through Illustrated Medication Lists

Arun Mohan, MD, MBA; M. Brian Riley, MA; Brian Schmotzer, MS; Dane R. Boyington, PhD; and Sunil Kripalani, MD, MSc

ABSTRACT

Objectives
Strategies are needed to improve medication management among vulnerable populations. We tested the effect of providing illustrated, plain-language medication lists on medication understanding, adherence, and satisfaction among Latino patients with diabetes in a safety net clinic.

Study Design
Randomized controlled trial.

Methods
Intervention patients received a PictureRx illustrated medication list that depicted the medication, indication, and dosing instructions, accompanied by plain language bilingual text. Usual care patients received a written list of their medications in their preferred language, with indication but no images. Outcomes were assessed by telephone approximately 1 week later. The Medication Understanding Questionnaire measured patients' ability to report the indication, strength, dosing, and frequency for their medication regimen. Self-reported adherence and satisfaction were secondary outcomes. Analysis was performed by intention to treat.

Results
Of 200 enrolled participants, 197 (98.5%) completed follow-up. Most (71%) had not graduated high school, and 59% had low health literacy. Patients randomized to illustrated medication instructions had better overall understanding of their medications (P <.001), including greater ability to report the drug indication (P <.01), strength (P <.05), dosing (P <.01), and frequency of administration (P <.001). Self-reported adherence did not differ significantly between study groups. Patients who received illustrated medication lists were very satisfied with them.

Conclusions
In this randomized controlled trial, patients who received illustrated, plain-language medication lists demonstrated significantly greater understanding of their medication regimen. Such tools have the potential to improve medication use and chronic disease control, as well as reduce health disparities—although this requires further study.

Am J Manag Care. 2014;20(12):e547-e555

Caring for chronic medical conditions requires successful management of multiple prescription medications. Although successful medication-taking is rooted in a number of social, economic, medical, and behavioral factors, a growing body of evidence demonstrates that limited understanding of medication information contributes to poor adherence and outcomes.[1,2]

The situation may be particularly challenging for some Latino patients. Disparities in the prevalence, management, and outcomes of chronic diseases between Latinos and non-Latinos are well known,[3] and several studies have demonstrated that racial and ethnic minority groups, including Latinos, have significantly lower adherence to prescribed medications.[4-9] This may be due in part to challenges understanding health information. According to the National Assessment of Adult Literacy, Latinos, on average, had lower health literacy scores than any other racial or ethnic group.[10] Moreover, many Latinos experience language-related difficulties when navigating the US healthcare system, in which information is largely provided in English.[11,12]

Patient-centered medication lists and illustrated medication instructions may address obstacles to medication-taking caused by low health literacy or limited English proficiency.[13] The widespread adoption of medication lists has been championed by the American Society of Health System Pharmacists and supported by the National Quality Forum and American Medical Association.[13-15] A 2006 systematic review showed that illustrated medication instructions are generally effective in improving patient satisfaction, comprehension, recall, and adherence.[16] However, many of the studies reviewed involved simulated regimens and were conducted internationally. More recent studies from the United States examining the effects of illustrated medication instructions demonstrate mixed results.[17-21] For example, in a randomized trial of patients with heart failure, illustrated materials as part of a pharmacist intervention enhanced adherence and reduced costs.[18] Another randomized, controlled trial of an illustrated medication list among English-speaking patients in a safety net clinic dem-

Take-Away Points

Plain language, illustrated medication lists improve understanding among Latino patients with diabetes.

- Successful management of a chronic disease requires management of multiple prescription medications.
- Current medication information is difficult to understand, particularly among patients with low health literacy and limited English proficiency, such as some Latinos.
- Our paper is among the first to evaluate plain-language, illustrated medication instructions among Latinos.
- Plain language, illustrated medication instructions significantly improved medication understanding and were well liked by patients.
- Providing patients with plain language, illustrated medication instructions appear to be a low-cost approach to improving medication management.

onstrated increased adherence only among patients with a more complex regimen or low self efficacy.[22]

We previously developed an Internet-based tool, known as PictureRx, to facilitate the construction of illustrated, plain-language medication lists.[23,24] In qualitative evaluations, pharmacists and Latino patients expressed preference for these illustrated medication lists over traditional formats.[24,25] However, the lists' effect on understanding and adherence in this population is not known. We hypothesized that such a tool may be particularly valuable for patients who have low health literacy or limited English proficiency, because these patients are at greater risk for poor communication in clinical encounters and because of the inferior quality of medication information that is routinely provided to patients.[14,26-28]

Development of a culturally appropriate and effective tool to improve medication management by addressing barriers to health literacy among Latinos could lead to improvements in care and a reduction in health disparities. Here, we report the results of a randomized controlled trial to evaluate the effect of PictureRx medication lists, compared with traditional prescription instructions, on medication understanding, self-reported adherence and satisfaction, among Latinos with diabetes.

METHODS

Setting and Population

The study took place in a safety net clinic serving a predominately Spanish-speaking population in Nashville, TN. Providers and most staff were bilingual. Enrollment occurred between April 2010 and March 2011. The study was reviewed and approved by the New England Institutional Review Board, an independent, central institutional review board.

Latino patients who received care at the clinic were eligible if they were 18 years or older, had a diagnosis of diabetes recorded in the medical chart, and were prescribed at least 1 chronic medication. Patients were excluded if a list of their medications could not be located or if they had a corrected visual acuity >20/50 using a Rosenbaum Pocket Screener; had a hearing deficit; had dementia, psychosis, or disorientation; belonged to a special human subjects population (eg, pregnant or prisoner); were unable to communicate in English or Spanish; or lacked a regular phone number.

Procedures

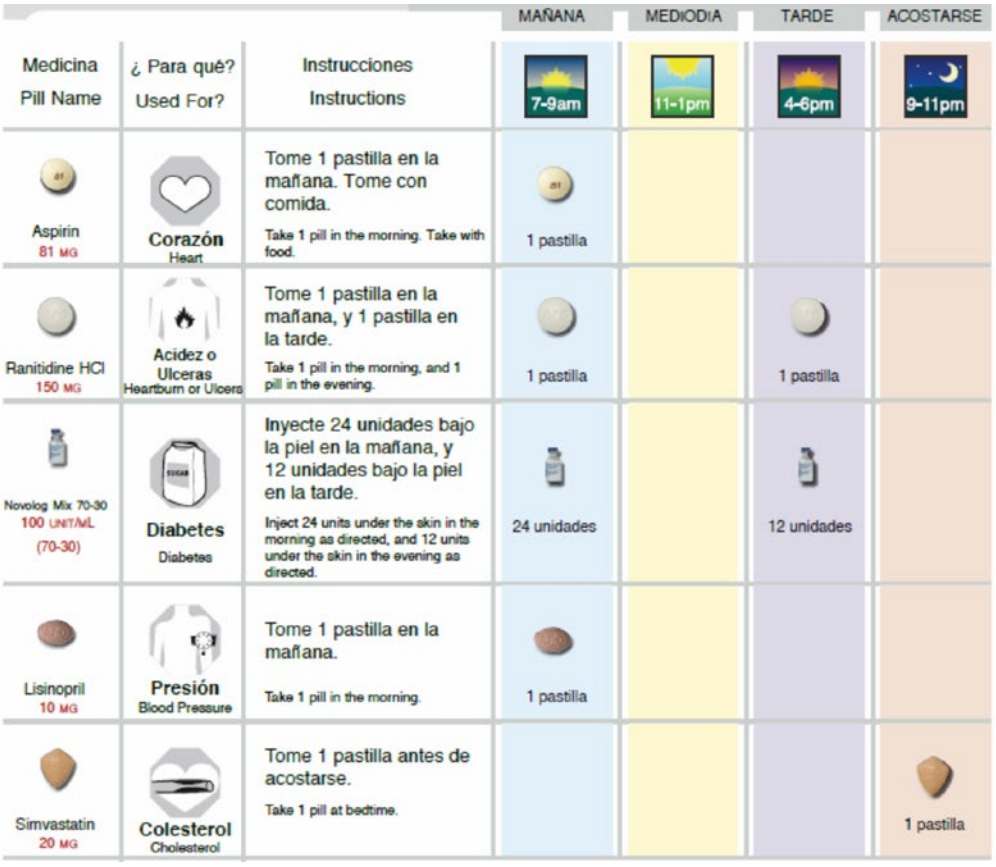
Research assistants (RAs) screened patient charts and received referrals from clinic staff to identify patients with reported diabetes. RAs directly approached patients in the clinic waiting room and other clinic areas to describe the study. Eligibility was assessed to the best of the RAs' ability at this time and was confirmed after enrollment, which resulted in exclusion of a few subjects for prespecified reasons. Participants provided written informed consentand received $30 each on the day of enrollment.

Consenting patients provided demographic information (age, gender, race, education, nationality, and preferred language). They completed a brief test of cognitive function, the Mini-Cog, which consisted of a 3-item recall and a clock-drawing test.[29] Participants also completed a 3-item test of health literacy, the Brief Health Literacy Screen (BHLS).[30,31] This assessment, which is now commonly used in health literacy research[32,33] and has been validated in English and Spanish,[34,35] asks patients questions such as "how confident are you filling out medical forms by yourself?" BHLS scores range from 3 to 15. Scores less than 12 can be taken to indicate limited health literacy.[34] A list of the patient's medications was abstracted from clinic charts.

Upon completion of baseline data collection, participants were randomized to receive their usual care or usual care plus the intervention. The randomization codes were prepared in advance using a computer random number generator, in permuted blocks of varying size, and sealed individually in opaque envelopes to maintain concealment of treatment allocation. Research staff and patients were not blinded. Investigators and the biostatistician were blinded.

For patients randomized to receive the intervention, an RA documented the patient's prescribed medication regimen, inclusive of any changes made that day by the clinic provider. While the patient was still in the clinic, the RA

Figure 1. Example of a PictureRx Illustrated Medication List



Illustrated medication instructions show medication name, dosage, indication, and dosing instructions.

entered the patient's prescribed medication regimen into a secure website (www.mypicturerx.com) to prepare and print a color, PictureRx illustrated medication schedule. This patient education tool (**Figure 1**) showed the patient's full medication regimen laid out in a simple grid, which has been called the Universal Medication Schedule,[36] showing how much should be taken at each time of day (morning, noon, evening, and night). The tool also included a picture of each medication, a labeled icon to show its purpose, and medication instructions printed in plain language, in both Spanish and English. The RA oriented the patient to the PictureRx card layout and showed the patient a 2-minute video about it. Patients also received a 1-page sheet with tips on how to use the PictureRx card as an aid for medication management, such as advice to keep it near their medicines or to post it on the refrigerator as a reminder.

Patients randomized to the control group received their usual care. This consisted of the treating provider reviewing medication instructions with the patient and the patient receiving a handwritten list of medications in their preferred language, with instructions for use and the drug indications, but no illustrations.

Follow-up and Outcome Assessment

Approximately 1 week after enrollment, an RA contacted patients by telephone. Patients completed instruments to assess their understanding of the medication regimen (primary outcome) and their self-reported adherence (secondary outcome). Patients in the intervention group were also asked several questions about the perceived utility of the PictureRx tool.

Medication understanding was assessed using the Medication Understanding Questionnaire (MUQ).[37] This method is a slight adaptation of other published measures of medication understanding that have been validated against cognitive and functional outcomes.[38] The MUQ assesses knowledge of the patient's own regimen, as opposed to a simulated regimen, and it can be administered effectively by telephone in a limited amount of time. For each medication tested, the RA states the generic and brand name of the medication and asks the patient to state its indication (1

point), strength (1/2 point), number of pills or units taken at a time (1/2 point), and dosing frequency (1 point). For patients prescribed 5 medications or less, each medication is tested. For patients prescribed more than 5 medications, 5 are selected using a random number table. The MUQ scores range from 0 to 3 per medication. Each patient's overall medication understanding score may range from 0 to 100, representing the percent correct for the medications tested. Prior to commencing the study, the MUQ was translated, checked for accuracy, and pilot-tested among a small population of Spanish-speaking patients.

To assess medication adherence, patients were administered a Spanish translation of the Adherence to Refills and Medications Scale (ARMS), a validated self-report measure.[39] The full ARMS is a 12-item instrument that assesses patients' self-reported adherence under a variety of different circumstances. An 8-item subscale, which assesses adherence with taking medication (as opposed to medication refills), was used in this study as the secondary outcome. Scores on this subscale may range from 8 (most adherent) to 32 (least adherent). The ARMS correlates well with other subjective and objective measures of adherence.[39]

To assess the presence of mild cognitive impairment, participants completed the Mini-Cog, a short validated instrument that consists of a 3-item recall and a clock-drawing test.[29]

Statistical Analysis

The primary analysis was an intention-to-treat comparison of medication understanding among patients randomized to receive the intervention versus patients randomized to usual care alone. Medication understanding was treated as a continuous variable and summarized as mean ± SD for the overall score, as well as for each domain of understanding (ie, medication indication, strength, units, and frequency). A multivariable linear regression model was used to determine the adjusted difference in medication understanding between usual care and intervention patients, controlling for several baseline characteristics: BHLS score, presence of cognitive impairment, number of medications, age, gender, and years of education. This technique controls for residual confounding that may persist despite randomization, and it also allows estimation of the effect of covariates (other than treatment assignment) on outcomes. The variables in the model were determined a priori. Additional analyses were performed separately to assess the presence of an interaction between treatment effect and health literacy or cognition.

Results for ARMS were analyzed similarly. Answers to questions pertaining to the utility of the PictureRx tool were summarized with descriptive statistics. All statistical analyses were performed using R version 2.15 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Across a total of 1058 screening attempts, 198 patients declined screening. Among those screened, patients were ineligible for already having been enrolled in this study (n = 516), not being diabetic (n = 60), not taking medications (n = 42), or for several less common reasons (**Figure 2**). Only 1 eligible patient declined participation. Thus, 208 patients were randomized, 105 to usual care and 103 to the intervention. Upon further assessment, 4 patients were subsequently excluded from each arm for not meeting eligibility criteria, leaving 101 patients in the usual care arm and 99 in the intervention arm. Of those 200 patients, 197 (98.5%) completed the follow-up outcome assessment, including the medication understanding measure.

Overall, patients' average age was 50 years, and they had 8 years of education; 59% had limited health literacy. Nearly all patients (N = 199) identified Spanish as the primary language spoken at home. The mean duration of diabetes was 6 years, and patients took an average of 4 medications. Participant characteristics stratified by study arm are presented in **Table 1**. Patients in the intervention arm were more likely to be male (38% vs 23%; $P = .017$) and more likely to be white (98% vs 92%; $P = .05$). Participants were similar in other respects.

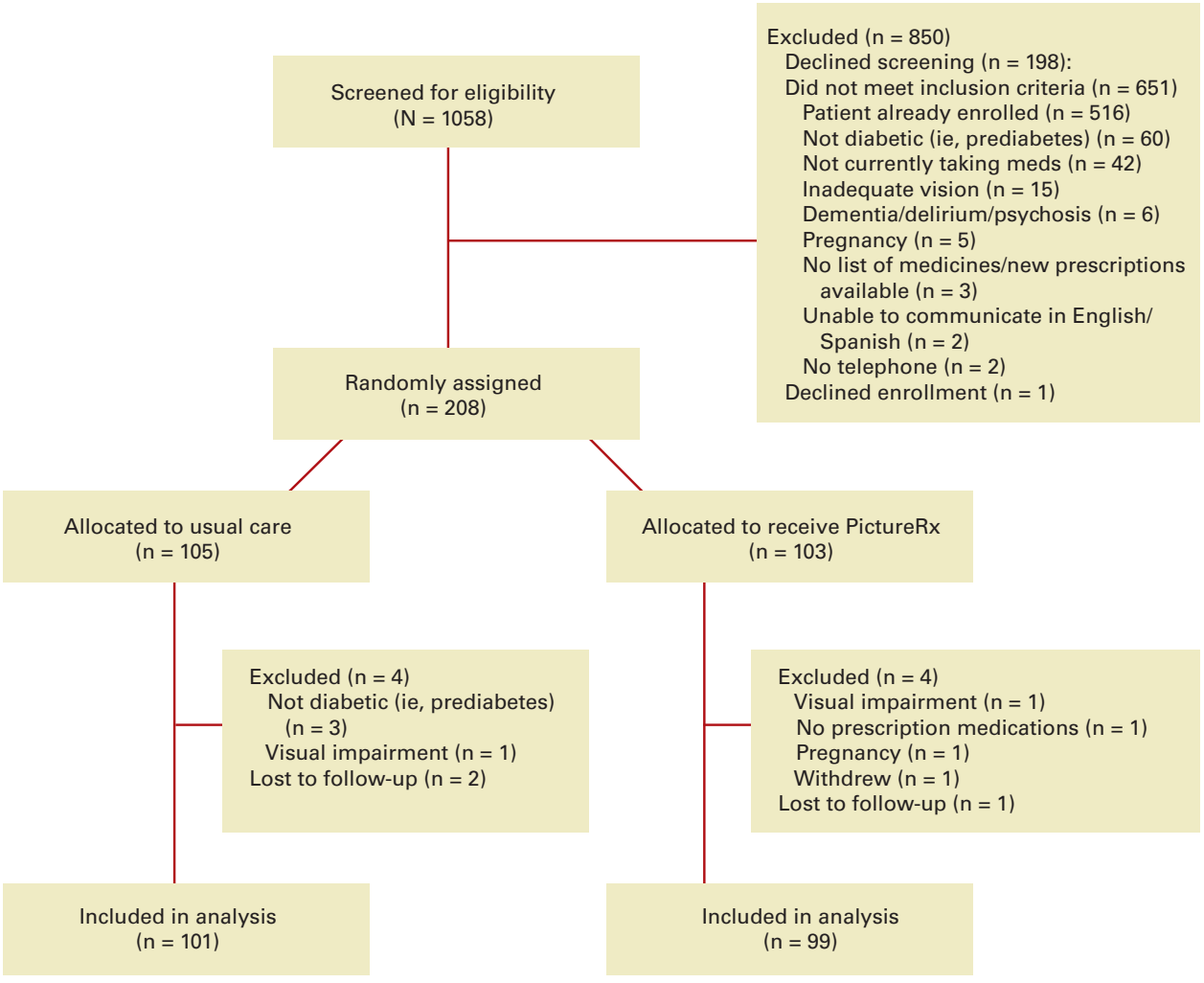
Medication Understanding

On the MUQ, patients' overall mean score was 81.4 (SD, 16.3). Patients had the best understanding of the number of units or pills of each medication to take at a time, and the poorest understanding of drug strengths.

As shown in **Table 2** and **Figure 3**, patients randomized to PictureRx instructions had better overall understanding of their medications. The mean MUQ score was 86.4 (SD, 12.6) in the intervention group compared with 76.4 (SD, 18.0) in the usual care group. In the multivariable model, the adjusted difference was 9.9 (95% CI, 5.7-14.2; $P < .001$). This effect was consistent across all 4 domains of the MUQ: knowledge of the drug indications, strength, units, and frequency. The adjusted differences between intervention and control groups ranged from 6.0 (units) to 12.2 (frequency); $P < .05$ for each comparison.

In addition to the treatment effect, each point increase in BHLS score was associated with an increase of 1.1 (95%

Figure 2. Medication Understanding Questionnaire (MUQ) Scores



CI, 0.3-2.0) in the MUQ overall score. The relationship was more prominent in understanding of drug strengths (increase of 3.3 for every 1-point increase in BHLS; 95% CI, 1.3-5.2). No other covariates were consistently associated with medication understanding scores. No interaction was present between treatment effect and health literacy or cognition.

Secondary Outcomes

Self-reported medication adherence at the time of telephone follow up was high in both groups, with mean ARMS subscale scores of 9.9 in the usual care group and 10.3 in the intervention group. In the multivariable model, the intervention group was associated with an increase, not statistically significant, of 0.5 (95% CI, –0.1 to 1.1) in the ARMS score compared with the usual care group. Each 1-point increase in BHLS score was associated with a decrease of 0.1 (95% CI, –0.2 to 0.0) in the ARMS score. Each 10-year increase in age was associated with a decrease of 0.4 (95% CI, –0.7 to –0.1) in the ARMS score. The other covariates were not associated with changes in ARMS scores on average.

Patients who received PictureRx instructions were very satisfied. Nearly all (99%) reported that the tool was clear, easy to read, and that it helped them to remember which medicines to take (96.9%) and when to take them (96.9%). Approximately 90% said that they planned to take the PictureRx card with them to their next medical appointment.

DISCUSSION

In this randomized, controlled trial among Latino patients with diabetes, receipt of an illustrated medication list, initially accompanied by a brief orientation, led to significantly greater understanding of medication instruc-

Table 1. Participant Characteristics

	Usual Care (N = 101)	Illustrated Medication Instructions (N = 99)	*P*
Age in years, mean ± SD	49.5 ± 11.7	50.3 ± 11.6	.603
Female sex, n (%)	78 (77.2%)	61 (61.6%)	.017
Race, n (%)			
White	93 (92.1%)	97 (98.0%)	.048
Black	6 (5.9%)	0 (0.0%)	.048
Other	2 (2.0%)	2 (2.0%)	.048
Years of education, mean ± SD	7.9 ± 4.2	8.0 ± 4.6	.898
At least high school education, n (%)	28 (27.7%)	30 (30.3%)	.688
Number of meds, mean ± SD	4.2 ± 2.8	3.9 ± 2.2	.372
Health literacy, mean BHLS score ± SD	10.4 ± 3.3	10.5 ± 3.0	.759
Limited health literacy, n (%)	60 (59.4%)	58 (58.6%)	.906
Cognitively impaired, n (%)	14 (13.9%)	18 (18.2%)	.405

BHLS indicates Brief Health Literacy Screen.

Table 2. Medication Understanding Scores by Treatment Assignment

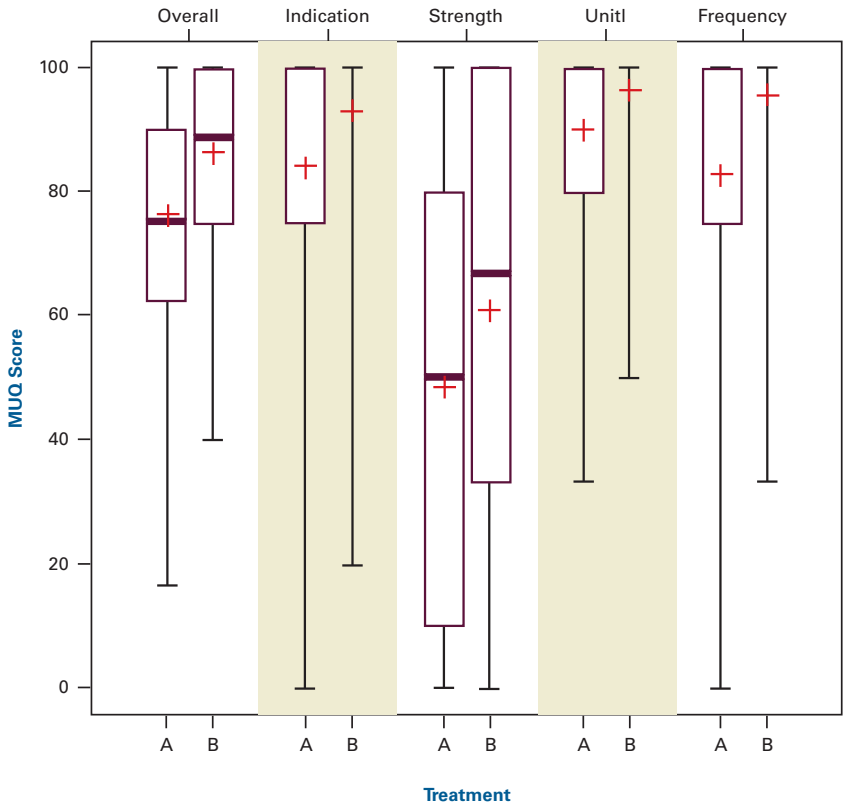
	Usual Care (N = 99), Mean ± SD	Illustrated Medication Instructions (N = 98), Mean ± SD	Adjusted Difference (95% CI)	*P*
Overall	76.4 ± 18.0	86.4 ± 12.6	9.9 (5.7-14.2)	<.001
Medication indication	84.2 ± 24.3	92.9 ± 17.9	9.4 (3.4-15.4)	.002
Medication strength	48.7 ± 38.0	61.0 ± 35.8	12.1 (2.2-22.1)	.017
Medication units	90.1 ± 16.8	96.5 ± 10.4	6.0 (2.0-10.0)	.004
Medication frequency	82.6 ± 27.3	95.2 ± 13.4	12.2 (6.0-18.4)	<.001

tions. This effect remained after adjustment was made for potential confounders in multivariable models. Patients receiving the intervention were very satisfied, reporting that the tool was clear and easy to read. However, there was no effect on self-reported adherence during the follow-up time frame.

Research demonstrates that medication understanding is an important barrier to medication-taking among patients with chronic diseases such as diabetes.[40] Medication understanding is especially challenging among patients with low health literacy and limited English proficiency.[1,41] This study is among the first to assess illustrated medication lists as a low-cost tactic to address this barrier among Latino patients, and demonstrates that they can be a useful tool. The effect of PictureRx instructions is particularly notable given that patients were previously taking many of the medications for which their understanding was tested; thus, they already had some degree of familiarity with them. Furthermore, the quality of care for the control group was high, as patients were seen by bilingual providers who communicated in the patient's preferred language and provided a clearly written medication list in that language. These features are unusual in the United States[12,42] and would tend to bias the study toward the null.

Our findings are consistent with other work demonstrating that plain-language medication instructions and illustrations can improve medication management.[17-19,22,43-47] A systematic review of studies conducted in the United States and internationally demonstrated that pictorial instructions generally improve patient comprehension of medication instructions, recall, and satisfaction.[16] More recently, a small body of research conducted in the United States among English-speaking patients suggests that pictorial instructions may help improve adherence and clinical outcomes.[17-19,22] In our study, the pictorial instructions may have benefited from the use of the Universal Medication Schedule (UMS), an approach followed by the PictureRx card to facilitate comprehension. The UMS specifies 4 standard daily dosing times—morning, noon, evening, and bedtime—which accommodate more than

Figure 3. Distribution of Medication Understanding Scores by Treatment Assignment



Side-by-side boxplots of MUQ scores (overall and by component) for usual care (A) versus illustrated medication instructions (B). Boxplots are augmented by the means in each group (plus signs).

90% of prescriptions.[46,47] Research demonstrates that patients prefer the UMS format and that it may improve medication understanding.[24,36,48]

Although PictureRx instructions were developed to meet the needs of patients with low health literacy, we found, interestingly, no interaction between health literacy levels and treatment effect, indicating that the intervention was helpful across all levels of health literacy measured in this study. One possible explanation for there being no difference by health literacy level is that the study was underpowered to detect this. Another is that a broad spectrum of Latino and other underserved patients may benefit from this format of medication instruction regardless of their measured health literacy levels.

Notwithstanding the positive effect on medication understanding and high levels of satisfaction with the illustrated medication list, we found no effect on self-reported adherence during the period of follow-up. This could be explained in several ways. First, adherence reflects the complex interplay of numerous behavioral, social, economic, and medical factors. Focused interventions such as ours, which concentrated on medication knowledge, are thus unlikely to have a large effect. Second, adherence was high in both groups and there may have been a ceiling effect. Third, our follow-up period was just 1 week. Previous work demonstrated that similar illustrated medication instructions increased medication refills during a 1-year follow-up period in certain patient groups.[22] Thus, further research is warranted to confirm these findings.

Limitations

Our study has several limitations. First, participants were recruited from a single safety net clinic; thus, the results may be limited in generalizability. Second, patients were relatively young in age and, on average, took 4 medications. Our prior work suggests that patients with a greater number of medications may derive additional benefit from illustrated medication instructions.[22] Further research is needed to determine whether that is the case in general. Third, although the MUQ has been validated among English-speaking patients, it had not been used previously in a Spanish-speaking population, which composed a large majority of the present sample. However, the questions were translated by na-

tive speakers and piloted before use, and the measured associations were consistent with expectations. Fourth, as noted above, the follow-up period for assessment of adherence was short.

CONCLUSIONS

Our study demonstrates that PictureRx medication instructions improve medication understanding among Latino patients recruited from a safety net clinic. Illustrated medication instructions may be a useful adjunct to traditional medication information. Further research is needed to determine the effect of PictureRx medication instructions on medication-taking behavior and clinical outcomes.

Author Affiliations: Division of Hospital Medicine, Department of Medicine, Emory University School of Medicine (AM), Atlanta, GA; PictureRx, LLC (AM, MBR, DRB, SK), Atlanta, GA; Center for Clinical Investigations, Case Western Reserve University (BS), Cleveland, OH; Section of Hospital Medicine, Division of General Internal Medicine and Public Health, Department of Medicine, Vanderbilt University (SK), Nashville, TN.

Source of Funding: This research was supported by Small Business Innovation Research award R43 MD004048 (Riley/Boyington), from the HHS National Institute on Minority Health and Health Disparities of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the views of the NIH or NIMHD. HHS, NIH, and NIMHD had no role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript.

Author Disclosures: Dr Kripalani is a stockholder of Bioscape Digital and PictureRx. Mr Schmotzer was paid a fee for statistical analysis work in this study. Dr Boyington is an employee of PictureRx. Dr Mohan is a consultant for and stockholder of PictureRx, and has received an NIH SBIR grant. Mr Riley has no conflicts of interest to disclose.

Authorship Information: Concept and design (DRB, SK, AM, MBR, BS); acquisition of data (SK, AM, MBR); analysis and interpretation of data (SK, AM, MBR, BS); drafting of the manuscript (SK, AM, MBR); critical revision of the manuscript for important intellectual content (SK, AM, MBR); statistical analysis (SK, BS, MBR); provision of study materials or patients (DRB); obtaining funding (DRB, SK, AM); administrative, technical, or logistic support (DRB, MBR); and supervision (SK, MBR).

Address correspondence to: Arun Mohan, MD, MBA, Emory University School of Medicine, 1364 Clifton Rd NE, Atlanta, GA 30322. E-mail: arun.mohan@emory.edu.

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