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Universal Health Literacy Precautions Are Associated With a Significant Increase in Medication Adherence in Vulnerable Rheumatology Patients

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Objective. Our objective was to determine the impact of the Health Literacy Universal Precautions Toolkit, adapted for rheumatology, on medication adherence, patient satisfaction, and feasibility in all patients; its effect on the clinical disease activity index (CDAI) was studied in a rheumatoid arthritis (RA) subpopulation.

Methods. Data collected during a 6-month prospective quality assurance intervention was compared with data from a prior 6-month period. Interventions included 1) encouraging questions, 2) teach-back communication, and 3) brown-bag medication review. Analysis was performed using linear regression or generalized estimating equation (GEE) regression.

Results. During the intervention period, 46 physicians completed 1737 patient visits. Questions were encouraged, and teach-back communication was performed in more than 90% of visits. Brown-bag medication reviews were performed in 47% of visits overall and 69% of visits in a subgroup that received additional reminder calls. Visit duration and patient satisfaction were not significantly increased. Adherence for rheumatology-related medications that were prescribed both before and during the intervention increased by 22% ($P \leq 0.001$; by GEE). Teach-back communication predicted a statistically significant improvement in medication adherence in this subpopulation (by linear regression). The mean CDAI did not improve; however, African American race and Hispanic ethnicity were associated with a decreased CDAI (by GEE).

Conclusion. Implementation of the Health Literacy Universal Precautions Toolkit, adapted for rheumatology, improved medication adherence in our safety-net clinic, with particularly strong effects seen with teach-back communication. In certain populations, use of the toolkit may also improve RA disease activity. This is the first study to document improved medication adherence with this intervention in a real-world setting.

INTRODUCTION

Health literacy (HL) is "the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health care decisions" (1). A complimentary conceptualization of HL considers the health care system's complexity (2). Nearly half of the adults in the United States have limited health literacy (LHL); LHL is more prevalent among ethnic minorities and the elderly (3). LHL is associated with poor outcomes in many chronic diseases, including rheumatoid arthritis (RA) (4).

Causal pathways proposed to explain LHL's impact on patient outcomes include access to and use of health care, patient-provider interaction, and self-care (5). This model is supported by research illustrating the association of LHL with many factors related to these mechanisms in patients with RA (4,6–

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SIGNIFICANCE & INNOVATIONS

- Performance of the Health Literacy Universal Precautions Toolkit, adapted for rheumatology, resulted in improved medication adherence in our rheumatology clinic, with particularly strong effects associated with the teach-back communication method in a linear regression analysis.
- This is the first study to document improved medication adherence with providers using teach-back communication in a real-world clinical setting, especially one that is enriched with vulnerable patients.
- African American race and Hispanic ethnicity were predictive of a statistically significant decrease in the clinical disease activity index.
- Performance of the Health Literacy Universal Precautions Toolkit, adapted for rheumatology, was feasible. There was no statistically significant increase in the duration of visits; questions were encouraged, and teach-back communication was performed in greater than 90% of the visits.

12). The interventions proposed to mitigate the negative effects of LHL address these pathways through the use of easier-to-understand written communication, health education sessions, patient-decision aids, patient-centered communication, active listening, teach-back, and enhanced shared decision-making (13). Although improving the process and outcomes of care of patients with RA with LHL is a priority (14,15), only two studies illustrate interventions successful in this regard (16,17).

The Health Literacy Universal Precautions Toolkit was designed to combat LHL's deleterious effects (18). The premise of HL "universal precautions" is that health care providers should deliver care under the assumption that the HL burdens of the health care system exceed the HL skills of every patient (19). This strategy is thought to be more effective over targeted interventions because not only is it challenging to identify which patients have LHL (20) but screening for LHL is also controversial given the propensity of such screening to elicit shame or embarrassment (21). The Health Literacy Universal Precautions Toolkit has been adapted for rheumatology practice (to be referred to as "toolkit" hereafter), including an abbreviated version that consists of three interventions: 1) encouraging questions, 2) the teach-back method of communication (to be referred to as "teach-back" hereafter), and 3) brown-bag medication review (22,23). The toolkit has been shown to raise provider awareness regarding LHL. No data exist regarding the feasibility of adopting the toolkit or its effects on patient satisfaction, medication adherence, RA disease activity, or concordance between patients' and providers' assessments of RA disease activity.

We implemented the toolkit at every visit with every patient during a 6-month intervention to examine its effect on several key domains. Our hypothesis was that its implementation would improve patient satisfaction, reduce discrepancies between the patient global assessments (PGAs) and evaluator global assessments (EGAs), improve medication adherence, and improve RA disease activity. We also measured effects on visit duration to determine the feasibility of the toolkit's adoption in routine clinical settings.

PATIENTS AND METHODS

Study design. Our study is a prospective quality assurance study to investigate whether the way physicians interact with their patients improves patient satisfaction and investigate the mean proportion of days covered (PDC) for rheumatology-related medications for rheumatology patients in our cohort. Additionally, in the subset of patients with RA, we studied the toolkit's impact on RA disease activity, as measured by the mean clinical disease activity index (CDAI), and discrepancies between PGAs and EGAs.

Study participants. The participants were the attending physicians and physicians-in-training at the rheumatology outpatient clinic at Denver Health in Denver, Colorado. These physicians and physicians-in-training were rheumatologists, rheumatology fellows, and residents rotating on a rheumatology outpatient elective. Because this was a quality improvement project, there were no inclusion and exclusion criteria, and all patients regardless of diagnosis received the intervention.

Study interventions. Interventions included 1) encouraging questions, 2) using teach-back, and 3) performing a brown-bag medication review. These interventions were to be used in every outpatient rheumatology clinic visit during the intervention time.

Study training and implementation. All physicians were trained in promoting HL in clinic visits. Training included in-person and video training, emails, handouts, and summary documents displayed in the work areas (see Appendix Item S1). Training was performed with attending and fellow physicians in a 1-hour orientation, which occurred on January 20, 2017, and included orientation to the project, the approaches to the interventions, how to train residents, and how to enter data into the electronic medical record (EMR). Rolling annual (for fellows) and monthly trainings (for residents) were performed along with their general orientation to the clinic. During the intervention period, quality assurance emails were sent to physicians with weekly intervention performance data. These emails gave detailed information to the physicians about their rates in each of the toolkit interventions from the week prior.

Questions were encouraged to create a permissive environment for patient questions by scripting physicians to ask, "What questions do you have?" rather than "Do you have any questions?" We trained physicians in teach-back, which, in a nontesting fashion, asks patients to state what they need to know or do,

for example, "What are you going to tell your family when you get home about what we discussed today?" Clerks who made appointment reminder calls as a matter of regular clinic flow also gave scripted instructions to patients to bring in all of their medications, supplements, and vitamins to their next appointment for a brown-bag medication review. When care of a patient included a resident physician, the attending physician performed the brown-bag medication review.

To encourage patient participation in the brown-bag medication review, signs were posted in English and Spanish in the waiting area and in the patient rooms, encouraging patients to bring their medications for review. In a convenience sample of select clinics, a bilingual research assistant performed additional reminder calls two days prior to patients' visits to remind patients to bring in medications for the brown-bag medication review.

Preintervention data were collected between October 1, 2016, and March 31, 2017. The wash-in period began April 1, 2017. This period was intended to last 3 months; however, because of the relatively low numbers of brown-bag medication reviews being performed, the wash-in period was extended to September 30, 2017. The intervention period was October 1, 2017, to March 31, 2018. This quality improvement project was reviewed by the local institutional review board and determined to be "not human subject research."

Outcomes. The primary outcome measures of this prospective quality assurance study were 1) patient satisfaction, 2) medication adherence, and, in patients with RA, 3) CDAI. A secondary outcome included any change in the mean visit duration attributable to the clinical interventions.

Data sources and measurements. The individual interventions that composed the toolkit were recorded in a multiresponse drop-down menu designed into the clinic's EMR template. Physicians recorded whether they encouraged questions, used teach-back, and performed a brown-bag medication review. Patient demographics, including age, sex, ethnicity, preferred language, RA disease duration, RA disease activity measures, and insurance were derived from the EMR.

Patient satisfaction was measured though rheumatology patient experience metrics by Press Ganey and was reported to Denver Health on a monthly basis as the "top-box" percentage and "top-box" percentile rank, comparing the intervention clinic with other academic rheumatology facilities.

Medication adherence was determined for rheumatology-related mediations filled at the study-site pharmacy by calculating the PDC. This measure assesses the number of days in an observation period in which a patient has the medication in his or her possession. Medications considered to be rheumatology related included 1) synthetic disease-modifying antirheumatic drugs (sDMARDs) (azathioprine, hydroxychloroquine, leflunomide, mercaptopurine, methotrexate, mycophenolate mofetil, mycophenolate sodium, and sulfasalazine), 2) targeted and biologic disease-modifying antirheumatic drugs (bDMARDs) (abatacept, adalimumab, anakinra, apremilast, certolizumab pegol, etanercept, ixekizumab, secukinumab, tocilizumab, tofacitinib, and ustekinumab), 3) gout medications (allopurinol and febuxostat), 4) osteoporosis medications (alendronate, denosumab, and teriparatide), and 5) corticosteroids (dexamethasone, methylprednisolone, prednisolone, and prednisone). This methodology excluded medications filled outside of study-site pharmacies (such as medications administered in or filled through infusion centers, medication assistance programs, and private pharmacies) and "as-needed" medications.

RA disease activity was assessed by the CDAI, which is composed of the PGA, EGA, tender joint count, and swollen joint count (24). All joint counts were performed by attending rheumatologists or fellow rheumatologists in the normal care of their patients with RA. These measures are routinely recorded in the study-site EMR for patients with RA.

For the feasibility outcome measure, a study assistant measured the duration of new patient and return patient visits for two providers on a convenience sample of seven clinics before the intervention and seven clinics during the intervention. Each sampling of seven clinics occurred over a 6-week period during the pre- and during-intervention periods.

Data recorded in the EMR were stored in the Denver Health Data Warehouse and subsequently extracted using Structured Query Language.

Analysis. Statistical analyses were performed using Stata 14.2 (StataCorp). Summary data were analyzed using *t* test, paired *t* test, χ^2 test, or Hotelling's T^2 test when appropriate. PDC was analyzed using the Stata add-on module by Linden (25). Linear regressions were used when appropriate. Generalized estimating equation (GEE) regression compared the per-patient first observation in the preintervention period with the last observation in the intervention period. Our planned analyses in the general rheumatology population included 1) demographics of the physician participants and the patients seen in the visits, 2) a report of implementation of the interventions, 3) the average PDC compared between the pre- and during-intervention periods, 4) a subanalysis of the PDC of individuals who were in both the pre- and during-intervention periods and were on the same medication in both periods, 5) characteristics and interventions associated with changes in the PDC by linear regression, and 6) patient satisfaction.

Our planned analyses of individuals with RA included 1) reports of disease activity measures in individuals with RA who were in both time periods, 2) reports of CDAI values and association with different clinical variables, 3) characteristics and interventions associated with changes in absolute value difference between PGAs and physician global assessments by GEE, and 4) characteristics and interventions associated with changes in the CDAI. Please see

Table 1. Physician and patient visit descriptors

Physicians		Pre, n=		During, n=		
Attending physicians		14		13		
Fellow physicians		4		5		
Resident physicians		25		28		
Patient information for visits		Pre, n = 1,584	SD, %	During, n = 1,737	SD, %	*P* value
Age, years		50.8	14.5	51.5	14.1	0.166
Gender, male, %		432	27%	463	27%	0.689
Race	White or Caucasian, %	1115	70%	1212	70%	0.847
	Black or African American, %	244	15%	266	15%	
	Other, %	225	14%	259	15%	
Ethnicity	Not Hispanic origin, %	787	50%	858	49%	0.868
	Hispanic origin, %	797	50%	879	51%	
Preferred language	English, %	1095	69%	1188	68%	0.871
	Spanish, %	417	26%	465	27%	
	Other, %	72	5%	84	5%	
Insurance	Medicaid, %	621	39%	647	37%	0.353
	Medicare, %	483	30%	529	30%	
	Financial Assistance, %	258	16%	281	16%	
	Commercial, %	222	14%	280	16%	
Visit type	Return patient visit, %	1419	90%	1509	87%	**0.016**
	New patient visit, %	165	10%	228	13%	

Bold value indicates statistically significant ($P < 0.05$).

Supplemental Figure 1 for a flow diagram of the data and planned analyses.

RESULTS

Demographics, visits, and interventions. During the entire observation time period (October 1, 2016, through March 31, 2018), a total of 99 physicians were observed, including 18 attending physicians, 8 fellows, and 73 residents, across a total of 5032 patient visits. During the preintervention period (October 1, 2016, through March 31, 2017), there were 14 attending physicians, 4 fellows, and 25 residents observed in 1584 visits (33%). During the wash-in period (April 1, 2017, through September 30, 2017), there were 12 attending physicians, 8 fellows, and 26 residents observed in 1711 visits (34%). During the intervention period (October 1, 2017 to March 31, 2018), there were 13 attending physicians, 5 fellows, and 28 residents observed in 1737 visits (35%) (Table 1).

Although counts of visit types (new patient versus return patient visit) did differ ($P = 0.016$), sociodemographic variables did not differ significantly between the pre- and during-intervention periods (Table 1). In the preintervention period, question encouragement, teach-back, and brown-bag medication reviews were documented in 66%, 17%, and 7% of visits, respectively. During the intervention, question encouragement, teach-back, and brown-bag medication reviews were documented in 98%, 92%, and 47% of visits, respectively. Question encouragement and brown-bag medication reviews were documented significantly more often among patients who received additional reminder calls during the intervention phase (n = 585) compared with patients who did not (n = 1152) (Table 2).

Patient satisfaction. Pre- and during-intervention patient satisfaction metrics did not statistically differ, although a nonsignificant trend toward improvement in patient satisfaction was seen regarding instruments assessing patient perception of provider instructions (Supplemental Table 1).

Medication adherence. During the entire observation period, data were collected regarding 2306 prescriptions for unique medications prescribed to 886 individuals. Four-hundred twenty-two unique prescriptions were filled during the preimplementation period only; 406 were filled only during the wash-in period; 926 were filled only during the intervention period; 552 prescriptions in which the same medication was prescribed to the same individual were filled during both the preimplementation and implementation periods. Of these 2306 prescriptions, 926 (40%) were for sDMARDs, 274 (12%)

Table 2. Interventions as documented during the intervention period

	Normal Clinic Flow[a] (n = 1152), %	Extra Calls[b] (n = 585), %	*P*
Questions encouraged documented?	98	99	**0.023**
Teach-back communication documented?	92	92	0.877
Brown-bag medication review documented?	36	69	**<0.001**

[a]Normal clinic flow: one reminder call.
[b]Extra calls: convenience sample of patients who received an extra reminder call asking them to bring in their medications.
Bold value indicates statistically significant ($P < 0.05$).

Table 3. Overall proportion of days covered (PDC) and PDC stratified by medication category, comparing pre- and during implementation periods; unpaired (not required to have a prescription in both periods)

	Pre-implementation			During implementation				
	n =	Mean	SD	n =	Mean	SD	% change	p-value
Overall PDC	974	35%	25%	1478	48%	32%	14%	**<0.001**
sDMARD	438	40%	24%	670	56%	30%	15%	**<0.001**
bDMARD	132	37%	22%	184	53%	30%	16%	**<0.001**
Gout	35	46%	28%	70	57%	31%	12%	0.061
Osteoporosis	27	41%	20%	67	65%	28%	24%	**<0.001**
Steroids	342	25%	24%	487	33%	31%	8%	**<0.001**

sDMARD = synthetic disease modifying anti-rheumatic drug; bDMARD = biologic disease modifying anti-rheumatic drug
Bold values indicate statistically significant ($P < 0.05$).

were for bDMARDs, 95 (4%) were for gout medications, 85 (4%) were for osteoporosis medications, and 926 (40%) were for glucocorticoids.

The overall mean PDC increased 14% when comparing the preimplementation and during-implementation periods ($P < 0.001$). Mean PDCs among individual medication categories also increased significantly (Table 3), with the exception of gout-related medications ($P = 0.061$). In a preplanned subgroup analysis, which required individuals to receive the same medication during both time periods, more profound and statistically significant improvements were seen in the mean PDC (22%) and in all subdivisions of rheumatology-related medications (Figure 1).

Linear regression was performed in this subgroup of individuals who had the same prescription during both the pre- and during-implementation periods to determine the impact of the individual toolkit interventions on the change in PDC. Variables used in this analysis included questions encouraged, medication review, teach-back, age, sex, self-identified race, self-identified ethnicity, preferred language, and insurance. In this subgroup, a statistically significant improvement was observed in PDC in association with documentation of teach-back (9% improvement; $P = 0.001$). Additional variables associated with an increase in individual medication PDC, when compared with the referent, included Spanish speaking, Medicare and/or commercial insurance status, white race, and non-Hispanic ethnicity (Table 4).

Disease activity. Among clinic patients with RA, 505 CDAI observations were recorded in the preimplementation period, and 696 observations were recorded during the implementation period. These observations were narrowed to a subpopulation of 217 patients with RA with CDAI observations during both periods and concurrent Denver Health pharmacy observations for sDMARD or bDMARD prescriptions. In an unadjusted analysis comparing differences in disease activity measures between the pre- and during-implementation periods, significant differences were observed in this subpopulation between the two time periods, including a decrease in the mean EGA (2.8 versus 2.2; $P = 0.005$), the

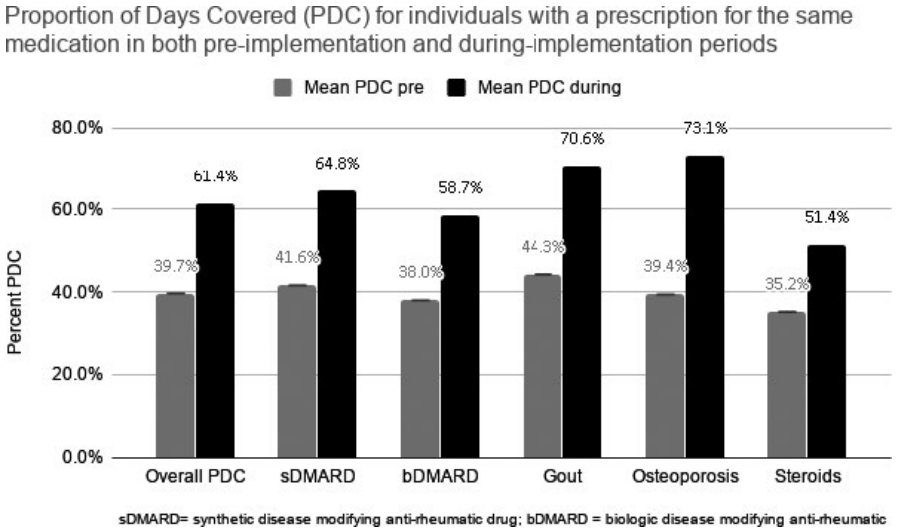

Figure 1. Proportion of days covered (PDC) for individuals with a prescription for the same medication in both the pre-implementation and during-implementation periods. bDMARD, biologic disease-modifying antirheumatic drug; sDMARD, synthetic disease-modifying antirheumatic drug.

Table 4. Interventions' and baseline variables' association with change in proportion of days covered (PDC) by linear regression

Variable		coef	95%	CI	*P* value
Documented questions encouraged		−0.02	−0.09	−0.05	0.579
Documented brown-bag performed		0.00	−0.06	−0.05	0.855
Documented teach-back performed		0.08	0.04	−0.13	**0.001**
Age		0.00	0.00	−0.00	0.842
Gender, male		0.02	−0.03	−0.07	0.469
Self-identified race	White or Caucasian	REF			
	Black or African American	−0.11	−0.19	−0.03	**0.008**
	Other	0.04	−0.02	−0.10	0.217
Self-identified ethnicity	Not Hispanic	REF			
	Hispanic origin	−0.16	−0.24	−0.08	**<0.001**
Preferred language	English				
	Spanish	0.12	0.05	−0.19	**0.001**
	Other	0.07	−0.03	−0.17	0.186
Insurance	Medicaid	REF			
	Medicare	0.12	0.05	−0.19	**0.001**
	Financial Assistance	0.03	−0.04	−0.09	0.388
	Commercial	0.15	0.06	−0.24	**0.001**

mean PGA (4.3 versus 3.5; $P = 0.009$), and the mean fatigue score (4.9 versus 4.0; $P = 0.021$). Non–statistically significant trends towards improvement in the mean CDAI and the mean multidimensional health assessment questionnaire score were noted (see Supplemental Table 2). In an unadjusted analysis in which we compared average CDAI values for different groups in the two time periods, the largest reduction in the CDAI was in those who were using financial assistance (unadjusted reduction in the mean CDAI of 8.2). There were non–statistically significant higher preimplementation mean CDAI values in African American, non-Hispanic, and English-speaking patients compared with referents (Supplemental Table 3).

In a further analysis of these 217 patients with RA, using GEE regression and the same variables used in the medication adherence analysis (with the addition of RA disease duration), predictors of a decrease in the CDAI included African American race and Hispanic ethnicity (Table 5).

Discrepancies between the EGAs and PGAs. Although there was significant decrease in both EGAs and PGAs between the two time periods, in this unadjusted analysis, the absolute value of EGA minus PGA was not significantly different (Supplemental Table 2). This absolute value is a measure of concordance between EGA and PGA without indicating whose evaluation is more severe. In an

Table 5. Variables and interventions associated with change in clinical disease activity index (CDAI) from pre-intervention to during-intervention period, by GEE

Variable		coef	95%	CI	*P* value
Documented questions encouraged		−0.52	−5.58	4.53	0.839
Documented brown-bag performed		−2.91	−7.73	1.91	0.236
Documented teach-back performed		−1.29	−6.12	3.55	0.602
PDC difference		−2.88	−9.21	3.46	0.373
Age		−0.15	−0.33	0.03	0.104
Gender, male		1.20	−3.51	5.91	0.618
RA disease duration		−0.18	−0.36	0.01	0.060
Self-identified race	White or Caucasian	REF			
	Black or African American	−7.47	−14.58	−0.36	**0.040**
	Other	−2.91	−7.96	2.14	0.259
Self-identified ethnicity	Not Hispanic	REF			
	Hispanic, Latino/a, Spanish, or Mexican origin	−7.57	−13.60	−1.54	**0.014**
Preferred language	English	REF			
	Spanish	4.42	−1.59	10.44	0.149
	Other	−3.55	−19.80	12.70	0.668
Insurance	Medicaid	REF			
	Medicare	2.25	−3.78	8.28	0.464
	Financial Assistance	1.06	−5.02	7.14	0.733
	Commercial	−1.89	−8.85	5.07	0.594

adjusted analysis using GEE, predictors of an increase in the absolute value of EGA minus PGA, compared with referents, were African American race and Hispanic ethnicity (Supplemental Table 4). Variables used in this analysis were the same as those used in the medication adherence analysis.

Feasibility. In the preintervention period, the mean visit duration was 21.4 minutes, whereas the mean visit duration during the intervention was 20.6 minutes, with no statistically significant difference by Hotelling's T^2 test ($P = 0.760$), after controlling for patient visit type, trainee presence, and medical interpreter use.

DISCUSSION

The toolkit, specifically teach-back, was associated with improved medication adherence in most rheumatology patients in a safety-net academic clinic with a diverse population. Notably, PDC increased more than 20% in patients with fills for the same prescription in both time periods of the study. The toolkit did not improve patient satisfaction, the gap between PGA and EGA, or RA disease control in our overall population. However, a greater decrease in the CDAI, when compared with referents, were seen in African American and Hispanic patients. It was feasible to implement the toolkit: two of the interventions were performed at more than 90% of the visits, and the toolkit did not increase visit time.

Medication nonadherence is a major issue in the treatment of all chronic conditions, including RA (26,27). Mediocre adherence to RA therapies is estimated to be as low as 30% and is associated with suboptimal disease control (28–31). Providers often do not recognize nonadherence, and it cannot be reliably predicted by demographic factors (26). Although patient education and mobile text messages have been shown to improve medication adherence in RA (32,33), the effects of interventions to improve medication adherence in RA are inconsistent (34).

Teach-back's dramatic impact on PDC can be explained by its ability to help patients learn more about their disease and the risks and benefits of medication therapy. These are the exact needs that have been identified as goals in recent publications in the rheumatology literature that have clarified the relationship between the intentional nonadherence of patients with RA and both their concerns about medication toxicity and the necessity of aggressive therapy (35,36). Improved patient-provider communication likely drove the PDC improvement because the toolkit does not entail other interventions to improve medication adherence such as pharmacy navigation training, regimen simplification, or medication cost control.

The toolkit's positive impact on medication adherence in Spanish-speaking patients is an important finding given the prevalence of limited English proficiency and its negative impact on health outcomes. More than 60 million persons in the United States speak a language at home other than English (37). Limited English proficiency has been increasingly studied in RA and has been shown to be associated with increased disease activity and worse functional status, which are perhaps mediated through suboptimal shared decision-making, poor knowledge about medications, and the challenges posed by patient-reported outcome instruments (6,9,38–40).

Our finding that African American race and Hispanic ethnicity were predictive of decreases in the CDAI with the intervention is of interest given the extensive evidence of ethnic and racial disparities in RA care in the United States. Studies have shown differences in processes of care, including delayed or reduced disease-modifying antirheumatic drug or biologic therapies among minorities (41–43). This adverse pattern of effective medication use likely contributes to the increased disability, worse global health, and higher RA disability documented in these vulnerable populations (38,44).

Patients and providers often differ widely in their assessments of RA disease activity (9,45). Although the PGA and EGA improved during our intervention, a possible explanation for its failure to narrow the gap between the PGA and EGA is that it did not create the additional time and improved communication needed for the providers to better understand the patients' perspective on disease activity and vice-versa. This goal may have been aspirational given the PGA's poor relationship to joint inflammation (46).

This study has several limitations. The low rates of documented brown-bag medication reviews potentially limited the ability of the toolkit to exert a positive impact. These low rates likely speak to both primary nonadherence and the fragility of our patients' medication-taking behavior. The lower rate of participation with the brown-bag medication review initiative in the patients who received regular clinic flow reminder calls only is a valuable finding in itself because most studies of brown-bag medication reviews provide information regarding the effects of reviews performed and have not reported how many persons were contacted or approached to obtain these data. The low rates of brown-bag medication reviews do not influence our conclusion that adoption of the toolkit is feasible because our feasibility study was conducted in the convenience sample of patients who received additional reminder calls. The brown-bag medication review levels documented in that subgroup are consistent with reported percentages in another urban teaching clinic (47). With our findings, we argue that rheumatology clinics caring for many vulnerable patients will need multifaceted strategies to encourage patients to participate with bringing medications in for brown-bag reviews.

Another limitation is that some of our conclusions about the impact of the intervention on patient satisfaction are hindered by our clinic's high baseline customer service. A ceiling effect is likely present because more than half of the patient satisfaction instruments had preintervention scores above 90% (see Supplemental Table 1). Additional research regarding the toolkit is needed in settings with lower patient experience scores.

Our clinic's low preintervention PDC may have limited the intervention's impact on RA disease control. The sDMARD adherence improved, but adherence only reached 64.8%, which may not have

been high enough to impact the CDAI. Additionally, our EMR is unable to capture PDC data from outside pharmacies, and very low numbers of observations were seen for prescriptions filled from our pharmacy for biologic agents because many patients in safety-net clinics receive high-cost medications through medication assistance programs. The lack of accounting for these bDMARDs creates some ambiguity about our observations regarding potential relationships between PDC and the CDAI. Our medication adherence data suggest that in a public health safety-net clinic with very low baseline medication adherence, the toolkit is an intervention that may improve medication adherence but that ultimately may need to be paired with other interventions. Research into the challenges that vulnerable patients face when trying to navigate patient assistance programs for biologic agents is also needed.

Strengths of this study include the simplicity of the intervention and its real-world setting, which is a public health clinic that includes a wide range of patients in terms of sex, age, race, and ethnicity. As such, it is part of a growing research agenda that seeks to share the great strides in RA care over the past decades in affluent societies with these communities' most vulnerable persons (6,16,42).

These findings expand what is known about strategies to improve medication adherence, reduce RA care disparities, and improve outcomes for underserved patients with LHL. Despite LHL's high prevalence and association with adverse RA outcomes, few interventions improve the care of such patients (16,17). The toolkit's universal deployment design also ensures that its potential benefits will not be restricted to patients with LHL. The toolkit is feasible to adopt and is able to improve medication adherence, with providers using teach-back in a real-world clinical setting.

AUTHOR CONTRIBUTIONS

Drs. Hirsh, Wood, Caplan, and Davis were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Hirsh, Keniston, Davis.
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