A Low-Literacy Medication Education Tool for Safety-Net Hospital Patients

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Background: To improve medication adherence in cardiac patients, in partnership with a safety-net provider, this research team developed and evaluated a low-literacy medication education tool.

Methods: Using principles of community-based participatory research, the team developed a prototype of a low-literacy hospital discharge medication education tool, customizable for each patient, featuring instruction-specific icons and pictures of pills. In 2007, a randomized controlled clinical trial was performed, testing the tool's effect on posthospitalization self-reported medication adherence and knowledge, 2 weeks postdischarge in English- and Spanish-speaking safety-net inpatients. To validate the self-report measure, 4 weeks postdischarge, investigators collected self-reports of the number of pills remaining for each medication in a subsample of participants. Nurses rated tool acceptability.

Results: Among the 166/210 eligible participants (79%) completing the Week-2 interview, self-reported medication adherence was 70% (95% CI=62%, 79%) in intervention participants and 78% (95% CI=72%, 84%) in controls (p=0.13). Among the 85 participants (31%) completing the Week-4 interview, self-reported pill counts indicated high adherence (greater than 90%) and did not differ between study arms. Self-reported adherence was correlated with self-reported pill count in intervention participants (R=0.5, p=0.004) but not in controls (R=0.07, p=0.65). There were no differences by study arm in medication knowledge. The nurses rated the tool as highly acceptable.

Conclusions: Although the evaluation did not demonstrate the tool to have any effect on self-reported medication adherence, patients who received the schedule self-reported their medication adherence more accurately, perhaps indicating improved understanding of their medication regimen and awareness of non-adherence.

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Introduction

Although patient adherence to medications is a key component of chronic disease management, studies consistently show average adherence to be 50%.[1] Multiple factors have been shown to underlie medication nonadherence, with patient knowledge being a key determinant.[1] Patient understanding of directions for prescribed medications is an essential prerequisite for adherence.[2,3]

Studies have shown an association between lower levels of health literacy and less medication knowledge and adherence.[4–7] Health literacy, "the ability to read, understand, and act upon health information,"[8] is associated with multiple outcome disparities.[9] More than one third of U.S. residents have low health literacy, such that they are unable to determine medication timing based on a common prescription drug label[10]; therefore, the IOM has named this issue as a priority area for national action.[11] However, interventions shown to diminish health literacy–associated disparities still need to be developed and evaluated.[12]

This paper describes the development of a customizable low-literacy picture- and icon-based medication tool in partnership with a large urban safety-net hospital in Southern California, and presents an evaluation

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of its effect on medication adherence and knowledge when used for teaching cardiac patients about their medications at hospital discharge. The team chose to target hospital discharge because medication adherence is especially important following hospitalization in cardiac patients,[13] and as medication adherence prevents readmission for cardiac patients,[13] this intervention point and patient population was of particular interest to the project's organizational partner.

Methods

This project used the principles of community-based participatory research as a framework for project development and implementation.[14] Organizational partnerships are essential for maximizing the relevance to and practicality of interventions for real-world healthcare settings.[15] The partner organization was integrally involved at all project stages, from conception through data interpretation and manuscript preparation. This partnership resulted in the prioritization of developing an intervention and evaluation that would be acceptable to and work in the context of the financial and organizational constraints of this safety-net organization.

Intervention Development

The project team, consisting of researchers and our partner organization's physicians, nurses, and administrators, designed a prototype low-literacy medication tool. Given that low-literacy patients are better able to identify their pills visually rather than by name,[16] and that pictures and simple icons improve patient understanding of medication instructions,[17,18] the tool featured pill pictures and instruction-specific icons. Customized for each patient's medications via interactive computer programming, and printed in color on standard paper in English or Spanish, the tool was designed to be used to supplement verbal medication education and then given to the patient for home use.

The team showed the prototype to our partner's physicians, nurses, and pharmacists, making serial modifications until reaching a saturation point of ideas. Customized schedules were made for ten (five English-speaking, five Spanish-speaking) patients being discharged from the cardiology service, and the team observed the nurse using the schedule to teach each patient. Patients were asked to provide feedback via a semi-structured interview, which asked about tool clarity, their interpretation of the pictures and icons, and whether and how they might use the tool postdischarge. The nurses who used the prototype for these patients provided feedback via spontaneous comments and anonymous surveys using open-ended questions about the tool's content, clarity, feasibility, and perceived usefulness. Based on these data, additional serial modifications were made. A sample of the final version is shown in Figure 1.

Recruitment

Between January 8 and July 30, 2007, research staff recruited English- and Spanish-speaking inpatients, aged ≥18 years, admitted to the cardiology, internal medicine, or renal ser-

Figure 1. Sample of tool

vices at the study hospital, and being evaluated or treated for congestive heart failure or coronary artery disease.

Research staff reviewed admission records of all patients and spoke with patients to determine eligibility. Patients were excluded if they lived in an institution, had moderate or severe cognitive dysfunction, or had psychiatric illness with psychotic features. Eligible patients available for recruitment were offered enrollment; those who agreed received a $10 prepaid phone card for personal use. Enrollment was finalized on the day of discharge if the patient was discharged to home during study hours (9:00 AM–6:00 PM Monday–Friday, 11:00 AM–3:00 PM Saturdays) and had discharge medications clearly documented by the discharging physician. To improve study efficiency, mid-study the investigators decided to add the additional eligibility criteria of being prescribed three or more scheduled discharge medications and having a verifiable and reliable phone number for completion of postdischarge interviews. Finally, patients readmitted prior to their Week-2 interviews were retrospectively excluded.

Although the intervention targets patients with low health literacy, the evaluation included patients from all literacy levels because it was believed to be possible that patients at higher health literacy levels could also benefit from receiving the tool. Moreover, although the team considered limiting the sample to persons with lower health literacy as a method of maximizing the probability of being able to demonstrate an effect, this was not done because this constraint would have compromised the generalizability of the results to the overall patient population at the community partner hospital. This lack of generalizability would have created results with limited value to the partner and, as a community-partnered endeavor, maximizing the relevance of the project to the partner was made a priority.

All participants provided verbal informed consent with written consent to access medical records. The IRBs of the University of California Los Angeles and the University of Southern California approved the study protocol.

Pre-Intervention Procedures and Covariates Measured

Prior to hospital discharge, research staff administered a structured interview to ascertain sociodemographic characteristics. Participants with corrected visual acuity of 20/100 or better, as measured by a hand-held Snellen card (Borm Bruckmeier Publishing LLC, Germany), completed the Test of Functional Health Literacy in Adults (TOFHLA), 14-point-font English or Spanish version per patient preference.[19] The TOFHLA, which classifies each participant as having adequate, marginal, or inadequate health literacy, has been shown to be a valid and reliable indicator of the ability to read health-related materials. Research staff examined administrative data to further characterize participants, assessing comorbidity burden, discharge diagnoses, discharge service, and length of stay.

Day-of-Discharge Procedures

At this hospital, it is standard to provide patients with a 30-day supply of all discharge medications, at no cost to the patient. The prescriptions are filled in the hospital pharmacy and delivered to the nursing unit. The unit nurse provides all discharge education, including medication instructions. The exception is when the patient is sent to a discharge-waiting unit and a nurse in that unit delivers the education. The standard written instructions include handwritten dosing directions by the discharging physician in addition to instructions typed onto the label of pill bottles. On the day of discharge, eligible participants were randomized into control and intervention arms.

Control participants received standard care. For intervention participants, research staff customized the medication tool to the patients' prescribed medications, in English or Spanish, per patient preference. To ascertain discharge medications and associated directions, the staff used discharge prescriptions and the medication list from the physician's handwritten discharge instructions. If there were discrepancies between sources, the discharging physician was contacted for clarification. The tool was then printed and provided to the discharging nurse. The nurse was briefly oriented to the tool's features, instructed to use it to teach the patient about discharge medications, and to provide it to the patient to take home.

Outcome Measures

Interviews of participants were conducted via telephone 12–18 days (Week 2) postdischarge to assess self-reported medication adherence. This procedure was repeated 26–32 days (Week 4) postdischarge. For each interview, an additional $10 was added to the phone card provided at enrollment.

Participants were permitted use of pill bottles, the medication schedule, or any other form of assistance (including a caregiver's input or designating a caregiver as a proxy) during the interview. The patient was asked about interim physician-directed medication changes. If the patient indicated that a physician had changed a medication's dosage or frequency, then that medication was excluded when calculating adherence. The interviewer was masked to the study assignment; however, no attempt was made to inhibit the patients from revealing their assignments. Questions were derived from the Medication Knowledge and Compliance Scale, modified to elicit information on adherence solely in the postdischarge period.[20]

The participant, or their proxy, was asked to list all medications being taken since hospital discharge. The interviewer accepted descriptors of pills, such as color, size, or function, in place of name. For any discharge medication(s) not spontaneously listed, the interviewer asked about their use, using both generic and brand names (e.g., "Are you taking a medication called Metoprolol, also known as Lopressor?"). Then, for each medication listed, the interviewer asked (1) if the participant had never started or had decided to stop taking the medication, (2) how many times daily the participant was taking the medication, (3) how many pills she or he was taking each time, and (4) how many times she or he had missed taking this medication in the prior week. Then, for each participant, research staff obtained the number of weekly pill doses prescribed from pharmacy dispensing records and compared this information to participants' responses to derive the number of doses taken correctly, taken incorrectly, and missed in the past week. Subtracting incorrect and missed doses from those taken correctly, and then dividing by the number of weekly pill doses prescribed, a self-report percentage adherence for each participant was calculated.

To validate this self-reported adherence, participants were asked to self-report pill counts during an additional Week-4 interview. Participants counted the number of pills left of each medication. For each participant performing this count prior to medication refill, one cardiac medication was randomly selected. The reported count was compared to the number expected to be remaining on that date, given that the patient was provided a 30-day supply at discharge. To measure participants' knowledge of their medications' purposes, for each medication the interviewer asked, "What is this medication for?" The answer was scored as correct if it included a reference to the general purpose of the medication, such as "heart" or "stomach."

The nurse discharging each participant was asked to complete, and submit via a locked box, a self-administered survey of the amount of time spent teaching the participant and, if the participant received the intervention, the nurse's impression of the schedule. The nurse received an entry into a raffle for each survey submitted.

Statistical Analyses

All analyses were conducted in 2007. All outcome variables were prespecified. Self-reported adherence, collected in Week 2 postdischarge, was the primary outcome. To achieve a power of 0.80, with an alpha of 0.05, a minimum sample size of 74 participants in each arm was predesignated; this calculation assumed a minimum 7% difference between arms and a maximum SD of 15% in the primary outcome. Analyses used two-sided *t* tests and chi-square tests to compare demographic information, clinical characteristics, and outcomes between study arms. A Pearson product–moment correlation coefficient was used to determine the correlation between self-reported adherence and self-reported pill count. Intention-to-treat analyses were performed using STATA version 10.0.

Results

Enrollment

Of the 1135 screened patients, 392 did not have an eligible diagnosis, 92 did not speak English or Spanish, 43 had dementia or psychosis, and 86 lived in an institution. Of the remaining 525 patients, 399 (76%) agreed to participate. Of these, 26 patients were excluded for having less than three medications specified at discharge, 27 because they had no reliable phone number, and 16 because they were not discharged to home. Thus, 286 (72%) participants were randomized on the day of hospital discharge. Because of the mid-study change in inclusion criteria, 14 patients were also retrospectively excluded from analyses who had fewer than three medications specified at discharge, and 39 patients were excluded because they had no reliable phone number. Additionally, 23 patients were excluded for having been readmitted prior to Week-2 interviews. These retrospective exclusions were approximately equal by randomization arm. In total, 100 intervention were randomized, as were 110 control participants who met our final eligibility criteria. Figure 2 shows the flow of participants through the trial.

Participant Characteristics

As shown in Table 1, intervention participants were more likely to be Hispanic (p=0.07); perform the interview in Spanish (p=0.05); use a non-English language at home (p=0.03); report limited English proficiency (p=0.07); have Medicaid (p=0.08); and have a lower comorbidity burden (p=0.04). Inadequate health literacy was prevalent at 47% and similar in each arm.

Self-Reported Medication Adherence

Of the 210 eligible participants, 166 (79%) completed the Week-2 interview, including 81 (81%) intervention and 85 (77%) control participants. A proxy was used by 41 (24%) participants, with no difference by study arm. In comparison to nonresponders, Week-2 responders had fewer comorbidities (p=0.03) but were otherwise similar.

As shown in Table 2, Week-2 mean self-reported medication adherence was 70% (95% CI=62%, 79%) among intervention participants compared to 78% (95% CI=72%, 84%) among controls (p=0.13). Sensitivity analyses for randomization imbalances did not

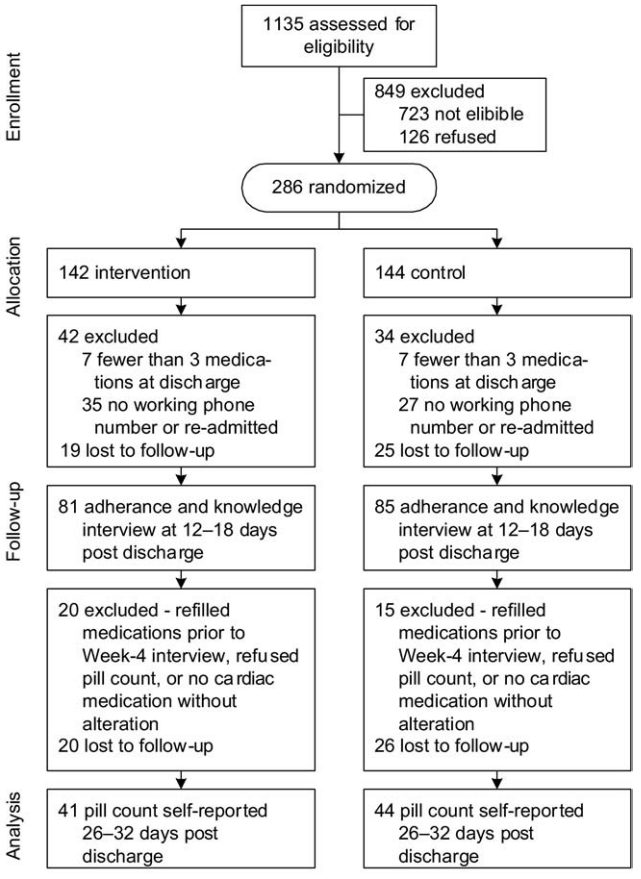

Figure 2. Participant flow diagram

Table 1. Sociodemographics, health literacy, English proficiency, and clinical characteristics of participants (% unless otherwise indicated)

	All (n=210)	Intervention (n=100)	Control (n=110)	p-value
Age (years, M [SD])	55.8 (11.7)	55.7 (11.6)	55.7 (11.6)	ns[a]
Female	38.9	36.4	41.3	ns
Married	43.8	49.0	39.1	ns
Race/ethnicity				
Hispanic	75.2	81.0	70.0	0.07
Black	13.3	10.0	16.4	ns
White	4.8	4.0	5.5	ns
Asian/Pacific Islander	2.0	1.0	2.7	ns
Other	5.2	4.0	6.4	ns
Foreign-born	73.5	77.8	69.5	ns
Insurance				
Uninsured	62.3	56.6	67.6	0.10
Medicaid only	30.4	36.4	25.0	0.08
Medicare and Medicaid	6.3	6.1	6.5	ns
Housing				
Homeless	3.3	5.0	1.8	ns
Lives alone	9.9	6.3	13.1	ns
Education (years)				
None	11.0	10.0	11.8	ns
1–8	36.7	40.0	33.6	ns
9–12	12.4	8.0	16.4	ns
>12	40.0	38.0	41.8	ns
Illiterate (%)	9.1	9.0	9.1	ns
Health literacy[b]				
Inadequate	47.1	51.6	43.4	ns
Marginal	16.5	17.2	15.8	ns
Adequate	36.4	31.3	40.8	ns
Language				
Interview in Spanish	66.2	73.0	60.0	0.05
Limited English proficiency	50.5	57.0	44.4	0.07
Uses non-English language in home	77.6	84.0	71.8	0.03
Clinical characteristics				
Documented CHF	48.9	49.6	48.2	ns
Documented CAD	50.4	51.9	48.9	ns
Comorbidities				
0–1	12.0	16.0	8.3	0.05
2–3	53.4	57.0	50.0	
>4	34.6	27.0	41.7	
Psychiatric disorder	6.2	4.0	8.2	ns
Substance abuse disorder	19.1	19.0	19.1	ns
Hospitalization and discharge characteristics				
Daily pill doses prescribed (M [SD])	7.8 (3.3)	7.7 (3.5)	7.8 (3.3)	ns
Myocardial infarction	15.4	14.8	16.0	ns
Discharged from cardiology service	43.4	44.4	42.3	ns
Mean length of stay (days [SD])	4.5 (3.9)	4.4 (3.9)	4.6 (4.1)	ns

[a]NS, non-significant
[b]Among the 140 (64 intervention, 76 control) participants who completed the TOFHLA, reasons for noncompletion: 55 secondary to inadequate vision, 15 refused
CAD, coronary artery disease; CHF, congestive heart failure

result in any significant change in findings. In exploratory analyses, we divided the self-reported adherence measure into its two components: regimen discrepancies (what patients reported their doctors had prescribed compared to what was actually prescribed); and self-reported missed doses (doses that the patient knew they had missed, based on their understanding of what they were prescribed) in the prior week. There was no difference by arm in prevalence of regimen discrepancies; however, for self-reported missed doses, the intervention arm self-reported missing a mean of 1.1 doses, compared to 0.5 doses in the control arm (p=0.03).

Self-Reported Pill Count

Eighty-five (31%; 44 control, 41 intervention) participants completed a Week-4 self-reported pill count prior to medication refill (Table 2). Mean difference between reported and expected counts was 2.9 pills, with no difference by arm. Comparing self-reported pill count to self-reported adherence, the two measures were correlated in the intervention participants (R=0.50, p=0.004). However, within the control arm, no correlation was seen (R=0.07, p=0.65).

Medication Knowledge

At Week 2, a total of 110 (65%) participants spontaneously named all medications prescribed to them. On average, participants correctly named 62% of medication purposes. Fifty-four (32%) correctly named the purposes of all medications and 74 (44%) correctly named the purposes of all cardiac medications. Neither the ability to spontaneously list medications nor knowledge of medication purposes significantly differed between study arms. Just over half of participants (51%) had one or more discrepancies between the medications (names, schedule, and dosages) they reported taking and those recorded as dispensed by the pharmacy. No difference was seen by study arm.

Nurse Survey

Of 126 nurses discharging at least one study participant, 69 (55%) returned surveys for 131 (48%) participants (70

intervention, 61 control). The nurse reported spending 5 or more minutes teaching about medications for 39 (56%) intervention participants compared to 41 (67%) control participants (p=0.18). Of the 66 surveys returned for intervention patients, 49 (74%) indicated that if the schedule were available for every patient, the nurse would use it for "every patient"; 11 (16%) would use it for "most patients"; and 6 (9%) would use it for "some patients." No nurse indicated that she or he "would not use it."

Table 2. Week-2 adherence and knowledge outcomes

	All (n=166)	Intervention (n=810)	Control (n=85)	p-value
Self-reported adherence (M % [95% CI])	74.5 (69.4, 79.6)	70.5 (62.2, 78.7)	78.3 (72.1, 84.4)	0.13
Doses reported as missed in prior week (M [95% CI])	0.78 (0.48–1.07)	1.1 (0.60–1.6)	0.46 (0.16–0.76)	0.03
All medications spontaneously named (# [%])	107 (64.5)	52 (64.2)	55 (64.7)	ns
Identified purposes of all medications (# [%])	54 (32.3)	28 (34.1)	26 (30.6)	ns
Identified purposes of all cardiac medications (# [%])	74 (44.3)	37 (43.5)	37 (45.1)	ns

NS, not signficant

Discussion

In partnership with an urban safety-net hospital, this research team developed and evaluated a novel icon- and picture-based tool for teaching low-literacy patients about their medications at hospital discharge. The tool showed high acceptance by nurses in the partner organization.

The evaluation of the tool's effectiveness in modifying medication adherence did not show a significant difference between study arms. Although this negative finding is clouded by potential measurement error, evidenced by the poor correlation between the self-reported medication adherence and self-reported pill counts in our control group, one can be more confident about the lack of effect seen with regimen discrepancies and medication knowledge. It is reasonable to expect that the primary mechanism through which the tool would affect adherence is patient knowledge of their medication regimen. Additionally, increased patient knowledge of the purposes of their medications has been shown to increase adherence.[2,3,21] Thus, the lack of effect in these findings suggests that the intervention truly did not affect adherence.

The lack of an observed impact on adherence may have been secondary to the tool's design, which focused primarily on affecting patients' medication regimen knowledge. Although medication regimen knowledge is a necessary precursor to adherence, other factors are also influential.[2,3,21] Moreover, although pictures and icons have been shown to positively affect patient knowledge, it is unknown if this is the best method for improving knowledge among patients with very low literacy levels.[22]

Alternatively, or in addition, the intervention may have been ineffective secondary to its implementation, which is referred to as a Type III error.[23] An example of how this type of error could have occurred is if the schedule was used in place of, rather than as a supplement to, verbal teaching. Implementation research methods, specifically those promoting and evaluating intervention fidelity, as well as those using qualitative techniques to measure how participants experience the intervention, should be used in future studies.[23,24]

Although the lack of correlation in the control group between self-reported pill count and Week-2 self-reported adherence prevents definitive conclusions about the tool's effect on adherence, the significant difference between the intervention and control group in this correlation has potential implications. Although there is no gold standard for measuring medication adherence,[25] in comparison to self-reported missed doses, pill counts have been demonstrated to correlate more closely with other objective data, such as pharmacy refill data.[26,27] If the self-reported pill count is the more accurate of the two measures, this differential validity of self-reported adherence between arms has three implications. First, poor validity of the self-report measure among control participants may have prevented the detection of any effect the schedule had on medication adherence. Second, the receipt of the medication schedule appears to have improved the accuracy with which patients reported their adherence. Given that self-reported adherence is dependent on patients' understanding of their medication regimens,[3] the tool may have improved participants' understanding of their regimens in a manner not adequately measured by the knowledge assessment. Third, this finding suggests that self-reported outcomes may not be appropriate for evaluating medication adherence in people with limited health literacy, and more objective measures would be needed to optimally assess the tool's effect. Finally, given the high attrition rate of participants for the Week-4 self-reported pill count, it is possible, but less likely, that this finding was due to a systematic difference, by study arm, in the attrition of participants between the Week-2 and Week-4 measures.

Limitations

In addition to the possibility of significant measurement error as discussed above, there are several limitations to the current evaluation. The surprisingly high adherence rates, much higher than the 50% in other studies,[3,28–31] found in both arms suggest potential selection and observation biases. There may have been selection bias introduced by the process of enrolling and/or the postrandomization attrition. Further, there may have been a selection bias, by more adherent patients being more likely to complete the Week-4 self-reported pill count. In addition, adherence may have been enhanced, in both study arms, through nurse and/or patient awareness of being observed.[32,33] The project may have changed nurses' subjective norms about discharge medication education.[33] Paradoxically, the process of partnering with the organization (during which a substantial effort was made to reach out to and obtain buy-in from the nurses, a key stakeholder group) may have increased this effect. Finally, the high adherence rates also raise the question of the generalizability of the findings. The study was set in a unique safety-net hospital with the unusual standard of care of providing patients their discharge medications without charge, which likely encouraged adherence.[34] Another threat to generalizability and explanation for high adherence is that the current sample had a high prevalence of immigrants and people of Hispanic ethnicity, patient populations that may be more adherent to healthcare-provider instructions.[3]

Apart from limitations in the evaluation, the process of designing the tool was also limited by including patient participation relatively late. The basic design of the tool was created by healthcare providers and researchers, soliciting input only after the initial prototype was solidified. A more effective tool may be developed by starting with in-depth qualitative explorations of literacy-compensatory systems used by low-literacy patients, and then building a tool based on these findings with continuous patient input.

Conclusion

This research team developed, in partnership with a major safety-net inpatient provider, a customizable low-literacy picture- and icon-based medication tool. This tool is a potential vehicle for achieving the IOM's recommendations for providing written medication instructions at hospital discharge such that, despite literacy or language barriers, each patient will know the medications he or she is receiving as well as the purposes and appearance of each medication.[35] Although this evaluation did not show a net positive effect on medication adherence, patients who received the tool more accurately self-reported their medication adherence, perhaps indicating an improved understanding of their medication regimen and awareness of when they were nonadherent. Further, given that physicians are often reliant on patients' self-report to measure adherence, a tool that improves the accuracy of this report could result in improved clinical care. The research team is continuing to work with this partner, building on this study and exploring further projects to develop and evaluate interventions to support patients with complex chronic diseases overcoming health literacy barriers.

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