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Development and testing of a communication intervention to improve chronic pain management in primary care: a pilot randomized clinical trial

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Abstract

OBJECTIVES: Effective communication skills are essential for optimally managing chronic pain and opioids. This exploratory sequential mixed methods study tested the effect of a novel framework designed to improve pain-related communication and outcomes.

METHODS: Study 1 developed a novel 5-step framework for helping primary care clinicians discuss chronic pain and opioids with patients. Study 2 pilot tested an intervention for teaching this framework using standardized patient instructors—actors trained to portray patients and provide immediate clinician feedback—deployed during regular clinic hours. Primary

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care physicians were randomized to receive either the intervention or pain management recommendations from the Centers for Disease Control and Prevention. Primary outcomes were pain-related interference at 2 months and clinician use of targeted communication skills (coded from transcripts of audio-recorded visits); secondary outcomes were pain intensity at 2 months, clinician self-efficacy for communicating about chronic pain, patient experience, and clinician-reported visit difficulty.

RESULTS: We enrolled 47 primary care physicians from 2 academic teaching clinics and recorded visits with 48 patients taking opioids for chronic pain who had an appointment scheduled with an enrolled physician. The intervention was not associated with significant changes in primary or secondary outcomes other than clinician self-efficacy, which was significantly greater in the intervention group.

DISCUSSION: This study developed a novel framework and intervention for teaching clinician pain-related communications skills. Although the intervention showed promise, more intensive or multi-component interventions may be needed to have a significant impact on clinicians' pain-related communication and pain outcomes.

TRIAL REGISTRATION: NCT03629197

Keywords

chronic pain; primary care; health communication; communication skills; pain management; opioid analgesics

INTRODUCTION

Patients and primary care clinicians have long cited poor communication and difficult patient-clinician interactions about opioids as important barriers to effective pain management.[1–3] Policy shifts—particularly the Centers for Disease Control and Prevention's (CDC's) 2016 opioid prescribing guidelines—and new evidence about opioid-related harms prompted shifts away from using opioids to treat chronic pain,[4, 5] increased rates of opioid dose reduction (tapering),[6] and state and federal restrictions on opioid access.[7, 8] However, tapering patients who are dependent on opioids is also risky. Tapering, especially rapid or unsupported tapering, is associated with higher rates of overdose, mental health crises (including suicide), and termination of care.[9, 10] In 2019 the US Department of Health and Human Services issued guidelines on opioid dose reduction for patients with chronic pain that recommended clinicians engage in shared decision-making with patients and avoid unilateral dose reduction unless patients are at imminent risk of serious harm.[11]

In this context, effective discussions about chronic pain and opioids require nuanced conversations and strong patient-clinician relationships. Primary care clinicians prescribe the majority of opioids for chronic pain, but traditional medical training focuses on pain intensity assessment and rarely includes training in the higher-level communication skills or strategies needed to navigate these conversations.[12, 13] Commonly used models for teaching effective, patient-centered communication are not pain-specific and do not address common problems and challenges specific to chronic pain and opioids.[14–17] In addition, educators

and researchers need strategies for effectively teaching pain-related communication skills to busy clinicians.

In this study, we first developed a novel framework for communication about chronic pain and opioids in primary care. We then developed and pilot tested an intervention for teaching this framework that used standardized patient instructors—actors trained to realistically portray patients and then provide immediate feedback on clinician performance—deployed during regular clinic hours. We hypothesized that clinicians who received this education would display more targeted clinician communication behaviors, and that patients seeing clinicians in the intervention group would report lower pain-related interference 2 months after their visit. A feasible, acceptable intervention for developing clinician communication skills to improve pain management and reduce opioid-related harms could inform design of larger clinical studies to definitively test intervention effectiveness.

This was an exploratory sequential mixed methods study in which we collected qualitative data to inform development of a communication framework and then conducted a pilot cluster-randomized trial of this framework delivered by standardized patient instructors.[18] Both studies were approved by the University of California Davis Institutional Review Board. Study 2 was registered at clinicaltrails.gov (NCT03629197).

STUDY 1: FRAMEWORK DEVELOPMENT

STUDY 1 MATERIALS AND METHODS

We developed a framework for communicating about chronic pain and opioids based on our clinical experience, reviewing relevant literature,[19] and conducting a series of individual, one-hour semi-structured interviews with 15 patients and 10 resident physicians to obtain their perspectives on patient-clinician communication about pain and opioids in primary care.

Patients were 18–80 years old who endorsed chronic pain (pain on most or all days for >3 months). Pregnant patients and patients receiving cancer treatment, hospice, or palliative care were excluded. Two-thirds of patients were prescribed opioids for chronic pain and one-third had been prescribed opioids for chronic pain within the past year. We included patients who had recently been tapered off opioids because in our experience these patients provide perspectives about effective versus ineffective communication strategies that are different and complementary to the perspectives of patients currently taking opioids. Patients were recruited from the community (not from a specific health system) by a Sacramento-based marketing research firm. Firm employees called patients, screened them for eligibility, and provided a secure interview space for interviews. Clinicians were second- and third-year residents in Internal or Family Medicine at University of California, Davis and were recruited by the primary author. We recruited residents because patients on long-term opioids disproportionately receive care in resident clinics.[20] Interviews were conducted by the primary author and an experienced qualitative research consultant. Patients and clinicians received $100 for participation.

Patient interviews began with a series of open-ended questions asking for examples or communication strategies that had either helped or impeded their chronic pain management. Patients then watched five 60–90 second video clips of patients and physicians discussing chronic pain and opioids during actual primary care visits that had been collected for a previous study.[21] After each clip, patients were asked open-ended questions about what the physician in the clip did well and what could have been improved. Finally, patients were asked to review of a list of nine pain-related communication skills and then to rate the importance of each skill on a 5-point Likert-type scale (1="not important" to 5="extremely important") and identify the top three skills for which they thought clinicians needed additional training.

Physician interviews followed the same format. They were first asked open-ended questions about challenges they face when communicating with patients suffering from chronic pain and effective and ineffective strategies for communicating and negotiating treatment plans. They then watched and answered questions about the same five video clips patients watched and rated the same nine communication skills. Interviews were audio recorded and transcribed for analysis.

The primary author and qualitative research consultant analyzed interviews using qualitative content analysis.[22] Analysis goals were to identify putatively effective and ineffective clinician strategies for communicating about chronic pain and opioids (i.e., communication "dos and don'ts") and to guide development of a framework for teaching pain-related communication skills to primary care clinicians. First, themes and strategies were identified by iteratively reviewing interview transcripts and comparing results. These themes were then integrated with participants' quantitative ratings and rankings of the nine pain-related skills and practices to identify high-value skills that the framework should emphasize. Analyses were conducted without any qualitative software program.

Once the initial qualitative analysis was complete, two co-authors (SGH and RLK) used these findings to create a 5-step framework for teaching pain-related communication skills to primary care clinicians. The initial framework was refined and finalized based on informal feedback and suggestions from primary care clinicians and pain management experts. Based on our team's prior experience, concrete algorithms or step-by-step approaches tend to be effective formats for conveying communication skills to clinicians,[23–25] likely because these formats are commonly used to teach clinical concepts and practice recommendations.

STUDY 1 RESULTS

The 15 patient participants had a mean age of 44 (SD 15) and were 53% female, 80% white, 20% black, and 33% Hispanic. Two-thirds reported currently taking opioids and one-third reported having taken opioids for more than 3 months within the past year. Two-thirds reported having pain for more than 5 years, and 53% reported average pain intensity of 7 or greater during the past week. The 10 physician participants had a mean age of 31 (SD 2) and were 60% female, 40% white, 60% Asian, and 20% Hispanic. Supplemental Digital Content 1 provides more detailed information on participant characteristics.

Table 1 shows how participants rated the importance of the nine pain-related communication skills during their interviews and the skills they identified as areas where physicians needed additional training. Participants' mean rating for all skills was between 4 ("important") and 5 ("extremely important") except for performing a physical exam during every visit. Patient and physician mean ratings for each skill were nearly identical, except that patients rated "committing to treating and partnering with the patient long-term" as somewhat less important than did physicians. A majority of both patients and physicians identified "asking details about the patient's pain, medication use, and side effects" as a skill to prioritize for additional physician training. A majority of patients also identified "showing that the patient's pain is taken seriously" as a priority skill, while a majority of physicians also identified "negotiating an individually tailored treatment plan" as a priority skill.

Table 2 shows the final 5-step framework we developed based on study results. Step 1 involves preparing for the visit, with a focus on managing clinicians' negative emotions —an important barrier to effective communication involving pain and opioids[2, 3]—and keeping an open mind. Step 2 involves showing the patient that the clinician takes their pain seriously by, for example, asking detailed questions about the patient's history, eliciting the patient's perspective, and showing empathy. Step 3 involves assessing patient's opioid-related risks, with a focus on effectiveness and medication side effects, which are more salient than overdose risk for the majority of patients taking opioids for chronic pain. Steps 4 and 5 involve developing mutually agreed-upon pain treatment goals and goal-directed treatment plans, respectively. More detailed descriptions of the framework components, along with specific strategies and techniques for accomplishing each step, have been published previously[26, 27] and are also available online (See PDF, Supplemental Digital Content 2).

STUDY 2: INTERVENTION DEVELOPMENT AND PILOT TESTING

STUDY 2 MATERIALS AND METHODS

Intervention development—To examine the effectiveness of our communication framework, we developed an intervention using standardized patient instructors to impart communication skills to primary care clinicians and then conducted a cluster-randomized trial to pilot test this intervention's impact on communication during clinic visits with actual patients and subsequent pain-related outcomes.

Standardized patients are actors trained to realistically portray patients when interacting with clinicians or trainees and are commonly used in medical education.[28, 29] Standardized patient *instructors* are standardized patients trained to both portray patients and then deliver formative feedback to clinicians about their performance. Deploying standardized patient instructors during usual office hours creates a highly situated learning experience.[30] Situated learning facilitates transfer, whereby learning in a particular context (e.g., negotiating treatment goals with standardized patients) leads to almost immediate application of what has been learned to similar "real-life" contexts (e.g., negotiating treatment goals with real patients).[31] Due to the relatively high speed and potency, transfer potential, and convenience of situated learning compared to other approaches, standardized patient

instructor interventions often yield strong, immediate beneficial effects on clinician communication and decision making.

Table 3 summarizes the components of our intervention. These comprised a 9-minute video summarizing the 5-step communication framework, a laminated pocket card, a booklet with detailed communication examples and strategies for accomplishing each step in the framework, two detailed standardized patient scenarios in which standardized patients role-played patients requesting opioid refills for chronic pain, and feedback scripts for standardized patients in each scenario to use when providing feedback to clinicians after their role play. Feedback scripts focused on walking clinicians through the 5-step framework and citing examples from clinicians' role play when providing real-time feedback to reinforce framework principles. The pocket card and booklet are available online (See PDF, Supplemental Digital Content 2).

We identified standardized patients for our study from the University of California Davis School of Medicine standardized patient program. Each standardized patient received approximately 40 hours of training from an experienced standardized patient instructor, including practice sessions with clinician investigators.

Clinical trial design and procedures—Once intervention materials were complete, we conducted a pilot cluster-randomized trial that randomized clinicians to the intervention versus "enhanced usual care." Study design and conduct followed CONSORT guideline extensions for pilot and feasibility trials.[32] The intervention was delivered by standardized patient instructors, while intervention effects were examined by assessing clinician communication during regularly-scheduled clinic visits with actual patients and subsequent pain-related outcomes. Trial goals were to evaluate intervention feasibility and acceptability and to generate preliminary data on effectiveness at two university-based primary care clinics. Pre-specified primary outcomes were clinician use of targeted communication behaviors and patient pain-related interference 2 months after their visit. Pre-specified secondary outcomes were patients' pain intensity 2 months after their visit, physician self-efficacy for communicating about chronic pain, physician-reported visit difficulty, patient visit experience, and clinician assessment of the intervention.

Clinician recruitment and randomization.: We recruited internal and family medicine residents with ≥1 year of residency training (to ensure participants were familiar with clinic logistics and had a chance to develop their clinical communication styles) who reported caring for patients prescribed opioids for chronic pain. We recruited clinicians through presentations at resident lectures and training sessions. To ensure allocation concealment, clinicians were randomized to receive either the intervention or the control after all clinician recruitment was complete. Randomization was a simple 1:1 allocation stratified by clinic site.

Intervention.: Clinicians randomized to the intervention received two visits from standardized patient instructors during their regular primary care clinic schedule; two patient appointment slots were blocked to provide time for the intervention. Study staff notified clinicians prior to each standardized patient visit; this was not a "secret shopper"

study. During the first visit, clinicians watched the video introducing the communication framework and received the pocket card and pamphlet from the standardized patient instructor. The standardized patient instructor then role-played a patient with chronic pain requesting an opioid refill. Finally, the instructor provided feedback on the clinician's performance relative to the 5-step framework. The second standardized patient appointment was scheduled 1–2 weeks later and comprised role-play and feedback from a different standardized patient.

Control.: Clinicians randomized to the control group ("enhanced usual care") received educational materials about opioid prescribing prepared by the Centers for Disease Control and Prevention.[33] To ensure that clinicians actually reviewed the materials, study staff delivered the materials in person and sat with the physician for a few minutes while they reviewed the materials.

Patient recruitment.: Eligible patients were established adult clinic patients who were prescribed long-term opioids for pain (defined as ≥1 opioid dose per day for ≥90 days) and had a regularly scheduled clinic visit with an enrolled physician who had completed all intervention or control activities. Patients were excluded if they were pregnant, spoke a language other than English during clinic visits, were receiving active treatment for cancer, were enrolled in hospice or palliative care, or were receiving opioids from someone other than their primary care clinician.

To recruit patients, research staff reviewed enrolled clinicians' clinic schedules to identify potentially eligible patients. They sent letters to these patients followed by phone calls during which they explained the study and assessed patient interest and eligibility. Research staff asked each interested, eligible patient three visit-specific screening questions to determine whether pain management was likely to be a substantive topic of discussion during the patient's scheduled visit:

1. How would you rate your average pain over the past week, with zero being no pain and 10 being the worst pain possible?
2. At your upcoming visit, how likely are you to talk about ways to get better control of your pain? (1-very unlikely to 5-very likely)
3. At your upcoming visit, how likely are you to talk about changing the dose or type of your pain medicine? (1-very unlikely to 5-very likely)

Patients were eligible if they rated their pain as ≥4 and answered "likely" or "very likely" to either question 2 or 3. Interested patients who did not meet these criteria were re-screened prior to subsequent appointments. We recruited up to two patients per enrolled clinician; each patient was recorded during a single visit.

Data collection.: Clinicians completed a baseline questionnaire at enrollment, an assessment questionnaire after they had completed intervention or control activities, and a post-visit questionnaire immediately after each patient visit. Patients completed questionnaires immediately before and after their visits. Prior to each visit, research staff set up unobtrusive audio recorders in the exam room to record the clinic visit. The research

assistant waited outside of the exam room during the visit and collected the recorders after each visit. Visits took place between December 2018 and August 2019. Patients completed a questionnaire by telephone approximately 2 months after their visit. Finally, we abstracted data from patients' electronic health records.

Study measures and outcomes.

Clinician measures.: At enrollment, clinicians provided demographic information and completed 8 Likert-type items assessing their self-efficacy for communicating about chronic pain. Items were developed for this project and used phrasing common in self-efficacy measures. [34, 35] Supplemental Digital Content 3 lists individual items. Clinicians completed these same self-efficacy items again after completing control or intervention activities; clinicians assigned to the intervention also answered 11 Likert-type items assessing intervention acceptability and feasibility. Finally, immediately after each visit with an enrolled patient, clinicians completed a post-visit questionnaire that included the self-efficacy items and the Difficult Doctor-Patient Relationship Questionnaire.[36] Clinician-reported visit difficulty has been associated with worse patient satisfaction, greater symptom burden, and higher healthcare utilization.[37, 38] Clinicians also reported any change in prescribed opioid dose.

Patient measures.: Patients completed questionnaires immediately before and after visits. Baseline (pre-visit) measures included demographics and the Brief Pain Inventory, an 11-item measure that includes subscales for pain intensity and pain-related interference.[39] Physical and mental health were assessed using the Veterans RAND 12-item Health Survey (VR-12), a non-proprietary version of the SF-12. Responses to the VR-12 were used to calculate physical health component scores (PCS) and mental health component scores (MCS). PCS and MCS range from 0 to 100 (with 100 indicating perfect health) and have been benchmarked against nationally representative surveys.[40] Patients' anxiety and depressive symptoms were measured using the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-8, respectively.[41, 42] Patients' problems and concerns about their opioid medication were measured using the Prescribed Opioid Difficulties Scale.[43]

Post-visit patient measures included three measures about their experience during the visit: agreement with treatment plan was assessed using a 3-item scale developed by Staiger et al;[44] appraisal of clinicians' communication skills was assessed using 6 items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Adult Visit Survey;[45] trust in clinician was assessed using the short form of the Wake Forest physician trust scale.[46] These 3 patient-reported measures were all highly correlated (r range 0.75 – 0.79). Exploratory factor analysis indicated that all 3 measures assessed a single latent construct. Therefore, we combined them into one standardized composite variable called "patient experience."[47] This measure provides information about how patients felt about the clinician and their clinical visit. Patients also reported whether the visit was with their usual primary care clinician. Study staff called patients two months after their visit and administered the Brief Pain Inventory by phone.

Patient-clinician communication.: To assess clinician communication, we first identified observable clinician communication behaviors that were aligned with, or explicitly encouraged by, each step in our framework. Next, four co-authors (GW, HN, WMG, and SGH) independently coded two visit transcripts using the preliminary list of behaviors and then met to compare results, discuss disagreements, and refine coding definitions. Transcripts were identified using only encrypted patient study identifiers (not clinician identifiers) to ensure coders were blind to treatment allocation. We repeated this process with additional pairs of transcripts until everyone could reliably code study behaviors. Our final list included 26 communication behaviors; Table 4 shows representative examples. There were no behaviors associated with step 1 of our framework, which relates to clinician attitudes prior to the visit. Three co-authors (GW, HN, and WMG) independently applied the final coding system to each study transcript and met regularly to compare results. Disagreements were resolved through discussion, with conflicts resolved by the primary author. Each behavior was coded as a binary variable indicating whether that behavior was observed at least once during the visit or not; coding for a specific behavior (e.g., asking an open-ended question about the patient's pain) was the same whether that behavior occurred once or multiple times during a visit. This coding system produced a count of the unique clinician communication behaviors coded during each visit. Other health communication researchers have used similar approaches to assess clinician communication.[48, 49] Coding was primarily based on transcripts; however, coders consulted audio recordings when data on nonverbal communication was needed to resolve ambiguities (e.g., to determine whether an utterance was a statement or a question). Agreement among coders was moderate (Fleiss kappa 0.41–0.60) for most behaviors;[50, 51] however, effective reliability of the final data is higher than indicated by kappa statistics because coders jointly discussed and resolved all discrepancies. Supplemental Digital Content 4 lists frequencies and kappa statistics for all coded behaviors. The complete codebook is available from the corresponding author by request.

Chart review.: A trained research assistant manually abstracted electronic health record data after patients had completed their study procedures. A physician co-author (SGH or MLD) over-read abstracted chart data to ensure accuracy. Data abstracted were patients' prescribed daily opioid dose at the time of their visit and 2 months after the visit as well as the anatomic location(s) of patients' pain. Doses were converted into milligram morphine equivalents (MME) for analysis using standard conversion factors.[52]

Statistical analyses—For this pilot study, our target sample size of 48 patients was powered to have 80% probability of detecting an intervention effect of 0.78 standard deviations, assuming a two-sided test, alpha = 0.05, clinician-level ICC of 0.1, and a cluster size of 2. Primary outcomes were clinician use of targeted communication behaviors and patients' pain-related interference 2 months after their visit. Secondary outcomes were patients' pain intensity 2 months after their visit, physician self-efficacy for communicating about chronic pain, physician-reported visit difficulty, patient visit experience, and clinician assessment of the intervention (process measure). Additional, exploratory outcomes were change in prescribed opioid dose 2 months after each patent's visit and number of

targeted communication behaviors observed for each individual step in the communication framework.

We first examined baseline patient and physician characteristics by randomization status. Analyses involved comparing the intervention and control group by examining the coefficient associated with the arm assignment variable. We used Poisson regression with robust standard errors to model number of observed communication skills per visit and linear regression for all other outcomes. We used generalized estimating equation with robust standard errors to account for patients being clustered within clinicians,[53, 54] because this approach is more robust to outlier values in small samples than mixed effects models.[55] For dependent variables that were measured more than once (pain intensity, pain-related interference, clinician self-efficacy, and prescribed opioid dose), we adjusted models for baseline values rather than operationalizing these outcome variables as change from baseline. In addition to arm assignment, primary analyses were adjusted for clinic (family medicine versus internal medicine) because randomization was stratified by clinic. When measures had substantial unadjusted differences between arms (indicating failure of randomization), we explored adding them as covariates to multivariable models. Analyses were conducted using Stata 17.

STUDY 2 RESULTS

Figure 1 shows the study CONSORT diagram for study 2. Eight clinicians were excluded from the primary analysis because they did not see any study patients. Two patients were excluded after study completion because they were prescribed opioids by specialists rather than by their primary care clinician. The final sample for our primary analysis comprised 46 patients and 37 clinicians. Twenty-six clinicians saw one study patient; eleven saw two study patients.

Tables 5 and 6 show baseline clinician and patient characteristics, respectively. Clinicians had a mean age of 29.7 years, were 64% female, 47% Asian / Pacific Islander, and 27% non-Hispanic white. Patients had a mean age of 60.6 years, were 70% female, 37% non-Hispanic white, and 35% black. Patients had a mean baseline score of 6.9 out of 10 for both pain intensity and pain-related functional impairment; 54% reported being disabled or unable to work. Patients' mean PHQ-8 score was 10.3 and their mean GAD-7 score was 8.9. Scores ≥10 on both scales indicate likely major depressive disorder[41] and generalized anxiety disorder,[42] respectively. Based on chart review, the most common pain sites were back (70%), lower limb (hip, knee, or leg; 63%), and upper limb (shoulder, arm, or hand; 24%). Patients had a median of 2 different pain sites (IQR 1–3). Patients' median daily opioid dose was 30 MME; only four patients were prescribed >90 MME, the CDC's threshold for high-dose prescription opioid use.

Visits had a median length of 29.6 minutes (IQR 24.3 – 37.4). Clinicians displayed a mean of 3.2 targeted communication behaviors per visit (median 2.5, range 0–11). During coding we found that in a few visits (n=6) some targeted communication behaviors took place in the context of discussions about patient-clinician agreements, documents that include written documentation of opioid-related side effects and pain-related functional goals. Targeted communication behaviors that happen while reviewing these documents may not be causally

related to intervention exposure, so we added a sensitivity analysis excluding them. Most (58%) of all communication behaviors coded related to step 2 of our framework (show patients you take their pain seriously); 29% related to step 5 (develop a goal-directed treatment plan). Behaviors related to steps 3 (assess opioid-related risks) and 4 (set pain treatment goals) were relatively rare (7% each). These percentages are consistent with our observation during coding that clinicians typically spent a large proportion of visits taking patients' pain histories (which roughly corresponds to step 2 of our framework) but often deferred discussing pain-related functional goals (step 4 of our framework) due to insufficient visit time.

Table 7 shows results of our prespecified and exploratory analyses. Clinicians who received the intervention displayed a mean of 3.5 targeted communication behaviors per visit compared to 2.8 for clinicians in the control group. This effect was not statistically significant (IRR 1.25; 95%CI 0.76, 2.05; $P = 0.37$). After controlling for baseline values, seeing a clinician in the intervention group was associated with a nonsignificant 0.3-point improvement in pain-related interference after 2 months (coefficient = −0.3; 95%CI −1.8, 1.2; P = 0.7); a change of 0.6 points is generally considered the threshold of clinically meaningful improvement for 11-point pain scales.[56]

Among secondary outcomes, receipt of the intervention was associated with a significant increase in clinicians' self-efficacy for communicating about chronic pain measured after each patient visit (0.4 increase on a 5-point Likert-type scale; 95%CI 0.1, 0.7; $P = 0.005$). Results for other secondary outcomes—patients' pain intensity two months after their visit, clinician-reported visit difficulty, and patient visit experience—were not significant (Table 7). Results from primary and secondary outcomes did not meaningfully change when we excluded behaviors that occurred while reviewing patient-clinician agreements.

Clinicians who received the intervention felt it was effective and feasible. All clinicians in the intervention group (n=24) rated overall intervention quality as good or excellent; 100% of clinicians agreed or strongly agree that the training was helpful, easy to understand, relevant, would lead to improved patient care, and that they would use skills from the intervention in their practice. Only 8% agreed or strongly agreed that the study disrupted patient flow; 83% agreed or strongly agreed that the standardized patients' portrayal of patients with chronic pain was realistic. Open-ended feedback included praise about all intervention components (standardized patient instructors, pocket card, and pamphlet) with a few participants noting that standardized patients should be more resistant to tapering and non-opioid pain treatments in order to be more realistic.

Among exploratory outcomes, the intervention was associated with no significant change in prescribed opioid dose 2 months after the visit (Table 7). When we examined communication behaviors for individual framework steps, we found that the intervention was associated with a significant increase in targeted communication behaviors related to step 2 (2.4 unique behaviors in the intervention group versus 1.1 in the control group; IRR = 2.14; 95%CI 1.34, 3.42, $P = 0.002$). Between-arm differences in communication behaviors related to steps 3–5 were not significant. The intervention was associated with a

nonsignificant decrease in communication behaviors related to step 3 ($P = 0.06$); this finding should be interpreted cautiously given the small number of behaviors related to step 3.

DISCUSSION

In this mixed-methods study we first developed a framework for communicating about chronic pain and opioids and then pilot tested an intervention in which standardized patient instructors delivered the framework content with the goal of improving primary care clinicians' communication skills and, ultimately, pain-related patient outcomes.

Framework development

The novel, 5-step framework developed for this project advances health communication research by positing best practices for communication about chronic pain and opioids. This framework includes both general communication strategies that are widely accepted components of effective clinician communication (e.g., eliciting patient perspectives, showing empathy, striving for shared agreement on treatment goals and plans)[17, 57, 58] and strategies more specific to chronic pain and opioids (e.g., managing negative emotions, assessing risks and benefits of long-term opioid use, navigating disagreements, and broaching conversations about opioid tapering). This framework is also well-aligned with the Department of Health and Human Services' 2019 guidelines for opioid dose reduction and discontinuation, which emphasizes a collaborative, patient-centered approach to patients prescribed long-term opioids for chronic pain.[11] The most common paradigms used to define effective communication—shared-decision making and patient-centered care—have been criticized for providing inadequate guidance about how clinicians should discuss chronic pain and opioid use.[59–61] The strategies in this framework address this inadequacy and can be tested and refined in future studies by researchers and educators working on the often fraught topic of chronic pain and opioids.

Intervention feasibility and acceptability

We found strong evidence of intervention feasibility and acceptability. We met recruitment goals and no patients dropped out or were lost during the two-month follow-up period. One lesson learned was the need to over-recruit clinicians for this type of intervention, because we were not able to recruit study patients for all enrolled clinicians. We intentionally capped patient recruitment at two patients per clinician; recruiting more patients per clinician may be difficult in resident clinics (due to small panel sizes); however, this limitation is likely less applicable for community clinics. Our patient recruitment strategy involved reviewing and contacting patients scheduled to see enrolled clinicians, and screening patients to ensure that visits involved substantive discussions about pain management for which the communication skills taught in the intervention were relevant. This approach was time intensive but effective; nearly all visits included substantive discussions about opioids and pain management. This recruitment strategy requires access to electronic health records and so may need to be modified in multi-site studies that involve multiple different electronic health record systems. Interventions using standardized patient instructors are likely scalable; 90% of US medical schools maintain standardized patient programs from

which standardized patient instructors could be recruited and trained.[28] Standardized patient interactions and coaching sessions could also be conducted via video conference.

Clinicians who received the intervention provided uniformly positive assessments, indicating high acceptability. Factors contributing to acceptability likely included conducting all intervention activities during clinicians' normal clinic schedules (rather than during lunch or after hours) and providing a structured approach for talking about chronic pain and opioids —a topic that physicians routinely describe as among the most difficult clinical topics in both inpatient and outpatient settings.[3, 62, 63]

Intervention effectiveness

In pilot testing with clinicians at two academic primary care clinics, the intervention arm was not associated with significant changes in our two primary outcomes: clinician communication behaviors encouraged by the intervention or patients' pain-related interference two months after their visit. Results should be interpreted cautiously because our study was not powered to detect plausible effect sizes.[64] A possible explanation for these results, including the low rates of targeted behaviors during study visits, relates to competing demands in primary care. During many visits, pain-related discussions were truncated without thorough discussion of goal setting or treatment planning. The paucity of coded behaviors related to step 4 (goal setting) suggests that clinicians pressed for time may give short shrift to establishing pain treatment goals. It is also possible that our operational definitions of targeted behaviors were too narrow, so that we undercounted behaviors that did not fit into our specific coding categories. Another potential explanation is that more intensive interventions are needed to improve pain-related communication and outcomes due to the challenging and heterogeneous nature of discussions about pain in primary care. Future studies could increase intensity by adding additional standardized patient sessions. However, additional sessions may not be feasible for busy clinicians. Some researchers have recommended using multi-level interventions—interventions that simultaneously target both patients and clinicians—when trying to improve patient-clinician communication;[65] thus adding a patient intervention component could be another option for future studies. A previous study found that a multi-level intervention using standardized patient instructors effectively improved patient-centered communication with advanced cancer patients.[66] Finally, two months may be insufficient time to detect intervention-induced changes in pain; future studies could study changes in patient self-efficacy or mood symptoms, which may predict subsequent improvements in pain.[67, 68]

Among pre-specified secondary outcomes, the intervention arm was associated with significant improvements in clinician self-efficacy for communicating about chronic pain. Results for other secondary outcomes were not significant. Finally, our exploratory analysis found no association between the intervention and change in prescribed opioid daily dose two months after the visit. However, opioid dose reduction was not a goal of this intervention.

This study has limitations. The study was conducted in two academic clinics at a single heath system, so may have limited generalizability to other contexts. Deploying standardized patients in busy community clinics is more challenging than doing so in

resident clinics; however, prior studies have successfully deployed standardized patient instructors in community primary care clinics.[69, 70] Our study only examined one visit per patient; examining communication over multiple visits may have increased our ability to detect differences between study arms. Our assessment of framework uptake was limited to behaviors that could be reliably coded from written transcripts. Clinicians were not blinded to arm assignment; however, the intervention was delivered one-on-one in exam rooms, making cross-contamination unlikely.

In this study, we developed a novel framework for pain-related communication and then tested a novel intervention using standardized patient instructors to improve clinician communication about pain and pain outcomes among primary care patients taking opioids for chronic pain. Our pilot cluster-randomized trial found that the intervention was feasible and acceptable to clinicians and clinic staff. The intervention was not associated with significant differences in primary study outcomes; among secondary outcomes it was associated with greater clinician self-efficacy for communicating about chronic pain and more targeted communication behaviors showing that clinicians take patients' pain seriously. Although the intervention shows promise, more intensive interventions are likely needed to improve pain-related communication and outcomes in this population. Next steps for evaluating this intervention include conducting a fully powered clinical trial, and perhaps adding a patient-facing intervention component to increase intensity. Intervention feasibility among community physicians (rather than just residents) should also be assessed. The communication framework developed will likely be useful to other researchers and clinician educations working in this area.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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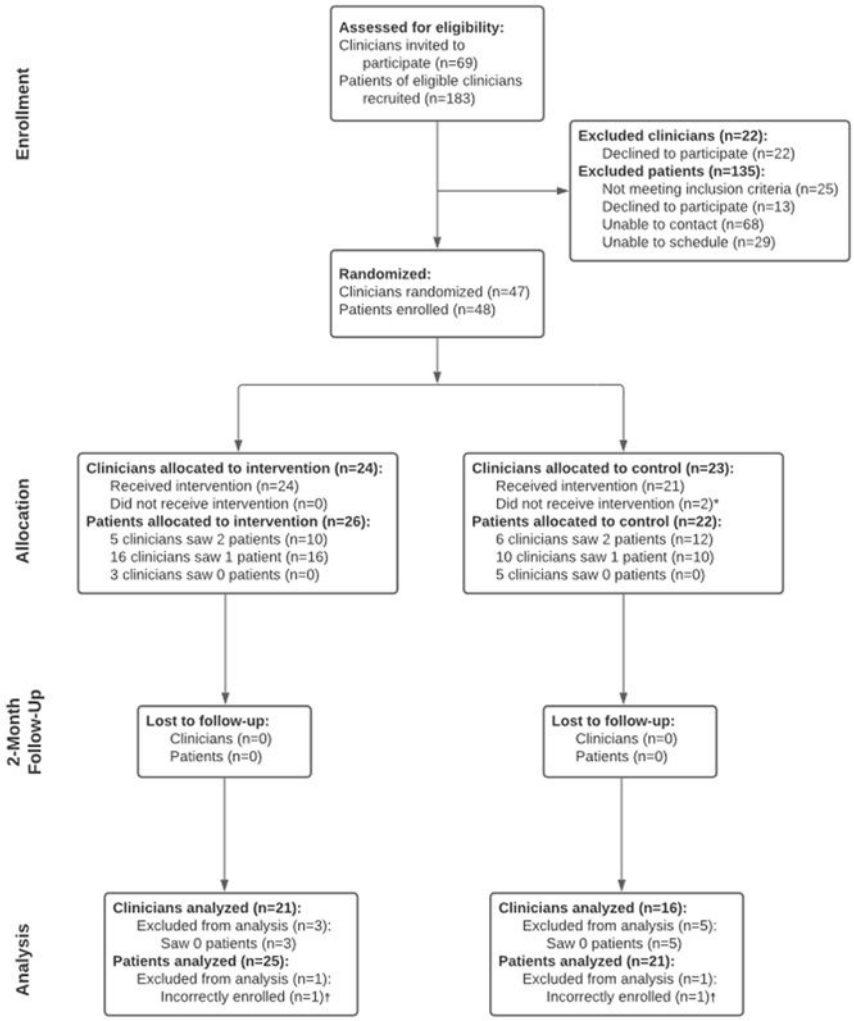

FIGURE 1. Study 2 CONSORT diagram

* Clinicians withdrew after enrolling but before learning of their randomization status.

† Participants were prescribed opioids by specialists rather than by their primary care clinician.

Table 1.

Patient and clinician perception of the importance and need for additional communication skills training (study 1)

Communication skill / activity	Importance mean (SD)[1]		Priority for additional training[2]	
	Patients (n=15)	Clinicians (n=10)	Patients (n=15)	Clinicians (n=10)
Be prepared for patient's visit	4.3 (0.6)	4.3 (0.8)	33%	20%
Perform a physical exam during every visit	3.1 (1.1)	3.1 (0.9)	7%	0%
Show that patient's pain is taken seriously	4.8 (0.4)	4.7 (0.5)	53%	10%
Ask details about patient pain, medication use, and side effects	4.8 (0.4)	4.6 (0.5)	67%	60%
Ask about patient's beliefs about cause of pain	4.1 (1.0)	4.0 (0.6)	20%	40%
Understand patient's functional goals	4.6 (0.6)	4.6 (0.5)	40%	30%
Assess patient risk for opioid-related harm	4.6 (0.5)	4.7 (0.5)	13%	30%
Negotiate a treatment plan tailored to the individual patient	4.7 (0.5)	4.7 (0.5)	40%	70%
Commit to treating and partnering with patient long term	4.3 (1.0)	4.8 (0.4)	27%	40%

[1] Participants rated the importance of each skill from 1="not important" to 5="extremely important"

[2] Each participant identified the 3 skills for which clinicians need the most additional training.

Table 2.

Framework for communicating about chronic pain and opioids

Step	Key communication goals
1. Mentally prepare for the visit	• Prevent negative emotions from impacting judgment • Keep an open mind about visit goals
2. Show that you take the patient's pain seriously	• Asks open-ended question about patient's pain and pain medication • Elicit the patient's perspective • Convey empathy and support
3. Assess risk of opioid-related harm	• Ask about opioid-related side effects • Assess patient's overdose risk
4. Set pain treatment goals *	• Negotiate a mutually acceptable pain treatment goal based on patient's function • Avoid goals based on pain scores or pill counts
5. Develop a goal-directed treatment plan *	• Focus on treating pain, not counting pills (especially when discussing opioid tapering) • Make continency plans and check in frequently

* Includes strategies for developing treatment plans for patients who are resistant to considering non-opioid treatment strategies and / or opioid dose reduction.

Table 3.

Intervention components

Component	Purpose
Standardized patient instructor roles	Ensure SPs portray realistic patients taking opioids for chronic pain
5-step communication framework	Gives clinicians a structured approach to discuss chronic pain and opioids
Standardized patient instructor scripts	Manual that guides SP instructors in giving clinician feedback
Introductory video	Introduce communication framework to clinicians
Booklet	Provide detailed examples (phrases, strategies) clinicians can use
Pocket card	Brief overview of framework clinicians can reference

Table 4.

Examples of targeted clinician communication behaviors

Framework step	Communication behavior	Fleiss K
1. Mentally prepare for the visit	N/A	
2. Show that you take the patient's pain seriously	Asks open-ended question about patient's pain	0.56
	Makes supportive or encouraging statement	0.40
3. Assess risk of opioid-related harm	Asks about opioid-related side effects	0.55
4. Set pain treatment goals	Suggests a functional pain treatment goal	0.76
	Elicits patient agreement about goals	0.41
5. Develop a goal-directed treatment plan	Discusses adding new treatments before broaching opioid tapering	0.55
	Makes a plan to check with patient about how treatment is working	0.42

Table 5.

Study 2 clinician baseline characteristics

Clinicians	**Control (n=21)**	**Intervention (n=24)**	**Total (n=45)**
Age, mean (SD)	29.8 (2.7)	29.6 (2.5)	29.7 (2.5)
Sex *, n (%)			
Female	8 (38%)	21 (88%)	29 (64%)
Male	13 (62%)	3 (13%)	16 (36%)
Race/ethnicity, n (%)			
Black	1 (5%)	0 (0%)	1 (2%)
Asian / Pac Island.	12 (57%)	9 (38%)	21 (47%)
Non-Hispanic White	5 (24%)	7 (29%)	12 (27%)
Hispanic White	2 (10%)	4 (17%)	6 (13%)
Multi / other	1 (5%)	4 (17%)	5 (11%)
Clinic **, n (%)			
Internal Medicine	14 (67%)	16 (67%)	30 (67%)
Family Medicine	7 (33%)	8 (33%)	15 (33%)
Self-efficacy for communicating about chronic pain †, mean (SD)	3.05 (0.57)	2.83 (0.46)	2.94 (0.52)

*T-test for baseline differences (*P*-value = 0.16)

**Randomization was stratified by clinic

†Mean of 8 items; range 1–5 (higher = greater self-efficacy)

Table 6.

Study 2 patient baseline characteristics

	Visit with control physician (n=21)	Visit with intervention physician (n=25)	Total (n=46)
Age, mean (SD)	59.9 (8.6)	61.2 (10.5)	60.6 (9.6)
Sex, n (%)			
Female	12 (57%)	20 (80%)	32 (70%)
Male	9 (43%)	5 (20%)	14 (30%)
Race/ethnicity, n (%)			
Black	7 (33%)	9 (36%)	16 (35%)
Non-Hispanic White	8 (38%)	9 (36%)	17 (37%)
Native American	1 (5%)	0(0%)	1 (2%)
Hispanic White	2 (10%)	4 (16%)	6 (13%)
Multi / other	3 (14%)	3 (12%)	6 (13%)
Household income, n (%)			
<$10,000	4 (19%)	8 (32%)	12 (26%)
$10,001 – $20,000	8 (38%)	5 (20%)	13 (28%)
$20,001 – $40,000	5 (24%)	6 (24%)	11 (24%)
$40,001 – $80,000	3 (14%)	3 (12%)	6 (13%)
>$80,000	1 (5%)	3 (12%)	4 (9%)
Employment status, n (%)			
Working full time	2 (10%)	2 (8%)	4 (9%)
Unemployed	1 (5%)	1 (4%)	2 (4%)
Disabled / unable to work	10 (48%)	15 (60%)	25 (54%)
Retired	5 (24%)	6 (24%)	11 (24%)
Other	3 (14%)	1 (4%)	4 (9%)
Clinic, n (%)			
Internal Medicine	11 (52%)	15 (60%)	26 (57%)
Family Medicine	10 (48%)	10 (40%)	20 (43%)
Saw usual MD, n (%)	14 (67%)	21 (84%)	35 (76%)
Brief Pain Index *			
Pain-related interference	6.2 (2.5)	7.4 (1.9)	6.9 (2.2)
Pain-related intensity	6.4 (1.8)	7.3 (1.8)	6.9 (1.8)
VR-12, mean (SD)			
Mental component score †	43.9 (11.3)	39.0 (11.9)	41.2 (11.8)
Physical component score †	24.0 (7.7)	24.3 (7.8)	24.2 (7.7)
PHQ-8	10.6 (6.1)	10.0 (6.8)	10.3 (6.4)
GAD-7	8.0 (5.0)	9.6 (6.4)	8.9 (5.8)
Prescription opioid difficulties, n (%)			
Low	16 (76%)	19 (76%)	35 (76%)
Medium	4 (19%)	3 (12%)	7 (15%)
High	1 (5%)	3 (12%)	4 (9%)

	Visit with control physician (n=21)	Visit with intervention physician (n=25)	Total (n=46)
Opioid dose in MME, median, (IQR)	21.7 (15, 40)	30 (15, 45)	30 (15, 45)

GAD = generalized anxiety disorder; PQH-8 = personal health questionnaire depression scale

*Scored on 0–10 scale, higher = worse pain

†Scored on 0–100 scale, higher = better health

**Randomization was stratified by clinic

Table 7.

Study 2 intervention effects on study outcomes

	Control group	Intervention group	Intervention effect[†]	95% CI
Primary outcomes				
Number of target clinician communication behaviors observed, mean (SD)	2.8 (2.4)	3.5 (2.8)	1.25	0.76, 2.05
Patient pain-related interference at 2 months, mean (SD)	5.8 (2.9)	6.3 (2.8)	−0.3	−1.8, 1.2
Secondary outcomes				
Pain intensity at 2 months	6.0 (1.8)	6.5 (2.3)	−0.3	−1.2, 0.5
Clinician self-efficacy for communicating about chronic pain, mean (SD)	3.4 (0.6)	3.8 (0.6)	0.4	0.1, 0.7**
Clinician-reported visit difficulty (SD)	22.8 (7.0)	25.8 (12.3)	3.0	−2.1, 8.1
Patient visit experience (SD)	0.1 (0.6)	−0.1 (1.1)	−0.2	−0.7, 0.2
Exploratory outcomes				
Opioid dose at 2 months in MME, median, (IQR)	21.7 (16, 40)	30.0 (12, 50)	−0.4	−6.7, 5.9
Step 2 behaviors, mean (SD)	1.1 (1.0)	2.4 (1.5)	2.14	1.34, 3.42**
Step 3 behaviors, mean (SD)	0.4 (0.7)	0.1 (0.3)	0.21	0.04, 1.09*
Step 4 behaviors, mean (SD)	0.1 (0.4)	0.3 (0.6)	3.14	0.44, 22.20
Step 5 behaviors, mean (SD)	1.2 (1.2)	0.7 (1.1)	0.55	0.26, 1.17

MME = milligram morphine equivalents

[†]Effects for rows 2–7 are expressed as beta coefficients with 1 decimal point; effects for rows 1 and 8–11 are expressed as incidence rate ratios (IRRs) with 2 decimal points. Analyses control for patients being nested within clinicians, clinic site (family medicine versus internal medicine) and baseline values (for pain intensity, pain-related interference, clinician self-efficacy, and opioid dose).

*$P < 0.1$

**$P < 0.01$