TITLE: A clinician training intervention to improve pain-related communication, pain management and opioid prescribing in primary care

NCT Number: NCT03629197

Protocol document date: April 27, 2018

1) Protocol Title

A clinician training intervention to improve pain-related communication, pain management and opioid prescribing in primary care

Protocol Version Date: April 27 2018

2) Objective

To 1) develop and 2) pilot test a clinician communication training intervention to foster effective pain-related communication

3) Background

Increases in prescription drug abuse and opioid-related deaths have led to new clinical guidelines that de-emphasize using opioids to treat chronic pain. Communication plays a key role in both opioid prescribing and in maintaining therapeutic relationships. Patients and primary care clinicians report that poor communication and difficult clinical interactions are among the most important barriers to safe prescribing and effective pain management. Effective communication requires more than clinicians just saying "no" to patient requests for opioids. Primary care clinicians need advanced communication skills that are both patient-centered and pain-specific to successfully navigate disagreements, exchange information, and negotiate pain treatment plans. An important knowledge gap for communication training research – particularly for pain – is the lack of empirical data to support communication best practices that can drive intervention development. To address this gap, this project will develop and pilot test a communication training intervention to improve communication and reduce high-risk opioid prescribing in order to reduce opioid-related harms and improve pain management. This intervention will use standardized patients (SPs) – actors trained to portray a patient role – as instructors to teach clinicians communication skills related to chronic pain and opioids.

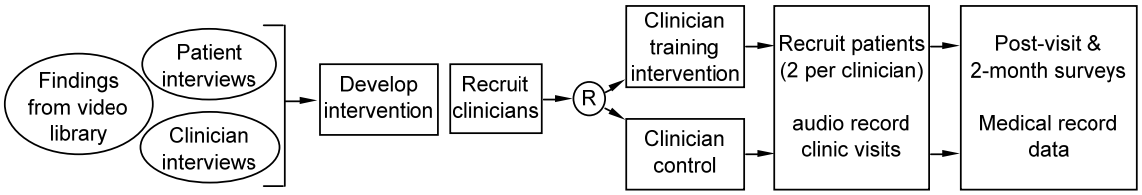
Preliminary data (part 1). The PI has collected a library of 87 video-recorded primary care visits (UCD IRB protocol 453824) involving patients on opioids for chronic pain. This library is a unique and valuable resource for identifying effective communication strategies to inform the design of an intervention that fosters effective pain-related communication. For 44 of 87 visits, both clinician and patient gave permission for their videos to be viewed by non-researchers for training and educational purposes such as proposed here. Only these 44 videos will be used in Part 1 of the study. No identifying info will be used from the other 43 videos.

Preliminary data (part 2). Based on analysis of data from part 1, investigators have identified 5 key communication skills that will be targeted by the intervention:

- Mentally prepare for the visit
- Show that you take the patient's pain seriously
- Assess benefits and risks of opioid therapy
- Establish shared pain treatment goals
- Develop a goal-directed treatment plan.

4) Study Design and Procedures Involved

Figure 1. Overall study design



Part 1 – Development of training intervention.
Part 1 of this project will develop an empirically-based, scalable clinician training intervention to foster effective communication skills about pain and opioids in primary care. The intervention will use SPs to teach clinicians communication skills related to chronic pain and opioids. Project co-investigators have used this SP-based approach in previous training interventions. *Activities in Part 1 are minimal risk.*

Data collection. The PI will review the video library to identify video clips showing instances of putatively effective and ineffective communication. Data collection will comprise the following:

- *1-on-1 interviews* conducted by investigators with a) primary care physicians and b) patients with chronic pain. During these interviews, we will elicit participant reactions to these video clips and obtain feedback on causes of poor communication and strategies to make communication more effective. Interviews will be transcribed for analysis. Identifying information (e.g. names, exact dates) will be removed from the transcripts so that they are not identifiable.
- Basic participant demographic and (for patients) health information.

Intervention development. Findings from interview data will be used to refine and confirm key patient-centered and pain-specific communication skills that will be targeted by the standardized patient instructor intervention. The intervention will include the following components:

a) 5-6 minute didactic lecture delivered by video
b) Pocket card showing key communication skills
c) 2 thirty-minute SP instructor visits, conducted at the clinician's office, that each involve an interaction with an SP followed by formative feedback based on clinicians performance.
d) A pamphlet or handout with more detailed examples for each communication skill

Part 2 – Pilot RCT.
Part 2 will conduct a pilot RCT of the intervention developed in Part 1 in order to evaluate intervention feasibility and estimate treatment effects. Primary care clinicians will be randomized to receive either the intervention or control; real patients (2 per clinician) will then be recorded during routine clinic visits with study clinicians and will provide data on post-visit perceptions and health outcomes. *The only intervention in the RCT will be clinician education. This RCT will not directly manipulate or influence patient care.*

Therefore, this study is minimal risk. The only foreseeable patient risks relate to data confidentiality and privacy.

Clinician recruitment and randomization (part 2)

We will recruit approximately 48 primary care clinicians for the pilot RCT. Our study goal is to enroll 24 residents and 48 patients (2 patient visits per resident). However, based on our previous experience with similar recruitment methods in these clinics, only about 50 % of enrolled clinicians will ultimately have visits with study patients. Thus, it will be necessary to over-enroll clinicians because we expect a large proportion of residents will have to be dropped from study due to not seeing any study patients.

Randomization assignment will take place after clinicians provide informed consent and complete the baseline questionnaire. Randomization assignment will be contained in sealed opaque envelopes that the RA (who will not be aware of assignment beforehand) will open after each clinician enrolls. Because of the nature of the intervention, it is not possible to blind subjects to randomization assignment. However, patients will be unaware of clinician randomization assignment.

Intervention clinicians will see study patients after they have completed both SP instructor visits. Control clinicians will receive a written summary of the 2016 CDC opioid prescribing guidelines, which include recommendations for best practices for use of opioids to treat chronic non-cancer pain. These guidelines will serve as an attention control.

Intervention materials will include the following.

1) A 5-6 minute didactic lecture (via video or DVD) that reviews key communication skills and shows examples of common challenges related to opioid prescribing

2) A pocket card for clinicians that summarizes key communication skills for talking about opioids

3) A pamphlet or brochure providing examples and additional details about the communication skills

4) Two 30-minute SP instructor visits, conducted at the clinician's office, that each involve an interaction with an SP instructor followed by formative feedback from the SP instructor based on clinicians' performance during the interaction. We will write 2 different SP scripts: one for a woman with low back pain and one for a man with knee and hip pain. Clinicians will be aware of the SP visits; these are not "secret shopper" visits.

The content of intervention materials, including SP roles and SP instruction manuals, is submitted with this protocol.

Standardized patient hiring and training. We will hire 4 SPs total (2 for each role) from the SP program at the UC Davis School of Medicine or from local actors if suitable SPs from the school of medicine are not available. Training will focus on learning the biographical details and portraying the attitudes and emotions of the role as well as on the key skills and on giving feedback to clinicians. SPs will be trained by an experienced SP trainer, who will also monitor SPs throughout the intervention to ensure that they maintain role fidelity.

Standardized patient deployment. We will arrange all SP visits in coordination with clinic leadership. All SP visits will take place during clinicians' regularly schedule clinic times, and visit paperwork (e.g., check in sheets) will be generated to make the visits as realistic as possible. During their visits, SPs will play the didactic video and provide clinicians with the other intervention materials.

Patient recruitment (part 2)

Patients will be recruited using an approach that has been successful in the past for this specific population and was previously IRB approved and is currently being used successfully by other IRB-approved primary care research studies at UC Davis. A research assistant will use the UC Davis electronic medical record to review clinic schedules of participating clinicians and to identify patients with upcoming appointments who likely meet study inclusion criteria (we will obtain a HIPAA waiver for recruitment). The research assistant will mail letters to patients informing them of the study and will follow-up with phone calls to verify eligibility and explain the study. Interested patients will be asked the following 3 screening questions during their phone call:

1) Thinking back over the past week, 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 will be eligible if they report at least moderate pain severity (≥4) for the first question and respond "likely" or "very likely" to either question 2 or 3. In prior research, we have found that this additional screening is needed to ensure that study visits include substantive discussions about opioids and chronic pain. Eligible patients will give verbal consent by phone. Because part 2 of this study is minimal risk, we will seek a waiver of the requirement of written documentation (i.e. signed) consent forms for clinician participants. We will obtain signed informed consent from patient participants. We will recruit 2 patients per clinician. We will obtain at least 2 phone numbers for each patient to ensure that we can contact patients about their study visits and their 2-month follow-up assessment.

We will collect the following data for Part 2 (See attached questionnaires for full details):

- Baseline clinician questionnaire (completed at the time of enrollment).
- Post-visit clinician questionnaire (completed after each study visit)
- Clinician assessment of intervention (completed by clinicians in the intervention group approximately 1 week after they complete the intervention)
- Standardized patient checklist (completed by standardized patients after each interaction with clinicians who receive the intervention)
- Patient pre- and post-visit questionnaire (completed before and after each study visit.
- Audio recording of patient-clinician study visit. For these recordings, a research assistant will arrive prior to the patient's regularly scheduled appointment and will set up 2 digital audio recorders in the exam room. The research assistant will wait outside the exam room until the visit is finished. Two audio recorders will

be used to minimize data loss from equipment malfunction. Recordings will be transcribed for analysis, and identifying information (e.g. names, exact dates) will be removed from the final written transcripts, so that they do not contain any personally identifying data. We have used similar procedures before for video recording without disrupting clinic flow; thus we are confident our procedures for this audio only study will not disrupt clinic flow and be acceptable to clinic staff and participants.

- Patient 2 month questionnaire (completed by phone 2 months after study visit).
- Patient medical record data (we will get a HIPAA release). Information collected will include but is not limited to medications and treatments prescribed / recommended for pain and for conditions commonly related to pain, pain diagnoses, and pain-related diagnoses including physical and mental health diagnoses and substance use diagnoses.

5) Inclusion and Exclusion Criteria

Clinicians – Parts 1 and 2
Internal Medicine or Family Medicine residents at UC Davis who have completed ≥1 year of training and see primary care patients in the ACC building. Clinicians will be recruited through clinic huddles, emails, and presentations at meetings. Clinicians can participate in either Part 1 or Part 2, but not both.

Patients – Part 1
Inclusion: Adults, ages 18-80, currently suffering from chronic (>3 months), moderate to severe musculoskeletal pain (e.g. low back, neck, hip, knee, shoulder).
All have been to the doctor for pain at least once in the past year
Have taken or are currently taking opioid medications to manage pain. Patient recruitment and interviews for Part 1 will be conducted by an independent investigator (see Independent Investigator agreement form).

Exclusion: active cancer, hospice, do not speak English

Patients – Part 2
Inclusion: UC Davis Patients 18-80yo taking opioids (≥1 opioid dose per day) prescribed by their primary care physician for >90 days to treat chronic musculoskeletal pain, who have an appointment scheduled with a participating clinician at which they report they are likely to discuss pain management.

Exclusion: active cancer, hospice, do not speak English, prisoners, pregnant women, unable to consent.

6) Study Timelines

Part 1 We expect intervention development to take approximately year 1.

Patients and clinician participation will be restricted to a single session for the 1-on-1 interview.

Part 2 We expect the pilot RCT to take approximately 2 years (years 2 and 3).

Patients will participate for 1 clinic visit and will provide questionnaire data by telephone 2 months later.

Clinicians will remain enrolled until they can see 2 study patients during the RCT,

and will complete a post-visit questionnaire immediately after the visit.

7) Study Endpoints

Part 1 Endpoint will be completed clinician training intervention.

Part 2
Primary:
1. Change in pain interference at 2 months (assessed by Brief Pain Inventory)
2. Prevalence of high-risk opioid prescribing (assessed from medical record review).

Secondary:

1. Change in pain intensity at 2 months (assessed by Brief Pain Inventory)
2. Patient experience (measured by post-visit patient agreement with treatment plan, patient trust, and patient assessment of clinician communication skills)
3. Clinician use of targeted communication skills (measured from transcripts).
4. Clinician experience (measured by post-visit visit difficulty).
5. Clinician assessment of intervention (i.e. intervention acceptability)

8) Data and/or Specimen Management and Confidentiality

This study will not collect any blood or tissue specimens. All data collected will follow HIPPA-like procedures (as described in the initial application form) to protect privacy and data confidentiality. As stated elsewhere, all audio recordings will be transcribed, and patient identifiers will be removed from transcripts for analysis.

For Part 1, the patient and physician questionnaires will be linked to participant ID by encrypted numerical identifiers. A key linking the identifiers to participant names will be kept in a separate location on a password-protected spreadsheet stored on a private, restricted-access server. Identifiers for questionnaires are necessary so that we can link questionnaire responses to each participant's transcribed interview. The key linking participant identifiers to their study data will be destroyed after data collection is complete for Part 1. We will maintain a list of clinicians who participate in Part 1 (that is not linked to study data) because clinicians who participate in Part 1 will not be eligible to participate in Part 2.

In Part 1, existing video clips will be used ONLY from those videos where both patient and clinician gave permission. We will not use video clips that contain any identifiable information (e.g. patient or physician name) other than the participant faces.

For Part 2 only, we request a HIPAA waiver for recruitment and obtain patient consent for collecting HIPAA information. Based on our experience, recruiting primary care patients with chronic pain who also have scheduled visits is not practical without a HIPAA waiver.

9) Data and/or Specimen Banking – N/A

10) Provisions to Monitor the Data to Ensure the Safety of Subjects
N/A – study is minimal risk

11) Withdrawal of Subjects

For Part 2, physicians may be withdrawn from research involuntarily if they have not participated in any study visits by the time patient recruitment and data collection ends. Patients may be withdrawn involuntarily if they are determined not to be eligible.

For Part 2, if participants withdraw before completing participation (e.g. 3-month follow up data), data collected prior to that point will be retained for analysis. If patients withdraw from active study participation but do not withdraw HIPAA authorization, medical record data will be collected from these patients as necessary in order to follow best practices for ethical RCT intent-to-treat analysis.

12) Risks to Subjects

Part 1 involves only 1-on-1 interviews and written questionnaires, and so the only risk for participants would relate to privacy risks due to potential breach of confidentiality.

Part 2 is a pilot RCT that involves only physician education & training activities. The intervention will not directly involve patients or directly influence patient care. We are collecting personal health information, so the only foreseeable risk for Part 2 relates to privacy risks from potential breach of confidentiality.

We do not foresee any physical, psychological, social, legal, or economic risks.

13) Potential Benefits to Subjects

Part 1 By watching and reflecting on video clips during 1-on-1 interviews that show putatively effective and ineffective communication strategies, patients and clinicians may gain new insights about how to communicate (or how not to communicate) about pain management during clinic visits. This could lead indirectly to better patient-doctor relationships or more harmonious clinic visits.

Part 2 Clinicians randomized to the intervention are likely to gain improved communication skills that will lead to better relationships with patients and more successful chronic pain management. To the extent that the intervention is successful, patients in the intervention arm may experience benefits that include more positive clinic experiences, improved pain management, and lower risk of opioid-related harms.

14) Multi-Site Research N/A
15) Community-Based Participatory Research N/A
16) Sharing of Results with Subjects

There are no plans to share results with participants.

17) Prior Approvals

For Part 2, we will register with clinicaltrials.gov before starting recruitment.

18) Provisions to Protect the Privacy Interests of Subjects

Part 1 Using a 1-on-1 interview format (as opposed to focus group) will reduce any sense of unease or discomfort patients may feel about participating in the study. In our experience with prior research on the topic of chronic pain and opioids, patients and physicians willing to participate have been very open to discussing this aspect of clinic visits.

Part 2 For clinicians, we will make sure they know that the individual results of their sessions will be kept confidential. Rather than calling patients directly, we will send them recruitment letters first so they have a chance to opt out of further contact. We have successfully recruited patients and clinicians from these same populations for a prior study that video recorded clinic visits. This study will only audio record clinic visits, so is less likely to create a sense of unease among participants compared to video recording. We have worked out strategies at the 2 study clinics to maximize patient privacy when they are filling out questionnaires.

All study except audio recordings will be stored using numerical identifiers. A key linking identifiers to patient identities will be kept on an encrypted, password-protected computer separate from the study data. Identifying information will be removed from transcripts. We will store digital audio recordings in a separate folder and only authorized study personnel will be given access. Recordings will be erased from the recorders immediately after recordings are uploaded to secure computers behind the UCD firewall.

19) Compensation for Research-Related Injury N/A

20) Economic Burden to Subjects N/A

21) Drugs or Devices N/A