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The risks of opioid treatment: Perspectives of primary care practitioners and patients from safety-net clinics

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Abstract

Background—Patients with a history of substance use are more likely than those without substance use to experience chronic noncancer pain (CNCP), to be prescribed opioids, and to experience opioid misuse or overdose. Primary care practitioners (PCPs) in safety-net settings care for low-income patients with CNCP and substance use, usually without specialist consultation. To inform communication related to opioid risk, we explored PCPs' and patients' perceptions of the risks of chronic opioid therapy.

Methods—We conducted semistructured interviews with 23 PCPs and 46 of their patients, who had a history of CNCP and substance use. We recruited from 6 safety-net health care settings in the San Francisco Bay Area. We transcribed interviews verbatim and analyzed transcripts using grounded theory methodology.

Results—(1) PCPs feared harming patients and the community by opioid prescribing. PCPs emphasized fear of opioid overdose. (2) Patients did not highlight concerns about the adverse

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Author contributions

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health consequences of opioids, except for addiction. (3) Both patients and PCPs were concerned about PCPs' medicolegal risks related to opioid prescribing. (4) Patients reported feeling stigmatized by policies aimed at reducing opioid misuse.

Conclusion—We identified differences in how clinicians and patients perceive opioid risk. To improve the informed consent process for opioid therapy, patients and PCPs need to have a shared understanding of the risks of opioids and engage in discussions that promote patient autonomy and safety. As clinics implement opioid prescribing policies, clinicians must develop effective communication strategies in order to educate patients about opioid risks and decrease patients' experiences of stigma and discrimination.

Keywords

Ambulatory care; drug overdose; informed consent; opioid analgesics; qualitative research

Introduction

Pain is among the most common complaints reported in ambulatory care settings, with 22% of primary care patients reporting persistent pain.[1,2] Primary care practitioners (PCPs) are the largest group of opioid prescribers in the United States.[3,4] PCPs who practice in safety-net clinical settings care for low-income patients who experience a high prevalence of substance use and barriers to substance use treatment.[5–8] An estimated 10%–30% of patients receiving treatment for chronic noncancer pain (CNCP) have comorbid substance use.[9–12] Patients with substance use are more likely to be prescribed opioid therapy[13–16] and are several times more likely to experience opioid misuse,[14,17–23] defined as the use of opioids in a manner other than as directed.[24] In addition, opioid overdose, the leading cause of accidental death in the United States,[25] is more common among individuals with substance use.[26–28]

As evidence of the risks of opioid analgesics increased,[29–36] the number of clinical guidelines and government policies regarding opioid prescribing and monitoring increased.[37–40] Primary care clinics in the United States are in the process of implementing policies consistent with the American Pain Society (APS), the American Academy of Pain Medicine (AAPM), and the Centers for Disease Control and Prevention guidelines to improve opioid safety.[37,41,42] Changes in opioid prescribing policies include clinician education, limitations on morphine equivalent dose, mandatory and structured monitoring of risk, and the use of pain agreements, which outline the expectations of patients and clinicians when opioids are prescribed.[43,44] Experts call for an informed consent process for patients prescribed chronic opioids.[45,46] Informed consent, a discussion of risks, benefits, and alternatives to treatment, is ideally a component of the conversation between clinicians and patients when initiating or renewing an opioid agreement.[37,47] However, informed consent discussions are not required components of many pain agreements. It is not clear how clinicians and patients discuss the risks and benefits of opioid therapy and how patients perceive the risks of opioids.[46,47] Informed consent requires that both parties share an understanding of the risks and benefits and engage in a discussion that promotes the patient's autonomy in decision-making. Clinicians' and patients' perceptions of opioid risk impact discussions of informed consent, the clinical application of opioid safety policies,

patients' experiences of such policies, and patients' views of chronic opioid therapy. In order to recommend improvements in the informed consent process, we used qualitative methods to analyze how clinicians and their patients with CNCP and past or present substance use perceived the risks of opioids.

Methods

Recruitment and sample selection

Between October 2013 and March 2014, we recruited and interviewed 23 PCPs from 6 safety-net primary care clinics across 4 counties in the San Francisco Bay Area. We used a purposeful sampling approach[48,49] in which we identified clinics serving safety-net patient populations where clinicians had experience treating patients with CNCP and substance use. We identified clinics through discussions with regional health system directors. Study staff then met with clinic leadership who confirmed that the clinic served patients with a high prevalence of CNCP and substance use. We introduced study goals and procedures at clinic staff meetings or through e-mail recruitment to clinicians. We chose to investigate this question in safety-net clinical settings because most clinic-based studies of CNCP have taken place in specialized pain settings despite the fact that most patients receive pain treatment in primary care settings. In addition, safety-net primary care settings may lack resources and access to specialty consultation recommended by current guidelines.[37,50]

We defined a PCP as a physician, nurse practitioner (NP), or physician assistant (PA) who provides longitudinal primary care. In California, NPs and PAs can prescribe schedule II, III, IV, and V controlled substances, including opioids. Study staff introduced the study at each clinic and asked for clinician volunteers to participate. We defined CNCP as pain that persists beyond 3 months and is not caused by a malignancy or associated with pain at the end of life.[51] For each participating PCP, we recruited between 1 and 4 of their patients who had both CNCP and a history of past or current substance use (including illicit drugs and/or alcohol). Clinicians identified potential patients based on these 2 criteria. We did not evaluate patients for a clinical diagnosis of a substance use disorder (SUD). We assessed patients' demographics, prescribed pain medications, and both past and recent (within 30 days) substance use with a screening instrument. PCPs and patients received a $50 gift card for their participation. One clinic did not allow PCPs to accept compensation. All participants provided written informed consent. The institutional review board approved this study.

Data collection

We developed a semistructured interview guide organized by topic that included interviewer-directed open-ended questions. This approach allowed the data content to vary in an interviewee-driven manner, according to the experiences and topics that were interviewee relevant. We sought contextual and conceptual depth in the interviews to identify interviewees' understandings and processes of pain management. We did not assume differences between clinicians and patients, nor did we seek to compare and contrast clinicians' and patients' responses a priori.

We (K.K., K.Z., R.C., J.C.) interviewed PCPs about their experiences caring for patients with CNCP and substance use, perceptions of the risks of opioid analgesics, and experiences with the implementation of opioid monitoring policies. We interviewed patients about their experiences with CNCP and substance use, perceptions of the risks of prescription opioids and illicit drugs, experiences with opioid monitoring policies, and their impressions of their clinicians' views on opioid therapy (Table 1). Each interviewer had training and experience conducting qualitative interviews. Three interviewers completed approximately one third of the interviews each, whereas one interviewer (K.Z.) completed 3 interviews. We recorded interviews, which had an average duration of 60–90 minutes, and transcribed them verbatim. We continued recruitment and interviews until we reached thematic saturation (i.e., a consensus that new themes and patterns were no longer emerging from collaborative review of the data).[48]

Data analysis

We used a modified grounded theory approach to code and analyze transcripts.[52,53] We took 3 breaks during the data collection period, during which our team of ethnographers and clinical investigators read and completed memos on interview transcripts and discussed emerging thematic topics. We developed an initial code-book based on our notes and lists of emergent themes. We combined deductive codes, based on broad topics from the semistructured interview guide, with inductive codes (i.e., those that emerged from the interview content and subsequent analytic discussions and memos). After successive iterations of coding transcripts independently and discussing transcripts as a group, we developed distinct codebooks for patient and clinician interviews.

Two researchers coded each interview. We resolved coding discrepancies through group consensus. We entered coded interviews into ATLAS.ti.[54] For this analysis, one investigator (E.H.) reviewed interview transcripts and completed thematic memos on perceptions of chronic opioid risk. The research team discussed emergent themes and relevant codes. We analyzed data without pairing clinician and patient codes because interviews were conducted independently, not during clinical interactions between patients and clinicians. We discussed divergent cases as a group in order to develop a set of consistent themes on risk perception for both clinicians and patients. The overarching narrative that emerged from our analysis centered around clinicians' and patients' differential perceptions of the risks and benefits of opioids for the management of chronic noncancer pain.

Results

Patient and clinician characteristics

We conducted 23 clinician and 46 patient interviews. Four out of the 50 patients approached by study staff declined to participate. Most of the clinicians were physicians (n = 18, 78%), 4 were nurse practitioners, and 1 was a physician assistant. Sixty-five percent of the clinicians were women. Thirty-nine percent worked in public hospital–based clinics; 39% worked in county-funded community-based clinics; and 22% worked in federally qualified health centers. Clinicians and patients were equally distributed across the 6 clinics. To avoid identifying participating clinicians, we did not collect demographic data on clinicians. Sixty-

one percent of patients identified as African American, and 54% were female (Table 2). Sixty-five percent had a history of cocaine use, 46% reported marijuana use, 30% reported methamphetamine use, and 24% reported heroin use. Most patients did not report current substance use. Six patients (1.3%) reported illicit use of cocaine or methamphetamine, whereas 26% and 40% reported current marijuana and alcohol use, respectively. Only 1 patient had never received an opioid prescription. Clinics had implemented the APS and AAPM guidelines on treating CNCP to varying degrees[37] (Table 3). All of the participating clinics were in the process of standardizing opioid prescribing policies and increasing monitoring.

Clinicians' perceptions of the risks of chronic opioid therapy

Clinicians reported 3 overlapping concerns related to the risks of opioid misuse and opioid overdose that had contributed to shifts in clinical practice: (1) causing harm to patients, including the risks of unintentional overdose or opioid addiction; (2) causing harm to the community through diversion of opioid medications; and (3) experiencing medicolegal consequences and related emotional costs due to prescribing opioids to patients with substance use (Table 4).

"First, do no harm": PCPs' fear of causing patient harm—Nearly all clinicians identified patient safety as a motivator for their opioid prescribing decisions. One clinician who had experienced a near overdose of a patient commented:

> [My patient] who took all the pills at once, what if he died from that medicine [opioids] I gave him? Whether or not I got sued, which I probably wouldn't …it's a very scary feeling for me.

Clinicians described a sense of personal responsibility to prevent overdose through "disciplined" prescribing (Table 4). At the same time, PCPs feared that tapering or discontinuing opioids could increase the risk of overdose, if doing so led patients to obtain opioids illicitly. Another clinician commented: "I can see [patients] going out and getting something [opioids] off the street and then overdosing because they never have done that before." PCPs feared for patient safety, specifically the risk of opioid overdose. Opioid dependence and opioid misuse were described as factors contributing to the potential for patient harm. Clinicians also discussed the risk of opioid diversion in patients with concurrent addiction. One PCP commented:

> The consensus in the medical community is that doing cocaine is a risk factor for addiction and it's a warning sign that she's involved in illicit economies in the community that purvey cocaine and that's also a risk factor for her [being] willing to divert the pills that I'm prescribing.

Avoiding community harm: PCPs' fears of diversion and the risk of overdose —PCPs felt responsible for limiting the risks that opioids posed to the community, including diversion and diversion-related overdoses. A PCP summarized the fear of community overdose: "God knows where those drugs [prescribed opioids] are going and who is dying from those drugs." PCPs worried that diversion could facilitate substance use in their patients by providing money that could be used to buy other drugs.

> It's a public health problem not only because other people can now use these drugs who shouldn't be, but you're facilitating the illicit drug use of your patient by virtue of giving her the means to do it.

Clinicians considered opioids unique among prescribed medications due to their potential to cause community harm and violence. One PCP recounted:

> You can off [kill] yourself with Tylenol. I think the real difference here [with opioids] is the diversion, violence, and the whole economy of diversion and the neighborhood violence that [it] begets.

"Lurking fears": Medicolegal and emotional risks to clinician—Clinicians expressed concerns that they could be found liable for the deaths of patients or community members who overdosed on opioids that they had prescribed. Clinicians suggested that fear motivated some clinical decisions on pain: "There's always a lurking fear … certainly someone could overdose on what I prescribed and then their family member could try to press charges." Clinicians described conversations where they had explained medicolegal issues to patients. One clinician recounted her communication with a patient at the beginning of opioid treatment:

> [Speaking to the patient:] Your health is important to me. Your pain is important to me, but we have to be on the same page and be transparent about how we're treating you because I'm responsible for you and my license is on the line as well.

Shifts in practice: PCPs' responses to opioid risk—PCPs acknowledged that fear of overdose, misuse, and diversion had prompted shifts in opioid prescribing, both at the level of the clinic and the individual clinician. One PCP suggested a pendulum swing in pain treatment:

> There was a recognition in the mid-80s to early 90s that we weren't treating the pain. We weren't treating it aggressively enough, and then you saw this overwhelming increase [in] these pain medications, opioids … And then we find ourselves a decade and a half later with a real problem on our hands because we're over-treating and we're actually doing more to injure people.

Three clinics had begun to co-prescribe naloxone, an opioid antagonist used to reverse opioid overdose. PCPs who did not work at one of these clinics had limited knowledge of naloxone. Some PCPs who practiced at the clinics that had recommended naloxone co-prescribing believed that educating patients about naloxone facilitated discussions about overdose. One PCP described how a discussion about naloxone could reframe a patient's perception of prescription opioids:

> 'If the doctors are giving me something [naloxone] because they think I could die from this [opioids],' it's a lot different than when you [the clinician] says 'We're worried about overdose,' and then the [patients'] response is 'You're just trying to take away my medicine [opioids].'

In contrast, another clinician worried that when PCPs co-prescribed naloxone, they were acknowledging the serious risks of opioids while continuing to prescribe them. "I'm giving

you a tool [opioids] to hurt yourself with and here's the tool to save yourself with [naloxone]."

Patients' perceptions of opioid risk—Patients perceived the risks and harms of opioids in ways that were different from their clinicians (Table 5). Patients' believed they could control how they used prescribed opioids, thus limiting the risk of adverse health consequences. Although patients described other risks of opioid therapy, including developing physical dependence on opioids, they did not emphasize a fear of addiction. Instead, patients feared being labeled as "an addict," being suspected of diversion, and being targeted by monitoring policies because of their histories of substance use. Patients identified risks to clinicians. They recognized clinicians' medicolegal concerns related to prescribing opioids and expressed concern that a small proportion of patients' opioid misuse had led to changes in clinic monitoring policies and opioid prescribing.

Opioid risk: Patients' perceptions of control—Many patients described their ability to control how they used their opioid medication. One patient commented, "I don't overdose because I follow the script." Most felt that their opioid use did not put them at risk because they controlled the amount of opioids they took and avoided mixing opioids with other substances. Another patient acknowledged that other patients misused opioids.

> Not [overdose risk] for me because I'm very careful and cautious of how I take it. But I've had friends that committed suicide that way [by overdosing]. So I see it [overdose risk]. I see people that are using [other] medications and not telling the [clinic] staff they have them.

A different patient perceived that misuse by others had motivated changes in clinic policies.

> I see a lot of people addicted to these pain meds [opioids]. I think the system [opioid monitoring policies] has its little flaws, but it also has its good points where they have to monitor what you take. Because some people overdo it and it could cause a lot of harm.

Although patients recognized clinicians' concerns about the concurrent use of opioids and illicit substances, some patients disagreed with clinicians' assessment of overdose risk.

> They're afraid that you might smoke some crack [cocaine] and then take your pills [opioids] and the combination will kill you. No, I haven't heard anybody die from that.

A patient recognized that he was at risk for overdose when he was using illicit substances and prescription opioids simultaneously. Yet, he only considered overdose risk as he got older and was no longer using illicit drugs.

> I wasn't thinking about overdose. But I as I got older I started thinking about it, but when I was really out there active [using] I didn't trip [worry about overdose].

Some patients expressed how they lacked control over illicit substance use, but felt they could control their use of prescription opioids. One explained:

> I was already working on knocking this other addiction back out of my life … the crack cocaine. I'm not trying to get hung up on something else that I can't control. The Norco [hydrocodone] … I know I can control that because I only do that when I'm in pain.

Patients recognized that clinicians worried about overdose risk in patients taking opioids. However, patients did not describe a fear of overdose for themselves, even in cases of concurrent substance use or opioid misuse.

Patients' fears of "addiction" or dependence on opioids—Patients often used the term "addicted" to describe physical dependence on opioids. Patients did not typically use the term "addiction" to describe characteristics in the medical definition, including a loss of control over use, experiencing craving for opioids, or failing to recognize problems that opioids caused in one's life or relationships.[55] A patient who had observed opioid misuse in others reported that he would rather use nonopioid analgesics because he feared developing "addiction" to opioids. "I would go for something that is not habit forming to just stop the pain. I don't want to become an addict like most people do." In response to a question about whether she obtained opioids from other people, a different patient commented:

> No, I'm not hooked on medicine [opioids] like that. Unless [you are referring to] my codeine. That's [the codeine] highly habit forming. And if you don't have it [codeine], you have diarrhea for three days.

In contrast, the distinction between physical dependence on opioids and "addiction" to opioids was clear to other patients.

> [My PCP] is just worried for me, she's afraid that [the prescribed opioid] will addict me. I don't get high off the stuff because I don't take enough to get high. I don't want to get high. If I wanted to get high I'd go shoot some dope [heroin], I wouldn't play around [with prescribed opioids].

Patients who had experience with addiction often viewed opioid use differently from illicit substance use. One patient used different language to describe how uncontrolled pain led to changes in both his cocaine use and opioid use.

> Then I find myself using crack more, so I was starting to be a drug addict. Every time I didn't have pain pills, that's what I would turn to [crack cocaine] … and the pain pills really don't do as much as the drug [cocaine]. I'm not trying to justify the drug because I don't want to do [it], it does take [away] the pain … But I like the pain pills. If I take so many of them along with the Lorazepams and the Benadryl I can get some ease and some sleep, but its just that I have to take so many different ones [pills].

Although it was often unclear how patients defined the term "addiction," patients feared that their clinicians perceived them as "addicted" to opioids due to their histories of substance use. Many patients were concerned that clinician bias against individuals with substance use could influence pain treatment. One patient described the discontinuation of his opioid prescription due to a urine toxicology test positive for an illicit substance [cocaine]:

> You don't punish a grown man for a decision that he made … the whole atmosphere [with the clinician] changed. Their whole way of talking to you changed [to] 'Oh, you're just a drug addict.'

Another patient described her view on addiction and how the definition of addiction might depend on who was using the substance.

> Everything is a drug; you get hooked on soda, you get hooked on coffee, everything is a drug. So why do people try to stereotype everything else [opioids, illicit substances] when you can get addicted to anything … what's the difference?

Recognition of clinicians' fears; perceived stigma and discrimination—Patients identified their clinicians' concern about opioid addiction and diversion. One reported: "[Prescription opioids] serve no purpose but a bad purpose … it's to sell them and that's mostly what doctors are worried about." Although patients agreed that others misused prescription opioids, they did not understand how urine toxicology screening assessed individual risk. A different patient did not understand his PCP's decision to taper his opioids as a consequence of a cocaine positive urine toxicology test. When asked why his PCP was upset about cocaine in his urine, he responded: "He [the PCP] told me it makes you look like you're 'addicted' to prescriptions. That's what I was told."

One patient explained that her PCP performed the urine toxicology test to ensure she wasn't "drug seeking" (Table 5). Another patient expressed frustration that others' behavior influenced decisions and opioid policies of clinics. "Just because your last person [patient] abuses these drugs [opioids], now you want to put me on the same page." Others felt that strict opioid policies were being applied disproportionately to poor people and people perceived to have "drug addiction." One patient explained:

> Poor people, they just really don't have options. Already because of how we live we're not trusted … it's like a little discrimination on drug addiction … [from] being poor … because we can't afford the best of medical care so we get all these stipulations.

Patients viewed safety policies and interventions as being applied unfairly. They felt that policies were designed to address clinicians' concerns about addiction, diversion, and legal issues, instead of being explicitly designed to improve patient safety.

Discussion

We found differences in how clinicians and their patients with CNCP and substance use viewed the risks of chronic opioid therapy. Clinicians reported concerns related to adverse health consequences for both patients and the community. Patients did not emphasize adverse health consequences of opioids, except for fear of "addiction," which patients often defined as physical dependence rather than describing characteristics of the medical definition.[55] Both patients and clinicians highlighted clinicians' medicolegal risks related to prescription opioids and identified how fears of litigation had changed opioid prescribing behavior.

In a prior study,[56] physicians described concerns about opioid misuse, diversion, and addiction when asked about their views on prescribing opioids to patients with histories of substance use. Although we describe similar clinician concerns, we identified additional concerns, namely, concerns related to community harm and medicolegal risks. Clinicians' fears about opioids are evolving in the context of publicity of opioid risks, the issuing of guidelines, clinician education on opioid risk, opioid monitoring policies, and reports of clinician prosecution. Although clinicians may exaggerate certain risks, including medicolegal risks and the risk of diversion,[57,58] press coverage of lawsuits could influence clinicians' perceptions and prescribing behaviors.[59] In addition, clinicians in our study described potential harms from not prescribing opioids, including the risk that patients would seek opioids in illicit markets, exposing themselves to the risk of overdose. These clinician concerns are important topics to incorporate into clinician education on risk assessment and responses to aberrant opioid use behavior.

A recent qualitative study of patients with CNCP described patients' fears of losing access to opioids and for patients with histories of substance use, a fear of opioid addiction.[60] In that study, patients described addiction in the context of fearing relapse to illicit drugs, developing cravings, and experiencing loss of control of opioid use. In contrast, patients in our study did not consistently describe "addiction" in ways that were concordant with the medical definition. [55] Patients' fear of "addiction" to prescription opioids has been described in other studies of both acute[61,62] and chronic[63] pain without describing how patients defined the term "addiction." In our study, patients often equated "addiction" with physical dependence. Inconsistent use of the terms "addiction," "dependence," and "opioid misuse" may complicate patients' understanding of opioid risks. Experts have argued that clinicians' use of terms such as "addict" and "substance abuse" increase patients' experiences of stigma.[64] Clinicians use different language when discussing opioids prescribed to treat pain compared with opioid dependence (i.e., methadone maintenance) or classify patients as individuals with addiction versus individuals with pain. Patients may be labeled as engaging in opioid misuse when taking opioids as prescribed while simultaneously engaging in illicit drug use. This ambiguity in language may exacerbate patients' confusion and experiences of stigma.[65] In this setting, patients may not feel comfortable discussing their fears with clinicians, particularly if disclosing fears of addiction to opioids may decrease the likelihood that the clinician prescribes an opioid analgesic for pain.

Opioid risk screening instruments and guidelines classify patients with past or present substance use as high risk for opioid therapy.[37,66,67] Although clinicians in our study viewed their patients as high risk for opioid misuse and overdose, patients did not focus on the health risks of opioids. Earlier studies demonstrated that young adults with nonmedical use of opioid analgesics (i.e., using opioids to self-treat a health condition or for recreation) minimized risks associated with opioid use[68,69] and demonstrated poor knowledge of overdose risk.[70] Veterans with chronic pain and risk factors for overdose believed they were at low risk for overdose.[71] We found that patients with histories of substance use did not emphasize the risk of overdose, in contrast to their clinicians. Instead, patients emphasized confidence in their ability to control how they used opioids. Our findings differ from those described in a sample from the general population where patients described fear of losing control over their opioid use.[72] In our study, the emphasis patients placed on control of

opioid use contrasted with their fear of being perceived as "addicted." This discrepancy may impact informed consent discussions, which rely on a shared understanding of risk and open discussion about strategies to mitigate risk.

Patients felt that clinics enacted opioid monitoring policies in response to other patients' opioid misuse and as a way to protect clinicians but did not see a connection to their own risk. We did not encounter examples where opioid prescribing policies influenced patients to reflect on personal opioid risk. Perhaps this finding is not surprising given the complexity and subjective nature of human risk perception.[73] However, it demonstrates that current opioid policies may not foster optimal patient-clinician risk communication. Patients with recent use of illicit substances viewed clinicians' decisions to discontinue opioids as a response to medicolegal concerns, as opposed to concerns about patient safety. This perception may influence how they viewed the relationship with their clinician. In one study, patients who reported a strong patient-physician relationship were more likely to regard treatment decisions about opioids positively, compared with those who did not report a strong relationship.[74] Although we did not assess patients' or clinicians' perceptions of the patient-clinician relationship, patients' descriptions of stigma related to opioid monitoring policies suggest that such policies have the potential to damage clinical relationships. In addition, patients felt that they were more likely to be perceived as misusing opioids because of their low-income status or minority ethnicity. This perception may be common despite the fact that these groups are not more likely to misuse opioids.[11,75]

The United States National Drug Control Policy and World Health Organization guidelines encourage the co-prescription of naloxone with opioids.[76,77] Half of the clinics we sampled had implemented naloxone co-prescription. We found varying levels of clinician comfort in prescribing naloxone. Although some clinicians feared that naloxone could encourage drug use behavior, no evidence exists to support this hypothesis.[78] Other clinicians expressed concerns that prescribing an antidote for overdose exposed clinicians to medicolegal risks, similar to studies that identified clinicians' fears of legal repercussions as barriers to naloxone use.[79,80] Overdose prevention counseling and naloxone instruction provide opportunities to discuss the risks of opioids with patients.[81,82] If medicolegal concerns dominate discussions of opioid agreements and naloxone instruction, overdose prevention counseling and informed consent discussions may be less effective in improving patient safety.

Limitations

Our results do not include clinical observations that illustrate how clinicians communicated the risks of opioids to their patients and how patients responded to these discussions. Clinical observations may illuminate aspects of our findings, including that patients may be reluctant to discuss fears of addiction because they threaten receipt of an opioid prescription. We did not evaluate measures of the clinician-patient relationship, which would be useful in helping us understand how much clinician continuity and trust impact discussions of risk. We did not evaluate patients for a clinical diagnosis of a SUD but asked clinicians to identify patients with past or present substance use and used a screening instrument to ask patients about their substance use.

Because we conducted our study in safety-net settings serving patients with substance use, our results may not be generalizable to other populations with CNCP. PCPs in our study may have more experience treating pain and addiction and may perceive risks differently than other clinicians. PCPs who agreed to participate may be different from other PCPs who treat chronic pain in safety-net clinical settings. Patients who PCPs identified for participation in our study may be different from other individuals with substance use and CNCP. Finally, both clinician and patient interviewees may have answered questions in ways that would foster positive portrayal.

Conclusions

Findings from this study suggest that clinicians and their patients do not share an understanding of opioid risk. In order to improve the informed consent process for opioid therapy, patients and clinicians need to share an understanding of opioid risks and be able to discuss risks and benefits without harming the patient-clinician relationship. Our findings have a number of clinical implications: To improve patient safety and CNCP treatment, clinicians should discuss the risks of opioid therapy and explore patients' understanding of those risks. Because opioid monitoring policies have the potential to stigmatize patients with pain, clinicians should consider that implementation of these policies may harm the patient-clinician relationship and impede frank discussions of opioid and substance use. Clinician education should move beyond teaching the risks of chronic opioid therapy and incorporate information on addiction, physical dependence, and overdose risk. Important questions for future research include how clinicians should communicate opioid risk, which communication strategies are effective in balancing pain treatment and safety, and how best to integrate opioid prescribing policies into discussions of informed consent.

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Table 1

Relevant interview guide questions.

PCP interview questions
• What are your views on the safety of chronic opioid therapies?
• Are you familiar with the 2009 APS/AAPM guidelines about CNCP pain management? Have they been implemented in your clinic?
• What are the clinic policies for co-occurring CNCP and substance use?
• Has this clinic distributed naloxone to patients on high-doses of opioid analgesics?
Patient interview questions
• How do you manage your pain?
• How do you understand medication “dose” and dosing?
• Tell me about your drug use (prescribed and not prescribed)?
• What role do prescribed and nonprescribed substances play in your everyday life? (in pain management, relaxation, pleasure, mental health, coping)
• Do you see a difference between street drugs and prescribed drugs?
• If yes, what is the difference? If not, why not?
• Are prescription drugs or street drugs safer? More effective? Cheaper?
• How do you talk about your pain with your clinician?
• How do you disclose substance use to your provider?
• What have your experiences been on discussing substance use in clinical settings?

Table 2

Patient participant characteristics ($N = 46$).

Characteristic	*n* (%)
Age (years) *	
25–40	5 (11%)
40–55	18 (39%)
55+	21(46%)
Gender	
Female	25 (54%)
Male	21 (46%)
Ethnicity/race	
African American	28 (61%)
White	14 (30%)
Latino	3 (6.5%)
Missing	1 (2.2%)
Substance use (past or present) **	
Cocaine	30 (65%)
Alcohol	26 (57%)
Marijuana	21 (46%)
Methamphetamine	14 (30%)
Heroin	11 (24%)
Nonprescribed opioids	3 (1%)

* Missing age for 2 individuals

** Possible to report use of ≥1 substance.

Table 3

APS-AAPM opioid management strategies implemented in participating clinics.

- Patients must receive opioids from a single prescriber.
- Patients must obtain opioid prescriptions from a single pharmacy.
- Clinics will use random and routine screening of urine for opioids and illicit substances.
- Clinics will schedule office visits at specified intervals for patients on chronic opioid therapy.
- Clinicians will limit opioid prescription amounts (i.e., to weekly or biweekly prescriptions, instead of monthly).
- Clinicians will use a prescription drug-monitoring program.
- Clinicians will interview family members or caregivers for opioid misuse or safety concerns.
- Clinicians will use formal screening instruments to identify aberrant behaviors.

Table 4

Clinicians' perceptions of the risks of opioids.

First, do no harm
"You've got methadone, oxycodone, and morphine in your urine. I've been prescribing the morphine. It's not safe and it's against clinic policy. First do no harm."
"I'm worried about you. You've got methadone in your urine and I'm prescribing oxycodone. You could overdose. I'm worried about your safety."
Community harm
"I'm a provider for a community. I don't just serve patients. I serve a whole community. Giving someone pain meds that they divert and then sell puts other people in the community at risk. So I want to keep the community safe, not just the patient safe, and then [keep] me safe too."
Medicolegal risk
"We've had patients in this practice die, and God knows how many people have died that we don't know about. That's on my license, on my prescription, and that's not okay."
"Doctors are under fire for prescribing these medicines and patients that overdose, their families are coming back and suing doctors 'Why did you prescribe that dangerous medicine to my [family member].' "
Naloxone (Narcan)
"I did [prescribe Naloxone] for one patient who I knew was a heroin addict … but it hasn't occurred to me to prescribe to people who have crack problems. It doesn't occur to me to give them Narcan."
"There's a lot of questions [about naloxone] … who is going to be there to give it to the patient? I guess another argument can be that [it] gives them more of a reason to go full blown on the narcotics, because they know they have an out with naloxone to bounce back."

Table 5

Patients' perceptions of the risks of opioids.

Patient control of opioid use
[What is your PCP is concerned about?] "That you might overdose. Yeah, but I know how much to take."
"I'm not going to take no four to five pills a day. If I have to take four or five pills a day then they need to figure out how to do something different with me. Because I'm not going to sit up there and commit suicide [unintentionally overdose.]"
Responding to clinicians' concerns
"She said she couldn't prescribe it [opioids] to me as long as I was unclean. She went on to tell me what effects it would have on me, that it wasn't good to mix the two [illicit drugs and opioids], that I have to give her a clean urine sample over a period of time before she can give it back to me."
"[Clinicians are] always afraid that it's going to cause you to go back and use[illicit drugs]. That's what bothers [my clinician] that it might make me go back and use. But I told her it doesn't affect me that way, it just doesn't. Thank God it doesn't make me feel like I want to go use."
Stigma related to opioid policies
"She did it [opioid monitoring] because … she's risking her reputation or practice…She wanted to make sure I wasn't drug seeking."
"People with jobs, when you can afford it, they don't put you through that [monitoring]. You don't sign all these contracts and, 'Oh, if you go and do drugs then I'm not going to give it to you.' No, you don't go through that.
But you get a county hospital all of a sudden, 'You need to sign a contract or we're not going to give you this [opioid].'"
Risk of addiction to opioids
"I have never been the type of person that likes pain medication, because I didn't want to get hooked on it. I'm not hooked on it now, but that has always been one of my fears."
"I don't want to be addicted to long-term medicine because I don't like taking pills. If I don't have to take them, I don't want to take them. Right now [my PCP is] helping me out, we're trying to get a drug that won't let me get addicted. Norcos, you can get addicted to them and you can get a tolerance toward them, but with the methadone, from what I researched and we both researched, it helps you … you don't get addicted to it."