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Opioid risk-reduction strategies for people with HIV on chronic opioid therapy: A qualitative study of patient perspectives

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1. Background

Although non-pharmacologic and non-opioid treatment modalities are integral to managing chronic pain in the outpatient setting, the longterm use of opioids can be an effective approach for some patients (Dowell, 2022). Potential safety risks of long-term use of opioids include sedation, addiction, overdose, death, and diversion to the community;

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CRediT authorship contribution statement

Karsten Lunze: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Jennifer J. Carroll:** Writing – original draft, Formal analysis, Data curation, Conceptualization. **Nishtha Ahuja:** Formal analysis, Data curation. **Marlene C. Lira:** Writing – review & editing, Project administration, Data curation. **Judith I. Tsui:** Writing – review & editing, Formal analysis, Conceptualization. **Alicia Ventura:** Writing – review & editing, Formal analysis. **Jonathan A. Colasanti:** Writing – review & editing, Formal analysis, Conceptualization. **Jane M. Liebschutz:** Writing – review & editing, Formal analysis, Conceptualization. **Carlos del Rio:** Writing – review & editing, Formal analysis, Conceptualization. **Jeffrey H. Samet:** Writing – review & editing, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

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strategies to reduce risks of chronic opioid therapy (COT) require acceptable careful medical management (Colasanti et al., 2020), and may include tools such as pill counts, urine drug testing, and treatment agreements. These tools validate patients' self-reported adherence to prescribed medication and substance use and also document stipulations around prescribing. In some cases, the treatment agreement also serves as an informed consent procedure.

The earlier Centers for Disease Control and Prevention's (CDC) 2016 Guidelines for Prescribing Opioids for Chronic Pain (Dowell et al., 2016) recommended initial and at least yearly urine drug tests to assess medication adherence and detect substance use not reported by the patient. The rationale for routine urine drug testing assumes the possibility of patients' non-disclosure of substance use. Treatment agreements when prescribing COT serve to document providers' expectations related to risk-reduction strategies. They also present an opportunity to explore and identify patients' substance use, recovery, and treatment goals and how they fit within the stipulations of the treatment agreement. While these strategies have been widely adopted with the intention to reduce risk, the quality of evidence for effectiveness in lowering such risk is poor (Asamoah-Boaheng et al., 2021). Likewise, evidence of these risk-reduction strategies' effectiveness on care outcomes (McEachern et al., 2019) and on substance use reductions is very limited (Starrels et al., 2010).

Chronic pain is very common among people with HIV (PWH), affecting about half of this population (Jiao et al., 2016). Several novel clinical approaches have been tested to improve safety and effectiveness of COT in the outpatient setting. In the *Transforming Opioid Prescribing in Primary Care* (TOPCARE) study, a randomized controlled trial (RCT) implementing a multicomponent intervention intended to increase the use of treatment agreements and rates of urine drug testing in a primary care setting, guideline-concordant care improved, but reductions in early opioid refills were not achieved (Liebschutz et al., 2017). The Targeting Effective Analgesia in Clinics for HIV (TEACH) RCT conducted a similar trial in safety-net hospital-based HIV clinics in Boston and Atlanta (Samet et al., 2020). Guidelines by the *Infectious Diseases Society of America* on COT for PWH recommend both urine drug testing and treatment agreements (Bruce et al., 2017), but little is known about the effectiveness of these approaches on pain or HIV care outcomes and about patients' perception of these strategies. In the TEACH RCT, receipt of a multicomponent intervention for HIV care providers, including academic detailing on safer prescribing of COT and the use of treatment agreements, urine drug tests, and pill counts for patient monitoring, was associated with higher odds of urine drug testing without adverse effects on pain or HIV care outcomes (Samet et al.). The intervention increased provider confidence around COT and was neutral toward provider satisfaction with prescribing COT, patient satisfaction, and trust in the provider (Colasanti et al., 2022). Yet, a qualitative exploration among patients in this trial revealed how the approach of routine drug testing is often a source of conflict in the patient-provider-relationship (Carroll et al., 2020). The attitudes of PWH receiving COT towards opioid risk-reduction approaches have not garnered much attention in health services research.

Sense-making conceives of people's cognitive information processing activities as a social process, in which experiences with rules, regulations, and interactions with providers and

other clinical staff influence patient perspectives in and out of clinical settings (Maitlis and Christianson, 2014). Sense-making theory can, in other words, help explore how people process their beliefs, knowledge and experiences with healthcare, and integrate those with their current experiences and circumstances (e.g., to make sense of risk-reduction strategies and other care aspects) (Pope et al., 2019). Exploring COT patients' sense-making could inform how opioid risk-reduction strategies relate to this population's healthcare decisions and health behaviors. The aim of this qualitative study was thus to investigate the experiences of PWH receiving COT in their process of interpreting risk-reduction strategies intended for safer prescribing.

2. Methods

We analyzed data from semi-structured interviews with 16 PWH who receive COT at primary care HIV clinics located in safety-net hospitals in Boston and Atlanta. This nested qualitative study included patients whose physicians participated in and received the TEACH intervention (Lira et al., 2019). We recruited participants through range-maximizing sampling to explore the range of experiences with and perspectives of monitoring strategies across age, race, and health conditions, including 6 individuals from Boston and 10 from Atlanta. Interviews took place after the conclusion of the trial and were digitally recorded and transcribed. Interviews lasted 30–60 min and participants received a $50 gift card as compensation for their time and effort.

We used a content analysis approach (Hsieh and Shannon, 2005) to assess participants' experiences and perspectives. Where applicable, the analysis was guided by sense-making theory (Maitlis and Christianson, 2014) to help understand contested meanings surrounding treatment agreements and monitoring practices; and to see how these might influence people's attitudes and behaviors around their COT. In a first inductive coding cycle conducted by KL and NA, we organized the interview text data around emerging themes including experiences and perspectives around opioid prescribing practices, care navigation and its determinants, and perceived power imbalances in care access and utilization. In a subsequent analytic cycle, we deductively explored the various aspects of sense-making of treatment agreements and related patients' perceived provider attitudes. We summarized our findings in periodic meetings, involving JJC, and discussed results with all coauthors.

2.1. Reflexivity statement

JJC is a medical anthropologist who designed the primary qualitative study and conducted all data collection. NA was a medical student at the time of study, mentored by KL who is fellowship trained in clinical preventive and addiction medicine, with a background in pediatrics and training in qualitative health services research. MCL was the study's research coordinator and is a DrPH student. AV is a clinical addiction researcher and JIT, JAC, JML CdR, JHS are all medical doctors with long experience in chronic opioid therapy, HIV care and health research, including qualitative research. KL and JJC co-led this secondary qualitative analysis.

This study was approved by the Institutional Review Boards at Boston University Medical Campus and Emory University and the Grady Memorial Hospital Research Oversight Committee.

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3. Results

The study sample was comprised of 16 participants whose characteristics are summarized in Table 1. They mostly reflected the clinic population's demographics: about 2/3 were male, a majority in this sample were in their fifties, half of them were African American and almost half identified as lesbian, gay, bisexual, transgender, queer, intersex or from another minority group regarding sexual orientation (LGBTQIA+).

Three major themes emerged from participant interviews. First, patients frequently viewed treatment agreements as an administrative hurdle to be cleared to receive COT—a perception that motivated minimal engagement with the content of that agreement. Second, even with a treatment agreement, appropriate communication of patient and provider treatment goals often fell short. From the participants' perspectives, providers tended to primarily consider medical concerns about opioid risks and dangers to the public; this often conflicted with the patients' own diverse concepts of recovery from pain and/or substance use disorder, sometimes perceiving ongoing non-prescribed substance use legitimate in the context of their personal goals. Participants often experienced stigmatizing attitudes about their pain conditions and their opioid use. Third, diverging meanings of urine drug tests, specifically, meaning patients often perceive them as a manifestation of distrust rather than a tool for safety or accountability, may serve to reinforce stigma and power imbalances more than keep patients safe. When discussing urine drug testing, patients felt that their substance use, treatment, and recovery goals are not sufficiently explored and understood to prepare treatment agreements. We discuss these themes in turn below.

3.1. Treatment contracts as "work" in COT

In interviews, participants described care circumstances to receive COT as different from, say, chronic disease management or primary care. Put simply, they described COT care as requiring 'work' (i.e., activities and tasks). Some perceived that work as manageable ("*I'm doing urine screens a lot more–every time I come to pick up my prescription, I have to see [someone] with that, but I don't see that that's a major problem*"). Others found these tasks quite burdensome ("*I'm living in Maine, so I drive back and forth to Boston … I couldn't just leave work and go in there [for a pill count]. I didn't have a vehicle. So, it was kind of hard*"). Yet, however challenging they found these tasks, patients consistently viewed their participation in monitoring activities as non-therapeutic tasks—as boxes that needed to be checked to receive COT.

To this end, patients perceived treatment agreements as a barrier to (or *pro forma* requirement for) treatment that could most easily be overcome by simply agreeing to its terms with minimal consideration of what those terms may be. For example, one participant, when asked, said she could recall neither the content of the contract ("*I think it was no [cocaine] or something, or no drugs*?") nor its intent ("*I just signed it because I wanted the pain medicine*.") Such low engagement with the treatment agreement process emerged in similar fashion across interviews, with patients voicing that they simply "*wanted pain medicine*" and recognized that assenting to the agreement as presented to them was the fastest way to achieve that goal. One participant indicated that they felt the contract was simply an administrative barrier they needed to pass, noting, "*I didn't really listen to what they had to say*."

Diminished interest in the treatment agreement process appeared linked to participants' piecemeal understanding of clinical expectations. One participant who had signed a treatment agreement with his provider (as all participants in the TEACH study had) claimed no recollection of entering into such an agreement. When prompted to elaborate, he suggested, "*So like … I know I signed something when I got the Percocet.*" Further, this same participant only recalled the expectation that early refills might not be honored ("*If you lose a prescription, you're not going to get a refill of it.*") Other participants shared similarly poor recollection of the details of treatment agreements.

Some patients did reflect a clear understanding of some, but not all, of their treatment agreement's terms; however, in these cases, the stipulations recalled were often framed as behavioral prohibitions ("*[I agreed] just that I would take my pills like I'm supposed to and not try to go outside and get pills from somewhere else*"). In this case, the patient changed behaviors to comply with this expectation (*"So, I just stopped the emergency room stuff [visits for additional analgesic prescriptions] after my pain was coming around, yeah*"). Yet, once again, the patient framed their treatment contract only as a set of rules with which they were obliged to comply to receive the COT, rather than a safety approach.

3.2. Forced accountability, avoidance of being labeled "an addict," and status loss

For many participants, strategies like pill counts and urine drug testing were perceived to increase—rather than mitigate—the myriad risks they face as PWH receiving COT. The primary risk these practices posed for patients was losing access to their medication and experiencing uncontrolled pain. For some, this risk was real but minimal, as with one participant who said he "*[didn't] care*" about regular urine drug tests "*because I do my shit the way I'm supposed to be doing my shit. If I want to have a buzz, I'll smoke a joint, have a couple of shots"* (i.e., only consuming substances they assumed their prescriber would tolerate). For others, the risk of losing medication access was perceived as immediate and, in some cases, a nonsensical forced accountability, as most patients did not perceive the co-use of cannabis or cocaine with COT to be of any clinical importance (*"[You want to limit my COT] because I get high [on cocaine]? What's that got to do with my pain?*").

Losing trust—and especially losing face (i.e., social status)—in the patient-provider relationship was another risk frequently mentioned in connection with patient monitoring practices. Many patients voiced fear of being perceived as having a substance use disorder

(and labeled with the stigmatizing term "addict"), concerned with suffering the loss of autonomy and good-will that often stems from prejudice against people with addictions. One participant recalled, "*So when [the nurse care manager] was telling me about the pill count and I say, 'You think I'm addicted, don't you?' [She said] 'No, I didn't say that.' I said, 'Well, why you want to count my pills?'"* Similarly, some participants saw these monitoring practices as checks on their accountability ("*I said [to the doctor], 'I know you all don't believe me.' He said, 'Yes, I believe you.' I said, 'But I know you're going to take the urine test anyway'"*). In this instance, and others, patients saw these practices as forced accountability and an indication that they could not be trusted to report their own behavior honestly.

Participants reported a few occasions when pill counts and urine drug tests produced accounts contradictory to their own. One participant described this conversation with his prescriber:

> He would say, "Well, we're not giving it to you. They're only giving you such and such amount because your urine was something," and then I was like, "Are you serious? But I've been taking it … I know I took the medication. "

This participant further described his decision to acquiesce to the results of the test, declining to engage in further discussion with his provider, even though he believed those results to be inaccurate. He noted that his response to the test results could be used to discredit him further, saying, "*But I'm not going to do that [argue about it] … because then it seems like I'm a drug addict, like I'm really bad about something. I'm not bad about anything […]."* Thus, the provider's adherence to the guidelines for urine drug testing resulted in the loss of trust and status for this patient, who tried to mitigate those losses by not advocating for himself, as he perceived no value in doing so.

3.3. Urine drug testing and "the bad guy"

Urine drug testing repeatedly emerged in interviews as a contested practice, often evoking heated emotions from participants. For example, one patient reported feeling furious when told that urine drug tests would be required ("*Oh, I flipped out on [the nurse care manager] when she first asked me for a urine*"), regaining his calm only upon learning that this was a clinic-wide practice, not something that had been imposed upon him specifically ("*And then I found out that it was system-wide … I was like, 'I'm so sorry. I thought you were the bad guy'"*). This participant's use of the term "bad guy" in reference to the nurse care manager seeking a urine sample is similarly informative. It illustrates the assumption—echoed by many participants—that urine drug tests could only be used to harm or discredit them. Some participants directly connected urine drug testing for COT with compulsory testing in the criminal justice system, where results were only leveraged to hinder their success ("*I went in a program court ordered. I did six months, the day of graduation they're going to say I had a dirty urine [so even if not true I won't graduate]*").

Other participants reported feeling tricked through urine drug screening, recalling that their prescriber had not been complete in their communication about how urine drug testing would be used in their COT care. Despite having a treatment agreement in place, one participant reported, "*They didn't tell me in detail that if you keep coming in with dirty*

urine, you're going to be shut off. They didn't give me that [information] all." Another reported having received contradictory messages, being told at first that "*it doesn't matter if the urine's dirty,*" but experiencing a different reaction when his urine tested positive for cocaine metabolites ("*The fact that the urine had cocaine in it, all of a sudden that's what she was focusing [on] … And I said, "Yeah, but that's not what you said. You said it's okay if the urine is "dirty", it doesn't matter"*"). Importantly, these reported experiences alone cannot prove or disprove the claim that clinicians in the TEACH study deceived their patients or misapplied the COT guidelines. They do, however, serve as an indicator of how difficult the challenge of securing patient trust can be in the context of urine drug testing —especially when patients' prior experiences with such tests are characterized by strong feelings of antagonism and mistreatment.

4. Discussion

In this qualitative study of PWH in care at clinics in Boston and Atlanta, we explored sense-making of risk reduction strategies for COT implemented as part of the TEACH study on safer opioid prescribing. These strategies included a patient-provider treatment agreement implemented by clinic providers, urine drug tests to monitor COT adherence, and pill counts to monitor diversion. This study's participants experienced the required risk mitigation strategies for COT as tasks—sometimes offensive or burdensome tasks—designed to control their behavior or to justify limited access to COT, not as strategies to increase their and the public's safety, that is to reduce risks from COT for self and others.

A 2017 study on treatment agreements for COT suggested that patients found them easy to understand and that patients and prescribers both found them helpful for guiding treatment (Pergolizzi et al., 2017). Yet, since their inclusion in federal safe prescription guidelines, some clinicians have criticized the lack of standardized treatment agreements and of evidence on their effectiveness in reducing substance use (Kraus et al., 2015; McAuliffe Staehler and Palombi, 2020). In a 2021 survey, almost 3 out of 4 prescribers doubted the effectiveness of treatment agreements at reducing illicit opioid use (Laks et al., 2021).

Our findings suggest that patient and provider goals were almost completely un-aligned, despite the fact that achieving alignment is a central purpose of treatment agreements. Some participants continued to use substances while on COT, and urine drug testing often conflicted with their concepts of integrity and substance use recovery. For some, continued (poly)substance use was not at odds with pain management and COT. Key organizations such as the Substance Abuse and Mental Health Services Administration have set "abstinence from the use of alcohol, illicit drugs, and non-prescribed medications [as] the goal for those with addictions" (Nugent, 2012). Abstinence can be one important substance use recovery goal, but it has been increasingly argued by researchers, patient advocates, and patients themselves that abstinence should not be a mandatory goal of either recovery or risk-reduction strategies in the context of ongoing substance use (Witkiewitz and Tucker, 2020). The need for COT, notably, adds complexity to safe recovery.

While provider perceptions of treatment agreements are mostly positive, the required patient-provider time (Pergolizzi et al., 2017) and unclear potential therapeutic effectiveness

(McAuliffe Staehler and Palombi, 2020) argue for more critical examination or, if possible, optimization of its use. The possibility of developing and agreeing on a patient-centered shared treatment plan merits consideration. Addressing health literacy issues would also be important as most agreements are formulated beyond patients' education and reading levels (Laks et al., 2021). Sense-making, a cyclic process people undertake to give meaning to novel, ambiguous, or confusing experiences (Maitlis and Christianson, 2014), may be a useful framework here. In particular, a strict focus in treatment agreement development on concrete clinical processes (e.g., medication adherence, substance use monitoring via urine drug tests, pill counts) rather than on shared sense-making between patient and provider misses the opportunity to provide patients with important information and create a shared meanings, goals, and values of COT monitoring practices. Sense-making theory would suggest that including *appropriate* information about risks and benefits of COT and formulating treatment goals that have a meaning for patients (ideally based on patients' treatment priorities for themselves) might help narrow the provider-patient disconnect manifested in this study's findings.

Importantly, the implementation of compulsory urine drug tests for patient monitoring produced power imbalances, status loss, fear of being perceived as medication seeking, and fear of receiving the stigmatizing label of "an addict". Substance use disorder, HIV, chronic pain, and receiving opioids are all stigmatized conditions (Cooper and Nielsen, 2017). Stigma related to HIV has known adverse health care implications, particularly for people with opioid use disorders (Vetrova et al., 2021). PWH often experience their pain to be poorly controlled by health care providers due to the intersection of HIV and chronic pain stigma (Dunne et al., 2022). Intersectional HIV and pain stigma has adverse care implications, and is also related to poor health: high intersectional stigma in this population is associated with more severe depression symptoms (Goodin et al., 2018).

This study suggests that the compulsory nature of urine drug tests and their potential care consequences represent structural sources of and further exacerbate intersectional stigma. Given that evidence for an association between urine drug testing and addiction treatment success is lacking (McEachern et al., 2019), our findings suggest that there is merit in carefully re-considering whether urine drug tests are appropriate for some or all COT patients. Our findings further confirm that risk reduction strategies aimed at increasing patient safety might decrease trust in providers, at least among some patients. Generally, patients receiving COT have high trust in provider judgment, but rates of patients' trust in providers and perceptions of how providers trusted them were lower in clinics with risk reduction strategies, and their concerns about treatment discontinuation were higher (Sherman et al., 2018).

5. Limitations

This was an exploratory, post-hoc analysis of qualitative data collected within the framework of a larger controlled trial. Consequently, our data cannot assess the frequency or correlates of identified trends within the population represented by our sample, and these findings may not be applicable to patient populations with different health, demographic, socio-economic, or cultural profiles. This study may have been further limited by its sample size, previously

determined by the parent study; however, we determined that we reached data saturation given that no new themes emerged during advanced analysis, suggesting that additional recruitment would not have altered these findings.

6. Conclusions

Risk reduction strategies require a common understanding between providers and patients about the risks involved with (poly)substance use while on COT. As documented in these qualitative interviews, patients perceived strategies such as treatment agreements and urine drug testing as inherently problematic and eroding trust when they are mandatory, and when treatment (continuation) is contingent on fulfilling provider conditions. Opioid prescription should therefore not be contingent on abstinence and drug testing results, as punitive approaches seem not effective in improving (illicit) substance use outcomes but rather effective at perpetuating stigma. Providers should better seek to understand and communicate understanding of patients' goals, to better address treatment risks, and to build with their patients a shared and mutually acceptable strategy for reducing those risks. A shared strategy may lead to the use of a treatment agreement on treatment goals for some, or result in guidance for others about continued use of substances with approaches that minimize the risks of such continued use.

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Table 1

Characteristics of study participants living with HIV and receiving chronic opioid therapy for pain (n = 16).

Sample characteristics	Percentage, distribution, or range
Sex	11 males (69%), 5 females (31%)
Age range	Between 29.5 and 64 years (median 51 years)
Race/Ethnicity	6 (38%) white, 8 (50%) African American, 2 (12%) other
Sexual Orientation	9 (56%) heterosexual, 7 (44%) LGBTQIA+
Time living with HIV	Between 4 and 27 years (median 16 years)
Undetectable viral load	10 (63%)
Duration of Rx opioid use	Between 1 and 30 years
Ever Injected Drugs	5 (31%)
Married or in a domestic partnership	5 (31%)
Employment status	3 (19%) working full or part time, 12 (75%) permanently or temporarily disabled
High school graduate or higher education	10 (63%)
Living in own home	14 (88%)
Jail or prison in the past 12 months	2 (13%)