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Clinician Perspectives on Opioid Treatment Agreements: A Qualitative Analysis of Focus Groups

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ABSTRACT

Background: Patients with chronic pain face significant barriers in finding clinicians to manage long-term opioid therapy (LTOT). For patients on LTOT, it is increasingly common to have them sign opioid treatment agreements (OTAs). OTAs enumerate the risks of opioids, as informed consent documents would, but also the requirements that patients must meet to receive LTOT. While there has been an ongoing scholarly discussion about the practical and ethical implications of OTA use in the abstract, little is known about how clinicians use them and if OTAs themselves modify clinician prescribing practices.

Objective: To determine how clinicians use OTAs and the potential impacts of OTAs on opioid prescribing.

Design: We conducted qualitative analysis of four focus groups of clinicians from a large Midwestern academic medical center. Groups were organized according to self-identified prescribing patterns: two groups for clinicians who identified as prescribers of LTOT, and two who did not.

Participants: 17 clinicians from General Internal Medicine, Family Medicine, and Palliative Care were recruited using purposive, convenience sampling.

Approach: Discussions were recorded, transcribed, and analyzed for themes using reflexive thematic analysis by a multidisciplinary team.

Key Results: Our analysis identified three main themes: (1) OTAs did not influence clinicians' decisions whether to use LTOT generally but did shape clinical decision-making for individual patients; (2) clinicians feel OTAs intensify the power they have over patients, though this was not uniformly judged as harmful; (3) there is a potential misalignment between the intended purposes of OTAs and their implementation.

Conclusion: This study reveals a complicated relationship between OTAs and access to pain management. While OTAs seem not to impact the clinicians' decisions about whether to use LTOT generally, they do sometimes influence prescribing decisions for individual patients. Clinicians shared complex views about OTAs' purposes, which shows the need for more clarity about how OTAs could be used to promote shared decision-making, joint accountability, informed consent, and patient education.

KEYWORDS

opioids; pain medicine; risk mitigation; opioid treatment agreements; qualitative

Introduction

Patients with chronic pain, particularly those who are seeking or currently prescribed long-term opioid therapy (LTOT), encounter a number of barriers to care, including stigma associated with opioids (Goldberg 2020; Starrels et al. 2010). One recent study found that 81% of primary care physicians across the US

are reluctant to take on new patients currently prescribed opioids (Wohlgemuth, Kaufman, and Drury 2019). Another study conducted in Michigan found that 41% of primary care practices refused to schedule a first visit with a new patient already on an opioid analgesic for chronic pain (Lagisetty et al. 2019). Clinician hesitancy about opioid prescribing may further stigmatize a larger and already marginalized

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population of patients with chronic pain, who have difficulty accessing care even when they neither request nor want opioid therapy (Goldberg 2020).

One possible clinical tool that may have an impact on clinician hesitancy and patient stigma are opioid treatment agreements (OTAs). In many states in the US, it is now legally required for some patients on LTOT to receive and agree to the terms of opioid treatment agreements (OTAs) (Ohio Administrative Code 2023; Pennsylvania Code 2020; 22 Tex. Admin 2023; FL Stat § 2002). While the US federal government does not require the use of such agreements for LTOT, new CDC guidance issued on November 4, 2022, recommends their use; notably the guidance recommends the use of OTAs “although the clinical evidence reviews did not find studies evaluating [their] effectiveness.” (Dowell et al. 2022)

Opioid Treatment Agreements are distinct from and supplement standard informed consent procedures. Not only do they enumerate the risks associated with opioid medications, they also stipulate the behavioral requirements that patients are expected to meet in order to receive these medications on an ongoing basis (Starrels et al. 2010). The language of OTAs varies widely, but among the common stipulations that patients must formally agree to in order to receive LTOT are the expectation that they only receive prescriptions from one clinician and one pharmacy, that they comply with surveillance and monitoring policies such as routine urine drug tests, that they not seek out early refills, that they are respectful of clinic staff, and that they acknowledge the clinicians’ authority to discontinue their treatment if these conditions are not met (Voon, Karamouzian, and Kerr 2017).

In general, studies have found that clinicians view OTAs as valuable, though it is unclear whether these agreements serve to meet clinician goals of safer opioid prescribing and consumption (Starrels et al. 2010; McGee and Silverman 2015; Laks et al. 2021; Starrels et al. 2014). As noted in the recent CDC guidance, there is little evidence to show that OTAs are effective in decreasing opioid misuse or diversion (Starrels et al. 2014; Argoff, Kahan, and Sellers 2014). However, it is possible that OTAs may be of value in a different and unexpected way: the presence of OTAs may make clinicians who are hesitant about prescribing opioids or treating chronic pain patients more willing to work with patients for whom opioid therapy may be clinically indicated. Our study is the first to investigate directly and empirically whether the institutional requirement to

use an OTA affects clinician willingness to prescribe LTOT.

Our study builds on the body of literature describing the use of OTAs and clinician attitudes toward these documents. Before OTAs were mandated by state regulation and institutional policy, Starrels, et al. used semi-structured interviews to explain variation in voluntary adoption of OTAs as a function of how OTAs impact the clinician-patient relationship as well as clinicians’ perceptions of how effective OTAs are at reducing opioid misuse and diversion (Starrels et al. 2014). Kay, et al. also conducted a retrospective chart review to determine whether OTAs reduced healthcare usage (e.g., emergency department visits and hospitalizations) in a Midwestern Veterans Affairs primary care clinic and found they did not; in fact, patients with OTAs were more likely to have more telephone calls, secure messages, and nurse visits than those without them, but it was unclear how this contact with providers was related to other patient health outcomes (Kay et al. 2018). In a more recent national study of opioid prescribers who use state or institutionally required OTAs, Laks, et al. found that these clinicians felt OTA use was a time-intensive ordeal that was generally worth the effort, despite most respondents feeling that OTAs were ineffective in reducing opioid misuse and diversion (Laks et al. 2021).

While there has been an ongoing scholarly discussion about the practical and ethical implications of OTA use in the abstract (Arnold, Han, and Seltzer 2006; Fishman et al. 1999; Rager and Schwartz 2017; Roskos et al. 2007), there is not enough information about how OTAs are actually used in practice and how they affect clinicians’ decision-making regarding patient care. This study moves beyond the current bioethical literature to focus on ways in which OTAs are being used in clinical practice. Understanding the variety of ways that clinicians are already making use of OTAs is necessary for making ethical claims about how best to implement them and recommending what language should be used in such agreements.

Given the growing ubiquity of OTAs and the difficulties patients with chronic pain face when attempting to access care, understanding the impact OTAs have on clinicians’ comfort with prescribing LTOT is important – in particular, whether OTAs expand access to pain management in a transparent and non-discriminatory manner. Therefore, we additionally sought to evaluate whether OTAs play a role in clinicians’ decisions whether to prescribe LTOT: From the clinicians’ perspectives, does the use of OTAs make them more or less likely to prescribe LTOT? In investigating this question, we can gain a fuller

understanding of whether OTAs are potential tools for expanding access to safe chronic pain management or whether they impose one further barrier for patients seeking LTOT.

Finally, this study moves beyond questions of trust when assessing the ethical appropriateness of such agreements. In the bioethical literature, concerns have often been raised that asking patients to sign OTAs may interfere with the development of trust in the clinician-patient relationship because OTAs may communicate to patients that their clinicians are suspicious of their motives in seeking opioid therapy (Starrels et al. 2014; Buchman and Ho 2014; Tobin, Keough Forte, and Johnson McGee 2016; Toye, Seers, and Barker 2017). To ameliorate this concern, Tobin et al. have argued that clinicians should explicitly discuss OTAs with patients as tools for facilitating shared decision-making, and that the documents themselves should refer to clinician responsibilities as well as patient responsibilities (Tobin, Keough Forte, and Johnson McGee 2016). We agree that it is important to consider the effects of OTAs on trust, and this topic was addressed in these data. However, our data also include a broader focus on clinician perspectives on the use of OTAs in practice and the influence of OTAs on attitudes and choices related to opioid prescribing. We hope that this will help to expand an existing conversation on the relationship between OTAs and access to pain management.

This paper shares the findings of a focus group study of General Internal Medicine, Family Medicine, and Palliative Care physicians and nurse practitioners in a large Midwestern academic medical center to better understand the ways they use OTAs and their perspectives on these agreements as well as on opioid prescribing more generally.

Methods

Research team

Methods are reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong, Sainsbury, and Craig 2007). Our interdisciplinary research team consisted of three university faculty, a postdoctoral scholar, a research scientist, and a doctoral student who work in various disciplines, including general internal medicine, philosophy and bioethics, law, public policy and management, and English. This includes a physician who cares for patients on long-term opioid therapy and with substance use disorders.

Design

We selected participants using purposive convenience sampling, aiming to select participants from multiple departments and to include clinicians who self-identified as prescribers of LTOT (Tong, Sainsbury, and Craig 2007; Creswell and Creswell 2018). Though this was a convenience sample insofar as the population's location, we specifically chose clinicians from specialties that are most likely to prescribe OTAs in order to gather in-depth and detailed information about how OTAs are used. We intentionally included Palliative Care, General Internal Medicine, and Family Medicine to account for a range of prescribing practices and different cultures of prescribing that each specialty may have. One central difference between these groups includes LTOT for chronic malignant pain versus nonmalignant pain; recruiting from Palliative Care and other specialties accounted for such differences in the patient population being treated.

In the study, we included both clinicians who identify as prescribers and non-prescribers to capture different perspectives about opioid prescribing. We defined "prescribers" as clinicians who regularly prescribe LTOT for multiple patients and "non-prescribers" as clinicians who either do not prescribe LTOT at all or have few patients for whom they manage an LTOT prescription under exceptional circumstances (for example do to absorbing legacy patients into their practice). Participants were asked whether they identified as a prescriber or non-prescriber on the basis of this categorization. Importantly, identifying as a non-prescriber does not necessarily mean that the clinician does not currently prescribe LTOT for any patients, has not done so in the past, or is not otherwise knowledgeable about OTAs. In order to capture a sample that was representative of the varied perspectives on OTAs, and the perspective of clinicians who are in a position to prescribe LTOT but may be hesitant to do so, it was necessary to include both groups.

Our study was reviewed and approved as exempt by our University's Institutional Review Board. We recruited participants by email and organized them into two focus groups consisting only of prescribers and two consisting only of non-prescribers of LTOT. Due to difficulty recruiting as clinical demands escalated during the COVID-19 pandemic, we obtained grant funding to offer participants in the last two groups (one prescriber and one non-prescriber group) a \$100 gift card for remuneration. No demographic differences related to this incentive were found. We

sent emails to 272 clinicians and 17 agreed to participate in the focus groups. Our focus groups were conducted *via* Zoom and lasted 60-90 min each.

The focus groups were guided by semi-structured questions (Tong, Sainsbury, and Craig 2007; Creswell and Creswell 2018; Bernard 2011; Barriball and While 1994). The use of semi-structured questions in focus groups was selected to promote discussion between clinicians and allow for a dialogue where clinicians could build on to what had been said, negate responses, or raise related points. They began with seven questions exploring why clinicians use or do not use OTAs, their likes and dislikes regarding OTAs, and whether/how OTAs affect their prescribing behavior and relationships with patients. The interview guides made reference to the prescriber/non-prescriber distinction such that slight differences (e.g. why do you/don't you) were present in the two scripts in order for the questions to be relevant to the identity in the focus group. The first two focus group sessions (one group of prescribers and one group of non-prescribers) ended with four questions about whether/how the COVID-19 pandemic has affected their perspectives on and use of OTAs. Three members of the research team conducted the interviews; all interviews were video-recorded and transcripts from the video sharing service were saved. Team members listened to the audio recordings and edited the transcripts for clarity and to remove all identifying information. We reached thematic saturation after the first two focus groups as little new information was obtained from the second two groups (O'Reilly and Parker 2013; Hagaman and Wutich 2017; Hennink, Kaiser, and Marconi 2017; Guest, Bunce, and Johnson 2006).

Analysis

The research team used reflexive thematic analysis, including inductive and deductive coding to analyze the transcripts (Bernard 2011; Vollstedt and Rezat 2019; Glaser, Strauss, and Strutzel 1968; Braun and Clarke 2019; Braun and Clarke 2006). On our methodological approach, we took themes to be “creative and interpretive *stories* about the data, produced at the intersection of the researcher’s theoretical assumptions, their analytic resources and skill, and the data themselves.” (Braun and Clarke 2019; Braun and Clarke 2006) Consequently we assumed that the

interpretations of the transcripts arise as a result of intersubjective meaning and are dependent upon both the focus group participants and the data analysts (Madill, Jordan, and Shirley 2000).

After the first two focus groups, all six team members independently inductively and deductively identified common codes, concepts, and relationships from the transcripts (Qureshi and Zuleyha 2020); this multidisciplinary approach to coding allowed identification of a diverse set of codes, concepts, and relationships to emerge from the focus groups, and ensured they did not arise from only a few perspectives (Gale et al. 2013).

Team members first analyzed the results using open coding by breaking up the data into smaller codes to be analyzed; they then grouped the codes into concepts and broader categories. Once complete, each team member shared their themes with the full group (Vollstedt and Rezat 2019; Strauss and Corbin 1990). Together, we reviewed diverse perspectives, identified broader categories and themes, and ensured there was consensus among the group members. Following analysis of the first two focus groups, the team made small revisions to the focus group questions for clarificatory purposes and held two more focus groups. The full team again analyzed the transcripts from all four groups together using the same process.

Results

We conducted four focus groups with 17 clinicians who work in divisions that make up the vast majority of institutional LTOT prescribing: General Internal Medicine, Family Medicine, and Palliative Care (Table 1). Eight of the participants self-identified as prescribers and nine identified as non-prescribers. Twelve of the participants were certified MDs, three were certified DOs and two were certified APRN-CNPs. All participants had been practicing in their respective clinical roles for at least four years; six clinicians had been practicing between five and ten years, five had been practicing between eleven and fifteen years, and five had been practicing for more than fifteen years. In addition to their division roles, participants had myriad specialties: one clinician held a Master’s in Public Health, two clinicians had specializations in sports medicine, one in emergency medical services,

Table 1. Participant background.

Participant Identification	Total Number	Female	Male	Palliative Care	General Internal Medicine	Family Medicine
Prescribers	8	4	4	2	3	3
Non-Prescribers	9	2	7	1	3	5

one in pediatrics, two in hospice care, and two in geriatrics.

For both prescribers and non-prescribers, the influence of OTAs on aspects of patient care fell into three thematic categories: (1) how OTAs influence clinicians' identities as prescribers or non-prescribers of LTOT and clinical decision-making for individual patients, (2) the impacts of OTAs on the clinician-patient relationship, and (3) varied interpretations of the purpose of OTAs.

Theme one: OTAs modify prescribing decisions, not prescriber self-identities

Participants were clear that the requirement to use OTAs did not affect whether they self-identified as prescribers or non-prescribers (QI) (Table 2). Rather, clinicians cited prior experience, such as their time in residency, training related to LTOT and substance use disorders, or experience with individual patients as more influential on making this determination (QII). However, OTAs did influence clinicians' decision-making for particular patients, such as whether it is appropriate to start a patient on LTOT or whether to stop prescribing (QIII, QIV). Moreover, the presence of these agreements may make patients who could benefit from LTOT more anxious about starting the therapy (QV).

Theme two: parenting, policing, and the impact on the therapeutic relationship

Participants repeatedly noted that OTAs intensify power differentials between themselves and their

patients (Table 3). To describe the increased power difference, participants invoked comparisons with other types of relationships such as parent-child (QVI, QVII) and police-potential offender (QVIII). Notably, participants in our study did not uniformly identify increased power differentials as always harmful to the therapeutic relationship. For some participants, the OTA provided clear guidelines, or "rules of the road" which empowered them to enforce the terms of the OTA in a way that did not feel punitive (QVII). On this view, initiating opioid therapy by signing an agreement with all patients on LTOT makes it clear to patients that they incur new responsibilities to keep them - both the patient and the clinician - as well as the community safe (QVII).

Multiple participants also defended the importance of the universality of these agreements to maintaining the therapeutic relationship: having a standard document created by the institution eased the difficulty of having conversations about discontinuing opioid therapy by making those conversations seem less personally directed (QVII, QXI). Furthermore, participants described that externality as limiting their own discretionary power, narrowing the opportunity for stigma and bias to influence clinical decision-making (QXXII).

Other participants described OTAs as exacerbating the power dynamic in a negative manner, undermining the therapeutic relationship they aimed to cultivate and potentially posing added barriers to patients accessing care (QVI, QIX, QX). Some worried that the use of OTAs targeted an already stigmatized population. These clinicians suggested that the universal requirement of signing these documents was

Table 2. Theme one representative quotes.

Theme One: Requirement to use OTA does not influence decisions about whether to be a prescriber or not. But once people are prescribers, it may influence medical decisions for particular patients about whether LTOT is right for them.	
Sub-Themes	Representative Quote:
Other factors besides OTAs contribute to decision to be a prescriber or non-prescriber	<p>QI. "I don't decide to how I'm going to practice based on the treatment agreement."</p> <p>QII. "None of us got enough training in assessing addiction, tolerance and misuse and diversion, and those are all extremely important features of being able to comfortably provide and competently provide opioid therapy or therapy with controlled substances."</p>
OTAs may influence clinician decisions about whether to start or continue to prescribe opioids to particular patients	<p>QIII. "I may be thinking about prescribing and then I look at the agreement and I may be reassessing my evaluation of the patient and their ability to comply and follow through with requirements we outline and I may change direction in that way."</p> <p>QIV. "I don't think it makes me more apt to prescribe an opioid compared to if I didn't have the agreement, so I don't think it increases my prescribing frequency or comfort. I think it does...make it a little more objective, instead of subjective, if we were to stop prescribing if they violate any aspects of the contract, so that we can clearly say 'you violated [the] contract so, I, as well as my whole office, will not be prescribing it.'"</p>
OTAs may influence particular patient hesitancy about whether to start opioids for pain management	<p>QV. "We have patients who need opioids and are low risk for diversion or abuse and are reluctant to take opioids because of fears of addiction and such. [They] are sometimes taken aback by the agreement...It hasn't prevented prescribing but it is sometimes a barrier to overcome."</p>

Table 3. Theme two representative quotes.

Theme Two: Effects of OTA relationship between clinician and patient	
Sub-Themes	Representative Quote:
Parenting	<p>QVI. "it really ends up you almost feel like [a] parent-child relationship, as opposed to a mutual relationship, ... because you're just, you're almost like scolding them for, you know, not agreeing to what we had talked about."</p> <p>QVII. "it sounds very paternalistic but you know, in a way it's parenting you know that this is the rules of the road, and if this happens, then this is a logical consequence of your choice. And it's not to be punitive but you know it's to keep you safe, it's to keep us safe, it's to keep the community safe."</p>
Policing	<p>QVIII. "I felt like, I felt like I was a cop or something, trying to watch them. I didn't like that part of it ... that's not the kind of relationship that I want to have with my patients."</p>
Impact on the therapeutic relationship	<p>QIX. "Yeah, I think, in the same way it can be harmful to the relationship between the patient and physician...even if it is something we do for everyone. [It makes] them feel like they're this cog in the system, as opposed to an individual and value[d] patient so it can make them feel somewhat dehumanized."</p> <p>QX. "[M]any of these patients [are] already so stigmatized ... that when I when I call attention in this way, it may be, it may put up some barriers... People would be really afraid to continue to come to me and be truthful about what their use [is] and other medications and how and their search for help if I throw this contract in front of them and they don't feel like they can trust me in the same way."</p> <p>QXI. "If you have an agreement and someone violates it, you can still have a therapeutic relationship, if you have the agreement first... If you don't have an agreement it's just like "oh my doctor's mad at me [and] not prescribing"... If you have any agreement it kind of puts the onus on the patient and it's their actions that result in not getting that prescription anymore so...you could still [say], "yes they broke it, but we can still work together and figure out other options, I just can't do opiates anymore."</p>

dehumanizing to the patient, turning them into "cogs in the system" (QIX). Some participants also said that the OTA reinforces to their patients on LTOT the idea that the clinician-patient relationship is not one of medical care, but one of surveillance (QVIII). Moreover, some participants worried that the presence of the OTA could make it more difficult for patients to be truthful about the challenges they face with their treatment regimen (QX).

Theme three: why use OTAs? A plurality of possibilities

Participants expressed varied understandings of the purpose of OTAs, which indicated potential differences between institutional policies around OTAs, how OTAs are in fact implemented in practice, and how clinicians think they should be implemented (Table 4).

Participants offered a range of purposes for the implementation of OTAs as institutional policy: purposes included informing the patient about expectations related to LTOT (QXV, QXVI, QXVII), supporting shared decision-making (QXII), and engendering joint accountability (QXIII, QXIV).

When asked about how OTAs are actually used in practice, clinicians added that the OTA could highlight the seriousness of LTOT (QXVIII), be a tool for

patient education (QXX, QXXI), offer clinicians legal protection (QXIX), and be referenced with patients during discussions about discontinuing LTOT and terminating the therapeutic relationship (QIV, QXIX).

In terms of OTAs highlighting the seriousness of LTOT and being a tool for patient education, participants compared the OTA to an "informed consent document". That is, the OTA facilitates informed consent for a "potentially dangerous drug" and is an opportunity to focus on the distinctive risks of opioid analgesics themselves (QXV). On the other hand, as one participant noted, opioid treatment agreements are primarily "not about a pill" but rather about what it means to "participate in the entire treatment plan" (QXII). While informed consent was referenced, patient education goes beyond informing patients about the risks associated with the opioid medications per se. Participants highlighted the distinctive features of LTOT that patients need to be informed about, including different management procedures (QXVI, QXVII). These clinicians discussed how the expectations associated with LTOT are unique (e.g., with respect to urine drug screening or medication refills) due to the public health crisis related to opioid overdoses. The OTA was thus viewed as a tool that could help facilitate a conversation around those elevated expectations so that patients are not taken by surprise (QXII, QXVI, QXVII, QXVIII).

Table 4. Theme three representative quotes.

Theme Three: Variety of interpretations concerning the purpose of the OTAs, how they are used in practice, and how they could be used for effective care.	
Sub-Themes	Representative Quote:
Shared decision-making	QXII. "Part of the treatment agreement is also that they're going to participate in the entire treatment plan... So it's not about a pill, you know it's a shared-decision making and shared responsibility."
Engendering joint accountability	QXIII. "I think they're necessary...There is such a culture of abuse around these medications, there needs to be expectations on both sides of this relationship." QXIV. "Patients may understand that there is a heightened [responsibility] or it may underscore to them the importance of their responsibility in the patient provider relationship."
Informing the patient	QXV. "informed consent for using a potentially dangerous drug" QXVI. "It may also set expectations for medication refills."
Distinctiveness of LTOT—Separate from other care	QXVII. "just so [patients] are aware and not caught off guard." QXVIII. "I think one of the things that it does is it helps set apart this management from some of the other things that we normally do in the outpatient setting...It shows that we mean business when we're talking about it...It just tells the patient I mean business when I'm talking about this. I take it very seriously."
Perceived legal protection	QXIX. "And also provides legal protection...This goes back to the provider protection, but if a patient tries to claim medical abandonment. From a legal sense, we don't have a case."
Patient education	QXX. "It reminds me of what to discuss with a patient. And I can't remember all of these things that I want to cover in the discussion...so having that in front of me I find very helpful to make sure I cover all of this." QXXI. "It can be a checklist...just a nice outline for both patients and me to remind, you know, us how to initiate therapy and what to look out for. So I think a well-designed OTA can really, really be a tool for kind of education and checklist."
Resource for mitigating bias	QXXII. "Take[s] some of the bias out of the picture where everyone has to sign this whether you're an 80-year-old lady or 35-year-old man. This is just something everyone does. You tell them that and then no one can complain that they're being treated unfairly." QXXIII. "So yeah, you know, the tools that we have are pretty blunt tools. You know, it's hard to individualize to people..."

Relatedly, participants discussed the OTA's role in engendering joint accountability. Some emphasized the OTA's role in setting expectations on "both sides of the relationship" (QXIII), while others saw OTAs underscoring patient responsibilities in particular (QXIV). While some emphasized the potential that these agreements have for facilitating shared decision-making (QXII), others worried that implementing and then enforcing the terms of the OTA did not feel like upholding a mutual agreement, but rather scolding the patient for not living up to the terms previously imposed on them (QVI).

Here, a central tension between the uniformity of OTAs and clinicians exercising discretion to serve individual patients was found. On the one hand, participants articulated that the OTA may be a resource for mitigating bias as it is a mandated policy applied to all patients on LTOT (QXXII). On the other hand, some worried that the OTA may not be adequate to handle individual differences among patients and may interfere with clinicians' abilities to appropriately consider the nuance required for personalized treatment (QXXIII).

In total, participants expressed a plurality of reasons for using OTAs and several different impacts the OTA has on their practice. The impact OTAs have on creating joint accountability and supporting shared decision-making was seen to be particularly complicated; while OTAs were said to contribute to joint accountability and shared decisions, these contributions must be made while simultaneously educating patients and clinicians alike about risk. Further, clinicians must also balance the uniformity of OTAs against their ability to tailor care to individual patients.

When asked about how OTAs should be used, clinicians suggested that they could be used to manage uncertainties as well as be a kind of "checklist" for clinician education and ensuring best practices (QXXI). These perspectives point to OTAs as a clinician education tool—rather than one that only informs and educates patients.

"Not about a pill"

All three themes point to the idea that clinicians found OTAs to signal and grow out of the uniqueness

of LTOT as part of a chronic pain patient's treatment plan. To reiterate what one participant noted, the conditions enumerated in the document are not just about potential risks and benefits associated with the medicine itself, but rather initiate the patient into a comprehensive treatment plan (Table 4; QXII). OTAs signal that to access LTOT, patients and clinicians must incur new responsibilities that they may not have had if not for the ongoing opioid public health crisis. This emphasis on shared responsibilities is also found in another quote which defended the use of OTAs, saying that rather than their being punitive, these documents communicate to the patient that "it's to keep you safe, it's to keep us safe, it's to keep the community safe" (Table 3; QVII). Here there three distinct groups that purportedly need protection with the help of OTAs – the patients themselves ("you safe"), the patient-clinician dyad ("us safe"), and the community as well. In contrast to informed consent documents, which are primarily presented as tools to keep the patient safe, OTAs identify responsibilities that the patient incurs when taking LTOT in relation to their clinicians as well as their community given the opioid overdose crisis.

OTAs thus inform patients of these "heightened" responsibilities, but also as some participants repeatedly said, the documents "set the expectations" of the patient so that the patient is "not caught off guard" regarding certain policies and regulatory requirements for managing LTOT (Table 4; QXIV, QXVI, QXVII). Some participants suggested further that rather than just informing patients of these elevated responsibilities, the presence of OTAs signals a shift in responsibility and puts more onus on the patient (Table 3; QXI). If a patient does not meet the conditions set forth in the OTA and changes are made regarding their access to LTOT, OTAs alert the patient in advance that such changes would "a logical consequence of [their] choice" rather than a decision made by the clinician (Table 3; QVII).

Discussion

Our study illustrates new aspects of the complicated relationship between clinicians, patients, and OTAs; it moves beyond clinicians' general attitudes about OTAs and examines how these documents are used in their practice in more detail, particularly how they affect patient access to LTOT (McGee and Silverman 2015; Kay et al. 2018). Putting the results of the three thematic categories together, a new contrast emerges between the role of OTAs and the of informed

consent processes. Whereas informed consent documents are primarily understood as tools to inform the patient about the personal risks and benefits they incur with a given medication or procedure, OTAs identify (and potentially create) responsibilities that the patient incurs in relation to their clinicians and community. This contrast has ramifications both for how OTAs affect patient access to LTOT as well as therapeutic relationships between clinicians and patients more generally.

OTAs and LTOT access

It has been hypothesized that OTAs raise the comfort level of clinicians, so they are more willing to prescribe opioid medication when it is clinically appropriate (Fishman et al. 2002). If OTAs expand access to pain management in a transparent and nondiscriminatory manner, they may be integral for ensuring that clinicians meet their care obligations to all patient populations as the medical community also takes steps to mitigate potential harms from over-prescribing. Our preliminary findings, however, do not suggest that OTAs serve such a role in practice.

While the requirement to use OTAs did not affect participant self-identification as a prescriber or non-prescriber, participants did note how OTAs could influence their clinical decision-making for particular patients (or the patients' own decision-making) and therefore could pose added barriers for those patients in accessing opioid medication when it is clinically indicated. In this way, OTAs can act as choice points in the clinical encounter, offering clinicians an opportunity to reconsider prescribing after evaluating how likely a patient would be to be able to meet the OTA's requirements.

Intensified power not uniformly considered problematic

Participants described OTAs as intensifying existing power differentials between themselves and their patients. This phenomenon described by the participants in our study is frequently discussed in the literature on OTAs (Arnold, Han, and Seltzer 2006; Fishman et al. 1999; Rager and Schwartz 2017; Hall et al. 2015; Wailoo 2015). However, our study revealed some variation amongst clinicians regarding the significance of these intensified power relationships.

Requiring all patients on LTOT to sign an OTA may constrain the expressive power of these documents, so that patients do not feel they are being singled out as exceptionally at risk or untrustworthy by their clinicians

(Hausmann et al. 2013). This is particularly relevant given findings that clinicians may have difficulty distinguishing which patients are at high risk for developing addiction without bias (Hausmann et al. 2013; Svirsky 2021; Beck, Svirsky, and Howard 2021; Hall et al. 2015). However, some clinicians still expressed concern that the use of OTAs colored their relationships with patients in undesirable ways, making them more like the relationship between parents and children or police officers and potential offenders than the kinds of relationships they would like to have with their patients.

We also found differences in how our participants described their perception of the reasons that OTAs are required as a matter of institutional policy, how they actually use OTAs, and how OTAs might ideally be used. Moreover, even as multiple participants converged on some possible uses of OTAs, such as the OTA being a mechanism for informed consent, shared decision-making, or engendering joint accountability, participants' understanding of these concepts differed and were sometimes in tension with each other. Further, some of the possible uses that clinicians attributed to OTAs may be based on misperceptions. For example, participant perceptions that OTAs protect against clinician liability may not bear out given that these treatment agreements are not thought to have the same legally binding nature as contracts (Arnold, Han, and Seltzer 2006; Rager and Schwartz 2017). Further research can clarify the legal effect that OTAs have in practice – both in judicial decisions as well as in medical board reviews.

Limitations of the study

While suggestive, this study has some limitations which indicate room for future investigation. We conducted in-depth focus groups until we reached thematic saturation exploring all the different ways in which OTAs are used, which included 17 clinicians. This is supported by Guest et al. (Guest, Bunce, and Johnson 2006) and Weller and Romney (Weller and Romney 1988), who showed that common themes and new information about a phenomenon tend to arise from fewer than 15 different people providing data (Bernard 2011; Guest, Bunce, and Johnson 2006; Weller and Romney 1988). Nonetheless, future research that includes a larger sample of clinicians would expand on our current findings.

In addition, the study recruited and solicited the views of a subset of potential prescribers in key clinical contexts where LTOT is prescribed: Palliative Care, General Internal Medicine, and Family Medicine. We selected these specialties because of evidence that

LTOT is prescribed frequently within these divisions (Guy and Zhang 2018), and because General Internal Medicine and Family Medicine are often patients' first point of contact with the medical system. Moreover, the clinicians interviewed serve a patient population from a large geographical region (including patients from both urban and rural areas) that has been significantly impacted by the opioid crisis (Hernandez et al. 2020). The inclusion of these specialties captured a range of perspectives on OTAs and LTOT prescribing, and the use of focus groups allowed for participants from different specialties to agree with, negate, or otherwise build on what others were saying. Similar issues were also raised and discussed in all four focus groups. However, the limited sample size did not allow for conclusions based on group comparisons to be made. We are aware of other specialties where LTOT is regularly prescribed, including dermatology, gastroenterology, and rheumatology (Cao et al. 2018; LeBrett et al. 2022; Day and Curtis 2019), and additional research is needed to understand clinician attitudes toward and use of OTAs in these other specialties.

Additionally, this study took place during the COVID-19 pandemic and so reflects certain practices and perceptions of OTAs at a particular moment in time. We believe this is a moment in time that is important to chronicle, and the COVID-19 pandemic continues to be the context within which patient-clinician relationships develop. Still, the requirements and recommendations involving the use of OTAs are evolving, and it will be vital to account for how these changes are reflected in clinical practice.

Conclusion

The increasing use of OTAs can be regarded as an attempt by regulators to contain and otherwise respond to the overdose crisis. Still, it is unclear that OTAs reduce opioid misuse or diversion, or that their specific contents (i.e., the requirements they place on patients and clinicians using LTOT) are being developed in evidence-based ways. Though current CDC guidance acknowledges that there is little evidence that OTAs reduce opioid misuse or diversion (Dowell et al. 2022), there may be other ways that OTAs support effective pain management which were explored in our study (e.g., by facilitating conversations about the expectations for patients on LTOT). We regard our study as offering a preliminary exploration of how the effectiveness of OTAs might be understood more broadly, and whether clinicians who are tasked with using OTAs regard them as helpful in the current fraught prescribing context.

Our study helps understand the day-to-day challenges associated with implementing OTAs as well as their possible uses. Taken together, our focus groups indicate that clinician attitudes toward OTAs are complex and sometimes in conflict with each other. While our data suggest that the required use of OTAs does not influence a clinician's decision to be a prescriber or a non-prescriber, these documents nonetheless influenced and facilitated individual prescribing decisions as well as other important aspects of patient care; for instance, OTAs may influence clinician perspectives as to whether a specific patient is a good candidate for LTOT and may be used as a justification for stopping LTOT for particular patients.

It would be laudable to try to develop OTAs that help the medical community meet its care obligations to all patient populations while also addressing patient and community safety concerns. However, it is important to think in a more expansive way about the variety of impacts OTAs are already having on the practice of pain management. Part of what these focus group data indicate is that identifying and understanding these impacts in an empirically sound way will require careful attention to the implementation of OTAs in practice.

Contributors

Only the coauthors contributed to the manuscript.

Disclosure statement

Dr. Fried and Prof. Zettler report being part of a team awarded a subcontract through Brilliant Corporation to complete an independent review of the Food and Drug Administration's regulatory actions and decisions on currently approved opioid medications. Prof. Zettler also reports serving as an expert witness retained by the Direct Purchaser Class Plaintiffs in *In re Suboxone Antitrust Litigation*, No. 2:13-MD-2445 (E.D. Pa) and the Direct Purchaser Class, End Payor Class, and Retailer Plaintiffs in *In re Opana Antitrust Litigation*, No. 14cv-10150 (N.D. Ill.). Prof. Howard, Dr. Svirsky, Dr. Richards, and Dr. Thomas report no conflicts of interest.

Prior presentations

Preliminary findings from this study have been presented at the Society of General Internal Medicine April 6-9, 2022 and the American Society for Law, Medicine, and Ethics Health Law Professors Conference, June 1-3, 2022.

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Data availability statement

The datasets during and/or analyzed during the current study available from the corresponding author on reasonable request.

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