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Using Nominal Group Technique to Identify Barriers, Facilitators, and Preferences Among Patients Seeking Treatment for Opioid Use Disorder: A Needs Assessment for Decision Making Support

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Abstract

Background—The opioid crisis requires rapid scale-up of evidence-based interventions to treat opioid use disorder (OUD), of which pharmacologic therapies with methadone, buprenorphine or long-acting naltrexone are most effective. With recently-developed formulations, there are unprecedented treatment options. Even when pharmacologic treatment is accessible, however, uptake remains low, suggesting individual-level barriers. Decision aids are an evidence-based strategy that may overcome these barriers. This study aims to inform such a tool by describing and rank-ordering patients' considerations when deciding whether to start medication and, if starting, choosing a medication.

Methods—Adults with OUD (N=81) attending an addiction treatment center or syringe exchange program completed focus groups using nominal group technique, a consensus method that generates and ranks response. The qualitative component generates a broad array of responses, followed by rank-ordering to prioritize responses. Responses to questions about starting any medications and the pros and cons of five specific medications were ranked and coded.

Results—The decision to initiate pharmacologic therapy and choose among medications was influenced by six key attributes in decreasing priority: (1) benefits, (2) side effects of treatment, (3) medication delivery strategies, (4) convenience, (5) how expectations for treatment are met, and (6) how medication (especially methadone) can represents trading one addiction for another.

Conclusions—Pharmacologic properties, logistical factors, and managing expectations were important themes in decision-making for starting, choosing, and staying on medications, and to a lesser degree, negative views about medications, specifically OAT, as an addiction itself. Desire for more control over treatment persisted in all themes. This study identified specific knowledge gaps, expectations, and priorities which are important for developing a decision aid for OUD treatment relevant to the target group. Nominal group technique is an established mixed-methodology that we have applied to a new population and purpose, that of conducting needs assessment for decision aid development.

Keywords

Decision science; Patient preferences; Opioid Use Disorder; Methadone; Buprenorphine; Naltrexone; implementation science

1. Introduction

The volatile and evolving opioid crisis (Centers for Disease Control and Prevention 2017) continues to be the leading cause of death among young adults in the US with no signs of abating (Case and Deaton 2015, Centers for Disease Control and Prevention 2017). The urgency of the epidemic demands successful implementation of strategies that can reduce the morbidity, mortality, and societal impact of opioid-use disorder (OUD). The best evidence for treating OUD supports using long-term pharmacotherapy for this chronic relapsing condition. Opioid agonist treatment (OAT) have been shown to reduce mortality (Sordo, Barrio et al. 2017), prevent relapse, improve social functioning, and mental and physical health, including HIV and Hepatitis C treatment and prevention (Nielsen, Larance et al. 2016). Opioid antagonist treatment (extended-release naltrexone) has been shown to reduce relapse (Krupitsky, Nunes et al. 2011, Lee, Friedmann et al. 2016), overdose (Lee, Friedmann et al. 2016), and improve HIV suppression (Springer, Di Paola et al. 2018). The recent introduction of multiple evidence-based medication formulations has also provided an unprecedented number of options. FDA-approved OAT options include 1) methadone, taken orally daily at specialized licensed treatment centers; 2) sublingual buprenorphine (Subutex®) or buprenorphine-naloxone (Suboxone®, BPN-SL), purchased at pharmacies and dosed daily at home; 3) implantable buprenorphine (Probuphine®, BPN-IMP), a surgical implant lasting 6 months; and 4) injectable buprenorphine (Sublocade®, BPN-INJ), administered subcutaneously every month. An opioid antagonist option is 5) extended-release naltrexone (XR-NTX, Vivitrol®) (Ling, Mooney et al. 2011, Bart 2012, Mattick, Breen et al. 2014, Connery 2015, Soyka 2015, Schuckit 2016, FDA 2017). Diverse effective treatment modalities allow opportunities for tailoring treatment to individual patient needs and preferences (Hewell, Vasquez et al. 2017).

Despite efficacy and new treatment options available in the U.S., fewer than 11% of people with OUD actually receive evidence-based pharmacologic treatments (Substance Abuse and Mental Health Services Administration and Center for Behavioral Health Statistics and Quality 2016). Even when accessible, uptake of these medications remains very low (20–25%) (Alderks 2013, Saloner and Karthikeyan 2015), suggesting that additional patient-level barriers exist. There is a need to better understand both individual-level barriers and system-

level barriers that prevent patients from entering and staying in treatment despite accessible and multiple treatment options (Oliva, Maisel et al. 2011, Bojko, Mazhnaya et al. 2016, Yarborough, Stumbo et al. 2016, Substance Abuse and Mental Health Services Administration 2018). Some known barriers include beliefs (Uebelacker, Bailey et al. 2016), especially for methadone, that medications are harmful, worsen physical health, “trade one addiction for another” (Pinto, Maskrey et al. 2010), and that “coming off it is worse than heroin itself” (Schwartz, Kelly et al. 2008). For XR-NTX, people fear the detoxification process or believe it is for an idealized patient that differs from themselves (Marcus, Bojko et al. 2018). Negative feelings about medications combined with low motivation for treatment reduce medication uptake (Ridge, Gossop et al. 2008). Moreover, medications, especially with methadone, are often stigmatizing for many patients (Pinto, Maskrey et al. 2010, Gryczynski, Jaffe et al. 2013, Yarborough, Stumbo et al. 2016, Bagley, Hadland et al. 2017) and many counseling and abstinence-based programs disparage medications, especially OAT, as inconsistent with recovery, a notion which may be perpetuated by peers, family, and clinicians (Olsen and Sharfstein 2014), despite contrary evidence (Substance Abuse and Mental Health Services Administration 2018). Patients may view pharmacotherapy as ineffective: only a third of people who inject drugs believe that medications were superior to detox for treating their addiction (Luty 2004). Consequently, pharmacotherapy for many remains a culturally controversial treatment. For those within the criminal justice system, evidence shows that release from incarceration without initiation of medication leads to a much higher risk of relapse (Lee, Friedmann et al. 2016), as high as 90% without methadone (Wegman, Altice et al. 2017). Individuals, however, are often overly optimistic about the control of their addiction and ability to avoid relapse (Polonsky, Rozanova et al. 2016). Transforming patient beliefs that are better informed by the evidence supporting pharmacotherapy is associated with increased treatment entry (Millery, Kleinman et al. 2002, Uebelacker, Bailey et al. 2016) and retention (Millery, Kleinman et al. 2002, Kayman, Goldstein et al. 2006, Winstock, Lintzeris et al. 2011, Bentzley, Barth et al. 2015).

One strategy to better inform patients, transform decisions, and consequently increase treatment uptake may be using a decision aid, which offers accurate information on treatment options and helps patients clarify their preferences and values. This is especially useful now that multiple evidence-based options for OUD exist, making decisions about treatment a preference-sensitive decision. The common elements of decision aids have been well-described (Elwyn, Laitner et al. 2010, Stacey, Legare et al. 2014) and criteria for developing such aids have been set by The International Patient Decision Aid Standards (IPDAS) (Elwyn, O’Connor et al. 2006). The National Academy of Medicine recommends the use of decision aids, which are supported by over 105 randomized control trials showing patients increase knowledge, confidence in decisions, active involvement in care, accurate risk perception, and likelihood that patients elect for more suitable treatment, by overcoming myths and misinformation when decision aids are deployed (Arterburn, Wellman et al. 2012, Stacey, Legare et al. 2014, Stacey, Legare et al. 2017). To date, no validated decision aid has been developed for point-of-care decision-making regarding treatment for OUD. There is an urgent need to develop such an intervention in OUD to increase evidence-based treatment acceptance and retention.

To inform decision aid development, we conducted a needs assessment of the target population, regarding their perceived barriers, facilitators, and preferences in OUD treatment. Patients' perspective of a decision can be very different from that of clinicians or public health officials (Feldman-Stewart, Brennenstuhl et al. 2007, Elwyn, Kreuwel et al. 2011), especially within the patient psychosocial context that can affect uptake of therapies. We sought not only to identify specific patient-centered concerns (about which health professionals may be unaware), but also to identify ranked priorities and obtain rich qualitative data that can examine these needs in adequate depth, as well as provide narratives and language that inform the heuristics and user-interface design of the decision aid.

We have focused primarily on treatment-engaged patients, since prior experience can shape preferences (Yarborough, Stumbo et al. 2016), and this initial decision aid will target treatment-seeking patients. Additionally, since OUD is a chronic, relapsing condition where patients often enter treatment repeatedly (McLellan, Lewis et al. 2000), many patients entering treatment are treatment-experienced who are reestablishing care (Fischer, Nava et al. 2012). Consequently, findings from this study are crucial for development of a decision aid for this population. We selected nominal group technique for this strategy (Delbecq, Van de Ven et al. 1975), a structured group method that simultaneously generates a breadth of responses, makes quantitative estimates (rank-ordering), and provides qualitative data (Jones and Hunter 1995, Sav, McMillan et al. 2015).

2. Materials and Methods

2.1 Setting

Participants were recruited from New Haven's largest provider of OUD treatment with methadone, BPN-SL, and XR-NTX, which serves over 7000 patients receiving these medications at 5 locations throughout Connecticut (N=74, recruited from 2 locations) and from New Haven's Syringe Services Program (SSP), which distributes 1600 clean needles weekly (N=7). The OUD treatment program has implemented an open access approach that provides same-day treatment, irrespective of a patient's ability to pay (Madden, Farnum et al. 2018).

2.2 Eligibility and Recruitment

Eligibility required age ≥18 years and meeting DSM-5 criteria for OUD. All patients were evaluated for OUD treatment at a facility capable of offering methadone, BPN or XR-NTX (by definition at the treatment facility and by self-report at the SSP). Recruitment was achieved using fliers, staff referrals, phone, and research assistants approaching individuals on site. We aimed for 8 groups to ensure saturation of themes for multiple questions. Maximally, 15 participants per group were allowed in sessions lasting 60 minutes. Participants were compensated $10 for their time. OUD treatment program participants consented to linkage with administrative data; SSP participants remained anonymous.

2.3 Study Design

Nominal group technique was selected as a mixed-methods strategy for identifying relevant attributes and relative ranking of importance (Delbecq, Van de Ven et al. 1975). This method

generates both quantitative estimates (rank-ordering) combined with a qualitative approach to weigh priorities among stakeholders (Jones and Hunter 1995, Sav, McMillan et al. 2015). Initially developed from social psychology for aggregating group decision-making, it has been successfully used in health services research (Delbecq, Van de Ven et al. 1975, Murphy, Black et al. 1998, Humphrey-Murto, Varpio et al. 2017), including prior research with addiction medicine providers to identify the barriers and facilitators of entering treatment for OUD internationally (Madden, Bojko et al. 2017). The advantage of nominal group technique relative to traditional focus groups is inclusivity, by facilitating equal participation despite group power imbalances. A silent generation of responses, followed by round-robin listing, then independent voting ensures each individual's participation. Voting and discussion allows aggregation of individual judgments into group conclusions.

2.4 Procedures

Focused questions were developed after a review of literature and consultation with experts in addiction treatment and nominal group technique methods. Questions corresponded with two decision points in treatment:

> Question 1 (Q1): "What are the considerations that someone should have when thinking about **starting** *any* medication treatment for opioid use disorder?"
>
> Question 2 (Q2): "What are the good and bad things that you know about or have heard about **choosing** *this* medication for treating opioid use disorder?

Q2 was repeated for methadone; BPN-SL; XR-NTX; BPN-IMP; and BPN-INJ and included brief descriptions of each medication with name; mechanism of action (opioid agonist, partial agonist, antagonist); dosing frequency (daily, monthly, twice-yearly); administrative route (oral, injection, implantation); induction or opioid withdrawal process, if any; and location of administration (treatment program, pharmacy with take-home, clinical office). Although oral naltrexone has been used for treatment of OUD, we did not include this because there is not good evidence for its effectiveness (Minozzi, Amato et al. 2011). We regarded buprenorphine SL (Subutex®) and buprenorphine-naloxone SL (Suboxone®) as equivalent, using only brand names familiar to the target patient group. BPN-INJ had not yet been approved at the time of the study. Participants were to draw from personal experiences and information from peers, clinicians, family, media, and other sources.

After the descriptions, participants first silently generated responses for 3 minutes, either in writing or quietly to themselves (so as not to exclude those with limited literacy). Then, during the "round-robin," each individual offered a single idea which was written on the board. Additional round-robins were completed until responses were saturated (individuals could pass). A discussion about each item and whether they should be combined with others, then clarified each response. Finally, individuals voted to prioritize items. Each participant had 3 votes in any combination for weighing responses (e.g., 3 votes on 1 item, 1 vote per each of 3 items, or any other combination). Votes were tallied and items ranked. A final discussion reviewed if the group endorsed the highest-ranking priorities. Audio-recording and transcription contextualized the responses and the rank-ordering. Given limited time, not all medications were addressed in each session, but each medication was addressed in at least one group.

2.5 Measurements

The OUD treatment program administrative database provided demographic information, treatment entry date, and the number of treatment episodes with the 3 available medications at that facility. Additional data included group size, the generated list of responses, distribution of votes, rank-ordering, and transcript of discussion.

2.6 Analysis

All generated responses to questions were recorded and votes tabulated per item per group. For Q2, all groups generated responses and voted for individual medication separately and sequentially except Group 4; Group 4 generated responses for all medications at once, then voted separately on responses for each medication. We identified the highest-ranking responses per question (the top 5 priorities with at least 2 votes; some groups had less than 5 priorities, others had more than 5 priorities if votes tied). Highest-ranking responses were pooled across groups and organized by question. Responses were consolidated across groups if identical; rephrased for clarity; and classified as negative, positive, or neutral based on discussion context.

Following recommendations for analyzing nominal group technique across multiple groups with a large number of participants (McMillan, Kelly et al. 2014), we consolidated raw ranking data, then conducted iterative rounds of thematic coding of both responses and transcript. Two reviewers (DM, JB) thematically grouped highest-ranking responses and coded transcripts independently, then reconciled differences to ensure reliability of framework. Since not every group addressed every question (Q1 and Q2 for each medication), coders were open to independently coding responses to each question and medication if necessary. The framework and data were presented to other research team members (LM, DB, FLA) for finalization of overarching and sub-themes. The thematic framework categorized the highest-ranking responses (Sav, McMillan et al. 2015) and transcript contextualized these priorities. We used RATS (relevance of study question; appropriateness of qualitative method; transparency of procedures; soundness of interpretive approach) guidelines for qualitative research to report our findings (Clark 2003).

2.7 Ethics Statement

This study was reviewed and approved by the institutional review board at Yale University and approved by the APT Foundation Board of Directors. All participants provided written informed consent.

3. Results

3.1 Participants

Eight groups included 81 participants, for whom demographic data were available for 72 (Table 1). Participants had a wide range of treatment experience, from 1 day to over 6 years. Most participants had experience with methadone, some with BPN-SL, and very few with XRNTX; none had received implantable or injectable buprenorphine.

Group size ranged from 6–15 individuals; 4 groups discussed Q1 (considerations for starting any medication treatment). For Q2 (the pros and cons of a specific medication), 5 groups discussed methadone; 3 groups BPN-SL; 4 groups XR-NTX; 1 group BPN-IMP; and 1 group BPN-INJ. Group 4 (SSP participants) addressed both Q1 and Q2 during a single two-hour group session.

3.2 Total responses generated

Eighty-one participants generated 220 total responses and cast 716 votes. Ninety responses were ranked highly, receiving 400 votes. Table 2 summarizes response and vote distribution. After coding independently for themes, we found very similar recurring themes, that rapidly saturated and dominated in ranked popularity across all medications. Given the robustly similar categories of motivations, barriers, and concerns, we consolidated responses across questions. The exception was injectable buprenorphine, which had not yet been approved at the time when these groups were conducted, and lacked saturation of themes, so this outlier was excluded from analysis.

3.3 Themes

Six themes emerged for Q1 (whether to initiate pharmacotherapy) and Q2 (pros and cons of specific medications), summarized in Table 3.

3.3.1 Benefits of Treatment—Perceived benefits of treatment were a leading motivation for treatment initiation and retention (Table 4). Responses largely arose from Q1 and Q2 for methadone; pharmacotherapy in general was frequently equated with OAT. Methadone and BPN-SL relieved withdrawal symptoms and cravings. Medications in general stabilized and improved quality of life (relative to continuing to use other opioids that were taken more frequently), saved money, supported employment, improved family relationships, and decreased legal problems. Treatment liberated patients from the effort required to obtain “illicit” opioids. For many, this outweighed any disadvantages of treatment.

> “[*Methadone] gives me balance, it keeps my mind off other drugs, I don’t think about doin’ other drugs anymore, I haven’t in a long time, you know, it keeps me at ease, it brings stability…I can still do things that I could have done when I was completely sober… I’ve been on [methadone] for quite a few years, and I don’t care about if I have to stay on it forever.”*

While many people found methadone’s daily site visits burdensome, several found daily access to be helpful, since it provided structured access to clinical care and peer support. Several individuals also cited methadone as advantageous in managing their chronic pain. A few (3 participants, 2 votes) endorsed methadone as a good “back up” (keeping them free from withdrawal symptoms) while they continued to use.

When XR-NTX was addressed in Q2, it was thought to be beneficial to only those who were “serious about sobriety” because of its opioid antagonist effects, which required a commitment for which they themselves did not feel ready (theme 5). Those with comorbid

pain preferred methadone; but those with comorbid alcohol disorders liked the potential of XR-NTX for treating both.

Overall, among this treatment-engaged sample, the greatest factor for starting and choosing pharmacologic therapies were the benefits in symptom relief, functional improvement, and treatment of comorbidities.

3.3.2 Side Effects—Patients also considered medication side effects when starting and choosing treatment (Table 4), though most had never considered multiple options when entering treatment. Answers derived predominantly from Q2. A predominant concern was the risk of overdose while simultaneously using other sedating medications (polysubstance use), prescribed or otherwise (*e.g.* opioids, benzodiazepines, alcohol).

Specific methadone side effect concerns included weight gain, drowsiness, impaired sexual function, and impact on bone and dental health. Bone pain and tooth decay concern persisted (8 votes) even though patients debated the validity of these concerns, reflecting deeply embedded narratives.

> "No, I'm gunna tell you it wasn't a myth when they had the orange meth back in the day and it did use to attack the bones, it did use to take out the teeth, but they took that off the market because it was attackin' too many people. It was strong… that was the kind if spilt on the floor, it stained the floor orange, you couldn't get it out nothin'…when they give it to you in the cup the cup turned orange cause the stuff is stickin' it to your bones but now it has marrows and protein in meth now today but back in the day it was…true."

The most concerning side effect for XR-NTX was its lack of certain effects, *i.e.* inability to treat withdrawal symptoms and any form of pain. Though its potential to reduce alcohol use was beneficial to some, others were concerned about potential impact on recreational alcohol use.

3.3.3 Medication Delivery System—Medication delivery concerns the physical and logistical features of medication administration (Table 4), and arose entirely in response to Q2. The leading delivery barrier for starting or switching to buprenorphine-containing medications and XR-NTX was the delay between initiating therapy and onset of benefits. Specifically, participants were concerned about the supervised abstinence from opioids until moderate withdrawal symptoms develop, which is required if actively using other opioids prior to BPN initiation (12–24 hours induction if actively using shorter-acting opioids like heroin, 1–3 days or more, if transitioning from methadone). Two participants also cited the barrier of laboratory screening that some individuals received before BPN-SL initiation. A small subset (3 votes) believed that the naloxone in buprenorphine-naloxone was acting as an opioid blocker, which patients perceived as "kicking out" any active opioid and inducing withdrawal symptoms. The participants who reported unexpected withdrawal exclusively described this as occurring with unsupervised buprenorphine shared between friends. Similar to BPN, 7–10 days of supervised opioid withdrawal before initiating XRNTX reduced enthusiasm for this treatment. In contrast, methadone, in this low-barrier clinic with same day access, was appealing for quick entry and same-day symptom relief.

The unpleasant taste of BPN-SL was a major disadvantage, with one participant citing this as the central reason for refusing this option. Others, however, liked the option of controlling their treatment through daily multi-dosing for BPN-SL (e.g., if they also had pain). Most, however, preferred convenience of infrequent supervised dosing (theme 4) and strategies that discouraged diversion, especially for BPN-IMP (theme 4), though participants expressed concerns about invasive procedures. A related concern was the irreversibility of long-acting medications. Though long-acting buprenorphine would require initiation with BPN-SL, this was not always reassuring.

3.3.4 Convenience—The inconvenience of supervised, on-site methadone dosing was widely cited as a barrier to treatment retention (Table 5). Largely in answer to Q2, participants reported that daily visits took time, prohibited travel, and conflicted with other responsibilities. The onset of withdrawal symptoms with missed doses (theme 6) meant little flexibility. Patients have the opportunity, after 90 days of demonstrated stability, to begin "take-home bottles," with decreasing visit frequency. For some, maintaining take-home bottles incentivized adherence and prevented relapse; for others losing that "privilege" after a relapse was discouraging and belittling. Treatment as "handcuffs," was a repeated concern, though participants find ways to navigate this over time.

> "[You have] your job…I come in at 6 o'clock in the morning, it's hard with me, I got kids…In the beginning it's hard…the first day it's like ok what do I do tomorrow, figuring everything out…"

Others participants emphasized that, however inconvenient, methadone was more convenient than the lifestyle required to obtain and use drugs of addiction.

> "There's nothing I wouldn't have done in the snow, rain, and sleet to go get my bundles [of heroin]…So when I hear people complain about…I got to take the bus here. The goddamn bus was late … You're not thinking correctly because…You'd run 4 miles…with no shoes in the snow for a bag…you can just come here, get on the program, and you don't need to go get bags anymore… That's a great thing."

In contrast to methadone, all other medications were valued for their convenience: even with daily home dosing of BPN-SL. Long-acting agents XR-NTX and BPN-IMP were especially appealing for convenience, though a few worried that it may be harder to keep track of a long-term dosing schedule.

3.3.5 Managing Expectations—Managing expectations includes expected treatment effects; uncertainty about unfamiliar medications; and psychological readiness for treatment. This theme emerged especially from Q2. Several participants reported disappointment that methadone effects were not what they expected: dosing appeared to vary in potency, effect duration was shorter than anticipated, and cravings persisted despite treatment. There was particular frustration about negotiating the right dose (higher *or* lower) and duration of treatment, with some individuals initiating medications with the expectation of short-term treatment.

> "I was first put on [methadone,] [and] they said well…give it 6 months, we'll see how it goes, but…I felt that I was being slighted, because … [I gave] some dirty

> urines, [so now I] need to go up [on the dose]…put me to feel that I had to be on longer, when I was looking for the short term, not the long term, having to be here every day, meetings, all of it."

All participants reported knowledge about methadone and BPN-SL, but unsurprisingly most did not know what to expect with the three newer medications (XR-NTX, BPN-IMP, BPNINJ). This unfamiliarity was mostly regarded neutrally, but for some, it was negative. In contrast, BPN-IMP's appeal was for containing the familiar drug buprenorphine.

Some emphasized psychological readiness for treatment as critical for effective therapy (10 votes). Diversion and misusing opioids while in treatment meant "you're just playing with it." Notably, 3 individuals in discussion equated sobriety from all substances with success. That is, successful opioid addiction recovery but ongoing cocaine use still meant a person was "not ready." Even if something like XR-NTX could ensure sobriety, true recovery required that deliberate readiness.

> "I feel like you don't got no freedom [on XR-NTX]. Like, you got no choices in life. Like-- if I wanted to use, I wouldn't be able to. I'm not, I'm not saying I would, but that's not honest. There's really no benefit for you as a patient. It's like if, if they do it a lot with people they know in prison, I guess it's great for everybody else. But, you know, it really takes the choice away from you."

3.3.6 Trading one addiction for another—Several participants endorsed that pharmacotherapy, specifically methadone, is "trading one addiction for another" (38 votes) in that methadone produced withdrawal symptoms when not dosed daily, could be mind-altering, and that there was stigma from attending daily supervised pharmacologic treatment. This theme emerged from both Q1 and Q2, but entirely in reference to methadone. Withdrawal symptoms from stopping methadone lasted longer than that of drugs like heroin, though withdrawal symptoms from stopping BPN-SL were milder. Fear of withdrawal inspired some ambivalence about having started methadone in the first place. Although many felt "normal" after settling on the right dose of methadone or BPN-SL, a few perceived medication effects (such as sedation) as similar to drugs of abuse, leaving them feeling like a "zombie." Finally, the attribute of stigma of OUD pharmacologic treatment received few votes (2), but discussion sometimes emphasized family suspicion of medications, especially OAT, as complicating treatment.

> "My grandmother… is against [methadone]. She's like 'oh, you're just going to use another drug.' You know what I'm saying? She doesn't know anything about it… it's automatically 'another drug'. But a lot of us…in active addiction have doctor shopped and abused prescription drugs…So when you tell your family that 'I'm going to a methadone clinic to…receive this drug that I can't take home… because it's a drug that's very commonly abused…especially if they're elderly, your family, they just see it as 'He's gonna find…a way of manipulating this, like he does all his other prescriptions…'"

But others noted that there is changing perception of pharmacologic treatment, even of longstanding medications like methadone, with time and increasing ease of access.

> “ Methadone has become more acceptable now…When I was growing up…like, in my 20s…you had to be, like, in prison three times, homeless, lost jobs, before they even consider you being on methadone…And that…with [a] year waiting list. Now, it’s like everybody’s on methadone. Like, the lines are unbelievable.”

4. Discussion

Pharmacotherapy with methadone, BPN, or XR-NTX is the cornerstone of evidence-based treatment for OUD, but in addition to structural barriers, individual-level barriers to initiation and retention in treatment limit adequate public health expansion. To inform the development of a decision-making aid that can increase treatment uptake, this study used nominal group technique to characterize the barriers and facilitators experienced by patients engaged in treatment, finding that the decisions to initiate treatment and select among medication options are influenced by six key attributes in the following order: (1) the benefits of treatment (2) side effects (3) medication delivery system (4) convenience (5) managing expectations for treatment and (6) the extent to which treatment is trading one addiction for another. This study builds on and adds to the international literature on patient perspectives on pharmacotherapy for OUD by not only identifying barriers, facilitators and preferences in treatment, but also comparing most available medication options (including agonist and antagonist treatment) and rank-ordering priorities, for the purpose of informing a decision aid.

Participants had initiated and stayed in treatment, even if they had negative attitudes towards medications because positive features outweighed negative ones. Individuals navigated this trade-off differently based on their circumstances and preferences, but commonly desired more knowledge and control over the structure and effects of their treatment, which supports the potential role for a decision aid to address knowledge deficits and related concerns. Participants debated these knowledge gaps, such as the longstanding historical lore about methadone’s effect on bones and teeth (Goldsmith, Hunt et al. 1984), which clinicians have often regarded as “myth”: “bone pain” is attributed to myalgia of withdrawal and tooth decay is attributed to dental neglect while using drugs of abuse, that becomes noticeable once patients stabilize. Long-term opioid use, of any type, can decrease bone density (Kim, Alford et al. 2006), especially in men whose testosterone levels decrease (Grey, Rix-Trott et al. 2011, Gotthardt, Huber et al. 2017), and methadone may increase affinity for high glycemic foods that might impact dental health (Mysels and Sullivan 2010). More research is needed to further substantiate these claims, but they remained a major concern for participants, indicating a role for a decision aid to directly address this uncertainty. Relatedly, buprenorphine of any formulation was not recognized as a partial opioid agonist. Instead, some participants attributed withdrawal symptoms from BPN-SL to the ingested naloxone (which is not active) rather than the buprenorphine itself. Patients taking this formulation unsupervised while still actively metabolizing heroin (*i.e.* without a supervised induction period), perceived this as “kicking out” any active opioid and inducing withdrawal symptoms. A decision aid could advise how to contextualize these non-supervised experiences.

The desire for increased control over treatment was characterized by the ability to opt in or out of more or less structured treatment strategies; interest in learning about unfamiliar medications; desire to better manage expectations about dosing, duration of treatment, and effects; and emphasis on the value of "readiness" (itself a predictor of retention (Joe, Simpson et al. 1998)). This patient desire for autonomy in OUD treatment confirms findings in two other studies describing patient views about structure (Notley, Holland et al. 2014), knowledge, and expectations (Yarborough, Stumbo et al. 2016) in OAT treatment, but we found that logistical features of pharmacotherapy (benefits, side effects, delivery system, and convenience) were collectively more important for preferences than expectations and fear of continued addiction.

Desire to incorporate preferences is rarely mentioned in addiction treatment, but remains an increasingly recognized need for patient-centered care in many chronic diseases (Epstein, Fiscella et al. 2010, Marchand and Oviedo-Joekes 2017). Patient-centered care that incorporates patient preferences has been historically lacking, especially in addiction treatment (Bojko, Mazhnaya et al. 2016, Kolind and Hesse 2017), mostly because few options were available and were not often available in the same setting. With treatment options increasing, there is emerging evidence that less restrictive approaches in treating OUD are at least as effective if not better than more restrictive approaches (Schwartz, Kelly et al. 2017). In other conditions besides OUD, decision aids improve patient outcomes, including satisfaction, and quality of care, while reducing costs and health disparities by democratizing treatment (Epstein, Fiscella et al. 2010). Findings here provide new insights into emerging strategies to address the current volatile opioid crisis where it is not only urgent to get many more patients onto treatment, but for them to remain satisfied and remain on treatment. With newer treatment options, there is now the ability to incorporate patient preferences into medical decision-making by giving patients more autonomy, thus encouraging patients to more effectively engage in treatment (Ahamad, Milloy et al. 2015).

This study also compares specific pharmacotherapy strategies to each other, including newer, long-acting formulations. Ambivalence about XR-NTX is similar to other studies which suggested low acceptability in about half of participants (Ahamad, Milloy et al. 2015, Springer, Brown et al. 2015, Friedmann, Wilson et al. 2018, Marcus, Bojko et al. 2018), with reluctance to stop using opioids ("readiness"), and concern for the discomfort of opioid withdrawal (Marcus, Bojko et al. 2018). Our findings emphasized the concern about induction, the leading concern for BPN-SL, which can be influenced by prior unsupervised use. This can be addressed in a decision aid. BPN-IMP is a promising option with general appeal for its convenience, but raised significant concern regarding implant procedure that may affect acceptability. We have confirmed a persistent fear of "continued addiction" with methadone, including concern for withdrawal from treatment medication, but to a lesser degree with BPN, similar to other research findings. Interestingly, although "continued addiction" was important enough to emerge as a major theme, it was the lowest ranking of the six themes. Additionally, in contrast to other studies (Yarborough, Stumbo et al. 2016, Hewell, Vasquez et al. 2017), there was no explicit emergence of stigma as a high-ranking concern, especially relative to the pharmacologic and programmatic factors. This apparent discrepancy may be due to differences in study samples (e.g., out-of-treatment vs. in-treatment individuals). We note that a recent study conducted in the Ukraine also found that

among individuals receiving OAT, stigma ranked lower than logistical barriers as a concern (Zelenev, Shea et al. 2018). Future research might benefit from using validated measures to more systematically examine the possible associations between stigma, decision-making, and medication initiation and retention.

These findings will inform the development of a decision aid by identifying the breadth of concerns for patients as well as rank-ordered prioritization (a decision aid must balance comprehensiveness with time efficiency and limits of tolerable information volume) as well as insight for constructing narrative heuristics, which are essential for the intuitive component of decision making, in addition to the deliberative component (Kerstholt, van der Zwaard et al. 2009, de Vries, Fagerlin et al. 2013). These findings indicate our decision aid will need to emphasize not only the benefits and side effects of individual drugs, but also the logistical aspects of medication delivery, especially the induction process for BPN. There is a need for an interactive decision aid to identify major subpopulations – those with the "readiness" for opioid antagonist therapy, chronic pain, or experience with diverted, unsupervised medications—in order to address how these experiences can shape the patient's understanding and preferences.

Finally, this study contributes a novel application of a methodology (nominal group technique) for this population and purpose, and our findings validate several themes seen in other studies, although with the unique insight of rank-ordering and findings specific to our context. This is a rapid methodology that is highly structured and can be interpreted in a replicable manner (McMillan, Kelly et al. 2014). When developing decision aids for other populations, such as treatment-naïve populations or in specific settings (e.g. criminal justice-involved individuals), this method can be used as an efficient needs assessment strategy for targeting decision aid development. Nominal group technique's equitable approach is especially useful in settings (incarceration, potentially stigmatizing treatment) where power imbalances are substantial.

4.1 Limitations

Despite many new insights, this study had some limitations. First, our sample focused on patients engaged in care, with limited generalization to out-of-care individuals who need treatment. That many in our study population had multiple treatment episodes and continued to use illicit opioids simultaneous with treatment does suggest an overlap between out-of-care and engaged-in-care populations, consistent with the known relapsing and remitting nature of OUD. Development of decision aids for treatment-naïve and out-of-care individuals are needed to identify barriers and preferences for these individuals to better construct a decision aid to promote treatment entry. Treatment-experienced patients may also have recall bias, and tend to favor the treatment they had already chosen (Salkeld, Ryan et al. 2000). Also, most participants in our sample used a unique 'open-access' clinic model, which can link patients to pharmacologic treatment within the same day they arrive. This may limit generalizability to other contexts where waiting lists, evaluation delays, and cost influence patient experiences. Our findings indicate however, that same-day, low-barrier access is greatly valued by participants. Such delays in treatment entry are also associated with high risk for mortality and other health risks (Sigmon 2015). These findings are

generalizable in that they add patient-centered findings to the literature that suggest eliminating delays to treatment may be an important target of intervention in other settings. Although nominal group technique is more equitable than traditional focus groups, vocal participants and Hawthorne effect could still influence the group. In our analysis, we consolidated responses even though not all groups addressed and voted on all medications (due to limitation on participant time and attention), following the guidance of previous research (McMillan, Kelly et al. 2014). It is possible that questions with fewer responses (*e.g.* Q2 about BPN-IMP) could bias findings. However, in our approach, two independent reviewers found similar recurring themes among different medications that met minimum vote cut-off and were rapidly saturated. The exception was BPN-INJ, which did lack strong saturation of themes, so this outlier was excluded from analysis to reduce risk of bias. Future studies should incorporate these findings and reduce potential bias using surveys, including conjoint-based assessments about patient preferences (Lancsar and Louviere 2008).

Notwithstanding these limitations, our study of treatment-experienced patients with OUD is unique in characterizing and prioritizing patients' perspectives about barriers and facilitators for initiation, preferences, and retention in a variety of medication options. While studies have looked at acceptability of BPN-SL (Sohler, Weiss et al. 2013, Fox, Maradiaga et al. 2015) and XR-NTX (Zaaijer, Goudriaan et al. 2016, Marcus, Bojko et al. 2018), there are no studies to date that address long acting OAT (BPN-IMP) nor ask patients to compare and rank-order newer medications to each other and the standard bearer, methadone. Additionally, our study is unique in using a method (nominal group technique) not previously used in this population, and in that it was conducted specifically as a needs assessment for a decision intervention to be used in the same target population Understanding how patients prioritize attributes in OUD treatments leads to better characterization of preferences, decision-making, and acceptability of novel therapies, which can inform patient-centered interventions, like decision-support tools, to improve initiation and retention in therapy.

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Highlights

- Benefits are the primary motivation for starting and choosing medications for opioid dependence
- Side effects, medication delivery system, and convenience are secondary influences medication initiation and retention
- Managing expectations and perceiving medication an addiction itself impacts initiation and retention to a lesser degree
- Participants value autonomy and adequate information within each of these themes
- Findings will inform a decision aid that addresses knowledge gaps, aligns expectations, and individualizes counseling

Table 1:

Participant characteristics (N=72) *

	No.	%
Total	72	100
Median Age, years: 42		
Sex		
Male	46	63.9
Female	26	36.1
Race and Ethnicity		
Hispanic Ethnicity of Any Race	10	13.9
American Indian or Alaskan native	3	4.2
Black or African American	15	20.8
White/Caucasian	43	59.7
Asian, Native Hawaiian or other		
Pacific Islander	1	1.4
Multiracial or other	9	12.5
Education		
Less than high school	29	40.3
High school graduate/GED	28	38.9
Some College, 4- year graduate or higher	14	19.4
Duration of treatment-engagement **		
Less than 1 week	1	1.4
1 week to 1 month	3	4.2
1 to 3 months	7	9.7
3 to 6 months	12	16.7
6 months to 1 year	9	12.5
1 to 2 years	20	27.8
More than 2 years	14	19.4
Have dropped out and re-entered since start of study	6	8.3
No. of MAT treatment episodes (Range 0–6 episodes)		
Not yet on MAT	7	9.7
First treatment episode	20	27.8
Second treatment episode	22	30.6
Three or more episodes	23	31.9

* Description of participants for whom data were available (9 participants were missing relevant administrative data, including 7 participants from Syringe Exchange Program

** Includes non-MAT clinical activities.

Table 2:

Number of responses and votes received for whether or not to initiate medication assisted therapy (MAT, Question 1) and evaluating individual MAT strategy preferences (Question 2)*

Topic	Total number of responses generated N=220 (*% of total responses*)	Number of highly-ranked responses N=90 (*% of highly-ranked responses*)	Total number of votes cast N=716 (*% of total number of votes*)	No. of votes cast for highly-ranked items N=400 (*% of votes cast for highly-ranked items*)
Q1, What are considerations for starting any medication treatment at all?	116 (*53%*)	24 (*27%*)	116 (*16%*)	83 (*21%*)
What are the positive and negative features of methadone?	45 (*20%*)	23 (*26%*)	141 (*20%*)	109 (*27%*)
What are the positive and negative features of buprenorphine-naloxone sublingual?	23 (*10%*)	17 (*9%*)	315 (*44%*)	74 (*19%*)
What are the positive and negative features of injected naltrexone?	28 (*13%*)	21 (*23%*)	110 (*15%*)	102 (*26%*)
What are the positive and negative features of implantable buprenorphine?	7 (*3%*)	5 (*6%*)	33 (*5%*)	32 (*8%*)

* Each individual was able to cast 3 votes for every question (distributed among 1–3 responses). High-ranking responses were 5 responses receiving most votes per question, with at least 2 votes (if tied, more than 5 were included),

Table 3:

Themes emerging from group responses

Themes		Votes N=400 (%)
1	**Benefits of Treatment** is the leading driver for initiation and retention in treatment, including symptom control, stabilizing effects, treatment of comorbidities, and restoration of social roles and functions after starting medication-assisted therapy (MAT).	121 (30%)
2	**Side Effects** remain a major concern before initiating therapy and during treatment, which included a few effects that are only partly or not substantiated by medical literature.	69 (17%)
3	**Medication Delivery System** (physical and logistical properties of medication administration) heavily shape the advantages and disadvantages of specific treatments	68 (17%)
4	**Convenience**, especially for daily on-site dosing, is perceived as a major barrier for initiation and retention in treatment whereas home dosing and long acting medications were facilitators.	58 (15%)
5	Issues with **Managing Expectations** included disappointment with treatment effects and duration; uncertainty regarding unfamiliar medications; and the critical role of “readiness” for initiating and staying in treatment	46 (12%)
6	Pharmacologic treatment for opioid use disorder can be perceived as “**Trading One Addiction for Another**,” largely regarding methadone, due to concerns regarding withdrawal symptoms from stopping medications, sedating or mind-altering effects, and stigma	38 (9%)

Table 4:

Themes 1–3 and their associated numbers and votes

Theme 1: Benefits of Treatment		Theme 2: Medication Side Effects		Theme 3: Medication Delivery System	
Response	**Votes**	**Response**	**Votes**	**Response**	**Votes**
Q1: Considerations for starting any medication treatment?					
Treatment programs connect patients to services such as group meetings, general medical care, housing	8	There is an overdose risk if you keep using drugs of addiction while on medications	9		
Eliminates withdrawal and cravings from drug of addiction	7	Side effects in general, and specifically weight gain, “brittle bones”*, tooth loss*, problems with breathing	8		
Increases connection to family	6				
Helps individuals avoid arrest, prison	5				
Helps treat comorbid pain	3				
“Sobriety”: no longer use of drug of addiction	2				
Treatment overcomes the risks inherent to addiction (e.g. overdose, high risk behaviors to obtain drugs), “I want to live”	2				
Q2: What are the pros and cons of methadone?					
“It works,” no longer use the drug of addiction, “feel normal”	12	Side effects in general, and specifically weight gain, water retention, restless legs, “nodding” (or drowsiness), sweating	9	You can get this medication and entry into the program quickly	4
Provides stability in daily life	11				
Helps treat symptoms of cravings and withdrawal	10				
Can also treat comorbid pain	6				
Reliable, helps individuals stay committed to treatment	4				
Save money that would have been used on drugs of addiction	2				
Q2: What are the pros and cons of buprenorphine-naloxone sublingual?					
Provides freedom from using drug of addiction and the struggles to obtain them	9	Side effects in general	6	Induction process requires 1–2 days of withdrawal symptoms that are uncomfortable	12
Effectively provides stability in daily life	9	There is an overdose risk if you keep using drugs of addiction while on this medication	3	The medication tastes bad	9
Saves money used to previously purchase drugs of addiction	6			You are able to divert or sell the medication.	3
Helps treat symptoms of cravings and withdrawal	3			In order to start this medication, it takes time to wait for appointments and blood work to be completed	3
“Backup plan”: even if individuals relapse into addiction, the medication is available at a time a person is unable or unwilling to use	2			It is combined with naloxone which means it can cause withdrawal.*	3

Theme 1: Benefits of Treatment		Theme 2: Medication Side Effects		Theme 3: Medication Delivery System	
Response	**Votes**	**Response**	**Votes**	**Response**	**Votes**
				The medication is dosed more than once a day, which gives you some flexibility with regards to timing doses.	3
Q2: What are the pros and cons of injected naltrexone?					
Unable to use drugs of addiction while on this medication, "serious about sobriety"	10	Does not also treat pain, or interferes with opioids treatment for pain	15	Induction process requires a "detox" off all opioids, which can involve withdrawal symptoms.	9
Can treat comorbid alcohol and opioid problems with same medication	4	Side effects in general	11		
		Not able to drink alcohol while on this medication	5		
		If you use opioid drugs of addiction while on this medication you may have withdrawal symptoms*	3		
Q2: What are the pros and cons of implantable buprenorphine?					
				Requires an implantation procedure that is unappealing	15
				If it is difficult to remove so it is harder to sell this medication	7

Table 5:

Themes 4–6 and their associated numbers and votes

Theme 4: Convenience		Theme 5: Managing Expectations		Theme 6: Trading One Addiction for Another	
Response	**Votes**	**Response**	**Votes**	**Response**	**Votes**
Q1: Considerations for starting any medication treatment?					
Treatment requires daily dosing, time, travel, energy, commitment	7	The dose seems to have a different effect everyday	7	You become dependent on the medication, you worry about withdrawals if you stop taking it or skip a dose.	16
		The medication effect may not meet expectations, a dose's effect may not as long as you are told it should	3	There can be fear, shame, and embarrassment about joining a treatment program	2
		You may still have cravings even after starting treatment	3		
Q2: What are the pros and cons of methadone?					
Requires daily visits to treatment center for some time, unable to travel, time consuming, impacts work, feels like "handcuffs"	24	You may not be ready still, "not ready to let go," you still want the drug of addiction	2	You are dependent on the medication, you worry about withdrawals and it is hard to stop or switch to another medication	20
Q2: What are the pros and cons of buprenorphine-naloxone sublingual?					
Does not require daily site visit	3				
Q2: What are the pros and cons of injected naltrexone?					
Once a month dosing is convenient, provides freedom, saves time and money by not requiring frequent visit	16	Too unfamiliar with this medication to have any expectations on the pros and cons	18		
This medication is so long acting, you may forget and miss dosing on time	3	Unable to continue using drugs if one is not ready to stop	8		
Q2: what are the pros and cons of implantable buprenorphine?					
Dosing only twice a year, no need to travel to any site frequently	5	This medication contains similarities to the familiar medication of Suboxone (buprenorphine-naloxone SL)	5		