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Assessing Barriers and Facilitators to Appropriate Care for Chronic Pain and Prescription Opioid Abuse

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ASSESSING BARRIERS AND FACILITATORS TO APPROPRIATE CARE FOR CHRONIC PAIN AND PRESCRIPTION OPIOID ABUSE

by

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A DISSERTATION

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HEALTH EDUCATION/PROMOTION

ABSTRACT

The objective of this study is to understand and assess barriers and facilitators to the uptake of appropriate care for co-occurring chronic noncancer pain (CNCP) and opioid use disorder. Rates of CNCP and opioid overdose have doubled in the past decade. When a patient transitions from appropriate use to misuse, significant changes must be made to their treatment plan. Considering most CNCP is treated with opioids in the primary care setting, primary care providers (PCPs) are potential change agents to remediate the epidemic of opioid abuse. Although studies have explored opioid stewardship, we still lack an understanding of the factors influencing the treatment of CNCP and opioid use disorder together, when opioids are no longer appropriate.

Guided by the Consolidated Framework for Implementation Research (CFIR), a semi-structured interview guide was developed and tested. A refined guide was used to explore multi-level factors influencing PCP's uptake of best practices. Eleven PCPs participated in the interviews, which were audio-recorded and transcribed. Open-ended text from an online questionnaire were also abstracted for analyses. The CFIR codebook was applied to all text, and then reviewed and amended. The qualitative text, literature review, and guidance of an expert panel were then used to create a 44-item draft survey questionnaire. The questionnaire was administered to a national sample on 509 PCPs and analyzed for dimensionality, inter-item reliability

Thematic analysis of interviews (N=11) and open-ended responses from the online questionnaire (N=9) revealed frequent barriers were available resources (staff, time, and alternative therapies), knowledge and training (addiction and/or pain management, attitudes towards opioids), and internal and external policies. While the most commonly cited facilitators were communication (ability to communicate/refer to specialists), knowledge of and access to alternative treatments, and the needs of the patients being served.

Principal component analysis resulted in a 22-item questionnaire. Twelve more items were removed because of their influence on coefficient alphas, resulting in a 10-item questionnaire with 4 domains: *Desire to Treat, Assessing Risk, Trust in Evidence, and Patient Access*. The final questionnaire and scales demonstrated adequate validity and good inter-item reliability. Future steps include testing the questionnaire's predictive validity.

DEDICATION

This dissertation is dedicated to my partner, Blake Panter, and dogs, Chester and Elly May. Thank you so much for your support through this process. This would not have been possible without you.

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Background

Chronic pain is a serious public health concern, with an estimated 25.4 million people in the United States experiencing it daily.[1-3] Opioids are one of the most commonly used treatments for chronic pain, but evidence for their long-term effectiveness is weak and understudied.[4,5] Rates of chronic pain have grown in the past decade, which has contributed to a rise in the prescription of opioid medications for treatment. This rise in prescription rates has been followed by an increase in opioid overdose deaths.[6] Fortunately, there has been a plateau in opioid prescription rates in the past 5 years, however overdose death rates continue to rise.[7] Because chronic pain is most commonly treated in the primary care setting, primary care providers (PCPs) are the main prescribers of opioid medications for chronic pain. Thus, PCPs have been a primary focus for initiatives aimed at curtailing the opioid crisis.[8,9]

Recent initiatives targeting opioid prescription have focused on pill control more so than increasing access to treatments for problematic opioid use or opioid use disorder.[10] Moreover, Von Korff et al (2017) found in a review of opioid safety initiatives that long-term implementation of opioid dose and risk reduction initiatives was not associated with lower rates of prescription opioid use disorder among chronic opioid therapy patients, highlighting the need for strategies designed to facilitate the implementation of evidence-based practices that go beyond pill control and monitoring.[11]. To identify such strategies, it is necessary to first understand the factors influencing a provider's decision-making process when treating this population.

A common approach to understanding the uptake of clinical guidelines or innovations is to identify barriers and facilitators to change, then tailor interventions to overcome those barriers and employing facilitators [12,13] To guide these implementation efforts, research must take into account the complexities of real-life primary care settings. Current research in pain management has identified the following barriers to guideline concordant opioid therapy[14]: attitudes that recommendations do not align with patient expectations[15,16], limited access to alternative therapies[15], low confidence in managing pain and prescribing opioids[17], lack of specialized training in pain management and/or addiction[18,19], limited ability to consult with a pain specialist about problematic cases[14], and difficulty assessing and diagnosing both pain and opioid addiction[18,20,21]. The CDC guidelines suggest cost and insurance coverage as a barrier to the uptake of nonpharmacologic treatments for chronic pain[22].

There is limited knowledge of the specific barriers and facilitators to appropriate care for patients with co-occurring chronic pain and opioid use disorder. Previous studies have focused on the application of opioid prescribing guidelines (like pill control and tapering), failing to capture the processes involved in providing quality, patient-centered care once opioid therapy is no longer appropriate. Previous research on the factors that influence the implementation of evidence-based practices in pain management suggest there is a great deal of individual variation among practitioners[14,23]. For example, a provider could have training in pain management, but lack the organizational support necessary to refer patients to alternative interventions like cognitive behavioral therapy or physical therapy. Moreover, the addition of opioid use disorder as a co-morbidity requires a more nuanced treatment plan when treating chronic pain.[24-26] Thus, the objective of the present study was to elucidate and better understand barriers and facilitators to providing appropriate care to patients with co-occurring chronic pain and opioid use disorder. This was accomplished through the analysis of semi-structured interviews and open-ended text from an online questionnaire with primary care providers.

Methods

All study activities were overseen and approved by the University of Alabama at Birmingham's Institutional Review Board.

Participants

Participants in the semi-structured interviews were recruited through a network of providers with expertise in primary care, chronic pain, and/or opioid use disorder in the Birmingham, Alabama area. Great effort was made to recruit a diverse population of PCPs. Using a purposive sampling approach, PCPs from the academic and community settings were sought out, as well as both physicians and nurse practitioners.[27] As participants were interviewed, they were asked to refer other providers that could potentially participate in the study as well. PCPs were recruited until saturation in themes was reached.[28,29]

For the online questionnaire, PCPs were invited to participate in a SurveyMonkey page via email. Email invitations were shared on social media (Twitter, Facebook, LinkedIN, Reddit) and sent to community and academic primary care clinics across the United

States. The launch page for the survey contained an information sheet and qualifying questions. Respondents who practiced in the United States, considered themselves to be PCPs, and had an advanced degree (Doctor of Medicine, Nurse Practitioner, Physician Assistant, or Doctor of Osteopathic Medicine) were permitted to proceed to the questionnaire items.

Interview guide development

Items for the semi-structure interview guide were adapted from the Consolidated Framework for Implementation Research's (CFIR's) qualitative interview guide. The CFIR can be used for a range of activities, from the planning to the evaluation of research aimed at better understanding the processes involved in implementing evidence-based practices. The CFIR is a practical guide for assessing potential barriers and facilitators in preparation for implementation and innovation. It is also recommended for the study of the implementation of evidence-based addiction treatments.[30] The framework consists of five broad constructs: intervention characteristics, outer setting, inner setting, characteristics of individuals, and processes. The CFIR website is a unique resource, offering tools to guide the systematic study of implementing empirically supported treatments and practices.

Online Questionnaire

After the semi-structured interviews were conducted, a quantitative questionnaire assessing capacity to treat co-occurring chronic pain and opioid use disorder was developed and distributed to 509 PCPs (results presented elsewhere). At the end of the survey, PCPs were asked to provide comments on the questionnaire content with one open-ended item, “Do you have comments about the content of this survey? Please leave them in the box below”. Comments that described either barriers or facilitators to appropriately treating this population were abstracted for analysis. Although the data come from two different data set, comments from the online questionnaire were appropriate to add the analysis because they contained text describing barriers or facilitators not revealed in the open-ended interviews.

Procedures

In-person semi-structured interviews were conducted with PCPs from March to November 2017. Online questionnaires were collected from March to May 2018. As participants were interviewed, they were asked to refer other providers who could potentially participate in the study. Interviews took place in provider offices. Participants were compensated $30. Interviews were audio recorded and transcribed. Interview transcripts and the extracted questionnaire comments were then loaded into NVivo 12. Using a thematic analysis approach and the CFIR codebook, the qualitative data were then coded and analyzed for themes.[31,32] Text that fit the definition of a CFIR construct and reflected a specific barrier or facilitator were coded and included in the analyses. During analyses, the codes were constantly compared to the definitions in the codebook to ensure their meanings did not shift or evolve.[33]

Results

Eleven PCPs from the Birmingham, Alabama area completed the semi-structured interview. Fifteen responses from the open-ended question were included in these analyses. Table 1 shows characteristics of the sample. Barriers and facilitators to appropriately treating co-occurring chronic pain and opioid use disorder were elucidated across all levels of the CFIR. Table 2 describes the frequency of PCPs mentioning each construct of the CFIR. The following constructs were the most frequent themes discussed by participants. Quotations from interviews are marked (I), while quotations from the online questionnaire are marked (Q).

Characteristics of Individuals

Knowledge and Beliefs- Knowledge and beliefs about treatments, policies, and treating the population were predominant themes in many of the interviews. PCPs described their understanding of the efficacy of opioids for chronic pain, the use of medication assisted treatments, and their beliefs about the nature of their job. In general, PCPs described treating co-occurring chronic pain and opioid use disorder as challenging (a barrier). For example, a PCP stated, "Primary care providers have incredibly high levels of empathy and want to help their patients, but dealing with chronic pain with comorbid substance use disorders is emotionally exhausting (I)" Similarly, a respondent to the online questionnaire said, "I am constantly hearing from specialists how primary care needs to do more. The whole issue of chronic pain has fallen to the bottom of my list of emotionally exhausting conditions--it drains my cup and diminishes my ability to care for other patients. We need a system wide response to combat this issue--not just asking primary care to do more risk assessments and start prescribing suboxone (Q). "When reflecting on other providers' beliefs one PCP explained, "And I think one of the barriers for other people would be just raw fear that every opioid prescription is a bad mark on their record as a doctor, because of the way we profile it (I)".

Buprenorphine was a common practice discussed in the interviews. One PCP stated, "We shouldn't be referring people for buprenorphine, we should be providing it in our setting, as integrating it into primary care is just as effective as providing it in specialized settings (Q)." This was also discussed in the interviews, "I actually think that a primary care doctor should be able to prescribe suboxone, particularly if they are addiction familiar (I)". On the other hand, some PCPs described how they avoid treating chronic pain or opioid use disorder with statements like this one from and online questionnaire respondent, "I try really hard not to end up having people on chronic opiates. Mostly because I feel like they don't work very well (I)" and "I don't really want the responsibility of chronic pain management. (I)" These statements suggest that PCPs' beliefs about their role in treating co-occurring chronic pain and opioid use disorder can be both a barrier and a facilitator to providing appropriate care.

Regardless of preferred treatments, knowledge and beliefs about the balance of benefits and harms were both a barrier and facilitator. For example, one provider described, "I will tell you that I started having real mixed feelings about what I was doing. I knew I was doing a lot of good, but I knew I also I felt I was doing harm at the same time. It was very hard, well impossible. If you're going to get into this area, if you're going to go there… you will do some good, and you will do some harm. You can't avoid…you can't do it perfect (I)". Other PCPs described how they valued clinical expertise over the use of an outside risk assessment tool, "Scales and screening tools are nice adjuncts, but no substitute for the clinical picture (Q)", "With time you don't need a tool for everything. The tools are a rough approximation for years of doing (Q)" and, "I constantly have to remind myself that I am doing the best I can, and I can advise my patients on best practices and try to motivate them, but I can't take it as a personal failure for every patient that fires me (I never fire patients--just tell them I can't treat their pain with opioids if it's too high risk) because I am trying to follow best practices for treating chronic pain (I)".

<u>Individual Identification with Organization</u>- Some of the PCPs worked at more than one organization and described different, organization specific, factors influencing their behavior. For example, one interviewee explained how barriers are different based on the organization they practice at, "My own practice really emulates what I prefer to do and how I practice on my own, given my own limitations. At my other organization, the patients don't have to opportunity to see outside providers as much, so I feel we are functioning much more as a team and I don't feel limited in what I prescribe (I)" Another PCP described an organizational barrier to obtaining a buprenorphine waiver, "I would be a data 2000 addiction provider if I was in an addiction treatment program, but I am in primary care. So, I have historically resisted it because it was at odds with the culture of the hospital, at odds with the service package of the hospital, and is a barrier (I)".

Innovation Characteristics

Cost- Patients' ability to afford recommended treatments, like buprenorphine and nonpharmacologic pain treatments, was a common barrier cited. "I'm speaking more about patients who do not have insurance because even by not having insurance if we send them to physical therapy they still had to pay a $25 copay, and when you have nothing there's no way to get it and the physical therapy people would not see them (I)". Another PCP explained, "If you go to a buprenorphine clinic in a private setting you're going to have to pay cash up front and the medicine is going to be expensive too. So, they'll say, 'You know you were buying heroin on the street at $20 a day, so you can do this' But how were they doing that? They were breaking the law, cheating, stealing, and we are trying to stop all of that. So, it doesn't make any sense to make people pay the same amount that they were paying for illicit drugs. In other words, right now, the treatment is more expensive than the heroin is. That's just crazy (I)." None of the PCPs in the present study described cost as a facilitator.

Evidence Strength and Quality- PCPs described how the level of evidence for either starting or discontinuing a treatment (or practice) was important in their decision-making process. When discussing tapering or discontinuing opioids a PCP explained that a barrier for both the patient and provider was, "A lot of lack of good evidence that it will benefit the patient to get off of it (I)". When discussing mandated psychosocial treatments with buprenorphine a PCP stated, "Even though the randomized trials have not shown that a required social treatment component produces better abstinence results… So, it troubles me that people do require it (I)". The generalizability of research evidence to the patient population was also discussed as a barrier to adopting new practices, “So, I think the problem with evidence is, evidence is derived from a trial, usually a randomized controlled trial, and by and large they are a very select group of people whose profile and demographics are different than the people I treat. So, do I keep up with the literature? Sure. Do I adopt new practices quickly? It depends on what they are (I)”

Complexity- Another theme discussed by PCPs was their perceived difficulty of using or adopting a practice. For example, one PCP described prescribing buprenorphine for opioid use disorder, “As we’ve gotten more experience with and have had more patients use it and have success it’s kind of a double-edged sword. On one hand, I thought maybe I should learn how to prescribe this and on the other hand I’ve also seen people abuse suboxone. And so, I think I feel like it’s best to leave that to the people who have more addiction training than me (I)”. Difficulty assessing risk for opioid use disorder was also described as a barrier, “Maybe I am missing it. I don’t know what I would do to screen for substance abuse other than looking at somebody’s medication list (I)”. The perceived complexity of treatments on patients was also discussed, “I also know that some of the therapies tend to be complicated in the sense that it's multiple drugs and people aren’t going to take multiple drugs. So, sometimes I will not do that (I)”.

Inner Setting

Networks and Communications- The ability to communicate and/or refer to other providers within an organization was another frequently described as both a barrier and facilitator to providing appropriate care. One explained the benefits of their integrated system as a facilitator, “I can consult with a bunch of people through electronic communication. This system at my organization is like electronic messaging. I can talk to their psychiatrist, their therapist, their everything. It’s an integrated system. There is no prohibition on the sharing of information about addiction or substance use disorder. If it says something, I can hit up their psychiatrist directly while in clinic and say, ‘Hey! You are prescribing valium, I’m prescribing hydrocodone. The system is giving me a flag saying I shouldn’t do it. Currently, I am leaning toward not honoring the flag because I think we’ve both made an individualized decision, but I really want to double check with you and see how you feel about that right now’ (I)”. Another participant from a different organization described this as a barrier, “There is no integration. Like, the person who is doing the buprenorphine prescription is probably not in communication with the primary care provider because of regulatory barriers. There is something which prohibits the sharing of mental illness or addiction information in the absence of very specific authorizations. Or you know, if I am running a buprenorphine clinic way outside of the city and patients use their primary care doctor in town, the likelihood of any cross talk is close to nil (I)”.

<u>Relative Priority</u>- Organizational priority for treating chronic pain and opioid use disorder were described by the interviewees as both a barrier and facilitator, depending on the organization. Some PCPs described how the implementation of appropriate treatments was high priority in their organization. For example, “As a group we have decided to identify those high-risk patients and we developed our own opiate safety clinic that is not open to other clinic to refer to, but we have a couple of general internists that did

additional training and were willing to volunteer their time to manage this clinic (I)". Another provider added, "So, often times, we use that as leverage with administrative people to say quality of life is really important to people and they have the expertise now where they can do their research. They're going to be intelligent consumers of their healthcare, and they're going to, they're looking for things that meet their needs. So, we can see, I can oftentimes convince administrative people who hold the purse strings to say, 'ah this gives us an edge above Joe Blow down the street.' So, it may not be reimbursable, but we're willing to spend some money on that because that gives us a foot up in this highly competitive world of healthcare (I)".

Goals and Feedback- Having appropriate feedback systems was an important factor influencing behavior for the PCPs in this sample. Someone explained, "Say I see someone have a negative [urine drug screen]. If it is not documented when they took their last opiate, then we can't prescribe it for you anymore because we don't have enough data (I)". Another PCP stated, "We have a lot of avenues of information to assess what is going on when we manage their pain. So, in comparison to standard primary care with the knowledge of what people do with their lives, basically comes down to what they tell you in a 10-minute visit. I think that is a systems issue, the ability to track what people do. The avenues of information from an extremely robust mental health service and social work service, which is providing the opportunity to observe patients, so we can actually see how things are working (I)".

Culture and Learning Climate- Organizational culture was a frequent characteristic described as a facilitator to appropriate care for co-occurring chronic pain and opioid use disorder. PCPs felt that their organization's culture and policy supported their decision when choosing not to use opioids. For example, an interviewee described, "But if they freely admit to using, you know marijuana or cocaine or admit to selling it or admit to anything, then I can say no we can't. And that's my organizations' policy, so that's one thing too. The organization definitely backs you up from the pharmacy stand point (I)". Furthermore, another PCP discussed the range of expertise in an organization as a potential facilitator, "I think being at a major medical center you have people coming from different training areas. So, they bring with them a knowledge base and clinical expertise, and it's very difficult to have these things when you're in a small, rural facility obviously, so we're at an advantage here. (I)"

PCPs described their learning climate as a facilitator to appropriate practice. For example, one provider described how they learn about new treatments by explaining, "I am a co-program director here, so we're constantly developing the curriculum. So, we're constantly having to find information to teach students that's up-to-date and accurate, so that's one way."

Readiness for Implementation- PCPs described organization characteristics, like available resources and knowledge, which indicated their readiness to implement treatments for chronic pain and opioid use disorder.

Available Resources- Availability of resources for treating co-occurring opioid use disorder and chronic pain were discussed extensively by the PCPs in the study as both barriers and facilitators. Specifically, PCPs described how it was difficult to access certain resources, like nonpharmacological treatments for chronic pain or evidence-based addiction treatment. For example, PCPs stated, “I know the data well enough for people to say ‘Yeah, but there is physical therapy, meditation, and other nonpharmacologic interventions.’ I don’t have access to that (I)” and “there is other sort of nonopioid interventions like CBT and some things that are a little bit easier to get at my organization, that are a little bit harder to get sort of in the outside world that would fit into the treatment algorithms (I)”.

Access to knowledge and information was also a common theme discussed by PCPs. Easy access to knowledge was identified as a facilitator. For example, “I use on a daily basis the sort of online medical textbook called Up-To-Date that my organization has a subscription for. I mean it’s literally embedded in the chart. So, you’re seeing a patient with x disease you can hit up to date and sort of pull down your evidence-based approach to a given process (I)” Another PCP added, “For example, one PCP described how their organization valued complementary therapies by describing, “There are other complimentary therapies that we have access to in our department that other providers don’t have access to. So, acupuncture, massage therapy, physical therapy, guided meditation, those sort of nontypical western things that we use a lot (I)”. Additionally, a PCP described accessing the Stratification Tool for Opioid Risk Mitigation (STORM), “In my organization, you have to request a special permission to access it. So, it exists, but you have to put in an electronic request to get it, and most people don't know about it (I)".[34]

Outer Setting

<u>Needs of Those Served by the Organization</u>- One of the more frequently described factors, which was both a barrier and a facilitator, influencing PCP behavior was the needs of their patients. Indeed, most providers noted that treatment plans were dependent on the individual needs of the patient; "There are plenty of anecdotes about people with very aggressive tapers if the patients don't really buy into, that can be really problematic (I)" and "The vast majority of the people I see have already been to multiple physicians and are already on a narcotic. So, when I inherit them, it's sort of like, it's the end of the road. It's either me or the street (I)" One participant emphasized the need to tailor treatment for opioid use disorder to the specific needs of their patient, "If somebody has opioid use disorder, a lot of them tend to have significant challenges in terms of how they think about themselves and how they cope. How they react to crises. It feels to me, correct to be willing and ready to provide support for those things (I)"

<u>External Policies and Incentives</u>- External policies regarding buprenorphine prescription were a described as a barrier for some of the PCPs; "The legal barriers are also real. Because if you are afraid that the DEA is somehow going to police you, you have to have a whole system to care for that. I think my organization can withstand DEA scrutiny. So, I am not as vulnerable to that (I)" and "the regulations. The fact that the board of medical examiners 2 or 3 years ago set some sort of threshold that if you were in the 10%

category you had to have fingerprints and a clearance and stuff like that. Then they just passed the regulation that you have to do 2 hours of CME around opioid addiction and what not. And there are people that are just saying I don't want to do that (I)". PCPs also described policies disseminated from PCPs outside of their organization, "I was at a staff meeting and one of the primary care physicians said to me 'You really think that that's okay? I can tell you this…in the community if you write a prescription for opioids and a patient tested positive for marijuana and anything happens, they will have your license. You are out.'(I)" Another PCP described how the media and policymakers dissemination approaches create a barrier to the uptake of guidelines, "Not all patients are the same. Different therapies work for different people. National guideline writers actually take this into account, but by the time that the state lawmakers or media commentators get to it, one size fits all (Q)"

Process

Engaging- PCPs described engaging appropriate individuals in the implementation process as an important factor in their decision-making process.

Champions, Opinion Leaders, Key Stakeholders- Engaging opinion leaders and key stakeholders was described by participants as both a barrier and facilitator; "So, it is worth saying that in our organization there is some level of thoughtfulness about a lot of these things among a fair number of senior people. I don't mean just locally, there are some local and national people who publish, people who contribute to data, people who are trying to set up systems. So, there are these thoughtful people that are like, 'yeah we need to do this in a very patient-centered way.'" Another PCP described engaging important team members, "My nurses immediately said wait a second, are you opening up a suboxone clinic in our clinic? We are already busy enough. I was like no. I just want us to be able to have that option for our patients who we currently take care of when we think that it is going to be hard to get them into the pain clinic."

Innovation Participants- Participant buy-in for treatments was also an important factor for PCPs; "Frankly, we encourage patients and say 'hey these are the people that you need to communicate with, tell them that we need this here. I mean they're generally the ones that are asking for it, so we then encourage them to be in touch with the powers that be, and that is obviously a driving force behind change. The patient should be the center of care, it should be the focus. If they get behind a movement and say we want x, y, and z, and they're perhaps, let's say, a breast cancer patient and then the whole breast cancer group gets behind something and then we've got momentum at that community level, state level, nationwide level, and that pushing in one direction, that carries a lot more weight than just little old me going, 'hello, I think we should do this.''

Planning- PCPs described future plans for implementing new treatments into their practice; "So, if I had someone who could help me… you know? We are hiring a nurse practitioner and one of her jobs is going to be to assess people's pain and write their pain medicines for them every month as opposed to me seeing them when I can and just mailing them prescriptions in between" and "I have gotten suboxone training (have the waiver) but my academic center has not been helpful in applying this; I'm trying with one other family med doc to get a suboxone clinic up and running this fall."

Executing- Some of the PCPs were already implementing practices. For example, "We as a practice, my practice, probably about maybe 3 years ago or so was when we really began to say we'd like to take the prescription narcotics more seriously than we have and we need to use our evidence-based guidelines as to what we are supposed to do. So, when we started doing that, that's when we brought our nurse practitioners into this. We actually have that support more than most people around here. We were able to do it so that it didn't all fall on the physician."

Reflecting & Evaluating- Some PCPs reflected on past issues with implementing certain practices. "When I look back we've been on this road for a couple of years and we didn't really intend to do that for that long. But it's like, she's had that pain and got better. Now she has this pain and now she has this pain. So, it has sort of become our answer for her pain. And that has been challenging" and "Then, there is highest concern, you know proven diversion, documented cocaine intoxication, strong indication of an untreated substance use disorder. You are still supposed to evaluate the same things, but here we say discontinue or taper, discontinue or taper. I am actually more and more concerned that discontinuing and tapering is leading people who are at the highest level of concern to be vulnerable to the street trade." Furthermore, a PCP reflected on recent initiatives which use number of opioid prescriptions as a metric of success, "Single number metric of performance overwhelm everything".

Discussion

The purpose of the present study was to explore factors influencing the provision of evidence-based treatments for co-occurring chronic pain and opioid use disorder. Guided by the CFIR, semi-structured interviews were conducted with 11 PCPs. Additionally, open-ended text from an online questionnaire were added to the analyses to enhance the generalizability of these results to practitioners outside of Alabama. Both barriers and facilitators to appropriate care were identified across all CFIR constructs. The most frequently described barriers were cost and access to appropriate treatments, complexity of practices, and available resources (like risk assessment tools). The most frequently described facilitators were presence of a network or team to work with, the needs of the patients being served, and organizational culture. Knowledge and beliefs about a specific practice were frequently described as both a barrier and facilitator to its implementation.

It is no surprise that cost of treatments was the most commonly described barrier, as misaligned financial incentives in primary care have been extensively highlighted in the literature.[35] Thus, cost is a significant barrier that will need to be addressed in order to increase access to evidence-based treatments. Fortunately, recent research suggests coverage for therapies, like medication-assisted treatments, are expanding as new policies roll out.[36] To ensure all patients have access to appropriate treatments, insurance providers should continue to expand coverage to include, at the very least, treatments that are recommended by empirically supported guidelines. Furthermore, organizations should consider providing incentives to providers who will treat patients with chronic pain and opioid use disorder, as this was highlighted as a facilitator in the present study.

Balancing the risks and benefits, with an emphasis on screening for risk, was a common theme that emerged in the present analysis. Indeed, risk/benefit analysis is a primary focus of recommendations for the treatment of both chronic pain and opioid use disorder.[1,8]. Several PCPs discussed how screening tools were not useful when one had adequate clinical expertise, suggesting a disconnect between best practice guidelines and PCP behavior. This could be due to a lack of screening resources, which was also a frequent theme in the data. However, there were PCPs who identified measures of risk as a facilitator to appropriately treating this population. One participant discussed Oliva et al's (2017) pilot study which developed a decision-support tool for opioid risk mitigation (STORM). It uses electronic medical record data and allows providers to assess risk for overdose events and identify high risk patients.[34] While more research is needed to validate the model, it provides an example of how a risk assessment tool can be easily integrated into clinical practice. Future studies should develop and test strategies that facilitate the implementation of empirically supported measures of risk, while taking into account the knowledge, beliefs, and clinical experience of PCPs.

The present study aligns with other research exploring barriers and facilitators to implementing different practices into the primary care setting, which highlight the importance of provider knowledge and training in both pain management and addiction.[9,37-39] Knowledge and beliefs about both pain and addiction treatments were frequently described as a key factor influencing the PCP's decision-making process when developing a treatment plan for patients with co-occurring chronic pain and opioid use disorder. These results suggest that education strategies may be useful in increasing the uptake of certain practices.[40] Unfortunately, few empirically supported education interventions exist and access to those that are available is dependent on the PCPs location and organization.[9] Future research should develop, tailor, and evaluate educational interventions aimed at changing knowledge and beliefs about appropriate interventions (like nonpharmacologic treatments for chronic pain, buprenorphine, or assessing and monitoring risk) for co-occurring chronic pain and opioid use disorder within the context of the primary care setting.

One size does not fit all when choosing an appropriate treatment for a patient with co-occurring chronic pain and opioid use disorder. PCPs described cases where they clearly knew which treatment was appropriate and cases where they did not. Because appropriateness of a treatment is dependent on the individual needs of the patient, initiatives aimed at increasing the uptake of appropriate practices for co-occurring chronic pain and opioid use disorder will need to use multiple implementation strategies to target different practices and take into consideration a range of contextual factors. For example, Quanbeck et al (2018) demonstrated the feasibility, acceptability, and effectiveness of a blended strategy that used audit and feedback, academic detailing, and external facilitation to implement opioid prescribing guidelines.[41] Considering these promising results, future research should develop and test a similar approach with a focus on the therapies and practices recommended for co-occurring chronic pain and opioid use disorder.

This study has its limitations. The interview sample was small and nonrandom. Qualitative data from the online questionnaire were added to the analyses to improve the generalizability of these results. Moreover, these results expand the current understanding of treating co-occurring chronic pain and opioid use disorder by revealing the perspectives of PCPs from multiple organizations. It is possible that other methods, like focus groups, might have resulted in the illumination of different facilitators and barriers. The use of focus groups may have allowed PCPs to reflect on the experience of their peers and identify different themes.[42] However, semi-structured interviews were deemed the most appropriate approach, as it allowed data collection to be tailored to each individual participant's practice and organization.

The present study provides a starting point for future research to better understand how to support judicious use of particular treatments (opioids) and increase use of other treatments (e.g.,for chronic pain and opioid use disorder) within the primary care setting, which may require a more nuanced understanding of context as well as a specific combination of particular implementation strategies. As interventions aimed at increasing the uptake of evidence-based practices for co-occurring chronic pain and opioid use disorder emerge for PCPs, it is necessary to understand the factors that influence their decision-making, while taking into account the complex environment in which these practices are to be implemented. Doing so will promote patient safety, increase access to alternative treatments, and support the implementation of evidence-based treatments for co-occurring chronic pain and opioid use disorder in the primary care setting.

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Table 1. Demographic Characteristics

Provider Characteristics	**% (N=26)**
Gender	
Male	54 (14)
Female	46 (12)
Primary Organization	
Academic	58 (15)
Community	38 (10)
Government	4 (1)
Degree	
MD	77 (20)
NP	15 (4)
DO	4 (1)
PA	4 (1)
Data type	
Interview	42 (11)
Online Questionnaire Open-Ended Comment	58 (15)

Table 2. Frequency of Themes by Participants

CFIR Construct / Theme	**% (N)**
Inner Setting	
Culture	20 (5)
Implementation Climate	
Compatibility	8 (2)
Goals & Feedback	15 (4)
Learning Climate	8 (2)
Organization Incentives	4 (1)
Relative Priority	12 (3)
Networks and Communications	30 (8)
Readiness for Implementation	
Available Resources	38 (10)
Leadership Engagement	4 (1)
Structural Characteristics	8 (2)
Characteristics of Individuals	
Knowledge and Beliefs about the Innovation	58 (15)
Individual Identification with Organization	12 (3)
Self-Efficacy	20 (5)
Innovation Characteristics	
Complexity	23 (6)
Cost	42 (11)
Design Quality & Packaging	12 (3)
Trialability	12 (3)
Innovation Source	4 (1)
Evidence Strength and Quality	23 (6)
Outer Setting	
External Policies & Incentives	46 (12)
Needs & Resources of Those Served by the Organization	50 (13)
Cosmopolitanism	20 (5)
Process	
Engaging	
Innovation Participants	4 (1)
Key Stakeholders	8 (2)
Opinion Leaders	8 (2)
Executing	20 (5)
Planning	15 (4)
Reflecting & Evaluating	15 (4)

INTEGRATING QUALITATIVE TEXT INTO A QUANTITATIVE QUESTIONNAIRE TO ASSESS CAPACITY TO TREAT CHRONIC PAIN AND OPIOID USE DISORDER

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Introduction

Chronic pain is a serious public health concern, with 10.6 million individuals in the United States reporting high impact chronic pain in 2011.[1] In the past decade, rates of chronic non-cancer pain have grown rapidly, and there has been a significant increase in the prescription of opioid medications for treatment.[2] This rise in prescription rates has been followed by an increase in opioid overdose deaths.[3] Fortunately, there has been a plateau in prescription rates in the past 5 years, but overdose death rates continue to rise.[4] Identifying strategies to increase access to evidence-based co-occurring chronic pain and opioid use disorder treatments is therefore a public safety priority.[5] The primary care setting is ideal for this type of intervention, as primary care providers (PCPs) see the majority of chronic pain patients and are the main prescribers of opioid medications. [2]

While very few treatments have demonstrated efficacy for the treatment of prescription opioid abuse in the context of chronic pain, best-practice guidelines exist that combine evidence-based treatments for both chronic pain and opioid use disorder. Significant treatment changes must be made when a patient transitions from appropriate opioid consumption to unsafe use.[6-8] A provider cannot simply treat the addiction; they must also work with the patient to effectively control the chronic pain.[9,10] Previous research on the factors that influence the implementation of evidence-based practices in pain management suggest there is a great deal of individual variation among PCPs. [11-13] For example, a PCP could have training in pain management, but lack the organizational support necessary to refer patients to alternative interventions like cognitive behavioral therapy or physical therapy. Previous work has also demonstrated that PCPs often lack training in the treatment of both chronic pain and addiction.[14,15]

As training programs and initiatives aimed at promoting the uptake of evidence-based care for co-occurring chronic pain and opioid use disorder emerge, it is critical to understand factors that impede their adoption. Furthermore, programs will need a means to assess the effectiveness of their intervention on changing provider behavior. Creation of such a measure requires more than one methodologic approach. A qualitative approach allows for the collection of in-depth narrative data, which will result in a better understanding of the context of the problem.[16] Quantitative methods allow for development and psychometric testing of a questionnaire to assess the factors identified in the interviews Thus, a mixed methods approach is necessary because neither qualitative nor quantitative methods alone can capture the information necessary to identify and measure factors influencing PCP behavior when treating co-occurring chronic pain and opioid use disorder.

While widely utilized in social sciences, there are few detailed guides on exactly how to use qualitative data to create quantitative measures.[17-20] Furthermore, the process of integrating qualitative data into a quantitative instrument has been described as inherently difficult by experts, highlighting the need for guidance on the application of this approach.[21-23] The purpose of this report is to provide detailed methods for an exploratory sequential instrument development study aimed to assess PCP capacity to provide appropriate care for co-occurring chronic pain and opioid use disorder.[24] The first phase of the study was a qualitative exploration of the factors influencing PCP's behaviors surrounding the treatment of patients with co-occurring chronic pain and opioid use disorder. The reason for collecting qualitative data first is that there have been no studies to date that have identified constructs specific to treating co-occurring chronic pain and opioid use disorder. Then, data from the interviews were transformed into questionnaire items. Quantitative methods were used in order to develop and test the psychometric properties of the questionnaire.

Methods

All study activities were overseen and approved by the University of Alabama at Birmingham’s Institutional Review Board.

Qualitative Phase- The objective of the qualitative phase of the study was to understand factors influencing PCPs treatment of co-occurring chronic pain and opioid use disorder. Guided by the Consolidated Framework for Implementation Research (CFIR) qualitative interview guide (Appendix X), a semi-structured interview guide was developed, pilot tested, and adapted for PCPs treating chronic pain and opioid use disorder.[25] Participants were recruited by contacting providers with expertise in primary care, chronic pain, or opioid use disorder in the Birmingham, Alabama area. Substantial effort was made to recruit a representative sample of PCPs. Using a purposive approach, PCPs from the academic and community settings were sought out.[24] As participants were interviewed, they were asked to refer other providers that could potentially participate in the study. Providers were recruited until saturation in themes was reached.[26,27] Interviews took place in PCP offices and conference rooms. Participants were compensated $30. Interviews were audio recorded. Using a thematic analysis approach and the CFIR codebook, the qualitative data were transcribed and coded. Data collection and analysis were conducted concurrently, so that the interview guide could be continuously adapted in an emergent manner to capture the most relevant data for developing the questionnaire.

Integration- Data collected from the semi-structured interviews and literature were adapted into quantitative questionnaire items. Table 1 displays examples of how the qualitative data were adapted to questionnaire items. Quotations were modified into statements that respondents could rate on a 7-point Likert scale from strongly disagree to strongly agree. If a quotation covered more than one behavior or construct, it was divided into two items to reduce ambiguity. To improve content validity, items were also drawn from the literature (see Table 1).[17] Recommendations and research for chronic pain, opioid prescribing, and opioid use disorder were examined to identify factors or practices that may not have been captured in the semi-structured interviews.[28] Once the pool of items was drafted, questions were reviewed by an expert panel with training in survey development, primary care, chronic pain, and opioid use disorder. Questionnaire items were then modified for clarity and content based on recommendations of the panel, which is also highlighted in Table 1. In the final stage of the project, both qualitative and quantitative results were integrated for a more holistic interpretation of the data (see discussion).[29]

Quantitative questionnaire- Quantitative methods were utilized in the second phase in order to develop and test the psychometric properties of the questionnaire items that were developed in the qualitative phase. PCPs were invited to participate in a SurveyMonkey page via email. Email invitations were shared on social media (Twitter, Facebook, LinkedIN, Reddit) and sent to community and academic primary care clinics across the United States. The launch page for the survey contained an information sheet and qualifying questions. Respondents who practiced in the United States, considered themselves to be PCPs, and had an advanced degree (Doctor of Medicine, Nurse Practitioner, Doctor of Osteopathic Medicine, Physician Assistant) were permitted to proceed to the questionnaire items. Individuals who did not meet the criteria were directed to a page that thanked them and explained their disqualification. To assess concurrent validity of the questionnaire, the online survey also included measures of attitudes towards evidence-based practices, knowledge of pain management, and a series of questions from a NIDA training module.[30-32] Responses were analyzed for dimensionality, inter-item reliability, and construct validity. Items were selected for inclusion in the final version of the questionnaire based on these tests.

Discussion

The purpose of this report was to provide a detailed description of the mixed methods design used to explore and assess barriers and facilitators to providing appropriate care to patients with co-occurring chronic pain and opioid use disorder. Given that this was an exploratory study in an area where little is known, collection of comprehensive qualitative data was necessary to inform and enhance content validity of the questionnaire items. Future research should continue to build the evidence for the application of this approach.

The present report describes in detail how qualitative and quantitative data were integrated, namely, by using qualitative data to inform the second, quantitative phase of the study. This was demonstrated by mapping out the adaptation of qualitative text into quantitative items in Table 1. The table displays how transcribed interview text was transformed into statements appropriate for a Likert-type response scale. Finally, the table demonstrates how review by an expert panel further modified the items and enhanced their clarity and content.

This report presents one of many approaches to integrate qualitative data into a quantitative instrument for the purpose of creating an evidence-informed measure. There are alternative approaches recommended to improve validity of instruments in mixed-methods guidelines that were not used in this study.[17] Use of another approach to collecting qualitative data might have resulted in different data and results. For example, focus groups may have allowed PCPs to reflect on the experience of their peers and identify different factors than those that were elucidated by the interviewer, a non-clinician.[16] Semi-structured interviews provided the most pragmatic approach, though, as it allowed data collection to be tailored to each individual participants' schedule, which is important when sampling health care providers.[33]

Participants recruited for the semi-structured interviews were all from the Birmingham, Alabama area. Policies regarding the management of chronic pain and opioid use disorder vary across the country.[15] Thus, the qualitative interviews may only be representative of providers practicing in states with similar regulations to Alabama.

However, effort was made to collect data from across the country for the questionnaire and items that remained in the survey are general and do not refer to any specific practice or policy. The interview and questionnaire were developed with US policies and recommendations in mind, which may limit the generalizability to those practicing in other parts of the world.

Obtaining feedback and recommendations from a panel of experts is a common strategy used to improve validity in measurement development.[28,34] The final step in item development for the present study was a review of the questionnaire by a local panel of experts. It is possible that selection of different panel members may have resulted in different item modifications. However, substantial effort was made to select appropriate individuals to review the items. For example, one of the interview participants provided feedback on the draft questionnaire, ensuring their perspective was appropriately reflected in the items.

Another similar strategy is cognitive interviews, a method used to identify sources of confusion in items and assess validity evidence on the basis of content and response processes.[19,35] The use of cognitive interviews might have resulted in additional qualitative data that could have further informed instrument development. In order to reduce participant burden, such interviews were not attempted. More research is needed to understand which, if any, of these strategies is most appropriate. Given that mixed-methods research is described as pragmatic, the appropriateness of these strategies is likely dependent on research questions, study population, and funding.[21,36]

This detailed report of methods advances the science of mixed-methods research by describing the application of an exploratory sequential instrument development design and mapping out the process by which qualitative interview text were transformed into quantitative questionnaire items. To our knowledge, this is the first attempt to outline these strategies and include examples of how qualitative interview data were meaningfully integrated and converted into quantitative items. Over the past decade, the use of mixed-methods approaches has grown in the social sciences, highlighting the need for reports addressing the application of different approaches.[37] While mixed-methods design guidelines exist, it is important to demonstrate how these approaches are applied so that effective models can be disseminated to other researchers interested in replicating similar study designs.[17,38] This report advances the field of mixed methods by describing in detail how semi-structure interviews and literature review were integrated to create an evidence-informed questionnaire.

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Table 1. Integration of Qualitative Text into Questionnaire Items

Source	Quotation or source information	Questionnaire Item
Interview plus literature review[10]	Everyone is convinced everyone has a serious addiction and should be off of opioids and on buprenorphine. "Opioid medications are not recommended for use to treat chronic pain in patients with opioid dependence."	• Patients who are addicted to opioids should be prescribed buprenorphine and not other opioids. • I know when it is time to transition a patient to buprenorphine.
Expert Recommendation	"Patients who are addicted to opioids should not be prescribed opioids and put on buprenorphine" should be split into two questions.	• Patients who are addicted to opioids should not be prescribed opioids. • Patients who are addicted to opioids should be on buprenorphine.
Interview	"I heard that the folks down here were in need of somebody who would be willing to come to work and take over the pain clinic because nobody wanted to take over the pain clinic."	• I want to work with patients with chronic pain. • I want to work with patients with opioid use disorders.
Interview	"It's not something that that we covered a whole lot in school to be honest, so I didn't have a lot of training."	• I have adequate training in addiction • I have adequate training in chronic pain.
Literature review/ Guidelines[5,39]	"Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs, urine drug	• I check the prescription drug monitoring system for each of my

	testing, and opioid treatment agreements. This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results."	patients being prescribed opioids.
Literature review/ CDC Guidelines[39]	"Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids."	• When choosing a treatment for chronic pain, I weigh the risks and benefits.
Interview	"This means we have a lot of avenues of information to assess what is going on when we manage their pain"	• I assess risk for opioid use disorder in my chronic pain patients. • I have the ability to assess risk for opioid use disorder in my chronic pain patients. • I have adequate avenues of information to assess what is going on

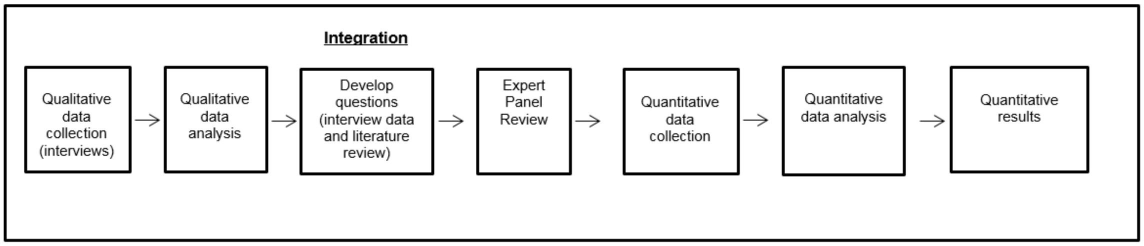
		with my chronic pain patients.
Interview	"In comparison to standard primary care with the knowledge of what people do with their lives, basically comes down to what they tell you in a 10-minute visit. I think that is a systems issue, both the ability to track what people do."	• I have the ability to track my patients' behaviors related to their chronic pain.
Interview	"You are assuming that I believe in evidence."	• I believe in empirical evidence.
Expert Recommendation	"I believe in empirical evidence" should be more specific.	• I trust research evidence related to chronic pain. • I trust research evidence related to opioid use disorder.
Interview	"I don't have anything else to use, but a narcotic. 'Cause there is nothing in between. I know the data well enough for people to say, 'Yeah, but there is physical therapy, meditation, and there are other nonpharmacologic interventions'. I don't have access to that."	• I have access to nonpharmacologic treatments for chronic pain.
Interview	"I think part of a challenge in this whole issue is that you really don't have much [treatment options] that is available to you."	• There are enough evidence-based treatments available for chronic pain. • There are enough evidence-based treatments for opioid use disorder.
Interview	"I think it's just raw fear that every opioid prescription is a bad mark on their record as a doctor, because of the way we talk	• I am afraid to prescribe opioids for chronic pain.

	about it and the way we profile it."	
Expert Recommendation	PCP suggested including item about time it takes to monitor patients medication.	- Monitoring patients medications takes too much time.
Interview	"There are other people though that are just chronic abusers and you fire them from your practice." "When we fired her she just sat there very calmly, and I said, "You know the rule, if I check the monitoring system and you've been getting prescriptions outside of this clinic, you're fired. She went, 'it's okay. I can get them'."	- When a patient on long term opioids begins to exhibit aberrant behaviors related to their medication, I fire them from my practice.
Interview	"I know what the therapies are. A lot of my patients can't afford the therapies that are recommended."	- My patients can afford the recommended therapies for chronic pain. - My patients can afford the therapies for opioid use disorder.
Literature review[40,41]	"For complex patients, prioritization of ***which*** issues to address during a given visit must precede discrete decisions about disease-specific treatment preferences and goals. Negotiating this process of setting priorities represents a major challenge for patient-centered primary care, as patient and provider priorities may not always be aligned."	- It is difficult to prioritize patients' clinical needs when treating comorbidities.

Literature review[42] Interview	The capacity of the primary care team influences the abilities of the provider. Interviewee describes	• My team wants to work with patients with chronic pain. • My team wants to work with patients with opioid use disorders.
Interview	Participant described “instant messaging” with patients’ psychiatrist about medications	• I communicate with other health care providers that are treating my chronic pain patients.
Interview	“So, the barrier that providers would have is A) They are unfamiliar with prescribing off label buprenorphine for pain. Or B) if they are wanting to refer, they don’t have somebody that they work with”	• I have a buprenorphine provider I can refer my patients to if necessary.
Literature review[43]	“In the private sector, interdisciplinary pain management services are challenging to assemble, separate from primary care and not typically reimbursed.”	• Interdisciplinary pain management services are challenging to assemble.
Interview	“I am addiction certified and could get this waiver pretty easily.”	• It is easy to acquire a buprenorphine waiver.
Interview	“I think the problem with evidence is that it is derived from a trial, usually a randomized controlled trial, and by and large they are a very select group of people whose profile and demographics are different than the people I treat.”	• Research participants in chronic pain studies are representative of my patients. • Research participants in opioid use disorder studies are representative of my patients.
Interview	“My hospital would require me to guarantee that people are in some kind of addiction social	• My organization makes it difficult to treat patients with chronic pain.

	treatment, even though there is no evidence that that actually benefits people. But they’ll do it because it’s the law, its regulation.”	• My organization makes difficult to treat opioid use disorder. • Regulations make it difficult to treat patients with chronic pain. • Regulations make it difficult to treat opioid use disorder.

Figure 1. Exploratory Design: Instrument Development Model



DEVELOPMENT OF THE CAPACITY TO TREAT CHRONIC PAIN AND OPIOID USE DISORDER (CTCPOUD) QUESTIONNAIRE

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Introduction

Promoting person-centered, empirically-supported practices for managing co-occurring chronic pain and opioid use disorder in the primary care setting is a public health priority. Rates of chronic pain, opioid use, and opioid use disorder have continued to rise over the past decade.[1-3] Much attention has been paid to primary care providers (PCPs), as they are the main prescribers of opioids for chronic pain.[4] Although the relationship between opioid prescribing for chronic pain and the onset of opioid use disorder is unclear, PCPs are nevertheless ideal change agents to help mitigate the current opioid crisis. However, recent research suggests PCPs are slow to adopt new practices.[5,6]

A person-centered, empirically-supported care plan involves weighing risks and benefits of treatment options, while taking into account the needs of the patient.[7] However, both individual and organizational capacity are necessary to do so.[8] Capacity refers to PCPs' knowledge, commitment, and ability to carry-out research-informed activities for the treatment of co-occurring chronic pain and opioid use disorder.[9,10] Improving PCPs' capacity to treat co-occurring chronic pain and opioid use disorder is important for several reasons. First, chronic pain is most commonly treated in the primary care setting.[4] If a patient transitions from appropriate to inappropriate opioid use, a change in treatment plan must be made by their provider.[7,11] Moreover, given the dynamic interaction of pain and opioid misuse, it is important to explore factors that might influence the treatment of pain and opioid use disorder together.[12,13]

The capacity to treat both chronic pain and opioid use disorder is a PCP characteristic that may influence the uptake of empirically-supported practices, which continue to evolve.[7,14,15] Thus, measures that assess this capacity are needed to understand its effect on delivering appropriate care to patients in need. Indeed, as initiatives aimed at improving chronic pain management and addiction care emerge, it is increasingly important to understand what may be influencing PCP behavior, with the goal of ultimately tailoring implementation strategies and evaluating their outcomes.[16] However, no measure exists that evaluates the factors influencing PCPs' capacity to treat co-occurring chronic pain and opioid use disorder.

The objective of the present study was to develop and test the psychometric properties of a questionnaire aimed to assess capacity for treating chronic pain and opioid use disorder in the primary care setting. This was accomplished by first developing draft items, then administering a draft version of the questionnaire to a large sample of PCPs, and finally using quantitative methods to evaluate the questionnaire's psychometric properties. Although the capacity to treat both chronic pain and opioid use disorder is relatively unstudied and thus few relevant, overlapping measures exist, concurrent relationships with measures related to provider knowledge and behavior were evaluated to assess its construct validity. It was hypothesized that respondents with greater capacity would report greater scores on attitudes towards evidence, a greater knowledge of pain management, and greater behavioral adherence to evidence-based practices.

Methods

All study activities were overseen and approved by the University of Alabama at Birmingham's Institutional Review Board.

Item selection

Draft items were developed through two approaches. First, items were developed based on a review of the literature and evidence-based recommendations. For example, CDC guidelines for prescribing opioids for chronic pain emphasize weighing risks and benefits when choosing a treatment plan, and therefore one item read, "When choosing a treatment for chronic pain, I weigh the risks and benefits.".[7] Second, semi-structured interviews, guided by the Consolidated Framework for Implementation Research (CFIR), were conducted with 11 PCPs in the Birmingham, Alabama area.[8] Items were then reviewed by an expert panel and amended for both content and clarity. This process resulted in 44 draft items related to the capacity to treat chronic pain and opioid use disorder.

Measures

1) <u>Capacity to Treat Chronic Pain and Opioid Use Disorder (CTCPOUD; Figure 1)-</u> The 44-item draft questionnaire asked providers to rate the extent to which they agreed with statements related to their capacity to treat both chronic pain and opioid use disorder. Respondents were give a 7-point Likert scale that ranged from strongly disagree (1) to neither agree nor disagree (4) to strongly agree (7).

2) Provider demographic and practice information- Age, gender, and region of the country currently practicing were collected from each respondent. Additionally ethnicity, title (type of provider), board certifications, and years practicing were collected.

3) Evidence-Based Practice Attitudes Scale- Attitudes influence a provider's decision to try a new practice or adopt a new innovation. The EBPAS is a 15-item validated scale that assesses providers' attitudes towards the use of EBPs [17]. The measure consists of four subscales: *Requirements*, *Appeal*, *Openness*, and *Divergence*. Respondents were asked to indicate the extent to which they agreed with statements related to adopting new interventions, with response options ranging from not at all (0) to a very great extent (4). The EBPAS demonstrated adequate to good reliability in this sample (Scale 1= .87; Scale 2= .81; Scale 3=.83; Scale 4=.62).

4) KNOWPAIN-12- The KNOWPAIN-12 is a validated measure of provider knowledge of pain management [18]. Respondents are asked to indicate the extent to which they agree with statements related to pain management. Response options range from strongly agree to strongly disagree, with higher scores indicating greater knowledge of pain management. The alpha coefficient for the measure in this sample was .47.

5) Behavioral Adherence to Evidence-Based Recommendations (Appendix D)- The use of vignettes to measure provider adherence to guidelines has been validated in previous studies.[19] Adherence to evidence-based recommendations was measured using a series of vignettes from a module on the National Institute for Drug Abuse (NIDA)'s

website.[20] The module, titled “Managing Pain in Patients Who Abuse Prescription Drugs” is intended for health care professionals and includes a case description with questions about treatment choices. A total of six vignettes were included. Modelling previous research on vignettes, respondents were given 1 point for each response answered correctly, with a total of 6 points possible.[21,22]

Participants

From March 2018 to July 2018, PCPs were invited to complete the online questionnaire battery. Participants were recruited via email invitation, social media, and referral by community partners. Within the email and social media invitations there was a link to a SurveyMonkey page containing the questionnaire battery. In order to obtain a representative sample, emails were sent to academic, community, and government providers and organizations in each state. Respondents were included if they practiced in the US, considered themselves a primary care provider, and had an advanced clinical degree. Respondents were excluded if they did not practice in the United States or did not have an advanced degree (MD, DO, nurse practitioner, or physician assistant).

Analyses

A principal components analysis using promax rotation was conducted to evaluate the dimensionality of the CTCPOUD and the Minimum Average Partial (MAP) procedure was used to determine how many factors to retain. Items with factor loadings of at least .50 and no cross loadings were retained for rotation. Reliability of each factor was determined using Cronbach’s alpha, and any item that did not improve measurement substantially was eliminated from each factor. Scales were constructed by computing the mean of the remaining items that loaded on each factor. Concurrent validity was tested by taking the total mean score of each scale and examining its correlation with the EBPAS, KNOWPAIN-12, and vignette scores.

Results

509 providers completed the 90-question survey. Approximately 7,000 emails were sent out resulting in a 7% response rate. This response rate was lower than expected, as other studies have had rates up to 35%.[23] This may be due to the length of the survey and absence of compensation.[24] Providers with incomplete data were removed from the analysis resulting in the inclusion of 493 total respondents in analyses.

Table 1 describes the demographic and practice characteristics of the sample. The respondents were predominantly white, physicians (MD), and practicing in an academic setting. Family and internal medicine were the primary certifications reported. Only 1.8% of the sample reported having a certification or licensure in addiction medicine.

Initially, 22 items were removed from the draft questionnaire. Analyses resulted in a 22-item, 4-factor solution that accounted for 49% of the variance. An additional 12 items were then removed based on their effect on alpha coefficients, resulting in the final 10-item final version of the questionnaire, which accounted for 80% of the variance.

Table 2 describes the questionnaire items, factor loadings, and coefficient alphas. The first scale, labeled, *Desire to Treat* (M= 3.5 SD= 1.5 R= 1 to 7) had its greatest loading on items that addressed both the provider's and their team's motivation to treat patients with both chronic pain and opioid use disorder. The second scale, labeled *Assessing Risk* (M=5.5 SD=1.2 R= 1 to 7), had it greatest loadings on two items that addressed the provider's ability to assess for opioid use disorder in their chronic pain patients. The third scale, labeled *Trust in Evidence* (M=5.7 SD=1.0 R= 1 to 7), had its greatest loading on two items that measure the degree to which the provider trusts research evidence related to chronic pain and opioid use disorder. The fourth and final scale, labeled *Patient Access* (M= 3.1 SD= 1.5 R= 1 to 7), had it greatest loadings on two-items that address the provider's perception of their patients' ability to afford the recommended treatments for chronic pain and opioid use disorder. Coefficient alphas ranged from .79 to .87. Table 3 displays the zero-order correlations among the scales of the questionnaire.

Tests of Construct Validity

Table 4 lists correlations of the questionnaire scales and the EBPAS, KNOWPAIN-10, and vignette scores with significant correlations in bold. Table 5 lists correlations with each individual vignette score and the total score. There was a modest positive relationship between the *Desire to Treat* scale score and the total vignette score and a moderate positive relationship between *Desire to Treat* scale and the KNOWPAIN-12 total score. The *Assessing Risk* scale score had a modest positive relationship with the total vignette score and a moderate positive relationship with the KNOWPAIN-12 total score. The *Trust in Evidence* scale score had a modest positive relationship with the

KNOWPAIN-12 total score and modest to moderate positive relationships with all subscales of the EBPAS. The *Patient Access* scale score was not significantly associated with the EBPAS, KNOWPAIN-12, or vignette scores.

Discussion

The primary objective of the present study was to develop and validate an instrument designed to assess PCPs' capacity to treat co-occurring chronic pain and opioid use disorder. To our knowledge, the current research is the first attempt to develop such a measure. Analyses revealed four domains underlying the items of the CTCPOUD, from which four scales were constructed: *Desire to Treat*, *Assessing Risk, Trust in Evidence,* and *Patient Access*.

All CTCPOUD scales were correlated with at least one of the measures used in tests of validity, with the exception of *Patient Access*. This could simply be because *Patient Access* assesses a construct unrelated to those constructs assessed by the other measures, notably one that is outside of the PCPs' locus of control. The CTCPOUD scales' relationships with knowledge of pain management, behavioral adherence to evidence-based practices (vignettes), and attitudes towards evidence-based practices were modest to moderate. While it was hypothesized that the questionnaire would demonstrate some degree construct validity, it is not surprising the correlations were not robust, as little research exists in this field and no measures specific to treating both chronic pain and opioid use disorder exist. Future work should look to further explore the concurrent relationships of the CTCPOUD to other indices more closely related to provider capacity to treat this population, including actual behavior.

The present study has its limitations. While great effort was taken to ensure a representative sample, more than half of the respondents were both physicians and academic practitioners and results may not be as generalizable to other types of providers. It is also unknown how generalizable the results are to other providers that treat pain, like emergency medicine, anesthesiology, or pediatric practitioners. Great effort also was made when developing the initial pool of questionnaire items. However, the final factor structure and scales are products of the items and sample used.

Results from the present study enhance the current understanding of PCPs' capacity to treat co-occurring chronic pain and opioid use disorder by producing a reliable tool with preliminary evidence of validity to assess this capacity. This study represents the first attempt to create such a tool and the results require further inquiry. Future research should explore the predictive validity of the questionnaire and test if capacity is predictive of provider behavior or patient outcomes. Recent reports suggest significant local, state, and federal funds will be allocated towards fighting the opioid crisis, with a large proportion going toward provider interventions and training.[25,26] Information collected from the CTCPOUD has potential to inform such efforts by identifying the specific needs of PCPs and then evaluating programs aimed at increasing their capacity to treat co-occurring chronic pain and opioid use disorder.

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Table 1. Demographic and Provider Characteristics

Demographic and Provider Characteristics		
Gender (%)		
	Male	38
	Female	61.8
	Other	0.2
Mean Age (SD)		48.1 (11.7)
Region (%)		
	New England	14.6
	Middle Atlantic	13.8
	East North Central	15.6
	West North Central	9.1
	South Atlantic	11.7
	East South Central	10.1
	West South Central	6.1
	Mountain	7.3
	Pacific	9.5
	Midwest	2.2
Ethnicity (%)		
	White or Caucasian	82.3
	American Indian or Alaskan Native	1.0
	Asian or Pacific Islander	6.7
	Black/African American	2.8
	Hispanic/Latino	3.7
	Multiple Ethnicities	1.0
	Prefer Not to Answer	2.6

Degree (%)		
	MD	65
	NP	23.6
	PA	2.4
	DO	9.0
Organization Type (%)		
	Community	36.0
	Hospital	8.1
	Government (including VA)	0.8
	Academic	54.0
	Other	1.2
Certifications/Licenses (%)		
	Family Medicine	34.8
	Internal Medicine	10.4
	Gerontology	1.6
	Sports Medicine	1.4
	Nurse Practitioner (non specific)	5.3
	Palliative Care	1.6
	Addiction Medicine (only)	1.2
	Physician Assistant	0.4
	Other	3.1
	No specialized licenses or board certifications	40.3
Addiction Certification (%)		
	Primary or secondary certification/license	1.8
	None	98.2
Mean Years Of Practice (SD)		16.7 (11.4)
Proportion (%) of Patients with Chronic Pain (SD)		15.1 (15.5)

Table 2. Questionnaire Items and Factor Loadings

Questionnaire Items and Factor Loadings

Scale (coefficient alpha reliability)		**Loading**
Desire to Treat (.87)		
	My team wants to work with patients with opioid use disorders.	.89
	My team wants to work with patients with chronic pain.	.85
	I want to work with patients who have opioid use disorders.	.80
	I want to work with patients who have chronic pain	.79
Assessing Risk (.82)		
	I have the ability to assess risk for opioid use disorder in my chronic pain patients.	.90
	I assess risk for opioid use disorder in my chronic pain patients.	.89
Trust in Evidence (.87)		
	I trust research evidence related to chronic pain.	.94
	I trust research evidence related to opioid use disorder.	.93
Patient Access (.79)		
	My patients can afford the recommended therapies for chronic pain.	.91
	My patients can afford the recommended treatments for opioid use disorder.	.90

Table 3. Zero-Order Correlations

Zero-Order Correlations

Subscales	**Desire to Treat**	**Assessing Risk**	**Trust in Evidence**	**Patient Access**
Desire to Treat				
Assessing Risk	**.339****			
Trust in Evidence	.082	**.092***		
Patient Access	**.113***	**.108***	**.103***	

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table 4. Correlations with Related Measures (Content Validity)

Questionnaire Correlation with Other Related Measures

	Capacity to Treat Chronic Pain and Opioid Use Disorder Scales			
Scales and Subscales	**Desire to Treat**	**Assessing Risk**	**Trust in Evidence**	**Patient Access**
KNOWPAIN-10	**.330****	**.354****	**.139****	.065
Vignette Score	**.130****	**.133****	.061	.065
EBPAS (Requirements)	-.021	-.080	**.164****	.016
EBPAS (Appeal)	.038	-.011	**.207****	.005
EBPAS (Openness)	.089	.034	**.172****	-.038
EBPAS (Divergence)	-.006	.032	**.257****	.029
EBPAS Total	.036	-.004	**.314****	.027

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table 5. Correlations with Total Vignette Score and Individual Vignettes

Questionnaire Correlation with Vignette Total Score and Individual Vignettes

	Capacity to Treat Chronic Pain and Opioid Use Disorder Scales			
	Desire to Treat	**Assessing Risk**	**Trust in Evidence**	**Patient Access**
Vignette Score	**.130****	**.133****	.061	.065
Vignette 1 Screening for substance abuse	.046	**.094***	.022	.032
Vignette 2 Risk factors	.061	-.011	-.066	.034
Vignette 3 Patient/provider communication	.057	**-.129****	.043	.045
Vignette 4 Pain assessment	**.129****	**.175****	.045	.004
Vignette 5 screening tools	-.041	-.035	**.101***	.066
Vignette 6 Patient/provider communication	**.142****	.079	**.097***	-.046

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Figure 1. Capacity to Treat Chronic Pain and Opioid Use Disorder Questionnaire

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
1	**2**	**3**	**4**	**5**	**6**	**7**

Using the scale provided, please rate the degree to which you agree or disagree with the following statements.

1. I want to work with patients who have chronic pain.
2. I want to work with patients who have opioid use disorders.
3. I have the ability to assess risk for opioid use disorder in my chronic pain patients.
4. I assess risk for opioid use disorder in my chronic pain patients.
5. I trust research evidence related to chronic pain.
6. I trust research evidence related to opioid use disorder.
7. My patients can afford the recommended therapies for chronic pain.
8. My patients can afford the recommended treatments for opioid use disorder.
9. My team wants to work with patients with chronic pain.
10. My team wants to work with patients with opioid use disorders.

APPENDIX A

SEMI-STRUCTURED INTERVIEW GUIDE

Semi-structured interview guide

- Do you have any specialized training or board certifications? If so, tell me about those.
- Do you belong to any professional organizations?
    - Where do you get information about advances in your field?
- Can you tell me about how you generally manage a patient who has chronic pain?
    - What are the most common treatments or procedures you use?
        - Why?
    - Are there any treatments you'd like to use but don't?
        - Why?
- How often do you prescribe opioids for chronic pain?
    - How do you feel about prescribing opioids?
- Can you tell me about what do you do if you believe someone is abusing their opioids?
    - If necessary, define abuse: a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year.
    - What types of treatments are currently used by you/your organization?

Now we are going to talk about some of the factors that may influence your decision-making process when treating patients who have co-occurring chronic pain and prescription opioid abuse. Specifically, I want to find out about some of the reasons why you may or may not use a certain treatment or treatments for this type of patient.

Note to interviewer: *at this point in time, specific practices will be listed, make sure to probe about specific practices that may have not been mentioned, like buprenorphine, CBT, referring to substance abuse treatment, exercise therapy, naloxone, or others.*

First, let's talk about the potential treatments for chronic pain and prescription opioid abuse.

- Please tell me your perceptions about what is considered "best practice" for treating patients with chronic pain and opioid abuse?
    - Tell me about your knowledge of the new CDC opioid prescribing guidelines?
    - Can you tell me about the organization/group that developed these guidelines?

- What kind of information or evidence are you aware of that shows whether or not the different practices for treating chronic pain and prescription opioid abuse are effective?

    - What was the source of that information?
    - How does this information shape your view of the practices?
    - How is your practice trying to implement these guidelines, if at all?
        - If so, why or why not?
    - Have you perceived a push for these practices to be implemented? What do you think about that?
- What kind of supporting evidence or proof is needed about the effectiveness of a practice to get staff on board?
- How do these practices that we have discussed compare?
    - Is one better than the others?
    - What are the advantages and disadvantages of using one vs. another?
    - Can you tell me about the circumstances in which you might use certain practices, instead of the others?
- How do you feel about the interventions currently being used in your setting?
- At what stage of implementation is the intervention at in your organization (if any)?
    - How do you think the program is going?
    - Why do you say that?

Ok, now let's talk about some of the factors outside of your practice that may influence how you treat patients with chronic pain and prescription opioid abuse. Let's talk about the practice that you generally think is most effective in treating individuals with chronic pain and prescription opioid use.

- Can you tell me which practice you think is generally the most effective for this patient population?
    - Why?
- How well do you think this practice meets the needs of the individuals served by your organization?
    - Why or why not?
- How do you think the individuals served by your organization do/will respond to the implementation of these practices?

- What barriers do/will the individuals served by your organization face in participating in trying to adopt these practices?
- Can you tell me what you know about any other organizations that you know about who have implemented this practice?
- What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced your/your organization's decision to implement the intervention?
    - How will the intervention affect your organization's ability to meet these measures, policies, regulations, or guidelines?

- What kind of financial or other incentives influenced your/your organization's decision to implement the intervention?

Now we are going to talk about some factors in your specific practice or organization that may influence how you treat patients with chronic pain and prescription opioid abuse.

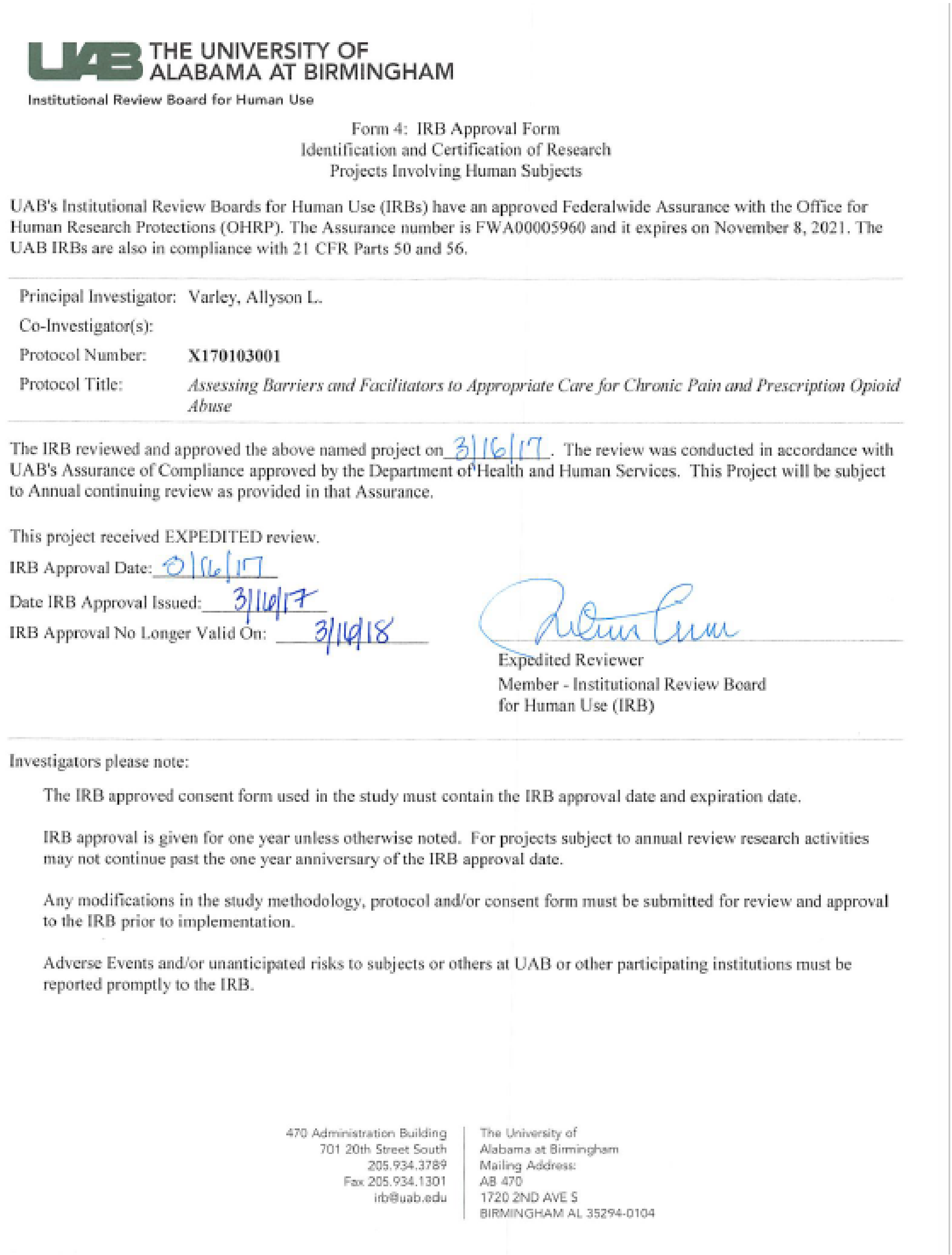
- What kinds of infrastructure changes were/will be needed to accommodate this practice?
    - Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?
    - What kind of approvals will be needed? Who will need to be involved?
    - Can you describe the process that will be needed to make these changes?

- Tell me a little bit about your team or colleagues, who would you consider to be in your team in your practice? How would you describe your relationships among members of your team?
    - Can you tell me about any factors related to your team that might influence how you treat a patient with chronic pain and prescription opioid abuse?

- How do you think your organization's culture (general beliefs, values, assumptions that people embrace) would affect the implementation of this practice?
- To what extent are new ideas embraced and used to make improvements in your organization?
    - Can you describe a recent example?
- What kinds of high-priority initiatives or activities are already happening in your setting?

APPENDIX B

INSTITUTIONAL REVIEW BOARD APPROVAL FORMS



THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on November 8, 2021. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	Varley, Allyson L.
Co-Investigator(s):	
Protocol Number:	**X170103001**
Protocol Title:	*Assessing Barriers and Facilitators to Appropriate Care for Chronic Pain and Prescription Opioid Abuse*

The IRB reviewed and approved the above named project on 3/16/17. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 3/16/17

Date IRB Approval Issued: 3/16/17

IRB Approval No Longer Valid On: 3/16/18

Expedited Reviewer
Member - Institutional Review Board
for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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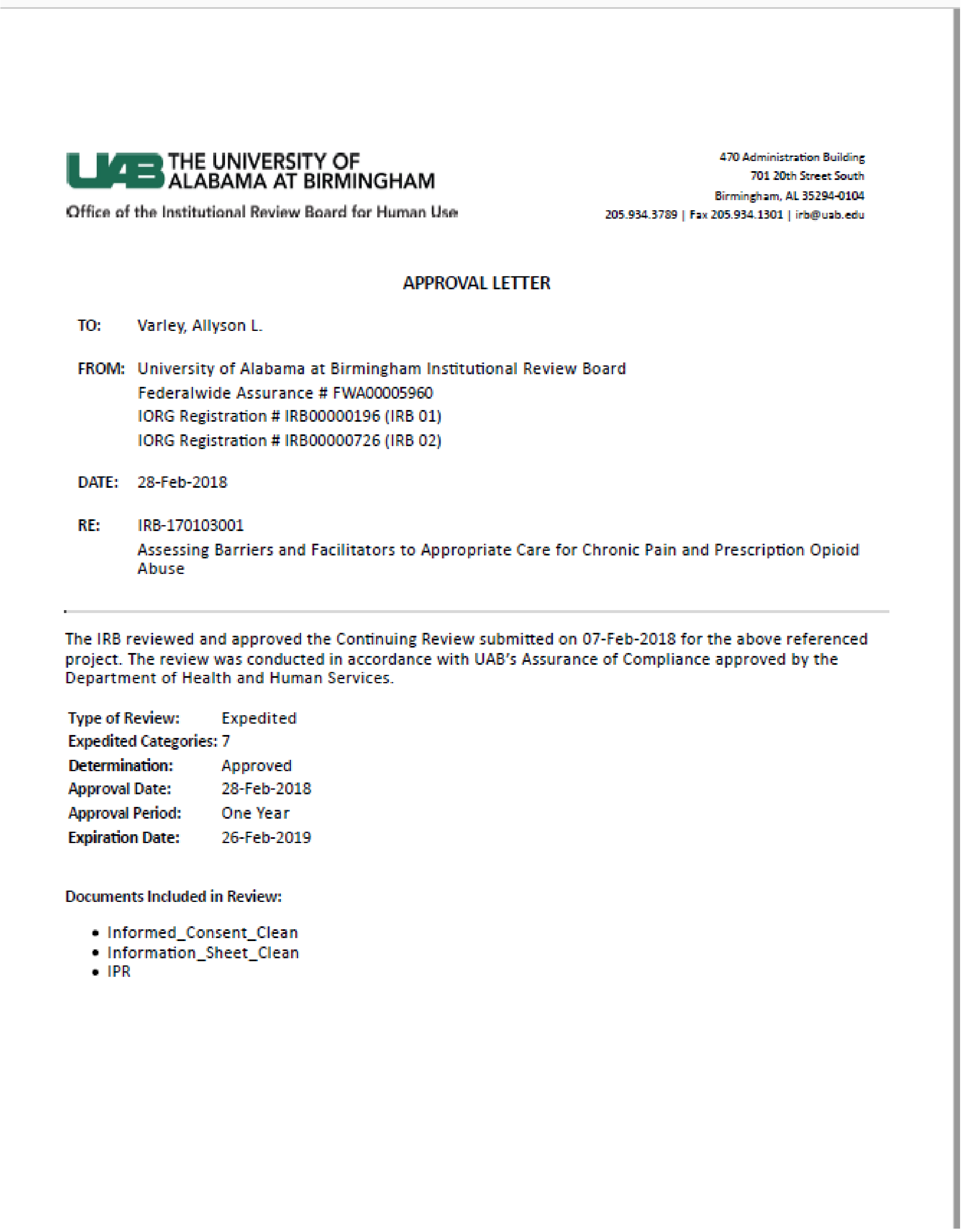

THE UNIVERSITY OF
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APPROVAL LETTER

TO: Varley, Allyson L.

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 28-Feb-2018

RE: IRB-170103001
Assessing Barriers and Facilitators to Appropriate Care for Chronic Pain and Prescription Opioid Abuse

The IRB reviewed and approved the Continuing Review submitted on 07-Feb-2018 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Expedited
Expedited Categories: 7
Determination: Approved
Approval Date: 28-Feb-2018
Approval Period: One Year
Expiration Date: 26-Feb-2019

Documents Included in Review:

- Informed_Consent_Clean
- Information_Sheet_Clean
- IPR