

# Patients’ experiences with prescription opioid use for acute and/or chronic pain management: A qualitative study

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## Background

- The United States (US) Food and Drug Administration (FDA) approved the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) in July 2012 for extended-release and long-acting (ER/LA) prescription opioids as a strategy to reduce the risks of opioid overuse and expanded it in September 2018 to include immediate-release and short-acting (IR/SA) opioid products.
- In 2016 the Centers for Disease Control and Prevention (CDC) issued its guideline for prescribing opioids for chronic pain that made recommendations for improving provider prescribing practices and patient pain treatment.
- This FDA-mandated study, approved in 2019 and conducted in 2021, was designed to better understand patients’ experiences with opioids including access to care, nonpharmacological options, and unintended outcomes following the issuance of the CDC guideline.

## Objective

- To better understand patients’ positive and negative experiences with prescription opioids for acute and/or chronic pain management.

## Methods

### Research Design

- Qualitative semi-structured telephone interview study, conducted among adult patients who were current or recent users of prescription opioids for acute and/or chronic pain management.

### Data Sources

- *Community:* Global network practitioner platform identified community sites with underserved populations in geographically diverse locations.
- *Pharmacy claims:* Healthcare Integrated Research Database (HIRD) used as sampling frame to identify current and recent adult opioid users with Medicare Advantage (MA) or commercial health insurance from opioid pharmacy claims.

### Patient Population

- *Current user:* Adults (≥18 years ) who had been dispensed ≥1 ER/LA or IR/SA opioid prescription for pain management in past ≤90 days.
- *Past user:* Adults who had been dispensed ≥1 ER/LA or IR/SA opioid prescription for pain management in past >90 days - ≤180 days.
- *Exclusions* included hospice, substance abuse treatment, employed as a physician, nurse practitioner, physician’s assistant, pharmacist, nurse, or dentist.

### Patient Outreach, Recruitment, and Screening

- *Community Sample*
  - Recruitment flyers handed out by community site providers.
  - Patients who responded to the flyer were directed to an online screener and, if they qualified, continued to an online informed consent form.
  - Name and contact information for patients who completed the consent form was sent to Carelon Research staff, who scheduled and conducted the interview.
  - Recruitment continued until the targeted number of 144 community interviews was completed.
- *Pharmacy Claims Sample*
  - Patients with MA or commercial health insurance identified from HIRD pharmacy claims.
  - Patients received recruitment emails and a letter describing the study; patients who did not respond to the emails or letter were contacted by telephone.
  - Interested patients were recruited and screened for eligibility using the recruiting/screening script.

- Qualified patients received a link to the online consent form and, following completion, scheduled a date and time for their interview.
- Recruitment continued until the targeted number of 48 interviews was scheduled.

### Interview Process and Methodology

- Two trained facilitators conducted the 60-minute telephone interviews using a standard interview discussion guide.
- Interview aims were to encourage a range of responses that provided greater understanding of participants’ attitudes, opinions, perceptions, and experiences regarding their use of opioid analgesic medications.
- Participants received a \$125 check or gift card to compensate them for time spent completing an interview.
- All patient materials were approved by WCG IRB and the FDA.

### Interview Discussion Guide

- The interview discussion guide was developed in alignment with the REMS Assessment Plan and REMS goals and consisted of questions and prompts for facilitators to use (**Exhibit 1**).

Exhibit 1: Interview Discussion Guide

High Level Domain	Targeted Domain   Example of Interview Questions
Patient History	<b>Medical and Medication Use History</b> <ul style="list-style-type: none"><li>• What medical condition(s)/problem(s) led to your use of opioids during the past 5 years?</li><li>• During past 5 years, have you taken opioids continuously or intermittently?</li></ul>
Opioid Use	<b>Everyday Experiences</b> <ul style="list-style-type: none"><li>• What does opioid use look like on a day-to-day basis?</li></ul> <b>Benefits and Risks</b> <ul style="list-style-type: none"><li>• What are the main benefits of taking an opioid?</li><li>• What are the downsides/negative aspects of taking opioids?</li><li>• In general, how do you feel about taking an opioid to manage your pain?</li></ul>
Education	<b>Provider Types</b> <ul style="list-style-type: none"><li>• What was your experience with the provider of your most recent opioid?</li><li>• Have you gotten opioids from other types of doctors?</li></ul> <b>Education</b> <ul style="list-style-type: none"><li>• What information has your doctor provided, in terms of how to use your opioid properly?</li><li>• How confident are you in your ability to use your opioid correctly?</li><li>• Has a doctor ever encouraged you to stop or cut back using opioids, or refused to refill your prescription?</li></ul> <b>Opioid Crisis Knowledge</b> <ul style="list-style-type: none"><li>• What are your knowledge and thoughts on the Opioid Crisis?</li></ul>
Unintended Adverse Outcomes	<b>Changes/Side Effects</b> <ul style="list-style-type: none"><li>• Have you stopped or cut back on your opioid use?</li><li>• Did you ever suddenly stop taking opioids?</li><li>• Did you ever have withdrawal symptoms as a result of stopping/decreasing opioid use?</li><li>• Have you ever experienced changes in mood/thoughts of suicide while taking opioids?</li></ul>
Coordinated Pain Management Services	<b>Other Medications, Treatments</b> <ul style="list-style-type: none"><li>• If you see more than one doctor, how does that work in terms of opioid use for pain management?</li><li>• What are your experiences with other medications/treatments for pain management?</li><li>• Has a doctor ever talked to you about other medications/treatments to manage pain?</li><li>• For those who haven’t ever used other medications/treatments for pain management, is there any specific reason?</li></ul> <b>Future</b> <ul style="list-style-type: none"><li>• Looking to the future, what do you expect to happen in terms of your opioid use for pain management?</li></ul>

## Results

- Semi-structured 60-minute telephone interviews were conducted in 2021 with 191 patients; 144 community patients and 47 pharmacy claims patients.
- Of the 191 participants, 44 (23%) were taking opioids for acute pain management, 91 (48%) for chronic pain management and 56 (29%) for both acute and chronic pain management.
- Exhibit 2 presents a profile of the participants.

Exhibit 2: Participant Profile

	All Participants N=191	Acute Pain Participants N=44	Chronic Pain Participants N=91	Acute & Chronic Pain Participants N=56
Interview Group, n (%)				
Community	144 (75%)	20 (45%)	77 (85%)	47 (84%)
Commercial/MA, Current User	34 (17%)	13 (30%)	12 (13%)	9 (13%)
Commercial/MA, Recent User	13 (7%)	11 (25%)	2 (2%)	0 (0%)
Female, n (%)	124 (65%)	28 (64%)	59 (65%)	37 (66%)
Current age (years), mean (SD)	54 (14)	47 (14)	56 (14)	55 (13)
White, non-Hispanic, n (%)	126 (66%)	31 (70%)	57 (63%)	38 (68%)
Married/Domestic partner, n (%)	101 (53%)	25 (57%)	49 (54%)	27 (48%)
High school degree or less, n (%)	46 (24%)	4 (9%)	27 (29%)	15 (26%)
Household income <\$50,000, n (%)	95 (50%)	14 (32%)	53 (58%)	28 (50%)
Participant location, n (%)				
Rural	34 (18%)	5 (11%)	18 (20%)	11 (20%)
Suburban	123 (64%)	30 (68%)	60 (66%)	33 (59%)
Urban	34 (18%)	9 (21%)	13 (14%)	12 (21%)
Age first diagnosed with pain condition (years), mean (SD)	41 (15)	37 (16)	43 (15)	42 (14)
Duration of pain condition (years), mean (SD)	12 (12)	10 (13)	13 (12)	13 (12)
Currently taking prescription opioid (yes), n (%)	165 (86%)	24 (55%)	87 (96%)	54 (96%)

### Themes and Patient Quotes

- A thematic content analysis was performed. Eleven themes and appropriate quotations from the most prominent themes were identified (**Exhibit 3**).

Exhibit 3: Themes and Participant Quotes

Theme	Participant Quotes
General feelings towards opioids	<ul style="list-style-type: none"><li>• "... thankful that I have an option "</li><li>• "... concern... about addiction"</li><li>• "I hate it. It makes me just feel like you're not strong enough to handle this on your own."</li></ul>
Reactions to Opioid Crisis	<ul style="list-style-type: none"><li>• "there's huge [opioid] use in the youth in my community. Kids have died from overdoses."</li><li>• "I've had friends who've gotten ruined... I've seen them wither away to the point where some of them have passed away."</li><li>• "I lost my daughter because of the opiate thing... she had been in a major car accident, and she had been on pain meds... they took her off them [and then she became] a heroin addict to deal with her pain... Unfortunately, I lost her last year due to it."</li></ul>
Prescribing decisions	<ul style="list-style-type: none"><li>• "I didn't ask for [opioid medication.] They just gave me a prescription when I left the hospital." (Acute pain)</li><li>• "There was no decision-making. They just came back with two [opioid] prescriptions." (Acute pain)</li><li>• "It was a very candid conversation...which made me feel that I had a decision in this whole process." (Chronic pain)</li></ul>
Non-pharmacological options	<ul style="list-style-type: none"><li>• "[I've] done physical therapy. That helped me get range of motion back in my arm and my knee."</li><li>• "I've had friends who've gotten ruined... I've seen them wither away to the point where some of them have passed away."</li><li>• "I lost my daughter because of the opiate thing... she had been in a major car accident, and she had been on pain meds... they took her off them [and then she became] a heroin addict to deal with her pain... Unfortunately, I lost her last year due to it."</li></ul>
Overprescribing	<ul style="list-style-type: none"><li>• "[doctors are] quick to prescribe"</li><li>• "[My doctors] kept me takin' them, takin' them, takin' them, takin' them...Now it's to the point that it's not even doin' me no good."</li><li>• "[my doctor] was writing 'scripts to whoever wanted them, pretty much. It was a big news story... there was four people that died... He's now in prison."</li></ul>

Exhibit 3: Themes and Participant Quotes (cont'd.)

Theme	Participant Quotes
Patient abandonment/premature termination of doctor-patient relationship	<ul style="list-style-type: none"><li>• "My family doctor I had back then... wanted to stay at home with her babies. I had to find another doctor. The first one that was a nightmare. 'Cause he was a pill pusher... I didn't like that. Because there was medications that he had me on that wasn't working, and a couple that I didn't like the way they made me feel. I didn't take 'em. He said he couldn't be my doctor anymore... Needless to say, he's in prison now ... [but] it just blew my mind that a doctor would try that hard to get me to take something I didn't want."</li></ul>
Illicit use of opioids	<ul style="list-style-type: none"><li>• "I don't want to do anything illegal [but]...there was a time when I did not have insurance and would get it elsewhere... I had a family member who had back surgery and back pain issues, and his pain doctor would always give him way more than he needed...[so] he would just give it to me."</li><li>• "there's always somebody that will sell it to you, but you don't know if you're actually getting the medication or you're getting something else."</li></ul>
Side effects	<ul style="list-style-type: none"><li>• "All I did was sleep for a couple of days. To me, I'm a pretty active guy, that's kind of a downside." (Acute pain)</li><li>• "For me, the major side effect is constipation... I was plugged up you wouldn't believe." (Chronic pain)</li></ul>
Mood changes	<ul style="list-style-type: none"><li>• "I'm a laid-back person, but it seems like I got more agitated [on the opioid medication]."</li><li>• "When I stopped [taking my opioid medication] ... I was more irritable... I would just go off on things and simple things."</li></ul>
Withdrawal experiences	<ul style="list-style-type: none"><li>• "[after stopping my opioid intake], the pain did continue, and it did increase."</li><li>• "It felt like cold turkey, I was [fully off the opioid medication] in about three days... my digestive system was ruined throughout that whole process... Sometimes my bowels are a little bit overactive [from] withdrawal symptoms." (Acute pain)</li><li>• "I was sweating profusely... It feels like death. It's awful. It feels like your body can't regulate temperature. You'll be sweatin', but you'll be freezing cold or have chill bumps. Your nose starts to run. You yawn, and your eyes water a lot. You get really uncomfortable, like restless legs. You can't sit still, and everything's just jerking and twitching. Then you start poopin', and then you start pukin'." (Chronic pain)</li></ul>
Expressions of suicidal ideation	<ul style="list-style-type: none"><li>• "I thought about [suicide] when I wasn't [taking my opioid medication] ... mostly more at the very beginning of stopping... I didn't really have a doctor then."</li><li>• "I've thought of [suicide] when I don't have [my opioid medication] and I'm in a lot of pain... if I had to live in that pain without any type of help, I'd rather not be here..."</li></ul>

## Limitations

- Since participation was voluntary, the set of participants may consist of a larger proportion of people with positive or neutral opioid medication experiences, because those with negative experiences or who felt they were dependent on or addicted to opioids may have been less inclined to participate.

## Conclusions

- In general, participants’ overall experiences with prescription opioid medications for pain management were positive or neutral; less than 5% were negative.
- Most participants associated their use of prescription opioid medications with an improved quality of life and felt their opioid medications had been helpful in managing their pain.
- One participant summed up her experience with opioid medications as “better living through science”, while other participants were thankful for their opioid medications and grateful such pain medicine existed.

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