

BMJ Open Exploring perceptions and experiences of patients who have chronic pain as state prescription opioid policies change: a qualitative study in Indiana

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ABSTRACT

Objectives The misuse and abuse of prescription opioids (POs) is an epidemic in the USA today. Many states have implemented legislation to curb the use of POs resulting from inappropriate prescribing. Indiana legislated opioid prescribing rules that went into effect in December 2013. The rules changed how chronic pain is managed by healthcare providers. This qualitative study aims to evaluate the impact of Indiana's opioid prescription legislation on the patient experiences around pain management.

Setting This is a qualitative study using interviews of patient and primary care providers to obtain triangulated data sources. The patients were recruited from an integrated pain clinic to which chronic pain patients were referred from federally qualified health clinics (FQHCs). The primary care providers were recruited from the same FQHCs. The study used inductive, emergent thematic analysis.

Participants Nine patient participants and five primary care providers were included in the study.

Results Living with chronic pain is disruptive to patients' lives on multiple dimensions. The established pain management practices were disrupted by the change in prescription rules. Patient-provider relationships, which involve power dynamics and decision making, shifted significantly in parallel to the rule change.

Conclusions As a result of the changes in pain management practice, some patients experienced significant challenges. Further studies into the magnitude of this change are necessary. In addition, exploring methods for regulating prescribing while assuring adequate access to pain management is crucial.

BACKGROUND

The misuse and abuse of prescription opioids (POs) is an epidemic in the USA today. Since 1999, the rate of drug overdose deaths in the USA has doubled in 29 states, tripled in 10 states and quadrupled in 4 states, including the State of Indiana.¹ In 2013, physicians wrote over 200 million prescriptions for opioids, and over 2 million Americans suffered PO use disorders.² The societal costs of PO abuse, including lost productivity and increased utilisation of

Strengths and limitations of this study

- Strengths of the study include the features of its design including the qualitative interview of patient and healthcare providers, the triangulated data sources and data analysis, and the selection of patients from underserved patient populations.
- Sampling the providers from the same clinics provides support for the trustworthiness of the patients' accounts.
- The study captured in depth the experiences of patients post policy implementation.
- Limitations of the study include the smaller sample size.
- The study does not reflect the full spectrum of patient experiences post policy.

healthcare, were estimated at \$55.7 billion in 2007.³ Not surprisingly, there is growing evidence for a correlation between consumption levels of POs and measures of morbidity and mortality, including PO overdose-related deaths and admissions to substance use disorder treatment programme.⁴ According to the 2012 National Survey on Drug Use and Health, Indiana ranked third for non-medical PO use (NMPOU): an estimated 5.63% of its residents aged 12 years and older reported NMPOU in the prior year.⁵ In the same year, Indiana ranked ninth among US states for opioid prescribing, with a rate of 109.1 per 100 000 residents.⁶ In 2012, 999 Indiana residents died of drug overdose, an increase of 57% over the prior decade.⁷

Many states have implemented legislation to curb the use of POs resulting from inappropriate prescribing.⁸ Legislative strategies include oversight by prescription monitoring programme, the regulation of pain clinics and the establishment of PO dosage thresholds above which pain expert consultation is mandatory.⁸ Indiana legislated opioid

prescribing rules (Title 844 IAC Article 5, Rule 6) that went into effect on 15 December 2013.⁹ The new regulations, while not setting a ceiling on opioid prescribing, require physicians to (1) screen patients receiving POs for psychiatric conditions, (2) review patients' drug prescription history in Indiana's drug monitoring database (INSPECT), (3) perform regular drug tests and (4) require patients on POs to sign a controlled substance agreement.⁹

Studies evaluating state-level initiatives' impact on opioid prescription rates and related morbidity and mortality have indicated significantly lower PO prescribing but mixed evidence of a favourable impact on death by drug overdose.^{6 10} The new Indiana rules have been associated with a similar decrease in the volume of prescribed opioids; the impact of the policy, however, differs by gender, age and payer types.^{11 12} The impact was larger for men than for women, for younger rather than older patients and for Medicaid and Medicare patients when compared with patients with private insurance.¹³ The 'success' of state policies in curbing the overprescription of opioids, however, raises two concerns. First, the sharp decline in opioid prescription rates suggests the excessive application of prescription guidelines, which may consequently (and unintentionally) result in the under treatment of pain.¹⁴ Second, the varying rates of decline across subpopulations may be an indicator of disparity in an area of patient care that is already laden with disparities.^{11 12} Pain experts agree that individuals with a legitimate need for pain control should have access to adequate pain management.^{15 16} However, there is little consensus about how to restrict the overprescribing of opioids, which results in misuse and abuse, while simultaneously maintaining legitimate access to pain care.¹⁷ This delicate balance is further complicated by considerations such as the impact on patient satisfaction, patient empowerment or the patient-provider/prescriber relationship.

This paper's aim is to evaluate the impact of Indiana's opioid prescription legislation on the patient experiences with pain management. The study explores the rules' effect on decision making and satisfaction with the prescriber-patient partnership and presents patients' perspectives, which often go unheard. To enhance the trustworthiness of the findings and provide confirmation of the clinical practices that define patients' experiences, the triangulation of participants was used to supplement patient accounts of experienced pain with the healthcare providers account of experienced pain management. The actual experiences of patients will help deepen understanding of the implementation of the rules and may also provide insight into the patterns observed in previous quantitative studies.

METHODS

Setting

Patients were recruited from clinics in a safety net health system, which consists of a set of healthcare facilities that provide care to the indigent and underinsured patients.

Patients receiving care at these clinics have diverse racial backgrounds, and most are either Medicaid insured or underinsured. The selection of the site was based on the assumption that patients with a lower socioeconomic status are more likely to be negatively affected by the PO rules.

Sampling, eligibility and recruitment

Critical case sampling, a type of purposive sampling, was used to recruit participants. This sampling technique is particularly useful in exploratory qualitative research, as it permits logical generalisation and maximum application of results to other cases, that is, 'If this is true for this case, it is likely to be true of others.'¹⁸ Patients who have chronic pain were eligible for the study if they met all of the following criteria: (1) received pain treatment through the health system's integrative pain programme (IPP) after the December 2013 policy change, (2) had been on long-term opioid therapy for a chronic pain condition for at least 1 year prior to policy implementation and (3) were proficient in English. Primary care providers (PCPs) were eligible to participate if they had been practising at one of the clinics in the system for at least 1 year prior to the enactment of the Indiana rules. We recruited these PCPs via email. The interviewer (Al Achkar) has no previous relationship with any of the patient participants. Two of the provider participants have teaching privileges at the interviewer's institute. MacKie provides care and oversee the IPP. He also works in the same health system with the provider participants. One patient refused to participate for no given reason. One provider also refused to participate due to time constraints.

Interview instruments

We designed a semistructured interview with a set of core questions and follow-up probes that were informed by literature and consultation with and input from a pain management specialist (see online supplementary appendix 1). Both the provider and patient interviews started with explaining the purpose of the study. The patient interview addressed patient descriptions of pain, experiences of pain before and after the policy change, perceptions about the impacts of the new policy, patient-provider communications and relationships before and after the policy change, and satisfaction with treatment/management before and after the policy change. The provider interview focused on the experience of managing pain before and after the implementation of the rules, knowledge of the rules and satisfaction with practice. Interviews lasted between 30 and 45 min on average. Interviews were performed until saturation was reached. Saturation was determined after the initial discussions between the qualitative researchers as the data were collected. The interviewer is a PCP and residency educator with a position that emphasise providing effective, equitable and safe care to all patients.

Interview protocol

Interviews with patients were conducted by phone by Al Achkar between July and December 2015. We conducted interviews with providers in person except for one provider who completed the interview by phone. The in-person interviews were conducted at the participants' offices (three interviews) or at Al Achkar's office (one interview). All interviews were audiotaped, and participants received a \$50 gift card at the conclusion of the interview. No one was present during the interviews besides the participants and the researcher.

Analysis

Audiotapes were transcribed verbatim and imported into Dedoose, a web-based application for managing, integrating and analysing qualitative data.¹⁹ A member of the analytical team (Al Achkar) added descriptors to each transcript that included demographic information. Three team members (Al Achkar (male), Revere (female), Dennis (female)) participated in an inductive, emergent thematic analysis.^{18–20} Team members individually read transcripts several times and subsequently met to discuss initial impressions. The sections of the interviews that are focused on the patient and provider experience with pain and pain management were selected for in depth analysis. Thematic analysis involves taking the perspective of the interviewees in order to code the meanings of participant talk in an emic (or internally consistent) way. Al Achkar, Revere and Dennis read through the transcripts, talked through the meanings and articulated code names to indicate the

various interpretations. Then, relationships across the initial codes were developed through dialogue across researchers about the meanings. To enhance the rigour of the study, team members independently coded the data and then collaboratively reconciled the codes until a classification scheme was developed. Discrepancies were identified and resolved by consensus throughout the analysis. Excerpts from the transcripts of the participants and providers were selected to support the themes. This paper is the result of collaborative efforts and dialogues between researchers from different philosophical backgrounds. All the authors reviewed the manuscript and contributed to the background and discussion.

FINDINGS

Characteristics of the sample

Nine chronic pain patients (CPPs) and five PCPs participated in the study. [Table 1](#) describes the participants.

Themes and subthemes

As outlined in [table 2](#), three overarching themes with associated subthemes emerged across both CPP and PCP groups: (1) living with chronic pain is disruptive in multiple dimensions; (2) established pain management practices were disrupted by the change in prescription rules; and (3) patient–provider relationships, which involve power dynamics and decision making, shifted in parallel to the rule change. Detailed results for each theme are as follows.

Table 1 Study participant characteristics

| | Age | Gender | Location of chronic pain | Pain duration | Currently on opioids? |
|------------------|--------|-------------------|---------------------------------|---------------|-----------------------|
| Patients* | | | | | |
| HQ | 45 | F | Knee | 5 years | Y |
| SW | 42 | F | Neck, shoulder, back | | Y |
| LJ | 61 | F | Knee | 18 years | Y |
| GW | 43 | M | Shoulder, back | 12 years | N† |
| EM | 43 | M | Hip, back, neck | 12 years | Y |
| NC | 73 | F | Back, legs, arms, hands | 42 years | Y |
| RJ | 54 | F | Back, knees | 15 years | Y |
| IS | 58 | M | Neck, back | | Y |
| DJ | 63 | F | Neck, arm, back | 13 years | Y |
| | Gender | Specialty | % of patients with chronic pain | | |
| Doctors* | | | | | |
| Dr RC | M | Internal medicine | 20%–30% | | |
| Dr AM | M | Internal medicine | 30% | | |
| Dr NB | F | Internal medicine | 10% | | |
| Dr KS | M | Family medicine | 15% | | |
| Dr PY | M | Family medicine | 30%–50% | | |

*The letters represent the initials of the participants' given pseudonyms.

†This patient was on opioids in the past but was taken off opioids at the time of the interview.

| Table 2 Major themes and subthemes | |
|---|--|
| Major theme | Living with chronic pain is disruptive on multiple dimensions |
| Subthemes | <p>CPPs report a wide range of emotional responses associated with their pain experience</p> <p>Unmanaged chronic pain disrupts the relationships CPPs have with others</p> <p>CPPs experience ongoing challenges to their QOL</p> <p>POs can help with daily functioning but their effect is not persistent or long-lasting and have negative side effects</p> |
| Major theme | Established pain management protocols were disrupted by the change in in prescribing rules |
| Subthemes | <p>After the rules, patients experienced changes in medication regimen</p> <p>The multiple layers of 'vetting' were disruptive</p> <p>Lack of care coordination with requirement to see pain specialists and additional providers</p> |
| Major theme | Patient-provider relationships, with respect to dynamics, power and decision making, shifted in parallel to the rule change |
| Subthemes | <p>The rule change shifted power and privilege that disempowered patients</p> <p>Providers found the law effective in supporting their need to change pain management and lower prescriptions</p> <p>Patients perceive themselves as being objectified by providers</p> <p>The objectivity of the rule and accompanying testing changed the patient from a person in pain to a public health problem that needed to be objectively addressed</p> |
| | The law overshadows caring for patients |
| | Patients experienced disenfranchisement that adversely impacted their trust of their doctors |

CPP, chronic pain patient; PO, prescription opioid; QOL, quality of life.

Living with chronic pain is disruptive in multiple dimensions

Embedded within this central theme are three subthemes that include CPPs report a wide range of emotional responses associated with their pain experience; unmanaged chronic pain disrupts the relationships CPPs have with others; CPPs experience ongoing challenges to their quality of life (QOL); POs can help with daily functioning, but their effect is not persistent or long lasting and have negative side effects.

Most CPPs reported feelings of depression, anxiety, frustration and anger about their pain experience. Living with chronic pain has disrupted their lives, led to unemployment or underemployment, reduced their ability to engage in activities they formerly enjoyed and undermined their sense of autonomy and independence, despite receiving pain treatment and medication.

I've not gone to work and don't even go out. I don't go out with my husband. I don't go out with my daughter. I don't go out with anybody. (...) My life is pretty much at a standstill. (HQ)

I get irritable. (...) Sometimes I get more aggravated. (...) I get impatient a lot. A little sadness too. (IS)

(Pain) affects your relationships because it affects your attitude. (...) Sometimes, somebody might want to talk to you or whatever and you are in pain and you don't mean to be mean and rude or not responsive. (...) You just don't wanna move; you just wanna sit there because of how bad you hurt and that's not fair to the person that you are with. (EM)

I can't do the things that I used to do and it kind of makes you feel like you can't do anything. (...) You have to depend on people to do stuff for you because, like I said, I can't even walk from here to the bus stop. (MN)

...to have to ask for help (...) to use instruments just to put your clothes on, tie your shoes, pick something up off the floor or, you know, just the normal daily stuff that people take for granted. (RJ)

While POs provided some relief, they alone were not sufficient for managing pain and were frequently considered ineffective, particularly when adverse side effects were taken into account. However, the use of non-PO medications and approaches also varied in effectiveness.

(Pain medications) would give me the shakes, not visual but the way I talked. My speech would be a little slurred and I just didn't like the effect. (KD)

...after so long (pain medications) just seemed that they just didn't work; they were only making me tired (...) and the injections only lasted for 10, 15 min. By the time I made it to the car, it was over. (...) the injections, the medicated rub, pain relief rub, and Ibuprofen, Proxen, I've tried everything, you know? Cold packs for my knees and hot packs to my knee, you know, they only work for a small period of time. (HQ)

I try to put like a heating pad on (my knees) to kind of control it while I sleep and then it kind of feels a little better but soon as I take it off, I mean, if I get up and I'll just try to walk or try to move on it, it kind of starts back. (MN)

Established pain management practices were disrupted by the change in prescription rules

Three subthemes emerged regarding the impact of the rules on perceptions of providing and experiencing pain management by providers and patients, respectively. These include the following: after the rules, patients experienced changes in medication regimen; the multiple layers of 'vetting' were disruptive; lack of care coordination with requirement to see pain specialists and additional providers.

Patients mentioned changes in their medications or medication regimen, having to undergo new protocols such as needing to be 'vetted' for medications by frequent urine screens, having more frequent doctor appointments, being given lower pill allowances that necessitated more frequent refills and pharmacy visits, and needing to see multiple providers for pain management. Some patients were taken off prescribed opioids when their drug screen results were inconsistent. During office visits, patients underwent additional monitoring procedures, such as pill counting and urine drug screening, among others.

(The doctor) kept lowering the medicine every month, lowering it down. (...) I'm still going in pain. (NC)

I get drug tested about (every) 2 or 3 months. (...) I think it (the rules) made it more difficult for patients to get their medicines (...) it's hard to take off work to be able to go in every month or 2 months to the physician, whereas it used to be able to get refills every 3 to 4 months without having to go to the physician. (Now) it's usually every 6 weeks I see (the pain management) doctor. (IS)

PCPs also described the change in rules as impacting their approach to pain management, their prescription practices and both the frequency and focus of their appointments with CPPs. Providers had to reconcile their enforcement of the law with how to best treat patients with chronic pain. On occasion, the providers' practices were even more restrictive than the mandates of the rules themselves, especially with respect to setting a ceiling on prescribing.

I prescribe lower volumes of opiates and patients that were on higher (...) morphine equivalent doses previously, I brought it down to much lower levels. (The law) effectively set a ceiling on (...) how much, what volume of opiates I'd prescribe to a patient. (...) It's really made us formalise a lot of what we do in terms of (...) how frequently we see the patients. (...) We don't just tell them to

come every 3 months; we force them to come every 3 months. (Dr AM)

In addition to lower dosages, more strenuous monitoring activities and more frequent appointments and prescription refills, some patients were also required to attend chronic pain self-management classes or see allied health providers such as occupational therapists. For CPPs who were employed, these requirements placed an additional burden on their lives, which were already disrupted by chronic pain.

(The law) affects people like me (who are employed) because they won't give (opioids) to you unless, you know, you go (...) to the special clinic, the classes, to get them. Well, I knew that I couldn't get (medications) until I went to the classes. I had to go to the classes in the winter. I had to hop out and catch the bus and go out west to go to the (pain) clinic to see the doctor. (MN)

The new and stricter monitoring requirements led some PCPs to refer their CPPs to pain management specialists who became overwhelmed by the demand. In addition, some CPPs experienced confusion when their primary and specialty care were not well-coordinated.

...after the policy came in (the pain) clinic got saturated. (...) I think it might have been a little harder to get into physical therapy and even into anaesthesia too. (Dr NB)

My rheumatologist tells him not to change my medicine but he changes it anyway. (EM)

Patient-provider relationships, with respect to power dynamics and decision making, shifted in parallel to the rule change

Six subthemes related to a reversal or shift in power dynamics and patient centredness emerged from both CPP and PCP interviews. These include the following: the rule change shifted power and privilege that disempowered patients; providers found the law effective in supporting their need to change pain management and lower prescriptions; patients perceive themselves as being objectified by providers; the objectivity of the rule and accompanying testing changed the patient from a person in pain to a public health problem that needed to be objectively addressed; the law overshadows caring for patients; patients experienced disenfranchisement that adversely impacted their trust of their doctors. Providers were empowered by the law to change their pain management approach or to enforce changes they had struggled to implement prior to the rule change.

Personally, I was happy because I never really believed in heavy use of narcotics to begin with (...) so I was grateful that finally I didn't have to say it was me being the bad guy. (...) I could point to the laws and policy around this and use that kind of statement with the patients to say that, 'It's not that I don't want to give you these narcotics or more narcotics, we are

not allowed to and we must document any change or escalation because the law's requiring it.' (...) It felt like a scapegoat in some ways, but in a way it felt like support, so I actually used it to my advantage. (Dr NB)

(The law has) given me support in drawing lines with patients to not only say, 'No, I won't prescribe that to you because I don't think it's likely to help you.' Some patients will argue that point endlessly, but if you say, 'No, I won't prescribe that to you because it's not likely to help you and I'm not allowed to.' (Dr PY)

These are the rules. You know the rules. They're not my rules. Uh, this is the law and we can both agree that, you know, and those situations really practice in a way that's against the law. Hum, and so this makes it, it makes it more clear and objective and greatly reduces that kind of degree of emotional energy that was stressful prior to that. (Dr KS)

In fact, some PCPs viewed the law as improving their practice with respect to CPPs.

I think people that were really actively drug seeking before being effectively weeded or weaned out of the system. I think a lot of them are using heroin, but you know they're not coming to my clinic and yelling at me and yelling at my staff and threatening people. (Dr PY)

Parallel with the rule change, some patients experienced a change in their relationship with their PCPs, from one in which they perceived that their needs and struggles were being heard and acknowledged to a relationship in which the law dictated changes in medication and changes in the quality of the provider encounter. This changed the patient's relationship from one where they felt heard and involved in the treatment process to one in which they felt controlled and treated in a more objective manner.

They didn't really allow me to speak about anything or tell them anything: they just came in and looked at me real quick. (...) The thing is that the doctor just don't (...) want to listen to me about my pain. They just... it's like they thought that I was making it up or something just try to get the medicine. They made me feel like (...) I was an addict trying to get fixed. (IS)

The doctors... you know, have too much control of... of the patient's care. The patient and the doctor should be a team. (...) It seems to me that the patient should come first. Ah, ah, I mean, isn't that what, what the doctor, one of the doctor oaths? Didn't they take the oath to help their patient? (EM)

Indeed, PCPs acknowledged that the law created a firmer boundary between their patients and themselves, leading to less personal or less patient-centric encounters and relationships.

(The law) shapes the conversation with patients about facing an expectation and then requirements and, uhm, boundaries, and makes the interaction more objective. (Dr KS)

I'm managing them more appropriately even though they may be less satisfied. (Dr RC)

Some patients expressed feeling less as individuals and more as an abstract public health problem that instigated the rule change in the first place. CPPs expressed an inability to negotiate this dynamic. Patients often used a passive voice when describing this change, seeing themselves as witnesses to the changes happening to them.

I don't care about people overdosing. I don't care about people getting robbed on the street because I'm not the person that's doing that; the only thing that I care about is my health (and) my quality of life. (...) What does (the law) have to do with the person that's in front of (the doctor) in a wheelchair – they can't walk, they can't do this, they can't do that, but they're in pain but you're telling them that, 'Oh, we can't give you any pain medicine.' (EM)

(The new law) messes up people that don't use drugs and the ones that do use it, that's on them. I don't put nothing in my body that's not prescribed by a doctor. (MN)

Both patients and providers started to feel as if that the main focus of the patient–provider relationship is enforcing the legal requirements regarding pain management.

So I stopped allowing the escalation, even, you know, that I just did out of maybe sympathy instead of objective and I started de-escalating (...) a lot of people, because of the (...)risk of managing these individuals (or) having someone say that you're doing something. (It) made this more sensitive to even prescrib(ing) opioids. (Dr PY)

I was doing just fine (before the law change). Now I have to struggle, suffer, to make to the next time that I can get my medicine. And I don't think it's fair to me because if I can take my medicine a little more regularly, I would be able to do more and thought that we have a better effect in your life and I don't think that law, people, politicians, or anybody should be able to tell anybody that's in pain what type of medicine that they can take. (EM)

However, patients who felt cared for and listened to tended to trust their PCP, despite needing to comply with the rule change.

I really felt like (the pain management doctor) and all of the team, they really did help me; they really did. They really did and got me on the way to where I need to be. (HQ)

This highlights a division among CPPs: the shift in the power dynamic and decision making between patient and provider was seen as adversely impacting the patient–provider relationship depending on patient perceptions of trust and caring and changes in provider practices after the rules. Some CPPs viewed their providers as preferentially treating other patients, despite the law, while other CPPs expressed anger and extreme dissatisfaction with treatment to the extent that they planned to change providers.

I know some women that smoke pot and do other drugs and he's prescribing them pain meds and giving them drugs and not treating the women like he does the men. I just think that he is playing favouritism towards the women. (...) (In fact) I don't care to see that doctor right now, am in the process now of trying to find another doctor. (VN)

(My doctor is) the coldest person you have ever seen in your life. (...) He don't care. I come at him crying... I can't stand the bastard. I will tell him what shape I am in and he just ignore it. (...) (As a) matter of fact, I signed up for another doctor; they don't know it yet but I signed up with another doctor. (NC)

In summary, a range of perceptions and experiences associated with the PO law change were described as creating barriers to effective pain management, both self-management by CPPs and pain management practices by PCPs.

DISCUSSION

Chronic pain is a complex, subjective phenomenon that is, our study confirms, disruptive to a person's day-to-day experiences and can greatly reduce QOL. We found that in subjective matters like pain, the patient's personal narrative is critical for healthcare providers who are designing and providing an effective pain management plan; however, the Indiana PO law change disrupted established pain management practices as well as shifted the power dynamics and decision-making relationship that are built on these shared narratives between providers and their patients.

A number of factors were described by patients as hindering their perception of 'being heard' regarding their pain experiences, particularly the mandate to use objective measurements of pain levels and ancillary experiences, such as surveys to screen for other health conditions and urine drug screening. While these measures can support understanding, collaboration and shared decision making in the context of the new PO rules, relying on these 'objective' scales are perceived by patients as diminishing their providers' ability to truly understand their pain. Patients viewed these tools as creating or increasing barriers to effective pain management, by increasing the frequency of these office visits, reframing the pain experience in an 'objectifying' way and, overall,

diminishing empowerment in regard to patient autonomy and decision-making.

In response to the opioid use crisis that stemmed partially from lax use of PO, the Indiana prescribing rules were developed to regulate prescribing and to foster a more biopsychosocial approach to pain management by increasing the contextual understanding of individuals and their unique experiences of pain, suffering and expectations.⁹ However, the providers' practices and patient experiences suggest that the new rules have over-empowered doctors to leverage the force of the law while transforming patient pain management into an administrative task. Some patients feel more marginalised as they are being denied medications and receiving impersonal care that fails to address their needs while focusing on the public health opioid epidemic—an epidemic they believe they have no part in.

Because patients perceive a disruption in the focus and goals of treatment, they are left feeling unheard, disempowered and even cheated. Many patients now endure additional struggles to obtain access to pain management and must adhere to requirements—in some circumstances, such as the urine drug testing, not paid for by some insurers, which add financial burden to both clinics and patients—to demonstrate their compliance with the demands of healthcare providers and the law. For some patients, such barriers are insurmountable; consequently, they seek care from different providers who might be more sympathetic or less rigid regarding clinical oversight.

In addition to disrupting prior pain management practices and shifting patient centredness priorities, we found that the concept of effective pain management is perceived by providers and many patients as an 'unwinnable fight' due to the complexity of subjectively experienced pain, the myriad conditions that lead to chronic pain, suboptimal effects achieved by most treatments and the risk of harm inherent in some treatment options. Opioids lack evidence for long-term effectiveness and can be detrimental to individuals and society as a whole when they are used excessively, abused or diverted. Thus, the decision to prescribe opioids can be difficult.

However, the findings presented here should not be understood or employed to reject or revise a law arbitrarily. Beyond the benefits that have already been reported about decreasing drug abuse and mortality,^{10 21} new legislation may be playing a role in bringing pain to the forefront of the doctor/patient interaction. Our findings invite the reader to reflect on the opioid prescription rules and their implementation in practice. Pain cannot be reduced exclusively to numbers, and a patient's experience cannot be fully characterised with surveys, even if such measures assess depression, anxiety and risk of abuse. This study attempts to add to the dialogue about how patient care can be centred on the patient while still providing safe and effective care and shared decision making between patients and providers. Furthermore, the study provides evidence to support the national initiatives and patient-led organisations that aim to give

patients a stronger voice in the discussion around healthcare reforms and to empower them in their day-to-day encounters with healthcare providers.

While this study gave voice to patients and presented providers' perspectives to validate their stories, it has limitations. First, the critical sampling of 14 participants may have highlighted certain aspects of patients' and providers' experiences while obscuring others. However, it can be argued that selecting patients from safety net clinics where the majority were either under-insured or uninsured gave voice to more vulnerable and often under-represented patients. Second, while the study presented perspectives of patients and providers, no attempt was made to correlate findings between the two groups or conduct cross-confirmatory analysis. Nonetheless, by sampling from the same clinic, it is likely that the two groups together represent a shared experience within the culture and space of the clinic. Moreover, to the best of the authors' knowledge, this study is the first to capture patient-provider experiences post policy. Finally, this work provides a foundation for much-needed future quantitative research studying the experiences of a broader patient population. Doing so would provide practitioners and researchers with a more comprehensive assessment of the opioid prescribing rules.

Contributors MAA, DR, BD, SG, SG and PM contributed to the literature review and the conceptualisation of the work. MAA conducted the phone and in-person interviews. MAA, DR and BD conducted the primary analysis of the data. MAA, DR, BD, SG, SG and PM contributed to the writing of the discussion. All the authors reviewed and approved the final version of the study.

Competing interests None declared.

Ethics approval The Indiana University Institutional Review Board approved the study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data available.

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