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Perceptions of patient provider agreements

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Abstract

Objectives—Use of patient provider agreements (PPAs) is increasing, yet there is limited evidence on the effectiveness of PPAs to prevent prescription opioid misuse and diversion, and few guidelines for providers. We conducted eight focus groups to understand patient and prescriber perceptions of PPAs.

Methods—We recruited 40 patients who had been asked to sign a PPA and 40 prescribers who had administered at least one PPA. We developed topic guides for the two groups based on prior literature. Focus groups were audio-recorded and transcribed verbatim. Two investigators independently performed the content analysis of the transcripts and reached consensus on recurring themes.

Key findings—PPA use varied according to physician specialty. General practitioners used PPAs the least but reported increasing pressure from liability insurers to use them. Many patients reported signing a PPA in the emergency room of a hospital. Prescribers and patients reported a lack of understanding among patients concerning the purpose and content of the PPA. Prescribers questioned the legal status of the PPA, while patients believed that the PPA was a legal document intended to protect prescribers. Patients and prescribers valued PPA content items differently, although both groups agreed that signing a PPA would not prevent opioid misuse.

Conclusions—We identified several themes concerning the administration, content, effectiveness and utility of PPAs that highlight areas of research to improve PPAs. We also describe trends requiring further investigation. Understanding content of importance to patients will facilitate the development of a patient-centred PPA.

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Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

Authors' contributions

JA drafted topic guides, conducted focus groups, analyzed data, drafted manuscript and approved the final manuscript. BK conducted focus groups, analyzed data, and approved the final manuscript. MC and JP drafted topic guides, conducted focus groups, analyzed data, and approved the final manuscript. FP, IH, and FP designed study, drafted topic guides, conducted focus groups, and approved the final manuscript. All Authors state that they had complete access to the study data that support the publication.

Keywords

focus group; opioid contract; opioids; patient provider agreement

Introduction

There has been an explosion in the use of opioid analgesics in the USA over the past decade. Prescriptions for opioid analgesics dispensed by retail pharmacies increased 48% from 2000 to 2009, and the milligram per person use of prescription opioids increased 402%.^[1,2] Opioids can cause serious adverse events, and as a consequence of greater access, increases in emergency department visits and drug overdose deaths due to opioids have been reported.^[1,3–5] To increase patient safety and education, and reduce adverse events, evidence based guidelines for safe prescribing of opioids, including patient prescriber agreements (PPAs), have been developed.^[6,7] Many organizations, including the American Pain Society, American Society of Addiction Medicine and British Pain Society, encourage their members to use PPAs when prescribing opioids for chronic pain relief to help prevent misuse and diversion.

A PPA, also called a patient prescriber contract, opioid contract or opioid agreement, is a formal, written agreement between a patient and healthcare provider that details the responsibility of each participant during therapy with controlled substances, typically opioid analgesics. The purpose of the PPA is to improve the quality of patient care and reduce the potential for misuse and diversion of opioid analgesics.^[8] PPAs vary in content, but most detail patient responsibilities concerning improper use of controlled substances, refills, drug testing, one prescriber/one pharmacy rule and consequences of noncompliance with the PPA.^[8,9] Although use of PPAs is increasing, there is limited evidence on the effectiveness of PPAs to prevent misuse.^[7] A 2010 systematic review examining the effectiveness of PPAs to reduce opioid misuse concluded that among 11 studies meeting inclusion criteria for the review, there was only weak evidence of effectiveness.^[10] However, the authors noted several limitations of the studies in the review, including multicomponent interventions and poor outcome definitions.^[10]

In addition to lack of evidence of effectiveness, criticisms of PPAs include: use of language that is poorly understood by patients or has an adversarial or intimidating tone; use of the word ‘contract’ which has legal implications; and potential breach of trust of the patient–physician relationship.^[10,11] Efforts to improve PPAs and to prevent opioid misuse require both patient and prescriber input. The objective of this study was to improve our understanding of patient and prescriber perceptions of the administration, content and effectiveness of PPAs using focus group methodology.

Methods

We conducted eight focus groups from July 16 to 24, 2013 to collect information on patient and prescriber experiences with and perceptions of PPAs. Focus groups are group discussions organized to explore a specific set of issues.^[12–14] They produce information on participants’ experiences and perceptions and rely on interaction between group members.

Focus groups are not intended to provide quantitative data or generate results that are generalizable to a broader population.^[12–14]

We contracted with a private marketing research firm to recruit focus group participants from an opt-in proprietary database consisting of over 4000 providers and 4500 patients in the Baltimore–Washington, DC metropolitan area. The marketing research firm requested that patients treated for pain by a doctor and prescribers who had treated patients for pain call in to be screened for participation in a study. Flyers and social media were also used to recruit study participants.

Patients were asked if they had ever been treated for pain with an opioid (examples of opioid medications were given). If so, the patient was asked if they had been asked to sign a document with any of seven possible components of a PPA (e.g. education, drug testing, one physician/one pharmacy). If the patient answered affirmatively, they were invited to participate in the focus group study and offered a monetary incentive of \$125. Patients were asked their sex and age, but no other demographic or clinical information was collected. No attempt was made to determine the context in which the patient was asked to sign a PPA.

Providers were asked whether they had ever treated a patient's pain with an opioid medication, and if so, if the patient had been requested to sign a document with any of seven possible components of a PPA (e.g. education, drug testing, one physician/one pharmacy). If the provider answered affirmatively, they were invited to participate in the focus group study and offered a monetary incentive of \$375. Providers were asked to provide their specialty and years in practice.

Consistent with accepted methodology regarding number, size and duration of sessions, the 90-minute focus groups were conducted separately for patients and prescribers, with 10 participants in each of the four patient and four prescriber groups.^[12–14]

Based on prior literature, we developed a topic guide to explore patients' experience with and perception of the administration, content and effectiveness of PPAs (Table 1).^[8,11,15–18] Similarly, topic guides for prescribers contained questions on administration, content, effectiveness and utility of PPAs (Table 2).

One moderator and one co-moderator conducted the focus groups. The co-moderator took note of all non-verbal cues (e.g. head nodding, frowning). Focus groups were audio-recorded and subsequently transcribed verbatim by a professional transcribing company. Two investigators (J.S.A and B.K.) separately performed the content analysis of the transcripts and reached consensus on recurring themes. The investigators compared findings and agreed on inclusion of recurrent themes into the final report.^[12,19] This study was approved by the Institutional Review Board of the University of Maryland, Baltimore and all participants provided written informed consent.

Results

Study participants

Patient focus groups were 50% female with an average age of 42 years. Most participants were asked to sign a PPA during an emergency room visit or pre-surgery. Only a few participants had chronic pain and were administered a PPA by their primary care physician or a pain specialist. Prescriber focus groups consisted of internists/primary care physicians (50%), pain specialists (28%) and other specialists (22%) who utilized PPAs for opioid prescriptions in practice or post-surgery. Average time in practice was 19 years.

Administration of PPAs

PPA utilization varied according to physician specialty. Pain specialists were the most familiar with PPAs and had been using them the longest. The pain specialists required a PPA for all patients on opioids, whereas usage among general practitioners varied greatly according to practice policy and subjective assessment. One general practitioner noted, '(using PPAs is) more of a case by case . . . sometimes just an oral agreement', while another stated, '(I use a PPA) when I anticipate that the patients is going to be on opioids more than a month'. Some prescribers chose to 'renew' the PPA on a quarterly or annual basis, while others never renewed the PPA. Many general practitioners reported using a PPA when they suspected prescription opioid misuse or for chronic (i.e. greater than 3 months) usage while others cited general practice policy. General practitioners also noted using PPAs for other drug classes, including stimulants, or for all controlled substances, and reported increasing pressure from professional liability insurance companies and review boards to utilize PPAs when prescribing opioids, or to refer chronic pain patients to a specialist. One general practitioner explained, 'The mutual (i.e. insurance company) tells us (primary care doctors) to be very careful about prescribing narcotics, so I'm very careful'.

Most general practitioners agreed that they would not use a PPA for an episode of acute pain requiring a single prescription of opioids. In contrast, many participants of the patient focus groups reported signing a PPA in the emergency department prior to receiving opioid medications, even when the opioid medication had no refills. In many of these cases, the patient was in great pain when they were asked to sign the PPA. As one patient noted, 'I was in so much pain, I'd sign anything.'

Patients reported a lack of understanding of both the need for and the contents of the PPA. Many reported that the PPA was handed to them along with paperwork containing privacy ('I thought it was an extension of the HIPAA form') or consent to treat documentation and was not well explained. If the PPA was explained, it was often by a nurse or physician's assistant, rather than the prescriber. Patients who were asked to sign a PPA during an emergency department visit were less likely to have understood the PPA and more likely to report that they had no choice but to sign the PPA. One patient noted, 'They throw a bunch of papers at you and you just sign. They don't really explain it.' Patients reported greater understanding if the PPA was presented to them at an office visit or if they were given forms in advance of an office visit or surgery. Patients cited the length, font size and medical jargon used in the PPA as barriers to understanding, but noted that their understanding could be

improved if the PPA was well explained by a nurse or doctor. Prescribers also expressed concerns about patient comprehension of PPAs and accountability for its contents, particularly among the cognitively impaired or those with low health literacy. One general practitioner asked, 'Who is responsible if there is a problem with (a cognitively impaired person's) medicine?'

Content of PPAs

Patients and prescribers agreed about the importance of many content items of a PPA. However, patients were more concerned about the impact opioids would have on their health, activities and employment while prescribers were more concerned about preventing diversion and potential misuse. Although many patients expressed the opinion that the 'PPA is to protect the doctors', they still felt that the PPA should contain information important to them. In particular, patients wanted information about side and long-term effects, drug interactions, privacy of drug testing, alternatives to opioids, addiction potential, percentage of those who become addicted and where to obtain addiction counselling if needed. Patients expressed concerns about the one pharmacy rule, 'Sometimes the pharmacy doesn't have the medication and you've got no choice but to go to another', and the early refill rule, 'We were going on vacation, and (asking for an early refill) made me feel like a drug user or something.' Patients also didn't understand the need for urine testing, 'I don't understand why they have to drug test you if you are taking the medicine'. In contrast, prescribers focused on accountability, drug testing and refill rules. Few prescribers mentioned side effects, drug interactions and addiction counselling as important PPA components. No prescriber mentioned the privacy of the PPA although this was brought up by several patients.

Utility of PPAs

Prescribers reported misunderstanding among patients concerning the meaning of the PPA. Some felt that patients misconstrued the PPA to mean that the prescriber agreed to prescribe opioid medication as long as the PPA was signed. This was confirmed by several patients who reported that signing the PPA meant they would get their pain treated. Many patients also indicated that the prescriber bore the majority of responsibility concerning the PPA. Both patients and prescribers questioned the legality of the PPA, although patients were more likely to believe that it was a 'legal document' that they had to sign while prescribers were unsure of its legality. 'It's not a legal document', said one general practitioner. Nonetheless, prescribers were likely to endorse the PPA as providing legal protection in cases of a PPA violation. One noted, '(with a signed PPA) I can't be accused of abandonment if I discharge a patient from the practice.'

Patients and prescribers agreed that the PPA highlighted the seriousness of opioid medication and set expectations for behavior. Prescribers suggested that the PPA shows the patient that 'someone cares and is going to help' while empowering them to take responsibility for their pain management. Nonetheless, both patients and prescribers reported that the PPA is time consuming to administer and to comply with due to increased office visits and drug testing for some patients. One general practitioner stated, 'If they have objections or questions, it becomes a 15 or 20 min ordeal that takes time away from other

patients who are waiting.’ Physicians also expressed concern about the increased financial burden to patients due to more office visits and drug testing.

Effectiveness of PPAs

The effectiveness of the PPA in preventing opioid misuse was questioned by both patients and prescribers. Both groups stated that patients who wanted to misuse opioids would do so regardless. One patient declared, ‘All the warnings and threats – it didn’t mean anything to me. It wasn’t going to stop me from doing what I want to do anyway.’ Prescribers suggested that the PPA could be a good screening tool to identify patients who were trying to obtain opioids for diversion or misuse. Prescribers also stated that PPAs are most effective when used with new patients, patients with addiction disorders and after the first PPA violation. Some prescribers suggested that the efficacy of the PPA lies primarily in its use as an educational tool for patients rather than as a punitive measure: ‘A lot of people have no ill intent and they don’t actually know that certain behaviors are dangerous.’

General practitioners were more likely to report discomfort in using a PPA, particularly among long-term patients among whom the PPA was perceived as indicating a lack of trust. One physician reported, ‘A lot of times that will cause rupture in the relationship.’ They also noted that the PPA was least effective among these patients. In contrast, pain specialists were more likely to report that the PPA improved the physician–patient relationship because it provided a platform for discussion and education while reassuring the patient that they would be helped. One pain specialist noted, ‘(PPAs) provide a valid and safe mechanism for prescribing medication for valid reasons.’

Discussion

We identified several issues surrounding the administration, content, effectiveness and utility of PPAs that suggest areas for future research to improve PPAs. They center on recommendations for use, patient centered design of PPAs and burden of compliance on patients and prescribers.

The scenarios in which a PPA might be used varied, highlighting a lack of guidelines or recommendations for prescribers concerning the administration of PPAs. Patient experiences with PPAs in the emergency department are of particular concern because signing a PPA under duress does not facilitate patient understanding. While providing informed consent may be one objective of PPAs, the ethics of asking a person in pain to sign a PPA are questionable.^[8,14] Increased awareness about the consequences of opioid misuse may have expanded the situations in which a patient is asked to sign a PPA. Nonetheless, use of a PPA in the emergency department when no patient follow-up is expected is inappropriate.

Prescribers, especially general practitioners, had many questions about PPA administration, content and legality. There were concerns about compliance with regulations: ‘I don’t run (urine) tests probably as often as I should’; ‘We all want to be compliant. The question is, what’s compliance?’ Several expressed the thought that ‘It would just be nice to have a reference out there (on PPAs) that the CDC or the FDA puts out.’ Some also expressed a desire for a ‘standard or blanket’ PPA. Although many organizations do publish guidelines

concerning the use of PPAs when prescribing opioids, these guidelines do not appear to be widely disseminated and do not address some of the specific questions that prescribers have. Clinical guidelines on chronic opioid therapy from the American Pain Society and the American Academy of Pain Medicine suggest that physicians can consider use of PPAs, but give very little detail about specifics of usage.^[6] The American Society of Interventional Pain Physicians also recommends PPA use (fair level of evidence) but does not provide many details.^[7]

Many prescribers thought that PPAs would soon be standard practice. General practitioners reported increasing pressure from insurers and payers to utilize PPAs when prescribing opioid analgesics. These prescribers have questions that would best be answered by a set of clear recommendations on PPA utilization.

An important goal of the PPA is to reduce opioid misuse and diversion by establishing a set of rules that the patient must follow.^[7] However, focusing on issues of importance to the patient could make the PPA more meaningful and increase the perception that it is an agreement between two parties.^[11,15] Patients would like information on side effects, drug interactions, addiction potential, privacy of the PPA and drug testing. However, a recent analysis of 41 PPAs from 18 states reported that while 98% of the PPAs stipulated the one doctor rule, only 83% contained information on adverse/side effects, 53% contained information about goals of treatment and 34% contained information on drug–alcohol or drug–drug interactions.^[16]

Based on results from these focus groups, suggested content areas for a PPA are physical health (side effects, drug interaction, dosing), mental health (alternative pain control, addiction) and community health (preventing diversion). Furthermore, PPAs should be streamlined and written as simply as possible, possibly with the addition of pictograph to aid understanding for those with poor health literacy.^[17]

Complying with the PPA is a time burden for both prescribers and patients. Several physicians reported that it can take more than ten minutes to explain a PPA and answer questions. For a general practitioner, that valuable time could be spent discussing the patient's health problems. This role could be shifted to a nurse or pharmacist. Many patients reported that a nurse explained the PPA to them. For patients, increased frequency of office visits and drug testing translates into more time and expense. Given the current state of evidence on the effectiveness of PPAs to reduce misuse and diversion of opioids, consideration should be given to reducing some of the more burdensome aspects of the PPA.^[10,15]

There was a dichotomy between the patients and prescribers who participated in these focus groups. Most patients had signed a PPA in the emergency department or pre-surgery, while prescribers used PPAs in private practice. This lack of conformity is likely due to inclusion of patients who were not chronic pain patients and possibly our method of recruitment (the opt-in database). Nonetheless, the objective of the focus groups was to explore all patient experiences and perceptions of PPAs, not only those of chronic pain patients. Furthermore, the composition of the patient groups may indicate that more patients are being asked to sign

PPAs in the emergency department and could signify changes at the institutional level with hospitals requiring PPAs with any prescription of opioids. Further research is needed to determine if this is the case.

Results from this study should be interpreted cautiously. Focus groups provide insight on the perceptions, attitudes and beliefs of participants but do not provide generalizable quantitative results. Therefore, the attitudes and perceptions described in this report do not represent those of all patients or prescribers. On the other hand, these results provide information on actual scenarios that patients and prescribers have experienced.

Conclusions

This study provides new information on utilization and perceptions of PPAs that can help guide future research. In particular, understanding what content is important to patients will facilitate the development of a patient-centred PPA. We also describe trends requiring further investigation: the increasing pressure to use PPAs described by general practitioners, especially given the level of evidence concerning effectiveness and use of PPAs in the emergency room. While beyond the scope of this study, establishing the effectiveness of PPAs in preventing diversion and misuse should be a focus of future research before PPAs become standard practice.

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Table 1

Topic guide for patient focus group interviews

Administration	(1) Had you ever heard of a patient prescriber agreement before you were asked to sign one?
	i. PROBES: If yes, what did you know about them?
	ii. Where did you get this information?
	iii. How do you feel about such agreements?
	(2) How was the patient prescriber agreement presented to you?
	i. PROBE: By whom?
	(3) What did you think of the patient prescriber agreement when it was presented to you?
	i. PROBES: Was it explained to you well?
	ii. By whom?
	iii. Did you feel that you had a choice about signing it?
Content	(4) What influenced your decision to sign/not sign the patient prescriber agreement?
	i. PROBE: Did the patient–physician relationship change because of your decision?
	(5) For those who did not sign a patient prescriber agreement, what happened?
	i. PROBE: did you go to another doctor?
	ii. Receive different medication?
	(6) For those who signed a patient prescriber agreement, what did you do if you needed an early refill?
	i. PROBE: Did you have any problems asking your prescriber for one?
	(7) In your opinion, who should administer the patient prescriber agreement?
	(8) How well do you think you understood the patient prescriber agreement when it was presented to you?
	i. PROBES: What specific areas of the patient prescriber agreement were not clear?
Effectiveness	(9) Did you have an opportunity to ask questions at the time you were asked to sign the patient prescriber agreement?
	i. PROBES: What questions did you have?
	ii. How were your questions answered?
	(10) What elements of the patient prescriber agreement were you most concerned about?
	(11) In your opinion, what is the most important information that should be in a patient prescriber agreement?
	(12) What are some of the good things about signing a patient prescriber agreement?
	i. PROBES: understanding risks of medication
	ii. Pain adequately treated
	iii. Feeling that doctor is ‘looking out for me?’
	(13) What are some of the bad things about signing a patient prescriber agreement?
	i. PROBES: drug testing
	ii. Reluctance to ask for more medicine if needed
	(14) Do you feel that your choice to sign/not sign the patient prescriber agreement resulted in adequate control of your pain?
	i. PROBE: first, for those who signed

ii. Now for those who did not sign

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Table 2

Topic guide for prescriber focus group interviews

Administration	<ol style="list-style-type: none"> 1. How are patient prescriber agreements used in your practice? <ol style="list-style-type: none"> i. PROBES: For all opioid patients? ii. Who administers a patient prescriber agreement? iii. Do you use a standardized template? 2. What kind of issues do you encounter with patients who have signed a patient prescriber agreement? <ol style="list-style-type: none"> i. PROBES: need early refills, refuses drug testing ii. Enforcement of patient prescriber agreements iii. Discharging a patient from your practice
Perceived utility	<ol style="list-style-type: none"> 3. In your opinion, what are some of the benefits of patient prescriber agreements? <ol style="list-style-type: none"> i. PROBES: to patients? ii. To providers? 4. In your opinion, what are some of the drawbacks of patient prescriber agreements? <ol style="list-style-type: none"> i. PROBES: to patients? ii. To providers? 5. What are your patients' main concerns about patient prescriber agreements? 6. What other concerns do you have about patient prescriber agreements?
Content	<ol style="list-style-type: none"> 7. In your opinion, what are the most important elements of a patient prescriber agreement? 8. In your opinion, what are the least important elements of a patient prescriber agreement?
Perceived effectiveness	<ol style="list-style-type: none"> 9. When do you feel patient prescriber agreements are more effective? 10. When do you feel patient prescriber agreements are less effective? 11. How has your use of patient prescriber agreements affected the patient–provider relationship? 12. How does signing a patient prescriber agreement affect patient's pain control or drug therapy management? 13. How does not signing a patient prescriber agreement affect patient's pain control or drug therapy management?