

Tools for Community-Based Pharmacist Patient Care Services to Support Optimal Opioid Use

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Introduction

Current opioid use challenges and the subsequent Centers for Disease Control and Prevention (CDC) “Guidelines for Prescribing Opioids for Chronic Pain” have tremendously influenced the trajectory of pain management. While focused on primary care providers, the guidelines specifically acknowledge the need for interprofessional, integrative care involving collaboration amongst pain management clinicians, behavioral health specialists, and pharmacists to optimize opioid use.⁽¹⁾ However, aside from looking for “red flags” in filling prescriptions, specific guidance to direct widespread pharmacist involvement is lacking. There is also currently limited data and information on how pharmacists can best aid in this public health issue. In this commentary, we describe tools and practices used in pain management and provide suggestions for incorporation into community pharmacy practice to enable pharmacists to contribute to optimal opioid use.

Opioid Agreement

Opioid agreements are documents outlining patient and prescriber roles and responsibilities during chronic opioid therapy. The three main purposes of agreements include establishing mutual agreement on safe treatment practices, improving adherence, and preventing diversion/misuse. Major pain associations and other government agency initiatives recommend their use,^(2,3) though the effectiveness of agreement use has not been fully established. Pharmacists can apply principles found in agreements to outline patient relationships, solidify expectations of their role in patient care, and prevent future issues.

Agreements are often divided into two components: terms of treatment and violation.⁽⁴⁾ Under the terms of treatment, expectations of the treatment and of the patient are described. Treatment expectations often include comprehensive patient education (eg, indications, side effects, risks for opioid abuse disorder, withdrawal symptoms, storage requirements, and disposal methods) aligning with a pharmacist’s duty to counsel. Expectations of patients are typically outlined to describe appropriate patient behavior and/or conditions required for continuation of care, such as the use of one prescriber and one pharmacy to obtain opioids, following appointment policies, and sharing relevant health information (i.e. emergency department/urgent care visits or initiation of new medications). Informed consent for screening (i.e. urine drug testing) and acknowledgement of the terms of treatment often appear here. Pharmacists can utilize terms of treatment elements to establish the need for authentic communication and avoidance of unacceptable actions, such as early refill requests or use of multiple prescribers/pharmacies.

Terms of violation define the conditions for termination of care. Termination of care may be for nondisciplinary or disciplinary reasons. Nondisciplinary termination reasons include lack of improvement, rapid development of tolerance, onset of intolerable adverse effects, or other clinical reasons determined by the prescriber. Disciplinary termination instances may result from patient failure of urine drug screens (i.e. testing positive for illicit drug use or nonprescribed controlled substances) and evidence of “doctor or pharmacy shopping.” These agreements allow pharmacists to describe the terms of violation when refusing to dispense; contribute information to prescribers to aid in their decision-making; offer alternative options for treatment; and engage with the patient in a discussion regarding their opioid use, misuse, or abuse. Table 1 summarizes the components of an opioid agreement and provides links to examples of publicly available opioid agreements. These agreements were designed for use by prescribers; however, they can be adapted as discussed above to fit the role of the pharmacist in caring for patients with pain.

Benefits of the use of opioid agreements can be overshadowed when perceived poorly by patients and prescribers (i.e. as a symbol of distrust and/or loss of autonomy) due its legal tone and regulatory nature. The potential to erode patient-prescriber relationships necessitates a delicate balance between reinforcing the terms of agreement and openly communicating the purpose and benefits of any principles adopted into practice. The primary goal of an opioid agreement is to foster and maintain trust between all involved health care parties.

Prescription Drug Monitoring Programs (PDMPs)

PDMPs are state-run, electronic databases used to track the prescribing and dispensing of controlled prescription drugs.⁽⁵⁾ PDMPs are intended for monitoring for suspected misuse or diversion, and helping prescribers and pharmacists identify high-risk patients who can benefit from early intervention. The National Alliance for Model State Drug Laws (NAMSL) compiles detailed accounts of differences amongst each state-run PDMP.^(6,7) Areas of differentiation between PDMPs include the substances monitored, data collection interval, agency responsible for PDMP administration, types of authorized recipients, data confidentiality, and mandated use. Currently all 50 states have an operational PDMP system, with 34 states requiring reporting of schedules II-V and 16 requiring reporting of schedules II-IV. Several states also require the reporting of noncontrolled substances that have been found to have abuse potential, such as gabapentin. The required time of reporting also varies from one to eight days depending on the state, with the majority of states requiring reporting

within one business day. However, all PDMPs collect: drug dispensed, quantity of drug dispensed, intended day supply, date dispensed, prescriber and pharmacy identifiers, and patient identifiers.⁽⁶⁾

In California, the PDMP is known as Controlled Substance Utilization Review and Evaluation System (CURES) and requires weekly reporting of schedules II-IV. Effective October 2, 2018, providers are mandated to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II-IV controlled substance for the first time and every four months with ongoing care. Currently there is no mandate for CURES consultation for dispensing pharmacists.

The use of PDMP data as a key public health and safety tool to address prescription drug abuse is steadily increasing. In Ohio, a 2010 study of PDMP use in an emergency room found that prescribers changed their clinical management approach in 41% of cases from original plans (61% of patients received fewer or no opioids; 39% of patients received more opioids because the prescriber could confirm absence of patients' recent history of controlled substance abuse).⁽⁹⁾ Intuitively, increased pharmacist PDMP utilization could reduce doctor shopping and complement other efforts to curb suspected abuse or diversion. Though routine pharmacist PDMP monitoring can feel like another burdensome, nonclinical task, successful incorporation into the workflow can enhance clinical activity related to use and safety of medications subject to abuse and diversion.

Opioid Treatment Risk Assessment Screening

Individualizing pain assessment and risk associated with chronic opioid therapy is an important aspect of pain medicine. There are a multitude of tools available for assessing patients' risk of developing problems, such as addiction or misuse on long-term opioid therapy. However, no single tool has been universally validated or accepted. Most tools are questionnaires completed by the patient and scored by the provider to determine level of risk associated with chronic opioid treatment. The Screener and Opioid Assessment for Patients with Pain (SOAPP) comes in various lengths and assesses risk potential for aberrant medication-related behaviors among chronic pain patients requiring opioids.⁽¹⁰⁾ The Opioid Risk Tool (ORT) collects age, family, and personal history of substance abuse, history of preadolescent sexual abuse, and psychological disease. When these screening tools are used along with other assessments, such as patient interview, urine drug screen, PDMP, they can offer providers vital patient risk information. Patient risk information can be used as a platform for conversation regarding chronic opioid use or can be used to identify patients who would benefit from frequent monitoring (i.e. PDMP or urine drug screening).

Pharmacogenomic Testing

The variable patient responses to medications due to genetic differences in drug metabolism presents treatment challenges as prescribers rely upon empiric treatment principles when initiating or rotating opioids when therapy failure or intolerability surfaces. Pharmacogenomic testing provides objective information to enable prescribers to individualize treatment by choosing medications that can illicit an optimal response and avoid medications posing higher risk. Additionally, markers that can indicate a patient's risk for opioid addiction,⁽¹¹⁾ opioid sensitivity,⁽¹²⁾ or level of sensitivity to pain⁽¹³⁾ have been identified for test inc-

lusion. Lastly, pharmacogenomic testing can lead to an overall decrease in health care costs (i.e. decreasing number of adverse drug reactions or failed drug trials).⁽¹⁴⁾

Most samples for pharmacogenomic testing can be conveniently collected in a pharmacy setting by performing a simple buccal swab. However, the cost of testing and lack of reimbursement for the service limits implementation. Some pharmacists partner with genetic testing companies for service implementation. The company benefits from data needed to show improved clinical outcomes through the use of testing, and pharmacists provide a valuable clinical service to patients visiting the pharmacy. For widespread access to clinical services, sustainable payment models to support these potentially valuable pharmacist-delivered patient care services are needed.

Urine Drug Screening (UDS)

Several guidelines address the potential utility of UDS for chronic opioid therapy and caution that the UDS results alone cannot guide pain treatment.^(3,15) Prior to initiating UDS, considerations of type of UDS and how UDS will be used in treating the patient are required. Though immunoassays are most commonly used for screening, limits to their use include purely qualitative results, often high cut-off levels resulting in false negatives, and risk for cross reactivity between agents resulting in false positives.⁽¹⁶⁾ Despite these limitations, immunoassays are low in cost and readily available as point-of-care tests performed while the patient is in the office or pharmacy. Immunoassays provide clinicians a general idea of the patient's recent medication use and provides for a productive encounter.

Furthermore, clinicians should understand how results will be used. Generally, UDS is done to detect presence of prescribed substances and to assure lack of nonprescribed substance use.⁽¹⁵⁾ When testing results are contrary to clinician expectations, discussion with the patient in a nonjudgmental, constructive manner must occur. For example, a negative test result received for a chronic opioid use patient allows the prescriber to engage in a conversation, rather than automatically assuming aberrant behavior has occurred. Other practical reasons for unexpected test results may exist, although reducing or discontinuing an opioid may be necessary if patient use is not appropriate. Patient accessibility to pharmacists can increase involvement in appropriate opioid use through point-of-care, CLIA-waived UDS. As medication experts with excellent understanding of drug metabolism, pharmacists are able to interpret UDS results and determine if the medications are being appropriately used. Pharmacists can also utilize refill history and current medications on file when discussing medication use with patients.

Naloxone Rescue

Harm reduction (decreased adverse consequences of legal/illegal psychoactive drugs without necessarily reducing their consumption)⁽¹⁷⁾ strategies are useful. Needle exchange for intravenous drug users and naloxone (mu-opioid antagonist) rescue for opioid overdose are important examples. Naloxone prescription programs have been shown to be effective in reducing opioid overdose-related deaths⁽¹⁸⁾ and have prompted widespread passage of some form of legislation in all 50 states and the District of Columbia to increase layperson access to naloxone.⁽¹⁹⁾

Table 1: Components of An Effective Opioid Agreement

Terms of treatment
Expectations of the treatment and of the patient

| Category | Examples |
|-------------------------|--|
| Patient education | <ul style="list-style-type: none"> • Indication • Side effects • Risks for drug opioid use disorder • Withdrawal symptoms • Storage requirements • Disposal methods |
| Expectations of patient | <ul style="list-style-type: none"> • Appropriate patient behavior • Conditions required for continuation of care • Use of one prescriber for opioids • Use of one pharmacy for opioids • Adhering to early refill policies • Adhering to appointment policies • Sharing relevant health information |
| Informed consent | <ul style="list-style-type: none"> • Urine drug screening • PDMP/CURES |

Terms of violation
Define the conditions for termination of care

| Category | Examples |
|--|---|
| Non-disciplinary termination of care | <ul style="list-style-type: none"> • Lack of improvement • Rapid development of tolerance • Onset of intolerable adverse effects |
| Disciplinary termination of care | <ul style="list-style-type: none"> • Aberrant urine drug screen results • Evidence of doctor or pharmacy shopping |
| <p>Examples of opioid agreements:</p> <p>National Institute of Drug Abuse https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf</p> <p>American Academy of Family Physicians https://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/agreement.pdf</p> | |

In April 2018, the Surgeon General issued an advisory emphasizing the importance of making naloxone widely available, and the CDC has identified patients with a history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use as patients who are at higher risk of opioid overdose and should be supplied with naloxone. Advantages of naloxone for take-home use include safety and ease of administration, as well as the lifesaving potential of reversing the detrimental effects of opioids. Naloxone has little to no side effects, though the precipitation of opioid withdrawal symptoms and exacerbations of pain may be unpleasant. Dosage forms available for take-home use are an intramuscular injection or intranasal spray. The prefilled syringes of injectable solution can be administered by intranasal route after attaching a nasal atomizer.⁽¹⁹⁾ Rescue kits (several doses of naloxone, needles/syringes, gloves, cardiopulmonary resuscitation face shields) are also commercially available.

Pharmacists can play a vital role in increasing access to naloxone rescue as they can furnish naloxone without a prescription pursuant to a statewide protocol and upon completion of continuing education in several states, including California.⁽¹⁹⁾ When pharmacists are unable to furnish naloxone, they can educate both patients and prescribers about naloxone rescue and encourage its coprescription with opioids. The California State Board of Pharmacy has developed a protocol, patient information handouts, and screening forms which are readily accessible on their website as a resource for pharmacists (http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml). In addition to the statewide protocol for pharmacists, the California Department of Public Health has implemented a statewide standing order for naloxone for other providers.

But despite these significant efforts, barriers to patients receiving naloxone still exist. On the patient side, stigma associated with the product, as well as cost, have been identified as significant barriers. From pharmacists, barriers include costs for patients, time constraints, and inadequate reimbursements. In addition, there are some concerns among pharmacists that making naloxone available will promote opioid abuse or attract undesirable clientele. In the face of the US Opioid Crisis, pharmacists should continue to strive to overcome these barriers in order to expand the availability of naloxone in the community.

Communication Skills

Strong communication and interpersonal skills are essential for pharmacists working with chronic pain patients and prescribers. Developing rapport and trust amongst them to address matters associated with managing pain with opioids can position pharmacists to be a valued resource, rather than a perceived barrier to medication access or perceived to be overstepping their scope of practice when contributing to the care of a pain patient.

Recognizing with sensitivity that patients may be unwilling to communicate due to feeling stigmatized and prescribers can feel threatened and defensive when their decisions are questioned, pharmacists can approach situations with care and compassion. Clearly communicating the intent for interactions *a priori* can help patients understand why pharmacists consistently require information before filling a prescription (basic medical and medication history, treatment goals, pain control, and treatment tolerability), how aforementioned tools might be utilized, and how (and

when) pharmacists will reach out to prescribers to share information or seek clarification.

Patients should be approached in a nonjudgmental and nonthreatening manner in a quiet, private location, especially as issues arise. Use of open-ended questions and avoidance of stigmatizing or judgmental words such as “addict,” “hooked,” or “narcotic” are recommended. Possessing knowledge of Medication Assisted Therapy (MAT) approaches (ie, methadone or buprenorphine/naltrexone) and local drug treatment programs will enable pharmacists to confidently speak to patients about MAT options when questions arise or the occasion for referral presents.⁽²⁰⁾ When speaking with patients about certain behavioral aspects of pain management, such as willingness to taper opioids, adherence, and utilization of nonpharmacologic therapies, motivational interviewing techniques are also an effective tool. Pharmacists should consider seeking further training in these techniques.

Pharmacists can represent themselves as a valued clinician when speaking to prescribers by avoiding anonymity (use of first name only or failure to acknowledge PharmD credential). Demonstrating a level of pharmacist accountability for the care of the patient can increase the importance of the information communicated or the weight of the recommendation offered. To promote safe and effective care, pharmacists should be well prepared with relevant, evidence-based information and approach prescribers in a nonjudgmental, nonthreatening manner when discussing patients.

Conclusion

The most assessable clinicians even amongst peers, pharmacists working in community practice settings are well positioned to leverage tools and practices to provide pharmacist patient care services to enhance the optimal use of opioids to manage pain.

About the Authors

Tania Gregorian, PharmD, received her Bachelor of Science degree in Microbiology, Immunology, and Molecular Genetics from the University of California, Los Angeles and her Doctor of Pharmacy Degree from the University of Southern California School of Pharmacy. She completed a pharmacy practice residency at USC with an emphasis in ambulatory care and community pharmacy practice. She is currently Assistant Professor of Pharmacy Practice in Ambulatory Care at Chapman University School of Pharmacy and a clinical pharmacist at the Cedars-Sinai Medical Care Foundation where she helped establish the chronic pain management, benzodiazepine tapering, and opioid tapering clinical pharmacy programs. Dr. Gregorian has no conflict of interest to report.

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Dr. Alvarez currently serves as reviewer for opioid calculation/rotation resources for the American Society of Health-System Pharmacists. She is a member of the American Pain Society and the Society of Pain and Palliative Care Pharmacists, and has engaged in advocacy efforts around the current opioid situations facing the nation as the 2017-2018 President of the American Pharmacists Association. Dr. Alvarez has no conflict of interest to report.

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