

## Medication violations and discontinuation of opioid therapy in a pediatric chronic pain clinic

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### Keypoints

1. Identification of opioid abuse is key in the safe management of opioid therapy for chronic pain management.
2. To date, there are limited data as to the best tools to use for the identification of opioid abuse during opioid therapy for chronic pain management.
3. The potential for opioid abuse or diversion should be considered if there are repeated minor violations such as early calls for refills, reporting pills lost or stolen, a failure to bring pill bottle to the appointment, missed or canceled appointments, and failure to provide a urine specimen.
4. Opioid abuse or diversion should be highly considered if the urine drug screen is negative for opioids, positive for non-prescribed schedule II medications, if another opioid prescriber noted on the national data base, or when there are concerns reported by another physician or a pharmacist.

### Abstract

#### Introduction

To better define the warning signs for possible opioid misuse or abuse that could be incorporated as a work flow screening process, we retrospectively reviewed cases where opioid therapy was discontinued due to suspected opioid misuse, abuse, and diversion in patients seen by the chronic pain service.

#### Materials and methods

After Institutional Review Board approval, a retrospective chart review was conducted to identify patients who were seen in the Comprehensive Pain Clinic at Nationwide Children's Hospital and had opioid therapy discontinued during the years 2015-2016 for reasons involving suspected or confirmed opioid misuse. Medical records were reviewed from the time of chronic pain service intake until the time opioid therapy was discontinued.

Minor violations (e.g., request for early refills, missing or canceling appointments) and major violations (e.g. negative urine drug screen [UDS] for opioids) were identified.

#### Results

The pain clinic team identified 8 patients (2 male/6 female, ages 13-23 years) whose opioid discontinuation was related to documented or suspected opioid misuse. Only 2 patients had opioid misuse explicitly documented as the reason for opioid therapy discontinuation. Five of the 8 patients had minor violations documented, while 3 had major violations. Only 2 patients had repeated medication violations noted, although both patients continued opioid therapy for >1 year after multiple violations became apparent.

#### Discussion and Conclusion

While missing or canceling 2 or more appointments was the most commonly documented violation, a discrepancy

on a UDS was the reason documented for discontinuation of opioid therapy in both patients overtly involved in opioid misuse.

### **Keywords**

opioids; opioid diversion; urine drug screen

### **Introduction**

Since the late 20<sup>th</sup> century, chronic opioid therapy has been a mainstay in the management of chronic pain.<sup>1,2</sup> As these medications were initially thought to be safe and effective, prescribing opioids for chronic non-cancer pain increased significantly. Additionally, when the Joint Commission Accreditation of Healthcare Organizations (JCAHO) released the new standards on pain management in 2000 the concept of pain being the “fifth vital sign” was more widely adopted by many healthcare organizations and providers and prescriptions of these high risk medications became even more prevalent.<sup>3</sup> In the 21<sup>st</sup> century, increasing awareness of opioid misuse, abuse, and diversion (MAD) has prompted routine surveillance for MAD using tools to assess for risk for opioid misuse/abuse, urine drug screens (UDS), and, most recently, computational tools based on the electronic medical record (EMR).<sup>2,4-8</sup> Unfortunately, many of the screening tools for opioid misuse are not validated in the pediatric setting. Current studies report very broad ranges of rates of problematic use, from <1% to 81% in patients on opioid therapy for chronic pain.<sup>1</sup> Another systematic review by Timmerman et al. report non-adherence rates between 8% and 62%.<sup>9</sup>

As opioid use among adolescents increases, along with dependence and fatalities from overdose, judicious opioid prescribing and prevention of MAD is of special concern in the pediatric population. Development of screening tools can help prescribers to identify patients at risk as well as increase awareness of subtle warning signs of MAD. When MAD is confirmed, physicians may begin the process of discontinuing opioid therapy, as the risks of continuing opioid therapy in patients with significant addiction or diversion issues may outweigh the benefits.<sup>2</sup> There has recently been a proliferation of predictive

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models for MAD leveraging demographic and clinical data; however, these tools have not been accepted for routine clinical use.<sup>6-8</sup> It remains unclear whether MAD can be detected according to repeated minor violations that fall below conventional thresholds for MAD behavior. Such minor violations may include early refill request and missed or cancelled appointments, as opposed to a major violation such as negative UDS for opioids.

At our institution, we sought to design a process for standardizing surveillance of MAD in a pediatric chronic pain clinic. As a first step towards this goal, we retrospectively reviewed patterns of minor and major medication violations among patients whose chronic opioid therapy was discontinued in relation to clinicians’ suspicion of MAD. Our primary objective was to describe patterns of minor medication violations and related treatment non-adherence that preceded cases of opioid therapy discontinuation in patients seen by the chronic pain service. We hypothesized that all cases of opioid therapy discontinuation where MAD was suspected were preceded by repeated instances of minor violations.

### **Materials and methods**

The local Institutional Review Board exempted this study from review as a quality improvement project. A retrospective chart review was conducted for patients who were seen in the Comprehensive Pain Clinic at Nationwide Children's Hospital, between January 2015 and June 2016. The list of chronic pain clinic patients was screened for patients whose opioid therapy was discontinued and not restarted during the study period. The resulting sample was reviewed by the Administrative Director of the Comprehensive Pain Service, along with pain clinic providers (attending physicians and a nurse practitioner) to identify patients whose opioid therapy was discontinued for reasons involving MAD, or was discontinued for other reasons (e.g., patient switched to another clinic) while possible MAD was suspected. Cases of opioid therapy discontinuation without suspicion of MAD were excluded from review. Our clinic currently uses an “opioid bundle” for each patient started on opioid therapy for pain

management. This bundle includes identification of a patient’s risk for opioid MAD, along with obtaining opioid consent and agreement, which states our policies for monitoring throughout the course of therapy. A flowsheet which includes minor and major violations was created in order to standardize the management of patients with suspected or documented MAD. Medical records were reviewed from the time of chronic pain service intake until the time opioid therapy was discontinued. All pain clinic notes, including free-text fields were reviewed to determine the reason for opioid discontinuation, and the presence of any information describing suspicion of MAD, provider compliance with opioid use monitoring, and referral for additional screening. The type and timing of minor and major violations (defined in **Table 1**) were recorded, as well as what actions were taken after each violation was discovered. Basic demographic information was collected, including age, gender, height/weight, diagnosis requiring opioid therapy, family history, and comorbidities. Data were summarized as counts with percentages for categorical study measures, and medians with interquartile ranges for continuous measures.

**Table 1.** List of minor and major violations queried in chart review. *OARRS, Ohio Automated Rx Reporting System; UDS, urine drug screen. The count of violations identified among patients in the study is listed in parenthesis*

Minor Violations
Call early for refills (3)
Reporting pills lost or stolen (1)
Failure to bring pill bottle to appointment (0)
Miss or cancel >2 appointments (6)
Failure to provide urine specimen (0)

  

Major Violations
Presenting impaired (1; parent)
Negative UDS for opioids (2)
Positive UDS for illicit substances or non-prescribed Schedule II medications (1)
Another opioid prescriber noted on OARRS (0)
Concerning report from other physicians or pharmacists (4)
Concerning behaviors around Schedule II medications (2)

**Results**

Initially, 79 cases of opioid therapy discontinuation were identified during the study period. After review by the lead author and the pain clinic team, 8 cases (ages 13-23 years, 2 males and 6 females) were selected for further review where MAD was documented or suspected; characteristics are summarized in Table 2.

**Table 2.** Demographic data of patients with detected or suspected opioid misuse, abuse, or diversion as a reason for discontinuing opioid therapy (N=8).

Average age (range in years)	18 (13-23)
Gender (M:F)	2:6
Mental health comorbid conditions	
Sleep disorder	3
Anxiety	5
Pain Diagnosis	
Back Pain	4
Osteogenesis Imperfecta	1
Systemic Lupus Erythematosus	2
Cerebral Palsy	1
Initial Opioid	
Morphine	2
Oxycodone/Percocet®	3
Hydromorphone	1
Hydrocodone-acetaminophen	1

Of these cases, only 2 patients had MAD explicitly documented as the reason for opioid therapy discontinuation. Five of the 8 patients had minor violations documented, while 3 had major violations (caregiver presenting impaired, UDS negative for opioids, UDS positive for illicit substance, concerning behaviors of the patient, and concerned medical provider—and in 1 case a pharmacist explicitly concerned about a caregiver’s behaviors). Only 2 patients had repeated medication violations noted, although both patients continued opioid therapy for >1 year after a pattern of multiple violations became apparent. Medication-related violations were most commonly reported by pain clinic providers and first occurred after a median of 3 months with an IQR of (1,5) after opioid therapy initiation. Documented responses to medication violations included repeat UDS to confirm initial results along with discontinuation of opioid therapy.

## Discussion and Conclusion

At our chronic pain clinic, we found that approximately 10% of cases where opioid therapy was discontinued were associated with documented or suspected MAD. However, there was significant provider variation in documenting MAD and medication violations. While missing or canceling 2 or more appointments was the most commonly documented violation, a discrepancy on a UDS was the reason documented for discontinuation of opioid therapy in both patients explicitly noted to be involved in opioid MAD. Interestingly, the time from first documented violation to discontinuation of opioid therapy in these patients was greater than 1 year, demonstrating significant room for improvement in provider compliance with guidelines for detecting and addressing medication violations.

Interest in predicting opioid MAD among chronic pain clinic patients remains high, despite challenges in implementing specific predictive models.<sup>10</sup> While other predictive models use aspects of patients' history prior to pain clinic intake (e.g., personal or family history of alcohol/drug abuse, personal or family history of mental health disorders, history of child abuse) for screening patients at risk for MAD, we are implementing a screening model that adds documentation of specific violations found commonly in patients with suspected MAD. These violations, or patient behaviors, have not previously been shown to predict MAD; however, as shown in this retrospective review, systematic early detection of repeated minor violations could reduce the time needed to recognize a pattern of behavior consistent with MAD. Yet, this approach will require significant improvements in provider documentation and follow-up of minor violation, as well as risking error in labeling some patients as suspected of MAD based on screening results.

In addition to the institution of stricter guidelines surrounding the prescription of opioids, research exploring the pathophysiology of chronic pain, specifically in children and adolescents, and the most effective treatment modalities is crucial. We have learned that the majority

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of chronic pain conditions are not effectively treated with opioids; in fact, sometimes pain can be worsened by phenomena such as medication overuse headaches and hyperalgesia, both associated with opioid use. A multimodal treatment approach, which includes use of non-opioid medications such as non-steroidal anti-inflammatory drugs, neuropathic agents, and selective serotonin/norepinephrine reuptake inhibitors, in combination with physical therapy, pain psychology, and other complementary and alternative treatments such as massage therapy and acupuncture, are most often used for patients with a history of drug abuse or significant risk factors. Additionally, nerve blocks and other regional anesthetic techniques, are always considered in the appropriate setting for patients suffering from chronic pain in order to limit opioid use.

In summary, we retrospectively reviewed our documentation of patients in a chronic pain clinic whose discontinuation of opioid therapy was associated with suspected or confirmed MAD. Although our approach resulted in a limited sample size and may have missed some cases of MAD due to inadequate documentation, we identified specific minor and major violations that were common among patients with suspected or documented MAD seen at our center. With this information, incorporating documentation of these violations into a screening tool would support a structured approach to recognize patients at risk for opioid MAD earlier in the treatment course, and allow for more timely intervention. Furthermore, the discrepancy in documentation and follow-up of minor violations among the providers in our clinic demonstrates an area for improvement in our practice, which may ultimately lead to improved patient care and safety.

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