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Pilot Study of a Preliminary Criterion Standard for Prescription Opioid Misuse

Robert C. Smith, MD,[1] Cathy Frank, MD,[2] Joseph C. Gardiner, PhD,[3] Lois Lamerato, PhD,[4] Kathryn M. Rost, PhD[5]

[1]Department of Medicine, Michigan State University, East Lansing, Michigan
[2]Department of Psychiatry and Behavioral Medicine, Northwestern University, Chicago, Illinois
[3]Department of Epidemiology and Biostatistics, Michigan State University, East Lansing, Michigan
[4]Department of Biostatistics and Research Epidemiology, Henry Ford Health System, Detroit, Michigan
[5]Department of Medical Humanities and Social Science, Florida State University, Tallahassee, Florida

Multidisciplinary experts created a behaviorally defined preliminary criterion standard definition of probable prescription opioid misuse (PPOM) that could be rated from material found in administrative, pharmacy, and electronic health record databases. They then derived a scoring system to identify PPOM patients requiring referral to a specialist. Experts next rated cases of misuse and nonmisuse. Rater no. 1 correctly differentiated 37 of 40 cases (92.5%); kappa coefficient was .79 (CI: .57, 1.00). Rater no. 2 correctly identified 39 of 40 cases (97.5%); kappa was .94 (CI: .81, 1.00). Kappa for comparing raters was .73 (CI: .49, .98). This preliminary study demonstrates that multidisciplinary raters can use behaviorally based criteria to identify patients with known PPOM from health plan databases. (Am J Addict 2010;19:523–528)

INTRODUCTION

Between 15% and 50% of primary care patients report chronic pain,[1–5] and up to 40% are prescribed opioids,[4,6] an increasingly severe problem.[5,7–13] Many primary care patients with chronic pain who are prescribed opioids fail to receive opioid treatment concordant with clinical guidelines.[14–21] Some patients seek opioids from multiple providers because they are prescribed less than they need to control pain. Other patients begin to abuse opioids over time,[15,19,22,23] using them in place of other nonpharmacological pain management strategies. Still others seek opioids from any available source for their recreational effects,[24] typically from friends or family, often meeting criteria for abuse/dependence.[15,16,18,19,25–29]

Capturing patients across this spectrum, our definition of prescription opioid misuse is *opioid-obtaining behaviors that raise clinician concern about their appropriate use*. This definition is consistent with some[13,15,26,29] but not all of the literature.[30] However, our goal was to identify opioid misuse only from medical record information, meaning that we will miss many patients obtaining opioids outside the medical system, although still identifying the sources of all prescription misuse, the prescribing physician, and the patient receiving the prescription.

Compounding the prescription opioid misuse problem is its strong comorbid association with alcohol and drug use disorders and with mood and anxiety disorders.[24,31,32] While the causal direction is not known, patients with mental health disorders are more vulnerable.

Researchers have used conceptually overlapping but operationally ambiguous definitions to define probable prescription opioid misuse (PPOM), making it impossible to compare prevalence rates across populations or examine treatment effectiveness.[15,25,33–39] In opioid treated primary care patients, Reid et al. estimate that 24–31% of patients taking opioids for at least 6 months met criteria for prescription opioid misuse; 4% of opioid-treated patients had complications such as overdose, mental status changes, and falls.[25] A recent prospective study found a 32% incidence over 1 year of opioid misuse.[29] Recent community studies report that prescription opioid misuse has become the most common substance for initial drug misuse, replacing marijuana.[13]

In this study, we seek to establish an initial criterion standard of PPOM so that the field can build upon it in the essential long-range task of providing a solid, agreed-upon gold standard definition of PPOM for teaching,

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Address correspondence to Dr. Smith, B312 Clinical Center, 138 Service Road, East Lansing, MI 48824. E-mail: Robert.smith@ht.msu.edu.

clinical care, and research. The objectives of this study are to develop a system of operational indicators for PPOM from published conceptualizations that can be measured in databases available in most health care systems, to make a preliminary estimate of interrater reliability when these operational criteria are used by clinician raters to identify PPOM patients, and to determine the system's criterion validity, its ability to distinguish expert-defined cases of PPOM from nonmisuse in opioid-prescribed patients.

MATERIALS AND METHODS

Three Henry Ford Health System (HFHS) clinician experts in pain and addiction medicine from different disciplines constituted our Expert Panel, coming from primary care (pain and addiction), psychiatry (addiction), and psychology (pain). All participated in initial identification of criteria but an unexpected, prolonged absence precluded participation by the primary care provider in subsequent ratings of the criteria.

Two of the authors (RCS, CF) met with the Expert Panel to review conceptual indicators for PPOM derived from the literature (Table 1).[6,14,15,19,25–27,35–39] We then charged the Expert Panel: (1) to add or remove conceptual indicators of PPOM from Table 1 based on their clinical judgment and knowledge of the field, (2) to develop operational indicators for each conceptual indicator that were observable in pharmacy, utilization, and medical record data, and (3) to weight each operational indicator to identify a total score that would indicate the need for referral to an addiction and/or pain specialist for "further evaluation" and/or "treatment" for PPOM. A modified Delphi process was used for Expert Panel members to offer operational criteria, to respond to others' definitions, and to resolve differences—conducted in person and via email. Following initial agreement, each Expert Panel member blindly rated four charts (one known misuser and three known nonmisusers). Last, Expert Panel members were asked to make any necessary revisions to their original definitions; however, they determined none were necessary.

Two authors (RCS and CF) reviewed randomly selected electronic medical records of chronic pain patients with chronic opioid use (minimum of 6 months) to identify 10 patients with expert-recognized PPOM, and 30 patients experts determined did not have PPOM. This proportion reflected the expected prevalence of 25% misuse in a chronic opioid-using population.[25] Two Expert Panel raters reviewed randomly presented 2007 administrative, pharmacy, and nonpsychiatric electronic medical records for these 40 patients. Blinded to expert misuse designation, the Expert Panel members used the scoring rules for operational indicators they had defined to determine whether each of the 40 patients required further evaluation and/or treatment by an expert for PPOM. Interrater reliability was determined for diagnoses of misuse or nonmisuse. Each rater's ratings were compared to expert-determined cases of misuse/nonmisuse. Post hoc, we also recorded ICD-9 pain diagnosis codes for the 40 subjects evaluated.

TABLE 1. Conceptual indicators for PPOM

1.	Noncoordinated prescribers from multiple practice settings
2.	Multiple patient requests for visits without appointment
3.	Multiple patient requests for early medication
4.	Multiple patient reports of lost/stolen medication
5.	Complaints about misuse from other providers/emergency room/family
6.	Patient reluctance to reduce medication in face of no benefit
7.	Patient reluctance to participate in other methods to control pain
8.	Patient attempt to obtain medication from other providers/pharmacies
9.	Violation of any terms in medication contract
10.	Injection of oral preparations
11.	Urine toxicology positive for any nonprescribed substance (or negative for prescribed substances)
12.	Selling/stealing medications
13.	Buying prescription drugs from nonmedical sources
14.	Prescription forgery
15.	Tolerance
16.	Withdrawal reactions when medication not taken

RESULTS

Table 2 presents the Expert Panel's operational criteria for PPOM and the associated scoring system. We note criteria that were added or consolidated, and that most DSM-IV criteria for dependence and abuse are addressed to some extent.[40]

When we examined the degree to which raters applying the scoring system successfully differentiated expert-determined misusers from nonmisusers, we demonstrated: (1) raters' excellent agreement with each other (ie, high interrater reliability), with a kappa of .73 (95% CI: .49, .98), and McNemar's test was $p = .32$, and (2) the application of the scoring system by both raters demonstrated high agreement with expert-defined cases (eg, high criterion validity). Rater no. 1 correctly identified 37 of 40 cases (92.5%), the kappa coefficient was .79 (95% CI: .57, 1.00), and McNemar's test for agreement was $p = .56$. Rater no. 2 correctly identified 39 of 40 cases (97.5%) with a kappa of .94 (95% CI: .81, 1.00), and McNemar's test was $p = .32$.

In a post hoc evaluation, ICD-9 codes among the 40 patients, of whom only 9 had just one pain diagnosis, were primarily musculoskeletal: low back pain = 20 (50%); neck pain = 4 (10%); arthritis/joint problem = 16 (40%);

TABLE 2. Criterion standard definition of PPOM

	OVER ANY 12-MONTH PERIOD
(1)	Noncoordinated prescribers from multiple practice settings **THREE VISITS OVER THE 12-MONTH RATING PERIOD FOR SAME OR RELATED CONDITION TO ONE OR MORE PROVIDERS NOT INVOLVED IN PRIMARY PROVIDER'S BASIC CARE PLAN, INCLUDING EMERGENCY ROOM VISITS UNLESS THE LATTER ARE SPECIFIC REFERRALS BY THE PATIENT'S MANAGING PHYSICIAN**
(2)	Multiple patient requests for visits without appointment **THREE VISITS FOR THE BASIC CONDITION FOR WHICH NARCOTICS ARE BEING PRESCRIBED**
(3)	Multiple patient requests for early medication **TWO REQUESTS, IN PERSON (VISIT) OR BY OTHER MEANS, FOR THE BASIC CONDITION FOR WHICH NARCOTICS ARE BEING PRESCRIBED**
(4)	Multiple patient reports of lost/stolen medication **TWO REPORTS**
(5)	Complaints about opioid use from other providers/emergency room/family **ONE COMPLAINT FROM PROVIDER OR FROM FAMILY**
(6)	Patient refusal to participate in other methods to control pain **RESISTS CHANGE OF NARCOTIC AND/OR OTHER FORMS OF PHARMACOLOGICAL AND NONPHARMACOLOGICAL TREATMENT FOR PAIN; DOES NOT INCLUDE REFUSAL OF REFERRAL FOR COMORBID PSYCHIATRIC DISORDERS SUCH AS DEPRESSION**
(7)	Violation of any terms in medication contract **ONE VIOLATION OF WRITTEN OR ORAL CONTRACT/TREATMENT AGREEMENT IF ONE IS NOTED IN THE RECORD**
(8)	Injection of oral preparations **ONE INSTANCE**
(9)	Urine and/or blood toxicology positive for any nonprescribed substance—or positive for one patient says they are not taking—or negative for prescribed substances **ONE INSTANCE**
(10)	Selling/stealing medications **ONE INSTANCE IF DOCUMENTED IN THE RECORD**
(11)	Buying or otherwise obtaining prescription drugs from nonmedical sources **ONE INSTANCE IF ADMITTED BY THE PATIENT**
(12)	Prescription forgery **ONE INSTANCE IF ADMITTED BY THE PATIENT OR DOCUMENTED IN THE RECORD**
(13)	Tolerance **INCREASING DOSE WITHOUT IMPROVEMENT OVER 6 MONTHS OR MARKED DECREASE IN EFFECT AT THE SAME DOSE**
(14)	Unexpected withdrawal reactions when medication taken at prescribed dose **ONE INSTANCE**
(15)	Increased interpersonal problems and/or decreased daily function (eg, work, school, home) attributable to opioids **THE NEW DEVELOPMENT OF INTERPERSONAL PROBLEMS AND/OR DECREASED DAILY FUNCTION FOLLOWING INITIATION AND/OR INCREASED DOSE OF OPIOIDS THAT IS NOT ATTRIBUTABLE TO OTHER FACTORS**
(16)	Arrest or other legal problems for misuse; eg, nonprescribed opioids found on person or in car **ONE INSTANCE**
(17)	Refuse referral to specialist for addiction evaluation **ONE INSTANCE**
(18)	Use of opioids in hazardous situation **ONE INSTANCE**
(19)	Past history of opioid misuse or abuse **ONE INSTANCE**
(20)	Current history of nonopioid substance misuse or abuse; eg, ethanol, Valium **ONE INSTANCE**

(*Continued*)

TABLE 2. Continued

	OVER ANY 12-MONTH PERIOD
(21)	Past history of nonopioid substance misuse or abuse; eg, ethanol, Valium **ONE INSTANCE**
(22)	Multiple opioids at the same time **THREE OR MORE DIFFERENT OPIOIDS BEING TAKEN AT THE SAME TIME, INCLUDING THOSE LISTED FOR USE ON AN AS-NEEDED BASIS**
(23)	Use of opioids for no objectively documented clinical or physiological reason **MINIMAL OR NO CLINICALLY RELEVANT PAIN**

SCORING POSITIVE INDICATES NEED FOR FURTHER EVALUATION AND/OR TREATMENT BY AN EXPERT: any one of numbers 5, 7, 8, 9, 10, 12, 13, 14, 15, 16, 18, 20, or 23; any two of those remaining numbers (1, 2, 3, 4, 6, 11, 17, 19, 21, or 22).

and miscellaneous muscular/skeletal aches and pains = 12 (30%). In addition, pain in other locations also was prominent: abdominal = 15 (37.5%); headache = 1 (2.5%); pelvic = 5 (12.5%); chest = 11 (27.5%).

DISCUSSION

The research team convened a multidisciplinary group of HFHS clinical experts in pain and addiction medicine to develop operational criteria for a comprehensive list of literature-based conceptual indicators to identify patients needing further evaluation/treatment for PPOM (Table 2). Comparison indicates that PPOM criteria are consistent with more general National Institute of Drug Abuse and DSM-IV criteria, which were not designed to be rated in the records treating clinicians often have available.[13,40] After careful review, raters retained all the conceptual indicators mentioned in the literature (Table 1) and added criteria reflecting adverse personal impact (interpersonal problems, arrest), current or prior use of opioids (hazardous situations, past history misuse/abuse, multiple opioids, use for no objective reason), and current or past history of nonopioid substance use problems (eg, alcohol and benzodiazepines) reflecting the comorbidity between opioid misuse and other substance problems.[24,31,32]

Raters then demonstrated that they could apply this comprehensive list of criteria and its associated scoring system to records that clinicians can readily review to reach agreement among themselves about patients at risk for PPOM, as well as to differentiate patients with and without known prescription opioid misuse. The clinical implications of these preliminary findings deserve comment. In our initial attempt, practitioners were able to reach consensus on patient behaviors that caused them to be concerned that an individual was at risk for PPOM. Practitioners were then able to reliably rate whether these behaviors were noted in records that are commonly available to practicing physicians. Most importantly, the scoring system that practitioners developed and utilized successfully differentiated patients with known prescription opioid misuse from patients without misuse. Regardless of how closely the operational criteria and scoring system we publish approaches the operational criteria and scoring system the field eventually adopts, our research indicates that the process we utilized holds substantial promise for improving the detection and management of PPOM.

We acknowledge important limitations in this initial pilot study to explore defining a criterion standard for PPOM, limitations that are shared across many preliminary initiatives. First, this project produced criteria to identify PPOM viewed as useful by literature-knowledgeable clinicians of a single institution. Because the long-range purpose of our project was to develop widely adopted and readily operationalized criteria for PPOM for use by teachers, clinicians, and researchers, it is important to further evaluate how locally generated criteria need to be modified for uptake by stakeholders with a wide variety of needs. Second, because this project was done with no external research funding, we used the same clinicians to define criteria as we did to rate whether patients met criteria. Because the process of defining the criteria may have created a shared perspective among raters that inadvertently increased interrater reliability estimates, it is important in the future to use separate individuals to define and to rate criteria. Third, expert-recognized cases were determined by reviewing the same clinical databases as chart raters used, which in all likelihood inflated the estimate of criterion validity by failing to include other indicators of prescription opioid misuse that may not have appeared in clinical records. Fourth, criterion validity studies in general can be criticized for spectrum bias, which can potentially inflate the agreement between the raters and the expert-determined cases by not including the "gray" cases, which clinicians often see. It is possible that spectrum bias may be less of a concern in this study since the 10 cases of known prescription opioid misuse represented a vast range of prescription opioid use behaviors. Fifth, because some misusers obtain opioids outside the medical system from friends or family,[24] we note that our medically based definition misses these individuals who take opioids prescribed to others. In our defense, we note that opioids taken by family and friends were prescribed to some patients by some clinicians. While the screen positive patients may be a "false positive" for

PPOM, clinicians will need to entertain the question about whether a patient's prescribed opioids are being diverted to others for nonmedical use. Scientists cannot work in this field without appreciating the need for a preventive approach: prescribing opioids should include education about overdose risk, risk of diversion, risk of accidental ingestion, and a clear commitment to not share medications and not to expect that lost or stolen medications will be replaced. Finally, we note a potential resource allocation issue: there are insufficient numbers of specialists to handle the problem, suggesting the need for developing both prevention and management skills in primary care providers.

Future study will need to be prospective and include opioid-using patients who have more complex clinical presentations, particularly those with comorbid substance and mood/anxiety conditions.[24,31,32] As well, future studies are encouraged to use a greater number of subjects in multiinstitutional settings, a more detailed evaluation of the reliability and predictive validity of individual criteria, and greater attention to expert case determination by incorporating more sources of information than generally available in the medical record.

Nevertheless, with no present agreed-upon criterion standard for PPOM, we have made a start and been able to operationalize criteria for PPOM using common health plan databases, and we have demonstrated raters' ability to use these criteria to reliably distinguish cases of misuse from nonmisuse. Much more work is needed, however, to advance this key area, and, in turn, to advance studies requiring an objective measure of PPOM; for example, screening, treatment.

Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

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