GuideMed®

SCIENTIFIC BASIS FOR THE GUIDEMED PROGRAM

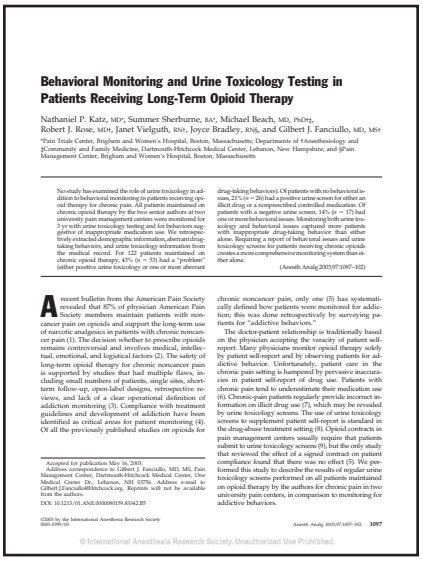
Overview

Prescribing rules implemented by many state governments follow a well-documented "body of evidence" that now asks healthcare providers to be more deliberate in 1) how and when they prescribe opioids, 2) monitoring patients for signs of misuse once prescribed chronic opioid therapy (COT) and 3) intervening as soon as opioid misuse is detected. However, there are currently no studies linking increased patient monitoring to better patient outcomes nor are such studies anticipated soon due to the variability of treatment options in response to monitoring results.

In general, the purpose for monitoring patients is simple. Practitioners who are not looking for objective signs of misuse cannot reliably detect signs of misuse. The key to preventing misuse, its downstream complications and staggering costs relies on the ability to detect misuse early enough to intervene before it becomes addiction or overdose. A significant body of evidence exists in support of monitoring patients and has formed the basis of many state recommendations.

GuideMed ensures clinicians are following state recommendations and/or best practice protocols. GuideMed does not establish those protocols; GuideMed simply executes the protocols. The evidence for GuideMed is based on how well the program increases compliance to prescribing rules. Vigilant monitoring provides healthcare practitioners the keys to prevention. GuideMed monitors vigilantly.

Evidence: The need to monitor patients using multiple tools



Behavioral Monitoring and Urine Toxicology Testing in Patients Receiving Long-Term Opioid Therapy

Nathaniel P. Katz, MD*, Summer Sherburne, BA*, Michael Beach, MD, PhD†‡, Robert J. Rose, MD§, Janet Vielguth, RN*, Joyce Bradley, RN§, and Gilbert J. Fanciullo, MD, MS§

*Pain Trials Center, Brigham and Women's Hospital, Boston, Massachusetts; Departments of †Anesthesiology and ‡Community and Family Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire; and §Pain Management Center, Brigham and Women's Hospital, Boston, Massachusetts

No study has examined the role of urine toxicology in addition to behavioral monitoring in patients receiving opioid therapy for chronic pain. All patients maintained on chronic opioid therapy by the two senior authors at two university pain management centers were monitored for 3 yr with urine toxicology testing and for behaviors suggestive of inappropriate medication use. We retrospectively extracted demographic information, aberrant drug-taking behaviors, and urine toxicology information from the medical record. For 122 patients maintained on chronic opioid therapy, 43% (*n* = 53) had a "problem" (either positive urine toxicology or one or more aberrant drug-taking behaviors). Of patients with no behavioral issues, 21% (*n* = 26) had a positive urine screen for either an illicit drug or a nonprescribed controlled medication. Of patients with a negative urine screen, 14% (*n* = 17) had one or more behavioral issues. Monitoring both urine toxicology and behavioral issues captured more patients with inappropriate drug-taking behavior than either alone. Requiring a report of behavioral issues and urine toxicology screens for patients receiving chronic opioids creates a more comprehensive monitoring system than either alone.

(Anesth Analg 2003;97:1097–102)

A recent bulletin from the American Pain Society revealed that 87% of physician American Pain Society members maintain patients with noncancer pain on opioids and support the long-term use of narcotic analgesics in patients with chronic noncancer pain (1). The decision whether to prescribe opioids remains controversial and involves medical, intellectual, emotional, and logistical factors (2). The safety of long-term opioid therapy for chronic noncancer pain is supported by studies that had multiple flaws, including small numbers of patients, single sites, short-term follow-up, open-label designs, retrospective reviews, and lack of a clear operational definition of addiction monitoring (3). Compliance with treatment guidelines and development of addiction have been identified as critical areas for patient monitoring (4). Of all the previously published studies on opioids for chronic noncancer pain, only one (5) has systematically defined how patients were monitored for addiction; this was done retrospectively by surveying patients for "addictive behaviors."

The doctor-patient relationship is traditionally based on the physician accepting the veracity of patient self-report. Many physicians monitor opioid therapy solely by patient self-report and by observing patients for addictive behavior. Unfortunately, patient care in the chronic pain setting is hampered by pervasive inaccuracies in patient self-report of drug use. Patients with chronic pain tend to underestimate their medication use (6). Chronic-pain patients regularly provide incorrect information on illicit drug use (7), which may be revealed by urine toxicology screens. The use of urine toxicology screens to supplement patient self-report is standard in the drug-abuse treatment setting (8). Opioid contracts in pain management centers usually require that patients submit to urine toxicology screens (9), but the only study that reviewed the effect of a signed contract on patient compliance found that there was no effect (5). We performed this study to describe the results of regular urine toxicology screens performed on all patients maintained on opioid therapy by the authors for chronic pain in two university pain centers, in comparisons to monitoring for addictive behaviors.

Accepted for publication May 16, 2003.
Address correspondence to Gilbert J. Fanciullo, MD, MS, Pain Management Center, Dartmouth-Hitchcock Medical Center, One Medical Center Dr., Lebanon, NH 03756. Address e-mail to Gilbert.J.Fanciullo@Hitchcock.org. Reprints will not be available from the authors.

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0003-2999/03

Anesth Analg 2003;97:1097–102 1097

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7 subject matter experts
31 references

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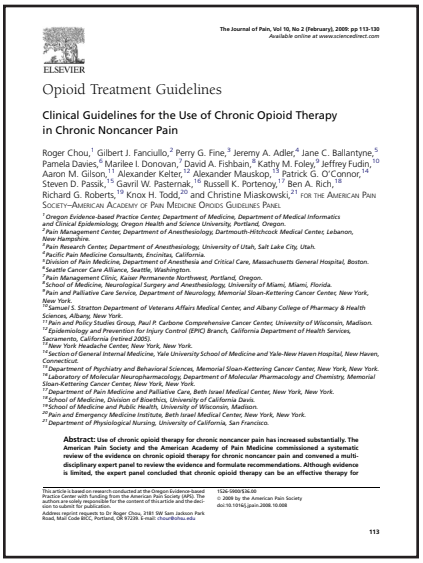
Summary: **Patients do not always tell the truth. Practitioners cannot always detect whether patients are misusing drugs by observed behavior alone. Urine drug testing is indicated for all patients on chronic opioid therapy.**

Quote, page 1101: "The relatively large proportion of patients in our sample with urine toxicology results divergent from their implied self-report suggests that self-report of compliance alone is an insufficient screening tool and that safety monitoring would be enhanced by routine urine toxicology screening. Furthermore, because the presence of behavioral issues did not predict urine toxicology results, our data do not support monitoring only patients selected on the basis of aberrant behaviors. Instead, our results suggest that all patients receiving long-term opioid treatment for noncancer pain should be monitored with urine toxicology testing."



The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130
Available online at www.sciencedirect.com

ELSEVIER

Opioid Treatment Guidelines

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

Roger Chou,[1] Gilbert J. Fanciullo,[2] Perry G. Fine,[3] Jeremy A. Adler,[4] Jane C. Ballantyne,[5] Pamela Davies,[6] Marilee I. Donovan,[7] David A. Fishbain,[8] Kathy M. Foley,[9] Jeffrey Fudin,[10] Aaron M. Gilson,[11] Alexander Kelter,[12] Alexander Mauskop,[13] Patrick G. O'Connor,[14] Steven D. Passik,[15] Gavril W. Pasternak,[16] Russell K. Portenoy,[17] Ben A. Rich,[18] Richard G. Roberts,[19] Know H. Todd,[20] and Christine Miaskowski,[21] for the American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel

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[2] *Pain Management Center, Department of Anesthesiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire.*
[3] *Pain Research Center, Department of Anesthesiology, University of Utah, Salt Lake City, Utah.*
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[9] *Pain and Palliative Care Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, New York, New York.*
[10] *Samuel S. Stratton Department of Veterans Affairs Medical Center, and Albany College of Pharmacy & Health Sciences, Albany, New York.*
[11] *Pain and Policy Studies Group, Paul P. Carbone Comprehensive Cancer Center, University of Wisconsin, Madison.*
[12] *Epidemiology and Prevention for Injury Control (EPIC) Branch, California Department of Health Services, Sacramento, California (retired 2005).*
[13] *New York Headache Center, New York, New York.*
[14] *Section of General Internal Medicine, Yale University School of Medicine and Yale-New Haven Hospital, New Haven, Connecticut.*
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[16] *Laboratory of Molecular Neuropharmacology, Department of Molecular Pharmacology and Chemistry, Memorial Sloan-Kettering Cancer Center, New York, New York.*
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[18] *School of Medicine, Division of Bioethics, University of California Davis.*
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[20] *Pain and Emergency Medicine Institute, Beth Israel Medical Center, New York, New York.*
[21] *Department of Physiological Nursing, University of California, San Francisco.*

Abstract: Use of chronic opioid therapy for chronic noncancer pain has increased substantially. The American Pain Society and the American Academy of Pain Medicine commissioned a systematic review of the evidence on chronic opioid therapy for chronic noncancer pain and convened a multidisciplinary expert panel to review the evidence and formulate recommendations. Although evidence is limited, the expert panel concluded that chronic opioid therapy can be an effective therapy for

This article is based on research conducted at the Oregon Evidence-based Practice Center with funding from the American Pain Society (APS). The authors are solely responsible for the content of this article and the decision to submit it for publication.

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1526-5900/$34.00

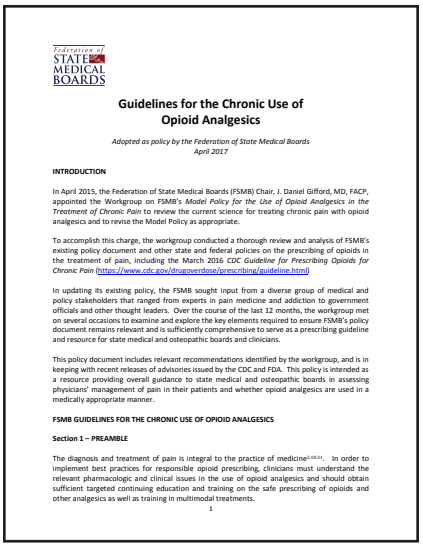
doi:10.1016/j.jpain.2008.10.008

21 subject matter experts
139 references

Chou, R., Fanciullo, G.J., Fine, P.G., et al. (2009 Feb). **Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain**. J Pain 10: 2. 113-30. Retrieved from www.jpain.org/article/S1526-5900(08)00831-6/pdf

Summary: Because patients do not always tell the truth about their drug-taking behavior, providers should 1) check the state prescription drug registry (PDMP), 2) conduct urine drug screens, 3) do pill counts and 4) interview people who know the patient well. Risk stratify the patients and monitor high risk patients more frequently than low risk patients.

Quote, page 118: "Because patient self-report may be unreliable for determining amount of opioid use, functionality, or aberrant drug-related behaviors, pill counts, urine drug screening, family member or caregiver interviews, and use of prescription monitoring program data can be useful supplements… However, risk stratification (see Section 1) is useful for guiding the approach to monitoring. In patients at low risk for adverse outcomes and on stable doses of opioids, monitoring at least once every three to six months may be sufficient… For patients at very high risk for adverse outcomes, monitoring on a weekly basis may be a reasonable strategy."



Federation of STATE MEDICAL BOARDS

Guidelines for the Chronic Use of Opioid Analgesics

Adopted as policy by the Federation of State Medical Boards
April 2017

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to serve as a prescribing guideline and resource for state medical and osteopathic boards and clinicians.

This policy document includes relevant recommendations identified by the workgroup, and is in keeping with recent releases of advisories issued by the CDC and FDA. This policy is intended as a resource providing overall guidance to state medical and osteopathic boards in assessing physicians' management of pain in their patients and whether opioid analgesics are used in a medically appropriate manner.

FSMB GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS

Section 1 – PREAMBLE

The diagnosis and treatment of pain is integral to the practice of medicine[1,20-21]. In order to implement best practices for responsible opioid prescribing, clinicians must understand the relevant pharmacologic and clinical issues in the use of opioid analgesics and should obtain sufficient targeted continuing education and training on the safe prescribing of opioids and other analgesics as well as training in multimodal treatments.

1

19 subject matter experts
including federal and state agencies

60 references

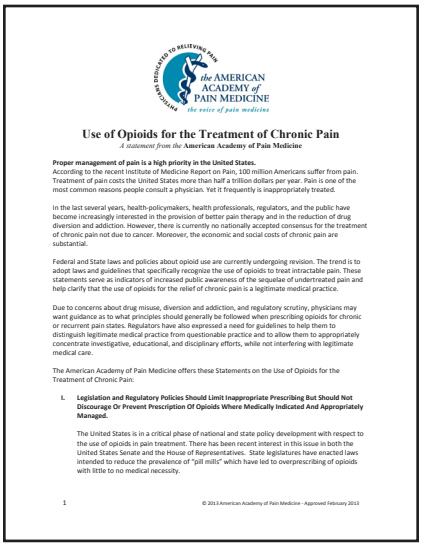
The Federation of State Medical Boards. (2017 April). **Guidelines for the Chronic Use of Opioid Analgesics.** Retrieved from https://www.fsmb.org/Media/Default/PDF/Advocacy/Opioid%20Guidelines%20As%20Adopted%20April%202017_FINAL.pdf

Summary: Assess risk of misuse with each patient, put controlled substance agreements in place, conduct periodic drug testing and PDMP reviews. All are useful in monitoring adherence to a treatment plan.

Quote, page 8: "Use of a written informed consent and treatment agreement is recommended for long-term chronic opioid therapy."

Quote, page 11: "Monitoring plans for a given patient should take into account the generally increased risk for dependence developing a substance use disorder and misuse the longer the patient uses them." "Periodic and unannounced drug testing (including chromatography) are useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs. Drug testing is an important monitoring tool because self-reporting of medication use is not always reliable and behavioral observations may detect some problems but not others."

Quote, page 12: "Clinicians are encouraged to consult the state's PDMP before initiating opioids for pain and during ongoing therapy."



Use of Opioids for the Treatment of Chronic Pain

A statement from the **American Academy of Pain Medicine**

Proper management of pain is a high priority in the United States.
According to the recent Institute of Medicine Report on Pain, 100 million Americans suffer from pain. Treatment of pain costs the United States more than half a trillion dollars per year. Pain is one of the most common reasons people consult a physician. Yet it frequently is inappropriately treated.

In the last several years, health-policymakers, health professionals, regulators, and the public have become increasingly interested in the provision of better pain therapy and in the reduction of drug diversion and addiction. However, there is currently no nationally accepted consensus for the treatment of chronic pain not due to cancer. Moreover, the economic and social costs of chronic pain are substantial.

Federal and State laws and policies about opioid use are currently undergoing revision. The trend is to adopt laws and guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.

Due to concerns about drug misuse, diversion and addiction, and regulatory scrutiny, physicians may want guidance as to what principles should generally be followed when prescribing opioids for chronic or recurrent pain states. Regulators have also expressed a need for guidelines to help them to distinguish legitimate medical practice from questionable practice and to allow them to appropriately concentrate investigative, educational, and disciplinary efforts, while not interfering with legitimate medical care.

The American Academy of Pain Medicine offers these Statements on the Use of Opioids for the Treatment of Chronic Pain:

I. **Legislation and Regulatory Policies Should Limit Inappropriate Prescribing But Should Not Discourage Or Prevent Prescription Of Opioids Where Medically Indicated And Appropriately Managed.**

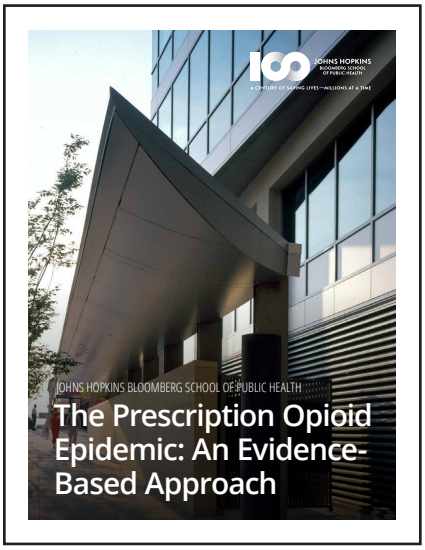
The United States is in a critical phase of national and state policy development with respect to the use of opioids in pain treatment. There has been recent interest in this issue in both the United States Senate and the House of Representatives. State legislatures have enacted laws intended to reduce the prevalence of "pill mills" which have led to overprescribing of opioids with little to no medical necessity.

1 © 2013 American Academy of Pain Medicine - Approved February 2013

American Academy of Pain Medicine. (2013 Feb). **Use of opioids for the treatment of chronic pain.** Retrieved from http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf

Summary: Monitoring patient compliance is critical and includes tools such as PDMP checks, drug testing and pill counts.

Quote, page 4: "Monitoring of compliance is a critical aspect of chronic opioid prescribing, using such tools as random urine drug screening, pill counts, and where available, review of prescription monitoring data base reports."



35 subject matter experts
152 references

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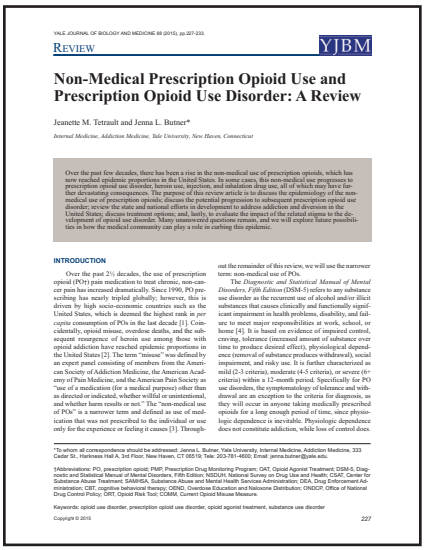
Summary: Repeal permissive laws and rules and mandate risk assessments at every medical visit, treatment agreements, drug testing and PDMPs.

Quote, page 15: "Federal and state agencies, state medical boards and medical societies should work to repeal previous permissive and lax prescription laws and rules. Rationale: Previous prescription policies, guidelines, statutes and rulings have been too permissive and have contributed to the current opioid epidemic. They require revision. Federal and state agencies, state medical boards and medical societies should require mandatory tracking of pain, mood and function through use of a brief validated survey at every patient medical visit; use of patient treatment agreements, urine drug screening; PDMP use when prescribing long-term opioids for non-chronic pain; and specialty consultation (via peer-to-peer video conferencing when in-person is unavailable) when prescribing over 120 morphine milligram equivalents (MME) per day without pain and function improvement."



YALE JOURNAL OF BIOLOGY AND MEDICINE 88 (2015), pp.227-233.

REVIEW YJBM

Non-Medical Prescription Opioid Use and Prescription Opioid Use Disorder: A Review

Jeanette M. Tetrault and Jenna L. Butner*

Internal Medicine, Addiction Medicine, Yale University, New Haven, Connecticut

Over the past few decades, there has been a rise in the non-medical use of prescription opioids, which has now reached epidemic proportions in the United States. In some cases, this non-medical use progresses to prescription opioid use disorder, heroin use, injection, and inhalation drug use, all of which may have further devastating consequences. The purpose of this review article is to discuss the epidemiology of the non-medical use of prescription opioids; discuss the potential progression to subsequent prescription opioid use disorder; review the state and national efforts in development to address addiction and diversion in the United States; discuss treatment options; and, lastly, to evaluate the impact of the related stigma to the development of opioid use disorder. Many unanswered questions remain, and we will explore future possibilities in how the medical community can play a role in curbing this epidemic.

INTRODUCTION

Over the past 2½ decades, the use of prescription opioid (PO†) pain medication to treat chronic, non-cancer pain has increased dramatically. Since 1990, PO prescribing has nearly tripled globally; however, this is driven by high socio-economic countries such as the United States, which is deemed the highest rank in *per capita* consumption of POs in the last decade [1]. Coincidentally, opioid misuse, overdose deaths, and the subsequent resurgence of heroin use among those with opioid addiction have reached epidemic proportions in the United States [2]. The term "misuse" was defined by an expert panel consisting of members from the American Society of Addiction Medicine, the American Academy of Pain Medicine, and the American Pain Society as "use of a medication (for a medical purpose) other than as directed or indicated, whether willful or unintentional, and whether harm results or not." The "non-medical use of POs" is a narrower term and defined as use of medication that was not prescribed to the individual or use only for the experience or feeling it causes [3]. Throughout the remainder of this review, we will use the narrower term: non-medical use of POs.

The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) refers to any substance use disorder as the recurrent use of alcohol and/or illicit substances that causes clinically and functionally significant impairment in health problems, disability, and failure to meet major responsibilities at work, school, or home [4]. It is based on evidence of impaired control, craving, tolerance (increased amount of substance over time to produce desired effect), physiological dependence (removal of substance produces withdrawal), social impairment, and risky use. It is further characterized as mild (2-3 criteria), moderate (4-5 criteria), or severe (6+ criteria) within a 12-month period. Specifically for PO use disorders, the symptomatology of tolerance and withdrawal are an exception to the criteria for diagnosis, as they will occur in anyone taking medically prescribed opioids for a long enough period of time, since physiologic dependence is inevitable. Physiologic dependence does not constitute addiction, while loss of control does.

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†Abbreviations: PO, prescription opioid; PMP, Prescription Drug Monitoring Program; OAT, Opioid Agonist Treatment; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; NSDUH, National Survey on Drug Use and Health; CSAT, Center for Substance Abuse Treatment; SAMHSA, Substance Abuse and Mental Health Services Administration; DEA, Drug Enforcement Administration; CBT, cognitive behavioral therapy; OEND, Overdose Education and Naloxone Distribution; ONDCP, Office of National Drug Control Policy; ORT, Opioid Risk Tool; COMM, Current Opioid Misuse Measure.

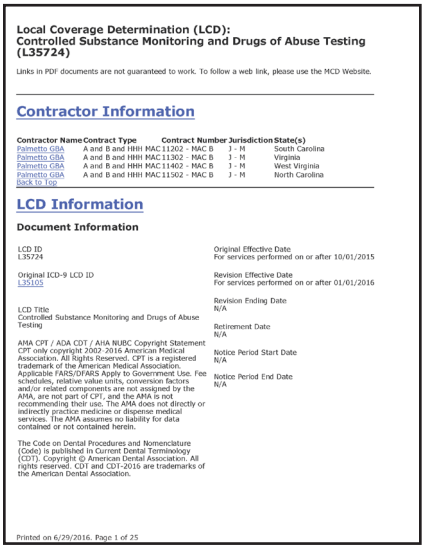
Keywords: opioid use disorder, prescription opioid use disorder, opioid agonist treatment, substance use disorder

2 subject matter experts
35 references

Tetrault, J.M., Butner, J.L. (2015). **Non-medical prescription opioid use and prescription opioid use disorder: a review Yale Journal of Biology and Medicine** 88: 227-333. Retrieved from www.ncbi.nlm.nih.gov/pmc/articles/PMC4553642/

Summary: Prescribers of opioids must risk-stratify all patients and constantly reassess treatment plans using many different tools including treatment agreements, drug testing, and pill counts, as well as prescribe small quantities more frequently.

Quote, page 231: "Prior to initiation of chronic opioid therapy, it is invaluable and necessary to risk-stratify all patients based on their risk factors for developing addictions… Risk management and harm reduction strategies are used for monitoring and controlling non-medical PO use. Constant reassessment of treatment plans and employment of many different measures to monitor adherence to treatment such as urine drug screenings, pill counts, signed treatment agreements, and prescription of small frequent quantities should be employed on an ongoing basis."



Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L35724)

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Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Back to Top

LCD Information

Document Information

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L35724

Original ICD-9 LCD ID
L35105

LCD Title
Controlled Substance Monitoring and Drugs of Abuse Testing

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For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2016

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

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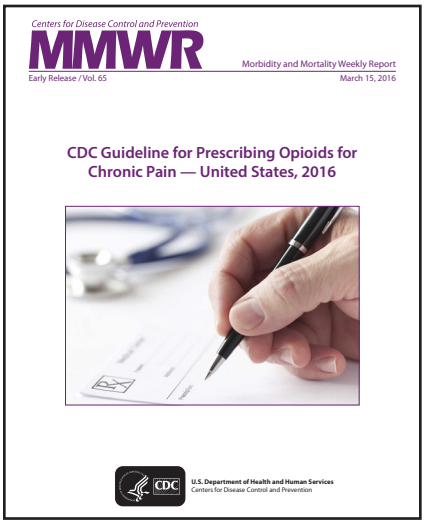
Printed on 6/29/2016. Page 1 of 25

38 references

Centers for Medicare and Medicaid Services (CMS), U.S. Government, Palmetto MAC, **Local coverage determination (LCD): Controlled substance monitoring and drugs of abuse testing** (L35724). Retrieved from: https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx

Summary: In its definition of Medical Necessity, CMS calls for assessing each patient for risk of misuse using a validated risk assessment and then urine drug testing with all patients undergoing Chronic Opioid Therapy at 1-2/year for low risk, 2-4/year for medium risk and 4-12/year for high risk.

Quote, page 13: "The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications. The clinician should perform random UDT at random intervals, in order to properly monitor a patient…. Low Risk Random testing 1-2 times every 12 months for prescribed medications, non-prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage. Moderate Risk Random testing 1-2 times every 6 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage. High Risk Random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage."



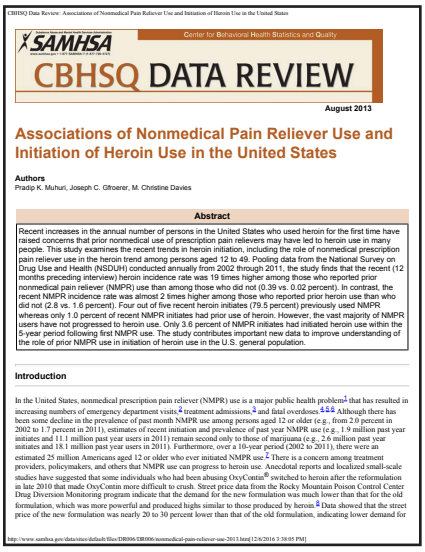
80 subject matter experts
223 references

Dowell, D., M.D., Haegerich, T. M., Ph.D., and Chou, R., M.D., (2016). **CDC guideline for prescribing opioids for chronic pain - United States, 2016**. Retrieved from http://www.cdc.gov/mmwr/

Summary: The CDC recommends risk assessment, treatment agreements, PDMP checks and urine drug testing for chronic opioid therapy patients.

Quote, page 16: "Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy… evaluate risk factors for opioid-related harms… review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months… When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs."

Evidence: The relationship between opioid use and heroin use

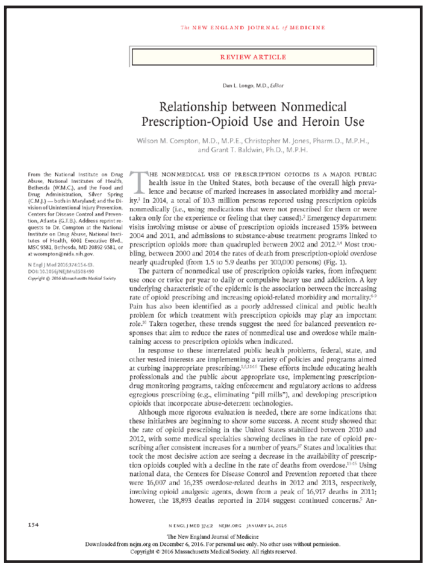


3 subject matter experts
28 references

Muhuri, P. K., Gfroerer, M., and Davies, C. (2013 Aug). **Associations of nonmedical pain reliever use and initiation of heroin use in the United States**. CBHSQ Data Review. SAMSHA, Center for Behavioral Health Statistics and Quality. Retrieved from http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

Summary: While the majority of heroin users have misused prescription opioids, heroin use among opioid users is very rare. Only 3.6% who have misused prescription opioids use heroin within five years of initial opioid misuse.

Quote, from abstract: "Pooling data from the National Survey on Drug Use and Health (NSDUH) conducted annually from 2002 through 2011, the study finds that the recent (12 months preceding interview) heroin incidence rate was 19 times higher among those who reported prior nonmedical pain reliever (NMPR) use than among those who did not (0.39 vs. 0.02 percent).... Four out of five recent heroin initiates (79.5 percent) previously used NMPR whereas only 1.0 percent of recent NMPR initiates had prior use of heroin....Only 3.6 percent of NMPR initiates had initiated heroin use within the 5-year period following first NMPR use."



The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Dan L. Longo, M.D., Editor

Relationship between Nonmedical Prescription-Opioid Use and Heroin Use

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THE NONMEDICAL USE OF PRESCRIPTION OPIOIDS IS A MAJOR PUBLIC health issue in the United States, both because of the overall high prevalence and because of marked increases in associated morbidity and mortality.[1] In 2014, a total of 10.3 million persons reported using prescription opioids nonmedically (i.e., using medications that were not prescribed for them or were taken only for the experience or feeling that they caused).[2] Emergency department visits involving misuse or abuse of prescription opioids increased 153% between 2004 and 2011, and admissions to substance-abuse treatment programs linked to prescription opioids more than quadrupled between 2002 and 2012.[3,4] Most troubling, between 2003 and 2014 the rates of death from prescription-opioid overdose nearly quadrupled (from 1.5 to 5.9 deaths per 100,000 persons) (Fig. 1).

The pattern of nonmedical use of prescription opioids varies, from infrequent use once or twice per year to daily or compulsive heavy use and addiction. A key underlying characteristic of the epidemic is the association between the increasing rate of opioid prescribing and increasing opioid-related morbidity and mortality.[5,6] Pain has also been identified as a poorly addressed clinical and public health problem for which treatment with prescription opioids may play an important role.[7] Taken together, these trends suggest the need for balanced prevention responses that aim to reduce the rates of nonmedical use and overdose while maintaining access to prescription opioids when indicated.

In response to these interrelated public health problems, federal, state, and other vested interests are implementing a variety of policies and programs aimed at curbing inappropriate prescribing.[5,8-11] These efforts include educating health professionals and the public about appropriate use, implementing prescription-drug monitoring programs, taking enforcement and regulatory actions to address egregious prescribing (e.g., eliminating "pill mills"), and developing prescription opioids that incorporate abuse-deterrent technologies.

Although more rigorous evaluation is needed, there are some indications that these initiatives are beginning to show some success. A recent study showed that the rate of opioid prescribing in the United States stabilized between 2010 and 2012, with some medical specialties showing declines in the rate of opioid prescribing after consistent increases for a number of years.[5] States and localities that took the most decisive action are seeing a decrease in the availability of prescription opioids coupled with a decline in the rate of deaths from overdose.[12,13] Using national data, the Centers for Disease Control and Prevention reported that there were 16,007 and 16,235 overdose-related deaths in 2012 and 2013, respectively, involving opioid analgesic agents, down from a peak of 16,917 deaths in 2011; however, the 18,893 deaths reported in 2014 suggest continued concerns.[2] An-

154 N ENGL J MED 374;2 NEJM.ORG JANUARY 14, 2016

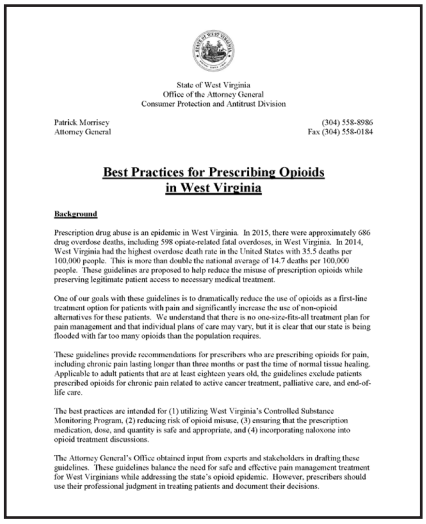
3 subject matter experts
66 references

Compton, W. M., M.D., Jones, C. M., PharmD, and Baldwin, G. T., MPH, (2016 Jan 14). **Relationship between nonmedical prescription-opioid use and heroin use.** N Engl J Med 374: 2, 154-63. Retrieved from www.nejm.org/doi/pdf/10.1056/NEJMra1508490

Summary: Policies and practices which tighten prescribing rules do not drive of the current heroin problem. We must not just treat. We need both treatment and prevention to stop addiction in the first place.

Quote, page 160: "Although some authors suggest that there is an association between policy-driven reductions in the availability of prescription opioids and increases in the rates of heroin use, the timing of these shifts, many of which began before policies were robustly implemented, makes a causal link unlikely. In the majority of studies, the increase in the rates of heroin use preceded changes in prescription-opioid policies, and there is no consistent evidence of an association between the implementation of policies related to prescription opioids and increases in the rates of heroin use or deaths, although the data are relatively sparse… Regardless of the causes of the high rates of both nonmedical prescription-opioid use and heroin use, in order to minimize overall opioid-related morbidity and mortality, efforts are needed to help people who are already addicted, in parallel with efforts to prevent people from becoming addicted in the first place."

Example state prescribing guidelines



State of West Virginia
Office of the Attorney General
Consumer Protection and Antitrust Division

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Best Practices for Prescribing Opioids in West Virginia

Background

Prescription drug abuse is an epidemic in West Virginia. In 2015, there were approximately 686 drug overdose deaths, including 598 opiate-related fatal overdoses, in West Virginia. In 2014, West Virginia had the highest overdose death rate in the United States with 35.5 deaths per 100,000 people. This is more than double the national average of 14.7 deaths per 100,000 people. These guidelines are proposed to help reduce the misuse of prescription opioids while preserving legitimate patient access to necessary medical treatment.

One of our goals with these guidelines is to dramatically reduce the use of opioids as a first-line treatment option for patients with pain and significantly increase the use of non-opioid alternatives for these patients. We understand that there is no one-size-fits-all treatment plan for pain management and that individual plans of care may vary, but it is clear that our state is being flooded with far too many opioids than the population requires.

These guidelines provide recommendations for prescribers who are prescribing opioids for pain, including chronic pain lasting longer than three months or past the time of normal tissue healing. Applicable to adult patients that are at least eighteen years old, the guidelines exclude patients prescribed opioids for chronic pain related to active cancer treatment, palliative care, and end-of-life care.

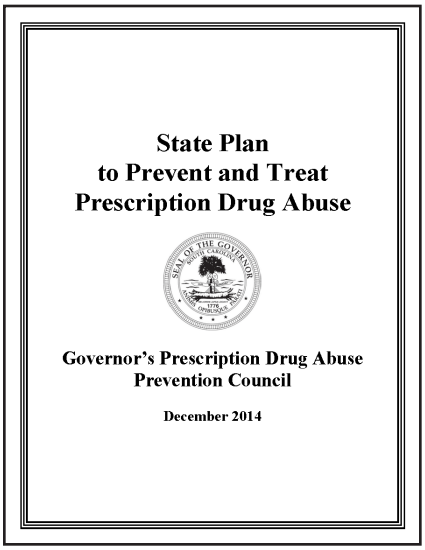
The best practices are intended for (1) utilizing West Virginia's Controlled Substance Monitoring Program, (2) reducing risk of opioid misuse, (3) ensuring that the prescription medication, dose, and quantity is safe and appropriate, and (4) incorporating naloxone into opioid treatment discussions.

The Attorney General's Office obtained input from experts and stakeholders in drafting these guidelines. These guidelines balance the need for safe and effective pain management treatment for West Virginians while addressing the state's opioid epidemic. However, prescribers should use their professional judgment in treating patients and document their decisions.

Best practices for prescribing opioids in West Virginia. (2016 Aug 19). State of West Virginia Office of the Attorney General Consumer Protection and Antitrust Division. Retrieved from: http://www.ago.wv.gov/Documents/2016.08.19%20BP%20Prescribing.PDF

Summary: West Virginia recommends a risk assessment, treatment agreement, PDMP ("CSMP") check and urine drug testing.

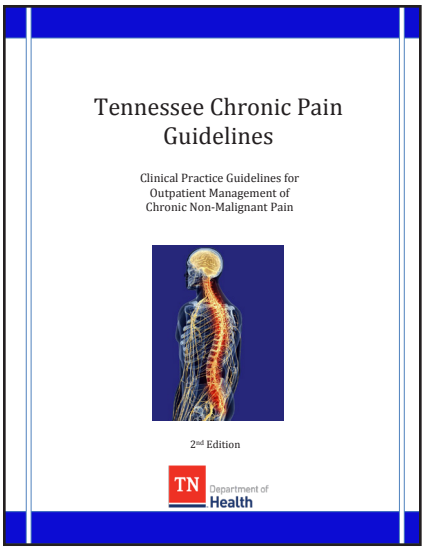
Quote, page 2: "Prescriber or his or her authorized designate should check West Virginia's Controlled Substance Monitoring Program ("CSMP") every time the prescriber writes an opioid or benzodiazepine prescription or at least once every three months... prescriber should conduct random urine toxicology screening and testing... screen all patients for opioid misuse risk and adverse effects using [a validated risk tool]."



South Carolina state plan to prevent and treat prescription drug abuse. (2014 Dec). Retrieved from http://governor.sc.gov/ExecutiveOffice/Documents/Prescription%20Drug%20Abuse%20Prevention%20Council%20State%20Plan%20December%202014.pdf

Summary: South Carolina recommends risk assessments and stratifying patient monitoring based on risk, treatment agreements, PDMP reviews and urine drug testing. 80 MED re-establishes treatment plan.

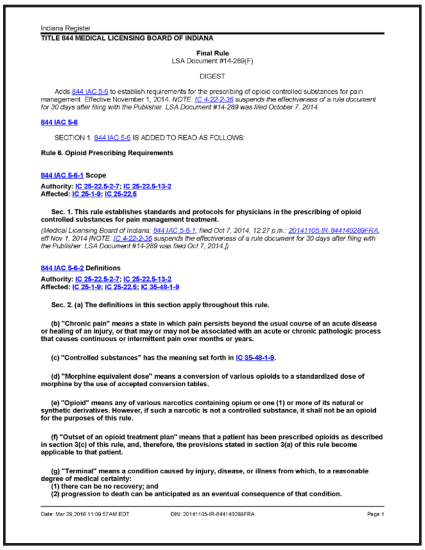
Quote, page 95: "Treatment agreements are indicated when opioid or other abusable medications are prescribed... SCRIPTS utilization should be part of every patient's initial evaluation and subsequent monitoring program and is considered the standard of care. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation.... When a patient is prescribed 80 Morphine Equivalent Dose (MED) for longer than three continuous months, it is recommended that the prescriber: re-establish informed consent; review the patient's functional status, including daily activities, analgesia, aberrant behavior, and adverse effects, as it relates to progress toward treatment objectives established at the onset of opioid therapy; consult SCRIPTS to verify compliance; re-establish office visit intervals; review frequency of drug screens; and review and execute a new treatment agreement.... Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs. Drug testing is an important monitoring tool because self-reports of medication use and behavioral observations are not always reliable."



Tennessee Chronic Pain Guidelines: Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain. (2016). Version 2. Retrieved from: https://www.tn.gov/assets/entities/health/attachments/ChronicPainGuidelines.pdf

Summary: Tennessee requires risk assessments, treatment agreements, PDMP ("CSMD") reviews and urine drug testing. 120 MED goes to a Pain Specialist.

Quote, page 12: "Based on the combined information of patient behavior, collateral information, the CSMD [Controlled Substance Monitoring Database] results, the UDT (or Oral Fluids Test) results and past records, an ongoing risk assessment should be made about a patient's risk of misuse, abuse or diversion of medications. The prescribing of opioids, if medically indicated, shall take this risk assessment information into account on an ongoing basis. Adjustments to the patient's treatment should occur in a timely manner based on this information. Inconsistent results from the treatment plan should be addressed immediately and documented action taken as appropriate."



Indiana Register
TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Final Rule
LSA Document #14-289(F)

DIGEST

Adds 844 IAC 5-6 to establish requirements for the prescribing of opioid controlled substances for pain management. Effective November 1, 2014. NOTE: IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed October 7, 2014.

844 IAC 5-6

SECTION 1. 844 IAC 5-6 IS ADDED TO READ AS FOLLOWS:

Rule 6. Opioid Prescribing Requirements

844 IAC 5-6-1 Scope
Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5

Sec. 1. This rule establishes standards and protocols for physicians in the prescribing of opioid controlled substances for pain management treatment.

(Medical Licensing Board of Indiana; 844 IAC 5-6-1; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 (NOTE: IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.)

844 IAC 5-6-2 Definitions
Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5; IC 35-48-1-9

Sec. 2. (a) The definitions in this section apply throughout this rule.

(b) "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(c) "Controlled substances" has the meaning set forth in IC 35-48-1-9.

(d) "Morphine equivalent dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

(e) "Opioid" means any of various narcotics containing opium or one (1) or more of its natural or synthetic derivatives. However, if such a narcotic is not a controlled substance, it shall not be an opioid for the purposes of this rule.

(f) "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in section 3(c) of this rule, and, therefore, the provisions stated in section 3(a) of this rule become applicable to that patient.

(g) "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:
(1) there can be no recovery; and
(2) progression to death can be anticipated as an eventual consequence of that condition.

Date: Mar 29,2016 11:09:57AM EDT DIN: 20141105-IR-844140289FRA Page 1

Title 844 Medical Licensing Board of Indiana Final Rule LSA Document #14-289(F) **Rule 6. Opioid Prescribing Requirements**. Retrieved from: www.in.gov/legislative/iac/20141105-IR-844140289FRA.xml.pdf

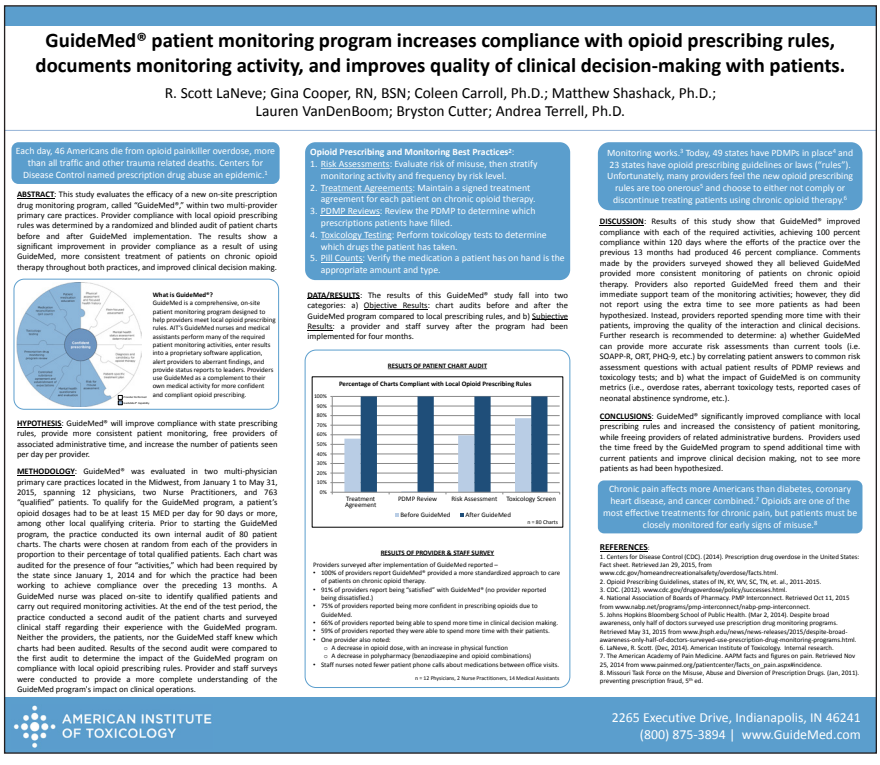
Summary: Indiana requires physicians by law to perform risk assessments, treatment agreements, PDMP ("INSPECT") reviews, urine drug testing and pill counts. 15 MED triggers monitoring.

Quote, pages 3-4: "Evaluation and risk stratification by physician Sec. 4" "Physician discussion with patient; treatment agreement Sec. 5" "At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient." "At any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class, on the patient."

GuideMed Pilot Study

In 2015 the American Institute of Toxicology, now a HealthTrackRx company, presented a poster using pilot study data that shows GuideMed successfully raised a clinic's compliance to local prescribing rules from 46 percent to 100 percent in just 120 days for 763 patients prescribed chronic opioid therapy.

The same clinic experienced a 20 percent drop in aberrant patient toxicology results. While encouraging, the reduction in aberrancies cannot be unequivocally attributed to GuideMed alone for the same reasons there are no studies available today that unequivocally show monitoring patients improves outcomes. Too much variability in treatment options in response to monitoring results exists for simple measurement of effectiveness.



GuideMed® patient monitoring program increases compliance with opioid prescribing rules, documents monitoring activity, and improves quality of clinical decision-making with patients.

R. Scott LaNeve; Gina Cooper, RN, BSN; Coleen Carroll, Ph.D.; Matthew Shashack, Ph.D.; Lauren VanDenBoom; Bryston Cutter; Andrea Terrell, Ph.D.

Each day, 46 Americans die from opioid painkiller overdose, more than all traffic and other trauma related deaths. Centers for Disease Control named prescription drug abuse an epidemic.[1]

ABSTRACT: This study evaluates the efficacy of a new on-site prescription drug monitoring program, called "GuideMed®," within two multi-provider primary care practices. Provider compliance with local opioid prescribing rules was determined by a randomized and blinded audit of patient charts before and after GuideMed implementation. The results show a significant improvement in provider compliance as a result of using GuideMed, more consistent treatment of patients on chronic opioid therapy throughout both practices, and improved clinical decision making.

What is GuideMed®?
GuideMed is a comprehensive, on-site patient monitoring program designed to help providers meet local opioid prescribing rules. AIT's GuideMed nurses and medical assistants perform many of the required patient monitoring activities, enter results into a proprietary software application, alert providers to aberrant findings, and provide status reports to leaders. Providers use GuideMed as a complement to their own medical activity for more confident and compliant opioid prescribing.

HYPOTHESIS: GuideMed® will improve compliance with state prescribing rules, provide more consistent patient monitoring, free providers of associated administrative time, and increase the number of patients seen per day per provider.

METHODOLOGY: GuideMed® was evaluated in two multi-physician primary care practices located in the Midwest, from January 1 to May 31, 2015, spanning 12 physicians, two Nurse Practitioners, and 763 "qualified" patients. To qualify for the GuideMed program, a patient's opioid dosages had to be at least 15 MED per day for 90 days or more, among other local qualifying criteria. Prior to starting the GuideMed program, the practice conducted its own internal audit of 80 patient charts. The charts were chosen at random from each of the providers in proportion to their percentage of total qualified patients. Each chart was audited for the presence of four "activities," which had been required by the state since January 1, 2014 and for which the practice had been working to achieve compliance over the preceding 13 months. A GuideMed nurse was placed on-site to identify qualified patients and carry out required monitoring activities. At the end of the test period, the practice conducted a second audit of the patient charts and surveyed clinical staff regarding their experience with the GuideMed program. Neither the providers, the patients, nor the GuideMed staff knew which charts had been audited. Results of the second audit were compared to the first audit to determine the impact of the GuideMed program on compliance with local opioid prescribing rules. Provider and staff surveys were conducted to provide a more complete understanding of the GuideMed program's impact on clinical operations.

Opioid Prescribing and Monitoring Best Practices[2]:
1. Risk Assessments: Evaluate risk of misuse, then stratify monitoring activity and frequency by risk level.
2. Treatment Agreements: Maintain a signed treatment agreement for each patient on chronic opioid therapy.
3. PDMP Reviews: Review the PDMP to determine which prescriptions patients have filled.
4. Toxicology Testing: Perform toxicology tests to determine which drugs the patient has taken.
5. Pill Counts: Verify the medication a patient has on hand is the appropriate amount and type.

DATA/RESULTS: The results of this GuideMed® study fall into two categories: a) Objective Results: chart audits before and after the GuideMed program compared to local prescribing rules, and b) Subjective Results: a provider and staff survey after the program had been implemented for four months.

RESULTS OF PATIENT CHART AUDIT

RESULTS OF PROVIDER & STAFF SURVEY

Providers surveyed after implementation of GuideMed reported –
- 100% of providers report GuideMed® provided a more standardized approach to care of patients on chronic opioid therapy.
- 91% of providers report being "satisfied" with GuideMed® (no provider reported being dissatisfied.)
- 75% of providers reported being more confident in prescribing opioids due to GuideMed.
- 66% of providers reported being able to spend more time in clinical decision making.
- 59% of providers reported they were able to spend more time with their patients.
- One provider also noted:
  - A decrease in opioid dose, with an increase in physical function
  - A decrease in polypharmacy (benzodiazepine and opioid combinations)
- Staff nurses noted fewer patient phone calls about medications between office visits.

n = 12 Physicians, 2 Nurse Practitioners, 14 Medical Assistants

Monitoring works.[3] Today, 49 states have PDMPs in place[4] and 23 states have opioid prescribing guidelines or laws ("rules"). Unfortunately, many providers feel the new opioid prescribing rules are too onerous[5] and choose to either not comply or discontinue treating patients using chronic opioid therapy.[6]

DISCUSSION: Results of this study show that GuideMed® improved compliance with each of the required activities, achieving 100 percent compliance within 120 days where the efforts of the practice over the previous 13 months had produced 46 percent compliance. Comments made by the providers surveyed showed they all believed GuideMed provided more consistent monitoring of patients on chronic opioid therapy. Providers also reported GuideMed freed them and their immediate support team of the monitoring activities; however, they did not report using the extra time to see more patients as had been hypothesized. Instead, providers reported spending more time with their patients, improving the quality of the interaction and clinical decisions. Further research is recommended to determine: a) whether GuideMed can provide more accurate risk assessments than current tools (i.e. SOAPP-R, ORT, PHQ-9, etc.) by correlating patient answers to common risk assessment questions with actual patient results of PDMP reviews and toxicology tests; and b) what the impact of GuideMed is on community metrics (i.e., overdose rates, aberrant toxicology tests, reported cases of neonatal abstinence syndrome, etc.).

CONCLUSIONS: GuideMed® significantly improved compliance with local prescribing rules and increased the consistency of patient monitoring, while freeing providers of related administrative burdens. Providers used the time freed by the GuideMed program to spend additional time with current patients and improve clinical decision making, not to see more patients as had been hypothesized.

Chronic pain affects more Americans than diabetes, coronary heart disease, and cancer combined.[7] Opioids are one of the most effective treatments for chronic pain, but patients must be closely monitored for early signs of misuse.[8]

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