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Prescription Drug Abuse: Epidemiology, Regulatory Issues, Chronic Pain Management with Narcotic Analgesics

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Synopsis

The epidemic of prescription drug abuse has reached a critical level, which has received national attention. Physicians must learn strategies to effectively treat chronic pain, and help reduce the rates of prescription drug abuse. This chapter will provide insight into the epidemiology of prescription drug abuse, explain regulatory issues, and provide guidelines for the assessment and management of pain, particularly with chronic opioid therapy. The use of informed consent forms, treatment agreements, risk documentation tools, and regular monitoring of the 4 “A's” helps to educate patients, as well as guide management based on treatment goals. By using universal precautions, and being aware of aberrant behaviors, physicians may feel more confident in identifying and addressing problematic behaviors.

Keywords

opioids; chronic pain; prescription drug abuse; pain management

Introduction

While prescription drugs have been used effectively and appropriately to treat medical and psychiatric illness in the majority of patients, rates of abuse have escalated at alarming rates in the past decade [1]. The increased availability of prescription drugs has contributed to a dramatic rise of non-medical use and abuse of these medications [2]. Increased clinician awareness is essential in helping reduce prescription drug abuse, while continuing to provide effective treatment.

In the last few decades, the treatment of chronic pain has expanded in the primary care setting [3]. Many primary care providers have had little specific training in pain medicine and addiction, and are unsure about how to safely prescribe opioids [4]. In addition, the high

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prevalence of psychiatric comorbidity in those that misuse or abuse prescription drugs contributes to the complexity in treating pain [5].

Chronic pain conditions and prescription drug abuse are becoming important public health issues. Population-based studies reveal that more than 75 million Americans (about 25% of the entire population) have chronic or recurrent pain. Of these, 40% report the pain as having moderate to severe impact on their lives [6]. Chronic pain has placed an undue burden in lost productivity and as a frequent cause of disability with an estimated cost to employees of greater than $61 billion annually [7]. The prevalence of chronic pain conditions will only increase with the advancing age of our population [8].

Navigating the complexity of treatment guidelines provided by the FSMB (The Federation of State Medical Boards), the U.S. DEA (Drug Enforcement Agency) and other health organizations can be confusing and intimidating. The difficulties in measuring pain, fear of regulatory issues, and legal risks are additional barriers to providing appropriate pain management.

This chapter will cover the epidemiology of prescription drug abuse, regulatory issues, and chronic pain management with narcotic analgesics. By understanding the scope of the problem, developing structured pain management plans, and being aware of “aberrant behaviors,” clinicians may feel more prepared and confident when dealing with acute and chronic pain.

Epidemiology

The most up-to-date and reliable sources on the epidemiology of prescription drug abuse include the National Survey on Drug Use and Health (NSDUH), the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), Monitoring the Future, and the Drug Abuse Warning Network (DAWN). These surveys collect different types of information that can give an accurate account of the trends of prescription drug abuse.

NSDUH is an annual survey of the civilian, non-institutionalized population of the U.S. aged 12 or older (N=67,500), sponsored by SAMHSA (Substance Abuse and Mental Health Services Administration) Office of Applied Studies in the Department of Health and Human Services [9]. NSDUH has provided information on the incidence and prevalence of substance use in the population, and the problems associated with use on an annual basis since 1999. In addition to describing socio-demographic characteristics of users, patterns of use, treatment, perceptions of risk and availability, criminal behavior, and mental health, the NSDUH covers four broad classes of prescription psychotherapeutic drugs: pain relievers, tranquilizers, stimulants, and sedatives. Non-medical use is defined as use of these medications without one's own prescription or simply for the experience of euphoria or other positive subjective drug effects. Non-medical use does not include the legitimate use of prescription drugs under a physician's direction, nor does it include use of over-the-counter medications.

The most recent NSDUH statistics for 2008 report an estimated 6.2 million (2.5%) persons aged 12 or older using prescription-type psychotherapeutic drugs non-medically in the past month [9]. The majority of non-medical users (55.9 percent) obtained these drugs from a friend or relative for free (of which, 81.7 of these friends or relatives received drugs from one doctor) [9]. About 18.0 percent of non-medical users received these drugs from only one doctor [9]. Only 4.3 percent got pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet [9]. For the first time, the largest number of past year initiates (first-time users) of illicit drugs for persons aged 12 or older were equal for marijuana use and non-medical use of pain relievers (both 2.2 million) [9]. While marijuana represented the illicit drug with the highest levels of past year dependence or abuse at 4.2 million, pain relievers (1.7 million) are now the second most commonly abused illicit substance [9].

New data on mental health was collected for 2008 NYSDUH reports, which revealed that adults with past year major depressive episodes (MDE) were more likely than those without MDE to be dependent on or abuse illicit drugs or alcohol (20.3 vs. 7.8 percent) [9]. Persons with serious mental illness (SMI) are defined as those aged 18 or older who have in the past year have had a DSM-IV-based mental, behavioral, or emotional disorder (excluding developmental and substance use disorders) that meet diagnostic criteria and resulting in functional impairment in one or more major life activities. Among persons with SMI, the rate of past year substance dependence or abuse was 25.3 percent (2.5 million) compared to 8.3 percent (17.9 million) for those without SMI [9].

Compared to reports of past month non-medical use of pain relievers in 2002, there are increases among young adults aged 18 to 25 in 2007 (from 4.1 to 4.6 percent), and adults aged 26 or older (from 1.3 to 1.6 percent) [10]. In older adults aged 50 or more, an estimated 4.3 million (4.7 percent) had used an illicit drug in the past year, according to data from 2006 to 2008. Thus, rates of non-medical prescription drug use are currently rising, particularly at both ends of the adult age spectrum. Indeed, among those aged 65 and older, non-medical use of prescription-type drugs is now more common than marijuana use (0.8 vs. 0.4 percent) [11].

With regard to stimulants, educational activity appears to predict the likelihood of non-medical use. Full-time college students aged 18 to 22 were twice as likely to have used Adderall ® non-medically in the past year compared to part-time students of the same age (6.4 vs. 3.0 percent) [12]. Those students who reported non-medical use of Adderall ® were 8 times more likely than non-users to be non-medical users of prescription tranquilizers (24.5 vs. 3.0 percent), and 5 times more likely to have concurrent non-medical use of prescription pain relievers (44.9 vs. 8.7 percent) [12].

The National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) was originally designed to look at the magnitude of alcohol use disorders and their associated disabilities in the general population [13]. NESARC is sponsored by the U.S. Department of Health and Human Services (DHHS)/National Institutes of Health/National Institute on Alcohol Abuse and Alcoholism (NIAAA). It is a longitudinal survey with its first wave of interviews fielded in 2001-2002 and second wave in 2004-2005. The NESARC is a representative sample (43,093 respondents) of the non-institutionalized U.S. population 18 years of age and older [13]. Public use data are currently available for the first wave of data collection.

The NESARC collects data on alcohol consumption, alcohol abuse and dependence, alcohol treatment utilization, drug abuse and dependence, drug treatment utilization, family history of drug abuse, major depression, family history of major depression, and other psychiatric disorders [13]. Information on the non-medical use of prescription opioids, sedatives, tranquilizers, and stimulants (which includes use ‘without a prescription, in greater amounts, more often, or longer than prescribed, or for a reason other than a doctor instructed to use them’) is also available [13].

Lifetime prevalence of non-medical prescription drug use in 2004-5 was highest for opioids and stimulants (both 4.7%), followed by sedatives (4.1%), and tranquilizers (3.4%), and the lifetime prevalence of abuse or dependence for these drugs (non-medical use) was highest for stimulants (2.0%), followed by opioids (1.4%), sedatives (1.1%), and tranquilizers (1.0%) [13]. There were significant associations between non-medical prescription drug use disorders and other substance uses disorders, as well as with co-occurring DSM –IV Axis I and II psychiatric disorders, most notably with alcohol (odds ratio [OR] 11.4-16.1), and with antisocial personality disorder (OR 8.1-9.9) [13].

When looking at age categories, young adults aged 18-29 years had the highest rates of non-medical use of opioids (7.4%) and tranquilizers (4.7%) [13]. Those aged 30-44 years had higher rates of non-medical use of stimulants (6.8%) and sedatives (5.1%) [13]. The NESARC report also analyzes demographic and regional differences in non-medical use and abuse of prescription drugs [13]. Men, especially in the western United States, had significantly higher rates compared to women, of non-medical use of all categories of prescription drug use [13]. Native Americans also had the highest rates of prescription drug abuse in all categories, followed by Hispanics, Asians and African Americans [13]. Compared to persons who were married and cohabitating, those who were never married, widowed, separated, or divorced had greater non-medical use/abuse of opioids, sedatives, and tranquilizers [13]. Thus, risk factors for non-medical use of prescription opioids include male gender, Native American or Hispanic ethnicity, and single status.

Monitoring the Future is an annual survey of high-school students in grades 8-12 and a smaller sample of previously surveyed high school graduates that looks at the prevalence of drug and alcohol use [14]. In 2007, 48, 025 students from 403 schools responded [14]. To determine non-medical use of psychotropic medications, participants were asked about use ‘on your own – that is, without a doctor telling you to take them’. Annual rates of non-medical use of prescription opioids has more than doubled in high-school seniors in the last 15 years from 3.5 % in 1991 to 9.2 % in 2007 [14]. The use of sedatives and tranquilizers has decreased from 11 % in the mid-1970's to 6.2 % in 2007 [14]. Among 12th graders, stimulant use has fluctuated through the years, from 20.3 % in 1982 to 7.1 % in 1992, and most recently to 7.5 % in 2007 [14]. When asked about availability of prescription medications, the percentage of 12th graders who reported that it was ‘fairly easy’ or ‘very easy’ to obtain drugs was 49.6 % for stimulants, 41.7 % for sedatives, 37.3 % for opioids, and 23.6 % for tranquilizers [14].

The Drug Abuse Warning Network is sponsored by SAMHSA, and adds additional insight to the scope of the problem of non-medical use and abuse of drugs. Data is collected from 355 non-federal US hospitals that have 24-hour emergency departments (ED) [15]. DAWN reports track ED visits related to the recent use of prescription medications, over-the counter (OTC) medications, dietary supplements, and alcohol [15]. In 2005, 1.5 million of the 108 million ED visits were associated with drug misuse or abuse, with most visits (55 %) involving multiple drugs [15]. Of these visits, more than a third involved the non-medical use of prescription or OTC drugs [15]. In decreasing order, there were 204,711 visits related to anxiolytics, sedatives, and hypnotics; 196,225 visits for opioids; 61,023 visits for antidepressants; and 10,616 for stimulants (amphetamine, dextroamphetamine, methylphenidate, and caffeine) [15]. In one DAWN report, there were an estimated 245,800 drug-related emergency department visits for patients diagnosed with co-occurring substance use and mental disorders in 2004 [16].

Although national surveys provide important information on the national burden of prescription drug misuse and abuse, there are limitations with regard to methodology, measures, and sample populations targeted. More specific and recent trends can be captured from other sources, such as the Drug Evaluation Network System, which has valuable information on patients admitted to addiction treatment programs [17]. This system has detected increases in abuse of oxycodone HCl from 2002 to 2004 [17]. Among the 27,816 subjects, 1425 subjects (5 %) reported ever using oxycodone HCL, and a majority (87%) had used it more than three times per week for at least one year [17]. The use of oxycodone

HCl with at least one other opioid was reported by 92% of the users [17]. Abusers of oxycodone HCL were more likely to be Caucasian (89 %), male (69 %), younger (mean 32 ± 10 years), employed (51 %), and to have used heroin compared to the rest of the group (all $p < 0.05$) [17].

Another trend is the use of the Internet as a growing source of controlled prescription medications for non-medical use [18]. The National Center on Addiction and Substance Abuse (CASA) at Columbia University has reported an alarming increase in the number of Web sites selling controlled prescription drugs (i.e. oxycodone HCl, acetaminophen/ hydrocodone, diazepam, and methylphenidate) from 154 in 2004 to 187 in 2007 [19]. Benzodiazepines are most frequently offered (sold on 79 % of such sites), followed by opioids (in 64 % of sites)[19]. In another study, 735 sites offered opioids without a prescription [18].

Online pharmacies have become a multibillion-dollar industry worldwide. In 2005, 32% of online customers surveyed reported having purchased medications or health care products on the Internet [20]. The availability of prescription drugs on the Internet raises the likelihood of unchecked medication interactions and side effects without reliable physician supervision. The use of “cyberdoctor” consultations to determine need for prescriptions through online questionnaires raises concerns about whether such programs involve participation by actual physicians, or if these are merely computer programs that help guide patients toward responses necessary to justify a prescription [21]. Few sites disclose the credentials of the doctors performing online services, and some state that physicians may not reside in the same country as the patient or the pharmacy [22]. Medications from these sites may also be expired, substandard or counterfeit, since Web sites are not required to provide information on where or when drugs are manufactured [23].

The existence of Internet pharmacies allows individuals to bypass the traditional safeguards placed by the FDA, Congress, and health care providers, thereby placing consumers at risk [24]. Fortunately, the FDA, drug manufacturers and professional organizations have been active in finding ways to reduce risk. The FDA website (www.fda.gov) provides useful information on how to spot and avoid health fraud and allows for reporting of suspicious sites. This system averages about 60,000 complaints per month [25]. The FDA website, www.fda.gov/oc/buyonline/others.html is also a reliable source for purchasing medications on the Internet, and www.fda.gov/ora/oasis/ora_oasis_ref.html lists international Web sites banned from offering prescription medications to the United States.

Regulatory Issues

The epidemic of prescription drug abuse has gained enough public attention to warrant governmental hearings to address this issue. On July 26, 2006, there were testimonies before the SubCommittee on Criminal Justice, Drug Policy, and Human Resources, Committee On Government Reform at the United States House of Representatives in a hearing titled “Prescription Drug Abuse: What is Being Done to Address this New Drug Epidemic?” Some key topics included what is being done at present, as well as future strategies to combat drug abuse, including prescription drug monitoring programs, reducing malprescriptions, public education, eliminating Internet drug pharmacies, and the development of future drugs which are not only tamper-resistant but also non-addictive.

The Drug Enforcement Agency (DEA) has been active in addressing the problems with prescription drug abuse. On October 27, 1970, The Comprehensive Drug Abuse Prevention and Control Act was passed by Congress [26]. This Act was a “consolidation of numerous laws regulating the manufacturing and distribution of narcotics ... and chemicals used in the illicit production of controlled substances” and provided a “legal foundation of the government's fight against drugs and other substances.” [26]. The DEA's diversion control program is involved in overseeing and regulating the legal manufacture and distribution of controlled pharmaceuticals. The DEA recognizes that controlled pharmaceuticals can be diverted intentionally or unintentionally by doctors, pharmacists, dentists, nurses, veterinarians, and individual users. Such diversion cases include physicians selling prescriptions to drug dealers, pharmacists falsifying records to obtain and then sell pharmaceuticals, individuals who forge prescriptions, “doctor shoppers” who visit multiple doctors to obtain multiple prescriptions for the same ailment, and individuals using the Internet to sell controlled medications without requiring prescriptions.

Despite receiving criticism by Congress in a 2005 House report for demonstrating a “lack of effort to address this problem,” the DEA contends that it has significantly increased the amount of resources and manpower dedicated to the diversion of controlled pharmaceuticals by increasing the number of special agent work hours by 114%, and of intelligence analysts by 234% from 2003 to 2005 [27][28]. Other DEA efforts include an anti-drug website for teens by the Demand Reduction Office, www.justthinktwice.com, which provides information on the consequences of drug use and trafficking, as well as health, social, and legal consequences [28]. In addition, the Demand Reduction Office provides presentations to the public and school age children regarding the abuse of controlled prescriptions [28].

Prescription Drug Monitoring Programs were first developed in the early twentieth century to detect and prosecute diversion cases. With the collaboration of the American Society of Interventional Pain Physicians (ASIPP), Congress passed and signed into law the National All Schedules Prescription Electronic Reporting (NASPER) Act on August 11, 2005 to establish or improve state-run prescription drug monitoring programs [29]. These statewide programs have served to track the flow of prescriptions of controlled medications. NASPER is housed within the Department of Health and Human Services, and has been allocated $60 million through fiscal year 2010. Prescription monitoring programs (PMP) first involves collecting data from physicians who prescribe medications and pharmacies that fill these prescriptions. Data collected can differ from state to state, but often includes the prescriber's name, DEA number, prescription date, the name and dose of the medication, the drug schedule code, and the patient's name, date of birth. Data is stored and centrally processed usually by a state government agency, and each state has varying rules as to how these data are made available to authorized persons and agencies. Physicians, pharmacists and law enforcement officials may acquire information, with the goal toward preventing prescription drug abuse.

The development of these programs has been slow and funding has not been guaranteed. In 2007, 38 states have established Prescription Monitoring Programs (PMP). California developed the triplicate prescription form in the 1940s, which became a gold standard for data collection. This system was replaced in California with an electronic prescription system in 1998, which many states have adopted. Since many programs are new, the effectiveness of these programs is difficult to determine. Recent data suggest that proactive use of PMP's results in lower sales of prescription medications [30]. Another study suggests that although these programs have helped shift prescription practice, the rates of prescription drug abuse have not been reduced [31].

At the state level, state laws govern prescription drug prescribing and dispensing of licensed clinicians. State Medical Licensure Boards respond to complaints, but do not actively seek out problematic prescribing practices.

Public education of authorities, physicians, pharmacists and patients can help to inform about the problems of drug abuse, as well as provide warning signs and strategies to combat abuse. Organizations such as Partnership for a Drug-Free America, state and local agencies, and medical and pharmaceutical societies have all made efforts to educate the public. Similarly, at the federal level, organizations such as the Office of the National Drug Control Policy, the National Institute on Drug Abuse to Prevent and Treat Prescription Drug Abuse, the Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration (SAMHSA) have also helped to inform and warn of the epidemic of prescription drug abuse.

Research efforts to understand factors that influence vulnerability to addiction, as well as factors that predispose or protect against opioid abuse, are being funded through programs such as the National Institute on Drug Abuse (NIDA) [32]. The effects of how genetic factors influence vulnerability to addiction in those exposed to pain medication are also of great interest to NIDA.

The Federal Food, Drug, and Cosmetic Act mandates that the Food and Drug Administration (FDA) ensure that all new drugs are safe and effective [33]. The FDA must assess a drug's potential for abuse and misuse based on drug chemistry, pharmacology clinical manifestations, as well as the potential for public health risks after introducing it to the general population [33]. Once abuse potential is determined, a drug is then assigned to 1of 5 schedules, depending on abuse potential and medical use, as defined by the Controlled Substances Act. The FDA also seeks expert advice from non-agency experts on the medical use of opioid analgesics. In September 2003, the FDA met with DEA officials, pain and addiction specialists to discuss the medical use of opioid analgesics, appropriate drug development plans to support approval of opioid analgesics, and strategies to communicate and manage risks associated with opioid analgesics, especially the risks of abuse of these drugs. The FDA is committed to protecting the public health by assuring that safe and effective products reach the market in a timely fashion, and monitoring products for continued safety after they become available. By working with federal agencies, professional societies, industry and patient advocacy groups, information can be shared to minimize risk. The FDA also participates in risk minimization action plans, which are safety programs targeted to reduce product risks by using interventions such as restrictions on prescribing, dispensing, or use.

Another effort to minimize prescription drug abuse is the development of drugs that are tamper-resistant and minimize the potential for abuse or diversion. The epidemic of OxyContin ® abuse highlights the difficulties in creating tamper-resistant formulations. Although initially intended to be slowly released over 12 hours, drug abusers were able to quickly learn how to disable physically or manually the controlled-release mechanism and extract oxycodone, a potent opioid, in order to experience a powerful and immediate high when ingested, snorted or injected, which increased its addiction potential. One way to prevent tampering is to take advantage of pharmaceutical technology, such as tamper-resistant capsules that are resistant to degradation in the usual methods that drug users use to destroy the extended-release mechanisms, such as chewing or crushing. Another approach is by combining an opioid agonist and antagonist (e.g. Oxitrex®, oxycodone/naltrexone). The development of buprenorphine-naloxone for the treatment of opioid addiction has also proven to be effective as a pain medication with minimum abuse potential. Continued efforts at development of formulations that are effective, yet tamper-resistant are now encouraged by the synthetic drug control strategy of the Office of the National Drug Control Policy, with the goal of reducing diversion and abuse [34].

Since the source of prescription drugs starts with the physician, we must be prudent to educate and provide training at all levels to ensure that physicians are aware of appropriate pain management, and warning signs of drug abuse. Past surveys have indicated that fewer than 40% of physicians have received any training during medical school in identifying prescription drug use and addiction, or drug diversion. In 2004, the rates of prescribing OxyContin ® and oxycodone had increased 556% since 1997 in the United States. Without adequate knowledge of the long-term safety and appropriate use of opioids, physicians may unknowingly contribute to prescription drug abuse. Physicians must also educate patients about storage of prescription medications, and warn about the risks of sharing these medications with family and friends.

Chronic Pain Management with Narcotic Analgesics

The use of narcotic analgesics for chronic pain management should be based on the need for long-term chronic opioid therapy (COT) after a comprehensive evaluation, a trial of non-narcotic medications, and awareness of potential risks for opioid abuse, dependence, and diversion. Once the need for long-term opioid treatment for pain management has been determined, physicians should consider a ten-step approach (Table 1) [35]. This process begins with a thorough medical evaluation including diagnostic studies (i.e. X-rays, MRI) to establish medical diagnoses and medical necessity for COT, but also considers whether treatment is beneficial (i.e. risk-benefit ratio), and addresses treatment strategies (e.g. informed consent and written agreements, dose initiation, adjustment, and stabilization, adherence monitoring). Treatment goals should be defined, including outcome measures and decisions. Not only must physicians consider if COT is necessary, but knowledge of patient selection and risk stratification, including the use of opioids in high-risk patients requires the careful implementation of essential monitoring tools: assessment of aberrant drug-related behaviors, the use of informed consent forms, controlled substance agreements, and risk assessment tools.

The definition of chronic pain is “pain that persists beyond normal tissue healing time, which is assumed to be three months.” [36]. The three-step WHO ladder for cancer pain has been widely used, and adapted for the treatment of chronic non-cancer pain (Figure 1) [37]. Step 1 recommends the use of non-opioid medication, with or without an adjuvant medication, if necessary. Adjuvant medications include antidepressants, anticonvulsants, and corticosteroids, and are used to enhance analgesic effect, to treat concurrent symptoms that may exacerbate pain, and to provide an independent analgesic effect. If pain increases, Step 2 recommends taking an opioid medication that is used for mild to moderate pain along with a non-opioid medication and an adjuvant medication, if necessary. If pain increases further, Step 3 recommends taking an opioid medication for moderate to severe pain along with non-opioid medication and an adjuvant medication, if necessary.

The American Pain Society (APS), in collaboration with the American Academy of Pain Medicine (AAPM), recently published evidence-based guidelines on the use of chronic opioid therapy (COT) for chronic noncancer pain [38]. The key clinical messages have been summarized [39], and will be discussed in this section.

Risk Assessment and Stratification

With regard to patient selection and stratification, a physician should routinely incorporate measures to assess risk for opioid abuse. All evaluations must start with a comprehensive physical; the medical history should also explore psychosocial factors and family history, which can help to determine risk stratification. A personal or family history of alcohol or drug abuse is the factor most strongly predictive of opioid abuse, misuse, or aberrant drug-related behavior [40][41]. Other predictors include a younger age, and the presence of psychiatric conditions [41][42]. Some tools that may be useful to quantify risk in a clinical setting include The Screener and Opioid Assessment for Patients with Pain Version 1

(SOAPP), The Revised Screener and Opioid Assessment for Patients with Pain, The Opioid Risk Tool (ORT), and Diagnosis, Intractability, Risk, Efficacy Tool.

Only when potential benefits outweigh risks, and when other non-opioid options have been maximized, should COT be considered. A thorough discussion with patients of common opioid side effects (i.e. constipation, nausea, sedation), other risks (i.e. abuse, addiction, overdose), and known potential long-term risks (i.e. hyperalgesia, endocrinologic or sexual dysfunction) is essential when considering COT. Once it is determined that opioid therapy should be initiated, clinicians should administer informed consent and have the document signed by the patient (see Figure 2). Patients should be told about the need to keep controlled substances in a safe, and locked location, if possible, to prevent diversion or easy access from friends or other family members. A controlled substance agreement is helpful to address expectations, goals, describe clinic follow-up and monitoring, rules for lost prescriptions and requests for early refills, and consequences of non-compliance, such as tapering or discontinuing COT when therapeutic goals are not met, side effects become intolerable, or serious aberrant behaviors have been identified (see Figure 3).

Screening for addiction should always be done at the start of treatment. Stratifying patients into risk categories for addiction liability will make it easier for a clinician to determine individualized treatment strategies, including the need for outside referrals [43]. It is advisable for clinicians to employ universal precautions in order to triage individuals to different categories (low-, medium-, and high-risk) in terms of addiction liability [44].

Low-risk patients with chronic non-cancer pain have no history of substance abuse and lack any major psychiatric co-morbidity. There are no indications of aberrant behaviors in such patients, or any warning signs that they may abuse medications. These individuals can be managed in a primary care setting.

Medium-risk patients may have a prior history of substance abuse, or may have psychiatric co-morbidity. These individuals can be managed in a primary care setting, particularly with consultation from a specialist (i.e. an addiction specialist or psychiatrist).

High-risk patients are those with active addictive disorders. These individuals are at an increased for aberrant behaviors and should be referred to a tertiary clinic that specializes in pain management.

Another measure to help guide clinicians with their therapeutic decisions is the Pain Assessment and Documentation Tool (PADT) [45]. This tool incorporates an assessment of the “4 A's”: analgesia, activity, adverse effects, and aberrant behavior. It is important to identify aberrant behaviors as they may signal potential misuse of opioids. Certain aberrant behaviors have been demonstrated to reliably indicate a substance abuse disorder [46][47]. Such behaviors range from failing to comply with a prescribed regimen to clearly illegal behaviors. These may include selling prescription drugs, forging prescriptions, stealing drugs, injecting oral formulations, obtaining prescription drugs from non-medical sources, concurrently abusing alcohol or other illicit drugs, escalating doses on multiple occasions or otherwise failing to comply with the prescribed regimen despite warnings, “losing” prescribed medications on multiple occasions, repeatedly seeking prescriptions from other clinicians or from emergency rooms without informing the original prescribing physician, and showing evidence of deterioration in the ability to function (at work, in the family, or socially) that appears to be related to drug use. The occurrence of any of these behaviors should warrant evaluation, and more rigorous monitoring.

The presence of multiple aberrant behaviors, or the recurrence of any of these behaviors may suggest the need for consultation with pain management physicians or addiction specialists.

Clinicians should also consider temporary or permanent tapering of opioid doses, and possibly discontinuation if more serious behaviors are evident (i.e. diversion or intravenous use of oral formulations). Psychiatric referrals or psychological support with individual counseling (i.e. cognitive behavioral therapy) may be helpful for some individuals, which highlights the need to screen for depression, anxiety and other psychiatric disorders at the beginning of COT. For those patients identified with an opioid addiction, structured opioid agonist therapy with buprenorphine or methadone at a licensed program may be beneficial to help treat pain and addiction.

For those patients with low- to medium- risk for addiction liability, opioids should be first started in a short-term therapeutic trial. In individuals who are opioid-naive, and in the elderly, opioids should be started at low doses and titrated slowly. Short-acting opioids may be safer due to a shorter half-life and a lower risk of unintentional overdose. However, the use of long-acting opioids may provide more consistent pain relief, and better adherence. Although long-acting opioids were originally thought to have a lower potential for abuse and addiction, studies have proven otherwise [48]. For most opioids, a dosing schedule of two to four times daily is recommended to provide continuous coverage for pain relief. Additional, but limited, amounts of breakthrough doses should also be available, which may help patients gain a greater sense of control over pain. After initiation of an opioid, if the pain relief is inadequate, an increase in dose can be made after 3 days; subsequent dose titrations can be made in 24-hour periods. As there is an absence of a ceiling effect with full-agonist opioids, doses can be increased until a desired analgesic effect is reached or until side effects are intolerable.

Caution should be used when prescribing methadone. There has been an increase in methadone-associated deaths that may be related to cardiac arrhythmias, or unintentional overdoses due to its very long and variable half-life [49]. The half-life of methadone ranges from 15-60 hours, which means it could take up to 12 days to reach a steady state level. A safe starting dose is 2.5 mg every 8 hours, with dose increases only once per week. For opioid-tolerant individuals transitioning from high doses of other opioids, methadone-starting doses should not exceed 30 to 40 mg per day.

Common side effects of opioids should also be addressed. Constipation may be treated with stool softeners, or other laxatives. For opioid-induced constipation, stimulant laxatives are recommended. Nausea and vomiting, which may occur during initiation of opioid therapy can be treated by a variety of anti-emetics. Sedation may require a reduction in dose. Routine testing for hormonal deficiencies should only be done for symptoms of decreased libido, sexual dysfunction, or fatigue. There is some evidence that opioid antagonist therapy may reduce glycemic control [50][51], in part through a delayed insulin response resulting from opioid-induced intestinal slowing [52][53], and glucose monitoring may be warranted for patients demonstrating weight gain or at risk for diabetes mellitus.

Monitoring should be done frequently at the start of treatment to assess pain relief, adverse effects, and for dose adjustments. For patients who are elderly, have a history of substance abuse, or where mental acuity is particularly important for occupational purposes, visits should also be more frequent. The use of monitoring tools, such as the (PADT) [45], or the Chronic Opioid Misuse Measure [54] can help with therapeutic decisions while assessing for risk. Urine drug testing is recommended, especially in high-risk patients, and can determine the presence or absence of opioids prescribed, and can detect the presence of other illicit drugs. If routine monitoring is too costly, random testing can still be beneficial. Pill counts can help determine if patients are compliant with treatment recommendations. Discussions with family members and caretakers may also provide valuable information about a patient's level of functioning. Prescription monitoring programs vary by state, but may be helpful in identifying patients who may be seeking controlled substances from multiple doctors, and who may be abusing prescription drugs.

When dose escalations reach upper limits, physicians should inquire about analgesic effect, function, quality of life, adverse side effects, and aberrant drug behaviors. If pain relief is not optimal at the highest dose of opioid prescribed, physicians must first evaluate any changes in health status. Opioid rotation may then be considered, which refers to the substitution of one opioid for another, when pain relief is inadequate or when side effects become intolerable. It is recommended to switch with a moderate reduction in the calculated equianalgesic dose [55].

Discontinuation of COT should be considered when patients are not meeting therapeutic goals, adverse effects are intolerable, or if serious or repeated aberrant behaviors have been identified. More complicated cases in terms of medical or psychiatric co-morbidity may be managed better in a detoxification or rehabilitation center, and cases where addiction is apparent are best referred to addiction specialists.

When tapering opioids, physicians can reduce the dose slowly with a 10% dose reduction per week, or more rapidly with a 25-50% dose reduction every few days, depending on patient comfort, and length of time the patient has been on COT. In general, doses can be tapered rapidly until daily doses of morphine (or equivalent) have reached 60 to 80 mg per day, when patients may experience more withdrawal symptoms, which may include pain hypersensitivity. Non-opioid medications should be used during this taper, while psychiatric and substance abuse issues are addressed.

There is no strong evidence that patients maintained on stable doses of opioid without impairment should be restricted from driving [56]. However, those individuals in certain professions (i.e. bus drivers, pilots) may be subject to strict regulations regarding the use of opioids. All patients who initiate opioid therapy, or are told to increase their dose, should be warned about the potential for sedation, and to use caution with driving or other dangerous work. Patients should also be educated about the risks of taking other drugs or alcohol while on opioids. Any suspicion or demonstration of any dangerous behaviors (i.e. driving when somnolent, incoordination) should be reported to the appropriate authorities.

The requirement for only a single prescribing physician or facility to administer opioids should be delineated in a treatment agreement. When all care can be established at one medical office, referrals can be better coordinated, and problematic behaviors can be identified. The presence of a patient-centered primary care medical home can facilitate the multi-dimensional care that a patient needs [57].

The use of COT can be safe and effective when physicians possess the clinical skills and knowledge to address all the facets of appropriate opioid management. With thorough ongoing clinical assessments, and the use of screening tools and treatment agreements, physicians can better determine if opioid therapy is beneficial, or if consultations are warranted. Ongoing evaluations can guide any change in treatment, and improve communication between the physician and patient. When goals have not been met, or aberrant behaviors have been identified, treatment agreements can delineate courses of action. By understanding the assessment and management of risk, a physician will also provide more effective treatment of chronic pain.

Conclusion

The epidemic of Prescription Drug Abuse has reached a level at which national attention has forced physicians to re-evaluate our need to provide appropriate care to our patients, while understanding the potential risks of diversion and abuse of prescription drugs. The statistics and strategies in this chapter have highlighted the importance of educating ourselves and our patients, and being aware of increased rates of prescription drug abuse particularly among young adults, full-time college students, the elderly, and in those with serious mental illness.

The development of Prescription Drug Monitoring Programs and NASPER are steps toward prevention and better detection of prescription drug abuse. The FDA, DEA, Office of the National Drug Control Policy, NIDA, SAMHSA, and organizations such as Partnership for a Drug-Free America have all made serious efforts to address this epidemic. With the collaboration of pain societies (i.e. ASIPP), Congress has made targeted and well-informed attempts to join the crusade against prescription drug abuse by signing laws such as NASPER, and holding hearings to better understand the issues and formulate guidelines to help physicians prescribe opioids safely and effectively. Pharmaceutical companies are also developing innovative tamper-resistant formulations. Better education in medical schools of pain management and substance abuse is necessary. It is also imperative that public service organizations continue to educate parents and the public about warning signs of abuse, and preventative tips, such as not sharing medications with family and friends, or keeping controlled substances in a safe, and preferably locked, location.

Physicians should also inform their patients of the risks of prescription drugs. Only after a careful and thorough assessment of a patient's medical conditions, with confirmatory diagnostic information, and assessment of risk-benefit ratio, should physicians consider starting opioid therapy. All non-opioid medications or therapies should first be maximized, and contributing psychological issues addressed. Informed consent and a treatment agreement should be discussed and signed prior to the start of treatment.

Risk assessment tools can help triage patients to determine the intensity and frequency of visits, and need for consultation. Monitoring tools and urine drug testing are also helpful when administering chronic opioid therapy. An evaluation of the 4 “A's” at all visits is essential to evaluate success, or to determine a need for change in management, such as dose escalation or discontinuation. If treatment agreements are violated in cases where serious or repeated aberrant behaviors have been detected, discontinuation or transfer of care are more easily addressed when rules have been delineated. With the knowledge of the appropriate use of opioids, and the risks involved, an organized approach toward assessing and managing pain can facilitate the development of individualized treatment plans that maximize patient comfort, satisfaction and safety. It is our duty as physicians to provide the best quality care to our patients, and well-informed opioid management should serve to reduce the epidemic of prescription drug abuse.

Acknowledgments

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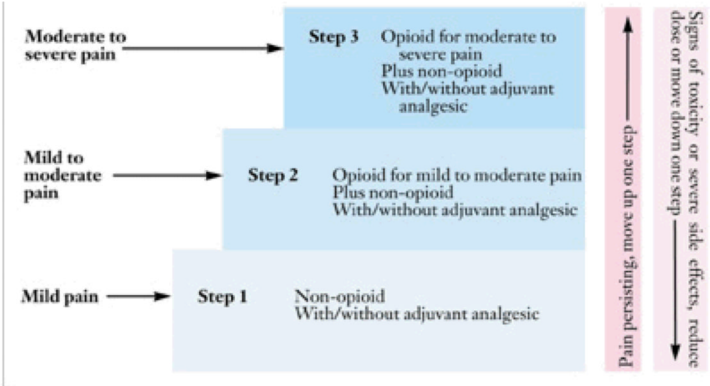
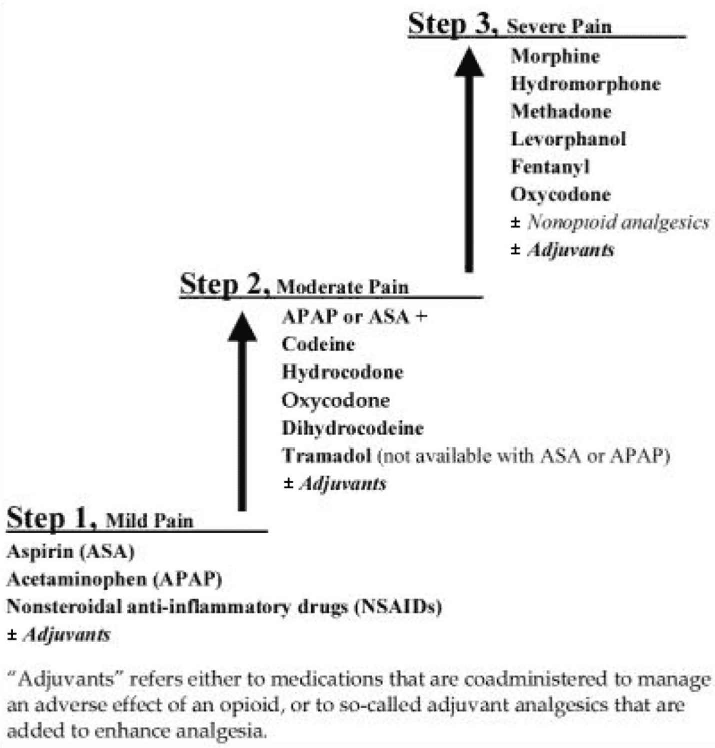


Figure 1: World Health Organisation (WHO) analgesic ladder



Adapted from: World Health Organization. *Cancer pain relief and palliative care.* Geneva: WHO; 1996, with permission.

Figure 1.
WHO Pain Ladder

PHYSICIANS DEDICATED TO RELIEVING PAIN
the AMERICAN ACADEMY *of* PAIN MEDICINE
the voice of pain medicine

Consent for Chronic Opioid Therapy

A consent form from the **American Academy of Pain Medicine**

Dr. ____________________ is prescribing opioid medicine, sometimes called narcotic analgesics, to me for a diagnosis of ____.

This decision was made because my condition is serious or other treatments have not helped my pain.

I am aware that the use of such medicine has certain risks associated with it, including, but not limited to: sleepiness or drowsiness, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, physical dependence, tolerance to analgesia, addiction and possibility that the medicine will not provide complete pain relief.

I am aware about the possible risks and benefits of other types of treatments that do not involve the use of opioids. The other treatments discussed included:

____

____

____

I will tell my doctor about all other medicines and treatments that I am receiving.

I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. I am aware that even if I do not notice it, my reflexes and reaction time might still be slowed. Such activities include, but are not limited to: using heavy equipment or a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for himself or herself.

I am aware that certain other medicines such as nalbuphine (Nubain ™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines and to tell any other doctors that I am taking an opioid as my pain medicine and cannot take any of the medicines listed above.

I am aware that addiction is defined as the use of a medicine even if it causes harm, having cravings for a drug, feeling the need to use a drug and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I am aware that the development of addiction has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.

Reviewed July 2004.

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Appendix 6. Continued

I understand that physical dependence is a normal, expected result of using these medicines for a long time. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not life threatening.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain, however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment.

(Males only) I am aware that chronic opioid use has been associated with low testosterone levels in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

(Females Only) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.

I have read this form or have it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.

Patient signature ______________________ Date __________

Witness to above ______________________

Approved by the AAPM Executive Committee on January 14, 1999.

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Reproduced with permission from the American Academy of Pain Medicine

Figure 2.

Informed Consent for Chronic Opioid Therapy

We are committed to doing all we can to treat your chronic pain condition. In some cases, controlled substances are used as a therapeutic option in the management of chronic pain and related anxiety and depression, which is strictly regulated by both state and federal agencies. This agreement is a tool to protect both you and the physician by establishing guidelines, within the laws, for proper controlled substance use. The words "we" and "our" refer to the facility and the words "I", "you", "your", "me", or "my" refer to you, the patient.

1. i. I understand that chronic opioid therapy has been associated with not only addiction and abuse, but also multiple medical problems including the suppression of endocrine function resulting in low hormonal levels in men and women which may affect mood, stamina, sexual desire, and physical and sexual performance.

   ii. For female patients, if I plan to become pregnant or believe that I have become pregnant while taking this medication, I am aware that, should I carry the baby to delivery while taking these medications; the baby will be physically dependent upon opioids. I will immediately call my obstetrician and this office to inform them of my pregnancy. I am also aware that opioids may cause a birth defect, even though it is extremely rare.

   iii. I have been informed that long-term and/or high doses of pain medications may also cause increased levels of pain known as opioid induced hyperalgesia (pain medicine causing more pain) where simple touch will be predicted as pain and pain gradually increases in intensity and also the location with hurting all over the body. I understand that opioid-induced hyperalgesia is a normal, expected result of using these medicines for a long period of time. This is only treated with addition of non-steroidal anti-inflammatory drugs such as Advil, Ibuprofen, etc., or by reducing or stopping opioids.

   iv. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped, or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable, but not life threatening.

   v. I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain; however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment, reduce the dose, or stop it.

2. i. All controlled substances must come from the physician whose signature appears below or during his/her absence, by the covering physician, unless specific authorization is obtained for an exception.

   ii. I understand that I must tell the physician whose signature appears below or during his/her absence, the covering physician, all drugs that I am taking, have purchased, or have obtained, even over-the-counter medications. Failure to do so may result in drug interactions or overdoses that could result in harm to me, including death.

   iii. I will not seek prescriptions for controlled substances from any other physician, health care provider, or dentist. I understand it is unlawful to be prescribed the same controlled medication by more than one physician at a time without each physician's knowledge.

   iv. I also understand that it is unlawful to obtain or to attempt to obtain a prescription for a controlled substance by knowingly misrepresenting facts to a physician or his/her staff or knowingly withholding facts from a physician or his/her staff (including failure to inform the physician or his/her staff of all controlled substances that I have been prescribed).

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3. All controlled substances must be obtained at the same pharmacy where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is: ____Phone:______________

4. i. You may not share, sell, or otherwise permit others, including your spouse or family members, to have access to any controlled substances that you have been prescribed.

   ii. Early refills will not be given. Renewals are based upon keeping scheduled appointments. Please do not make excessive phone calls for prescriptions or early refills and do not phone for refills after hours or on weekends.

5. Unannounced pill counts, random urine or serum, or planned drug screening may be requested from you and your cooperation is required. Presence of unauthorized substances in urine or serum toxicology screens may result in your discharge from the facility and its physicians and staff.

6. I will not consume excessive amounts of alcohol in conjunction with controlled substances. I will not use, purchase, or otherwise obtain any other legal drugs except as specifically authorized by the physician whose signature appears below or during his/her absence, by the covering physician, as set forth in Section 2 above. I will not use, purchase, or otherwise obtain any illegal drugs, including marijuana, cocaine, etc. I understand that driving while under the influence of any substance, including a prescribed controlled substance or any combination of substances (e.g., alcohol and prescription drugs), which impairs my driving ability, may result in DUI charges.

7. Medications or written prescriptions may not be replaced if they are lost, stolen, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen, it will not be replaced unless explicit proof is provided with direct evidence from authorities. A report narrating what you told the authorities is not enough.

8. In the event you are arrested or incarcerated related to legal or illegal drugs (including alcohol), refills on controlled substances will not be given.

9. I understand that failure to adhere to these policies may result in cessation of therapy with controlled substances prescribed by this physician and other physicians at the facility and that law enforcement officials may be contacted.

10. I also understand that the prescribing physician has permission to discuss all diagnostic and treatment details, including medications, with dispensing pharmacists, other professionals who provide your health care or appropriate drug and law enforcement agencies for the purpose of maintaining accountability.

11. I affirm that I have full right and power to sign and to be bound by this agreement, that I have read it, and understand and accept all of its terms. A copy of this document has been given to me.

____
Patient's full name

______________________________________ ____________________
Patient's signature Date

______________________________________ ____________________
Physician's signature Date

From Trescot AM, Helm S, Hansen H, et al. Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines. Pain Phys, 2008; 11:S48-49, with permission.

Figure 3.
Sample Controlled Substance Agreement

Table 1

Ten-step process: An algorithmic approach for long-term opioid therapy in chronic pain

STEP I	**Comprehensive initial evaluation**
STEP II	**Establish diagnosis** ➢ X-rays, MRI, CT, neurophysiological studies ➢ Psychological evaluation ➢ Precision diagnostic interventions
STEP III	**Establish medical necessity (lack of progress or as supplemental therapy)** ➢ Physical diagnosis ➢ Therapeutic interventional pain management ➢ Physical modalities ➢ Behavior therapy
STEP IV	**Assess risk-benefit ratio** ➢ Treatment is beneficial
STEP V	**Establish treatment goals**
STEP VI	**Obtain informed consent and agreement**
STEP VII	**Initial dose adjustment phase (up to 8-12 weeks)** ➢ Start low dose ➢ Utilize opioids, NSAIDS, and adjuvants ➢ Discontinue due to - Lack of analgesia - Side effects - Lack of functional improvement
STEP VIII	**Stable phase (stable – moderate doses)** ➢ Monthly refills ➢ Assess for four A's - Analgesia - Activity - Aberrant behavior - Adverse effect ➢ Manage side effects
STEP IX	**Adherence monitoring** ➢ Prescription monitoring programs ➢ Random drug screens ➢ Pill counts
STEP X	**Outcomes** ➢ Success – continue - Stable doses

	- Analgesia, activity - No abuse, side effects ➢ Failed – discontinue if - Dose escalation - No analgesia - No activity - Abuse - Side effects - Non-compliance

From Manchikanti L. Prescription Drug Abuse: What is being done to address this new drug epidemic? Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. Pain Phys 2006;9,316, with permission.

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