Nurse Practitioner Healthcare Foundation
Improving Health Status and Quality of Care through Nurse Practitioner Innovations

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Managing Chronic Pain with Opioids: A Call for Change

A White Paper by the Nurse Practitioner Healthcare Foundation

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The mission of the Nurse Practitioner Healthcare Foundation (NPHF) is to improve health status and quality of care through nurse practitioner (NP) innovations in education, research, health policy, service, and philanthropy. NPHF goals are to expand access to quality care and facilitate professional and patient educational opportunities. In addition, the NPHF engages in new research opportunities, fosters innovative interdisciplinary collaboration, and provides NP resource support to public health policymakers. In that spirit, NPHF periodically addresses relevant healthcare issues.

Two inter-related public health problems in the United States have reached levels where they can no longer be ignored. The first is the escalating problem of inadequately treated chronic moderate to severe pain, and the second is the misuse, abuse, and diversion of prescription opioids.

In 2008, nearly 5 million Americans reported using prescription pain relievers in the past month for nonmedical reasons[1]; that is, these individuals used prescription analgesics that were not prescribed for them or they used these medications simply for the feeling the drugs caused.[2] In too many cases, this unsanctioned use results in serious health repercussions, including increased risk for illness, injury, overdose, and death. Healthcare practitioners (HCPs) must address these public health problems, not only for the individuals directly affected but also for the welfare and safety of our communities. Therefore, well-intentioned HCPs who appropriately prescribe, dispense, and/or administer opioids to control pain must remain aware of the possibility that patients may use the medication in a manner in which the HCP did not intend. This White Paper addresses concerns related to the prudent use of opioids to treat chronic pain while preventing the misuse, abuse, and diversion of these agents.

The Problem of Chronic Pain

Acute pain is a universal experience and, although treatable, is considered a part of birth, life, and death. Unlike acute pain, which serves as a protective mechanism against injuries and illnesses, chronic pain has no known benefit, and is now regarded by many experts as a disease state.[3,4] According to 2006 data, approximately 76 million people in this country live with chronic pain.[5] Nevertheless, nearly half of chronic pain sufferers receive no treatment.[6]

The toll of chronic pain can be measured in terms of incidence (~76 million sufferers in this country) and financial impact,[7] as well as by the related suffering that lowers quality of life.[7-10] These data are especially alarming as our population ages; nearly 60% of older adults with pain have had pain persisting more than a year.[5] Studies have shown that chronic pain sufferers become socially isolated, in part because they are misunderstood, demeaned, or stigmatized by others. These undesirable social effects have been noted in a variety of different pain conditions, including endometriosis,[11-15] low back pain,[16-19] myofascial pain,[20-23] and neuropathic pain,[24] as well as in heterogeneous samples of persons with various chronic pain types.[8,25-29] Many patients with chronic pain require opioids as part of their treatment plan, which can add to the undesired social impact of their disease.

A Look at the Financial Impact

Chronic pain (regardless of whether it is effectively treated) and prescription opioid misuse, abuse, and diversion pose large financial burdens on patients, their families, their employers, and society at large. According to a 1998 National Institutes of Health (NIH) report,[30] the yearly cost of chronic pain was approximately $100 billion, with healthcare costs rising by as much as 9% for each of the 22 years since then.[31] Indirect costs such as work absences and disability are similar to, and perhaps exceed, the healthcare costs. Even when chronic pain sufferers are working, their reduced productivity may be as expensive as replacement costs.[32] Large corporations pay about $2 million per employee with chronic pain to cover absences, lost productivity, short-term disability, and healthcare costs.[33]

Although opioids may help some individuals function better, this gain is offset by the misuse, abuse, and diversion of these agents, which costs the United States nearly $1 billion per year.[34] In March 2010, the National Drug Intelligence Center (NDIC) released the National Prescription Drug Threat Assessment, which reported the costs associated with controlled prescription drug diversion occurring through *doctor-shopping*, prescription fraud, and theft.[35] Using this metric, the NDIC estimated the costs to public and private insurers of abuse/diversion of controlled prescription drugs, including opioids, to be $72.5 billion per year.[35]

Although the 2011 federal budget includes provisions for a 3.5% increase in spending for a media campaign to educate the public about preventing abuse of prescription and over-the-counter (OTC) medications, no money has been allocated to better educate the public about chronic pain and its treatment. This unbalanced funding perpetuates misperceptions, heightens fears, and sets the stage for the criminalization of prescribers of opioids who treat chronic pain. In fact, this media campaign money could be better spent funding an enhancement to the Prescription Monitoring Program,[36] making it both a national program and one that provides prescribers with instant, meaningful access to information before they write a prescription for an opioid. Other programs that merit enhanced funding include *safe-use* education programs about medication storage and disposal; *take-back* programs for unused medications; and better training for HCPs who prescribe, dispense, and/or administer opioid analgesics.

Finding a balance between providing opioids for suitable candidates with chronic pain—while keeping these medications out of the hands of persons who would misuse, abuse, or divert them—is a challenge. Both problems are among the top health priorities to be tackled this decade as part of the *Healthy People 2020* initiative,[37] which ensures funding and accountability at the top levels of government to address these problems. These priorities include decreasing the proportion of patients suffering from untreated pain because of a lack of access to treatment, decreasing the rate of serious injuries and deaths related to the use of analgesics, and decreasing the number of non–Food and Drug Administration (FDA)-approved analgesics that are prescribed. These problems are particularly important to primary care practitioners who are in the front line in terms of managing patients with chronic pain.

Barriers to Treating Chronic Pain with Opioids

Barriers to providing high-quality care to chronic pain sufferers who require opioid therapy are multifaceted. These barriers include (1) inadequate professional education/knowledge in these areas, (2) ineffective policies to support chronic pain interventions, and (3) inconsistency and lack of coordination of federal guidelines and funding.

Inadequate Professional Education and/or Current Knowledge About Chronic Pain and its Treatment—During their years of professional education, many HCPs do not receive sufficient or up-to-date information regarding the pathophysiology, assessment, treatment, and monitoring requirements of chronic pain. These curricular and clinical shortcomings have been clearly documented for medical, nurse practitioner (NP), and physician assistant (PA) students.[38,39] In a quantitative study,[38] attending physicians rated their medical school education (81.5%) and residency training (54.7%) regarding chronic pain management as inadequate. In the same study, the mean rating for chronic pain education for NP and PA programs was 0.5 (SD, 0.80) on a scale of 0 (not at all satisfied) to 4 (very satisfied). In addition, HCP students have not been adequately prepared to identify and treat patients who have coexisting chronic pain and substance addiction.[38,39]

If the basic information about chronic pain provided in professional educational curricula is scanty and outdated, the content about *treating* this pain, including strategies for safe and appropriate prescribing, dispensing, administering, and monitoring of long-term opioids, is even more limited.[40] Given the high prevalence of chronic pain and the recent alarming trends regarding the nonmedical use of opioids, professional schools must include these topics as essential content for all prospective HCPs.

Some HCPs may not know that one modality of therapy may be insufficient for pain that is severe and/or persistent. A treatment strategy called *multimodal analgesia* has shown promise for improving pain control. Multimodal analgesia is a rational combination of analgesic medications with differing mechanisms of action. In most cases, a strategy utilizing both analgesic medications and non-pharmacologic approaches has been shown to reduce opioid requirements, achieve better pain control, and improve functioning.[41-43] Use of multimodal analgesia reduces complications or side effects of opioid analgesia, but further studies are required to ascertain the efficacy of this treatment in reducing chronic pain.[44]

When long-term opioid therapy is indicated, HCPs have a responsibility to use meticulous approaches to assess and treat patients. This responsibility involves adhering to practice standards aligned with treatment guidelines set by the Federation of State Medical Boards Model Policy.[45] According to these guidelines, HCPs are to stratify patients by their risk factors for abuse/addiction—using more prudent approaches for those at highest risk. Despite the reluctance of some HCPs to prescribe opioids for patients with a past or current opioid abuse/addiction disorder, pain must be assessed and treated in all patients. High-risk patients are best treated in collaboration with specialists who understand the chronic relapsing nature of the disease of addiction. In addition, HCPs need to be familiar with formulations that have been designed to be abuse deterrent or tamper resistant as a method for reducing prescription opioid abuse.

All HCPs who prescribe, dispense, and/or administer opioids need optimal education with respect to a *universal-precautions* approach: using screening tools; periodically monitoring for treatment efficacy/tolerability and any aberrant behavior; and referring patients with addiction disorders to appropriate resources in the community.[46] This information should also be part of workplace orientation and ongoing credentialing.[47] Continued competency in this complex area of practice requires more than ongoing continuing education[40,48]; new ways of ensuring that HCPs understand the proper use of opioids are needed. There are times when the expertise of a pain and/or addiction specialist is needed to help guide or co-manage therapy.

Ineffective Systems and Policies to Support Chronic Pain Interventions—Many of the systems used to classify and treat chronic pain impede appropriate pain management. These systems include, but are not limited to, payer policies; preferred drug lists; and lack of reimbursement for longer patient counseling visits, self-management programs, and nontraditional therapies. The clinical realm lacks specialists in pain therapy, substance abuse, and the intersection of the two.

Payer policies. Third-party payment structures are geared toward reimbursement for acute therapy for chronic pain (eg, spinal fusion surgery, nerve block administration, neural ablation). Although the literature lacks documentation of these approaches' efficacy,[49-53] surgery centers and other healthcare practices may promote these interventions because of their high reimbursement levels.[54] Payer policies need to be scrutinized and perhaps reoriented toward an emphasis on lifestyle changes and patient self-management,[53] enhancing patients' physical capacity,[55-57] and psychosocial counseling[58,59] to optimize outcomes.

Preferred drug lists. Policies for reimbursement for the cost of analgesics often require that older, less effective medications be tried before newer, more effective medications are used. For example, an insurance company may not pay for pregabalin or gabapentin but will pay for opioids, even at high doses that might render a patient nonfunctional and might even exchange suffering from pain for suffering from addiction. At the same time, some of the newer opioid products, which may be safer than older opioid products, tend not to be available on formularies or covered by insurance companies. Because chronic pain is not even recognized by the FDA as a diagnosis, many needed pharmacologic treatments are considered *off-label* and are not reimbursed by many payers.

Lack of reimbursement for longer patient counseling visits, self-management programs, and nontraditional therapies. Although research supports the efficacy and cost-effectiveness of multidisciplinary multimodal chronic pain therapies over time, many centers that provided these services have closed because of a lack of reimbursement by insurance companies.[60] Current fiscal incentives reward therapies that entail brief visits and high-cost unimodal therapies that provide, on average, only partial temporary relief.

Patient-centered care provided in group settings—including stress management, exercise/conditioning, integrative therapies, and flare management—has demonstrated a return on investment and has proved cost saving over time.[61-69] Treating patients in a therapeutic group milieu, providing extensive and thorough education, and evaluating patients' level of understanding and skill mastery all take time, yet these are all proven strategies for managing pain.[64,70-78] Reimbursement for group encounters may reduce recurrent hospitalizations that entail more expensive interventions—and save money in the long run.

Inconsistency and Lack of Coordination of Federal Guidelines and Funding—Given the prevalence and cost of chronic pain conditions, many unanswered questions about chronic pain and substance abuse/addiction disorders still exist, demanding that more financial and intellectual resources be devoted to solving these problems. The NIH or Health Resources and Services Administration (HRSA) could provide tools to increase awareness of the magnitude of the problem among HCPs and patients, highlight disparities in treatment, and clarify terms and metrics required to standardize research and understanding of the problems—whether they occur in isolation or as co-morbid states. In addition, the NIH should coordinate the allocation of funds based on these recommendations and on related *Healthy People 2020* priorities. NIH funding for pain research should be commensurate with the magnitude of the problem—not its historically low allocation of only 1% of medical research funds.[79] Although attendees at recent NIH conferences have discussed the need for focused pain research, no permanent funding stream for this research—as is available for cancer or heart disease—exists. Finally, the NIH should expend greater effort to better coordinate activities with other federal agencies studying drug abuse and disseminating information to the public in order to debunk myths and influence the regulatory environment where the domains of healthcare delivery and law enforcement overlap.

The Agency for Healthcare Research and Quality (AHRQ) website[80] includes chronic pain management guidelines that are not largely known or followed.[81] The Centers for Medicare and Medicaid Services' conditions of participation pertaining to pain management have not kept pace with updated guidelines. With respect to The Joint Commission, although its Standards and National Patient Safety Goals

have been updated recently, these goals are not prescriptive and do not indicate how assessment/management of chronic pain should differ from that of acute pain.[82] Because national guidelines are linked to reimbursement and, thus, access to care, it is imperative that these guidelines be aligned with current best practices.

The Problem of Prescription Opioid Misuse, Abuse, and Diversion

The NDIC and the Drug Enforcement Agency (DEA) have issued a report on the serious and escalating public health threat of prescription opioid misuse, abuse, and diversion.[35,83,84] Determining an individual's potential for aberrant drug behaviors and preventing misuse of prescription opioids are important in the evaluation and management of patients with chronic pain.

For the purpose of this White Paper, *substance misuse* is defined as the use of any drug in a manner other than how it is indicated or prescribed.[85] *Substance abuse* is defined as the use of any substance when such use is unlawful, or when such use is detrimental to the user or others. *Prescription opioid addiction* is a primary, chronic, neurobiologic disease characterized by behaviors including one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. *Aberrant drug-related behaviors* are those suggesting the presence of abuse or addiction. A prescription opioid is considered *diverted* when it is given, sold, or traded to someone other than the patient for whom it was intended. The rate of *nonmedical use of prescription pain relievers*—defined as the use of a prescription analgesic that was not prescribed for a given individual or that was used by an individual simply for the feeling the drugs caused—has nearly doubled between 1997 and 2002.[86] In 2008, government data indicated that 6.2 million persons in this country took pain relievers for nonmedical purposes at some point in their life.[87(p16)]

Misuse of opioids, alone or in combination with other drugs, is the most common form of poisoning treated in US emergency departments (EDs). The most recent Drug Abuse Warning Network (DAWN) data reported a 111% increase in ED visits involving nonmedical use of prescription opioids, including hydrocodone, oxycodone, and methadone, between 2004 and 2008.[88] These trends have been ascribed to the easy access to prescription opioids and to the misconception that prescription medications are safer to use than illicit substances. In recent years, more deaths have been due to abuse of oxycodone and hydrocodone than of heroin or cocaine.[89]

One of the main adverse consequences of the rise in prescription opioid use is the potential criminalization of pain sufferers who use opioids and the HCPs who prescribe these agents to treat pain. To adjust the opioid dosage, many HCPs use the World Health Organization model for treating cancer pain. This accepted healthcare practice supports escalation of the opioid dosage until pain is satisfactorily relieved or until intolerable side effects intervene. The high doses reached using this model can raise the suspicion of other professionals and of law enforcement agents that result in patients being labeled *drug addicts* and prescribers being labeled *drug pushers*.

Compounding this problem is the fact that some patients feign pain to obtain an opioid for illicit purposes: to misuse the drug (ie, to get high) or to divert it to someone else. Diversion of a prescription opioid is a criminal act, and an unsuspecting prescriber can be held criminally accountable. In addition, if an autopsy report indicates that a prescribed opioid contributed to a person's death, the prescriber can be incriminated. This accountability creates a sense of vulnerability that has led many HCPs, including pain specialists, to avoid prescribing opioids altogether.

The goal of providing effective pain management with opioids, when indicated, is difficult to achieve amidst the escalating misuse, abuse, and diversion of these agents. The American Academy of Family Physicians has been concerned that if sanctions and criminalization of opioid prescribers continue, patients in pain who are denied opioid therapy will suffer needlessly.[90]

Managing Patients' Opioid Use

Healthcare practitioners, particularly primary care practitioners, are in a key position to balance the benefits of prescribing opioids sensibly to treat chronic pain against the risks of opioid misuse, abuse, and diversion—and devising and implementing strategies to ensure that this balance is maintained. Given their longitudinal relationship with patients, primary care practitioners have an opportunity to screen patients for prospective opioid use, monitor their use of these agents, and educate them about securing, properly using, and discarding unused medications to prevent unauthorized use by others. The fact that 70% of persons engaged in nonmedical use of opioids obtain their supply from family members or friends who got their medication from one prescriber[87(p30)] supports the importance of talking to patients about these dangers. This discussion is especially critical to hold with patients who live with teenagers; every day, 2500 teenagers use a prescription drug to get high for the first time.[91]

Healthcare practitioners need to familiarize themselves with guidelines developed for using prescription opioids for chronic pain relief.[60,92,93] The aforementioned AHRQ guidelines represent an approach increasingly being considered a standard of practice, which begins with a comprehensive assessment of pain, psychosocial factors, patient expectations, and a history of past substance dependence/abuse.[80] Screening tools may be used to stratify patients according to their risk for developing aberrant behaviors when prescribed opioids. Screening is *not* used to decide who does or does not qualify for an opioid trial but, rather, defines who may need more frequent follow-up or a referral to a specialist based on identified needs and available resources.

Opioids are neither first-line pain relievers nor drugs of last resort, and they are not the best pain relievers for all patients. Therefore, initiating opioid therapy is considered a trial that often is accompanied by an *opioid management agreement*. In each case, HCPs need to set clear parameters to determine what constitutes a successful trial (the benefits outweigh the risks) versus a failed trial, which necessitates tapering and discontinuing the opioid while continuing to treat pain using other strategies. General guidelines for opioid prescribing that are likely to optimize outcomes, while minimizing risks for misuse, abuse, and diversion, include the following:

Practice Universal Precautions—As with all treatments, ongoing monitoring of desired and undesired effects is needed. Given that all opioids are classified as *high-risk* medications,[94] they are used only after a proper biopsychosocial workup establishes that they are clinically appropriate. After opioids are prescribed, vigilant monitoring is needed early in therapy and periodically thereafter. Monitoring patients for analgesic effectiveness, improvement in function, side effects, and emergence of aberrant behaviors is suggested as part of universal precautions.[46] All HCPs and practice settings must develop consistent methods of integrating these monitoring elements into opioid users' care.

Use Screening Tools—Assessment of prospective opioid users must be standardized. All patients must be screened in a timely manner so that prescribers can determine their initial risk for drug abuse/addiction. The Screening Instrument for Substance Abuse Potential[95] or the Screener and Opioid Assessment for Patients with Pain[96] can be used to help predict who may be at higher risk for developing problematic behaviors associated with opioid use. For patients with a past history of substance abuse/addiction, the CAGE-AID[97] or the Drug Use Questionnaire[98] is a better screening instrument.

Devise Opioid Management Agreements—Opioid management agreements, accompanied by consent forms, urine drug toxicology (UDT) screens, pill counts, and patient education efforts, can reduce the risk for opioid misuse or abuse and identify persons engaged in nonmedical use of opioids. Before initiating opioid treatment, HCPs and patients discuss treatment goals; proper use of the medication; possible risks, benefits and alternatives; and rules regarding opioids that patients and prescribers must follow. Management agreements are used for all patients on opioid therapy to ensure that they receive consistent information. If a patient is unable to provide consent, the HCP discusses the opioid management agreement and consent form with a caretaker or legal guardian. Examples of opioid management agreements are available through the American Academy of Pain Medicine (www.painmed.org) and the American Academy of Family Physicians (www.aafp.org).

Perform Urine Drug Toxicology Screening—UDT screening, often carried out prior to therapy onset and randomly thereafter, can detect the use of illegal substances, the presence of the prescribed opioid, and the presence of a prescription drug not ordered by the HCP. UDT use is controversial because of its cost, imperfect accuracy, and the possibility that results can be misinterpreted. Regardless, the UDT screen is one method to monitor adherence and detect substance misuse or abuse, although it does not replace good clinical evaluation and judgment. UDT screening is advisable at least for patients stratified as being at higher risk, if not for all patients on long-term opioid therapy.

Monitor Adherence to the Overall Treatment Plan—Monitoring of opioid users includes their adherence to the overall treatment plan, not just the medication regimen. The treatment plan may include nondrug interventions such as physical therapy and coping-skills training. Patients are expected to attend all follow-up visits or reschedule them; skipping scheduled appointments suggests a lack of responsibility. A pattern of multiple missed appointments combined with medication refill requests between visits amounts to unsupervised opioid use, which is concerning at many levels. Expectations to attend scheduled appointments, avoid early refills, utilize one HCP and one pharmacy for opioid prescriptions, and adhere to monitoring programs such as pill counts or UDT screening are standard and reasonable, and are often included in opioid management agreements.

Maintain Awareness of the Duty to Alleviate Pain and Suffering While Preventing Iatrogenic Harm—When opioids are part of a treatment plan, a set of sensible precautions is needed to prevent harm to the patient and others.[45] Like many other medications, opioids are used at the lowest effective dose for the shortest time possible.[92,99] HCPs conduct ongoing monitoring for potential adverse effects of therapy, including aberrant behaviors that may signal problematic use of the medication. When these risks are identified, HCPs have a duty to modify the treatment plan to reduce risks while *maintaining appropriate access to treatment*. This modification may include timely referral to pain and/or substance abuse specialists for patients with worsening pain, disability, or aberrant behaviors despite treatment.[100]

The recent estimate that 76 million persons in the United States suffer from chronic pain indicates that this condition affects more persons in this country than do diabetes, heart disease, and cancer combined.[5] Like the insulin, anticoagulants, and antineoplastic agents used to treat patients with those respective diseases, opioids are high-risk medications that are appropriate for some, but not all, patients with chronic pain. Whenever used, opioids must be prescribed in a way that balances concerns for safety and efficacy. However, the added challenge with opioids is the need to better understand the intersection between proper treatment of pain and nonmedical use of these agents.

In an effort to curb diversion of prescription medications, many states have implemented *prescription drug monitoring programs* (PDMPs)—electronic databases that record and track prescribers and recipients of controlled medications. Many states have PDMPs that permit HCPs to gain access to their patients' prescribing information—that is, for medications in Schedules II, III, or IV, and even V in some states.* [Footnote: *As of July 2010, 34 states have operational PDMPs that can receive and distribute controlled substance prescription information to authorized users. States with operational programs include Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wyoming. Seven states (Alaska, Florida, Kansas, New Jersey, Oregon, South Dakota and Wisconsin) and one US territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational. Washington State's PDMP was operational but has been suspended because of fiscal constraints. Delaware has legislation pending to establish a PDMP.[101]] Of note, in some states, PDMPs do not identify patients who are receiving controlled prescriptions from Veterans Administration healthcare systems, nursing facilities, or methadone maintenance programs.

Access to a controlled prescription database allows HCPs to monitor patients for the development of aberrant drug-seeking behaviors, such as using multiple simultaneous prescribers or pharmacies to obtain one's drug supply. Information contained in the PDMP database can inform HCPs of patient behavior patterns that suggest that simply writing a controlled prescription may do more harm than good. PDMPs, when used as intended by skilled professionals with point-of-care access to real-time data, have been shown to reduce the amount of controlled prescription drugs that patients obtain through multiple providers.[35(p16)]

Prescription drug monitoring programs provide an opportunity for HCPs to educate and advise patients about the safest and most effective treatment for their pain. Identifying patterns (eg, obtaining multiple simultaneous prescriptions) constitutes a teachable moment calling for honest dialogue and treatment decisions to protect patients and the public from potentially harmful drug misuse, abuse, and diversion. A respectful approach that empowers patients can strengthen the partnership with their HCP and potentially change their maladaptive behavior.[69] Use of PDMPs must be combined with vigilant monitoring by skilled, compassionate prescribers who understand both the appropriate use of opioids for chronic pain and strategies to prevent their diversion for nonmedical use.

Claims-based health plans can identify individuals receiving multiple pain medication prescriptions from multiple HCPs. Claims data mining can flag suspicious utilization patterns that can be the basis for more scrutiny and intervention as necessary. Medicaid and Medicare agencies can collaborate to ensure that these medications are used appropriately. Commercial, Medicare, and Medicaid health plans can identify enrollees using their benefits to secure excessive opioid prescriptions and/or prescriptions from multiple sources.

Need for Standardized Databases and Terminology

Unlike common, well-studied diseases such as asthma or diabetes, chronic pain is not tracked by current databases as a disease. General opioid use is tracked, but use of specific opioids is not tracked, and most surveillance databases do not detect the motivations of individuals who use opioids for nonmedical reasons. Epidemiologic databases are useful, but they cannot provide insights needed to better understand and address these problems. Databanks that track *all* of the ramifications of chronic pain and of prescription drug misuse, abuse, and diversion are needed.

Precise, uniform terminology is needed as well. Some HCPs and researchers believe that the term *nonmedical use* is synonymous with misuse or abuse, but it embraces diversion as well. According to DAWN, which tracks trends in ED visits, *nonmedical use* includes taking more than the prescribed dose of a prescription medication or more than the recommended dose of an OTC medication or supplement; taking a prescription medication prescribed for another person; being deliberately poisoned with a pharmaceutical by another person; or misusing or abusing a prescription medication, an OTC medication, or a dietary supplement.[88]

The Substance Abuse and Mental Health Services Administration (SAMHSA) defines *nonmedical* use of medications as "use without a prescription of the individual's own or simply for the experience or feeling the drugs caused."[2(p19)] The second part of the SAMHSA definition captures the goal of achieving a state of euphoria, whereas the first part acknowledges that a desire/need for pain relief could still be a motivating factor when a person uses someone else's prescription opioids. In fact, McCabe et al[102] reported that, among 12,000 high school seniors who engaged in nonmedical use of opioids, 40% did so to alleviate physical pain, not to get high. These students were still engaged in nonmedical use because the opioid was not prescribed specifically for them. Instead, it was most likely obtained from a family member or a friend.

Educating Patients About Proper Use of Opioids

Merely prescribing opioids without educating and counseling patients is unlikely to result in favorable outcomes. HCPs must convey clear information delineating specific instructions for use; impart warnings about related risks, including addiction; set realistic expectations that opioids provide only partial relief; and ask that patients take actions on their own behalf, such as participating in therapy, classes, or support groups that promote mastery of pain-coping skills.[103]

Patients for whom opioids are prescribed need to understand that these medications have an abuse potential that can lead to serious harm, even death, if not used as directed. An opioid management agreement can standardize the process and establish realistic expectations for the medication's potential benefits and limitations. As part of this agreement, patients can be informed of their obligation to secure their medication supply and to not distribute these medications to other persons. Key principles to be explained include safe use, locking medications, and proper disposal of unused prescription medications.

Safe Use—Patient education about safe use of opioids is imperative, and includes the importance of taking medication exactly as prescribed. The delicate balance among safety, efficacy, side effects, and optimum functioning must be discussed.[104] Opioid analgesics are considered one component of an individualized, multimodal treatment plan. The discussion about safe use of opioids includes:

- An overview of prescription and OTC analgesics;
- Benefits and risks of all analgesics, including those with an abuse potential;
- Proper storage of analgesics in containers with lids and labels;
- Identification of when analgesics, including opioids and nonopioids, are misused or abused;
- Role of the opioid management agreement and why the agreement is used;
- Role of the therapeutic relationship with the HCP;
- Safeguarding and screening strategies that HCPs need to maintain; and
- Behaviors that may signal a need for a treatment change by the prescriber.

Patient education about opioid use must be culturally sensitive, and may necessitate the use of an interpreter. Attention to insurance coverage of the treatment plan ensures that HCPs are individualizing care and being sensitive to the financial burdens that pain and its treatment may impose. Ongoing reinforcement of adherence to the therapeutic regimen is needed, including identifying safety concerns inherent in misusing analgesics.

Pain sufferers who require opioid therapy must understand the risks of over-sedation and of using opioids for problems other than pain, such as anxiety or insomnia. Opioid users must be aware of such pharmacologic effects as physical dependence and tolerance, which are *not* harbingers of addiction. Patients must be able to distinguish these *expected* physiologic phenomena from opioid craving, compulsive use, and continued use despite known harm—all of which are hallmarks of the disease of addiction. Given the abuse potential of opioids, patients and family members must be aware of the signs and symptoms of an emerging addiction disorder and discuss these concerns openly. Without these discussions, patients may fail to follow rules for safe use (ie, they may skip doses, take unauthorized doses, stop medication abruptly, or operate heavy machinery), which can have serious adverse consequences.

Locking Medications—Safe storage of opioids includes protecting these medications against theft or diversion. The following websites provide safe-storage messages:

- **www.nfp.org/**: The National Family Partnership sponsors a *Lock Your Meds* ™ campaign that details methods of safe storage.[105]
- **www.drugfree.org/notinmyhouse**: The Partnership for a Drug-Free America has a website called *Not in My House* that provides useful information on motivation, access, and perceived risk.[106]
- **www.PainSAFE.org**: Pain Safety & Access For Everyone (PainSAFE™) is an educational initiative from the American Pain Foundation.[107] This web-based program is designed to educate people with pain, caregivers, and healthcare professionals about the appropriate and safe use of pain management therapies in an effort to improve access to pain care.
- **www.opioids911.org**: Opioids911-Safety is an independent, noncommercial, Internet-based educational activity from *Pain Treatment Topics* (Pain-Topics.org) for patients and their caregivers focusing on the proper and safe use of opioid pain relievers.[108]

Patients receiving opioids for pain relief are referred to these websites and instructed to lock their prescription medications. HCPs need to explore opportunities for community-wide initiatives to ensure that local pharmacists are supplying lock devices and counseling customers using opioids about their safe use. The individualized plan for locking up prescription medications is documented in the patient's health record.

Proper Disposal of Unused Prescription Medications—Patients or family members have two options for disposal of unused prescription opioids: (1) environmentally-friendly disposal or (2) disposal through community-sponsored take-back programs,[109] which require law enforcement oversight. Selection of either option is voluntary and based on community drives and support.

Proper disposal of medications will help preserve the environment and reduce the amount of drugs available for theft or diversion. Although the FDA disagrees,[110] the Environmental Protection Agency recommends against pouring prescription medications down the drain or flushing them down the toilet.[111] If community take-back programs are not available, the Office of National Drug Control Policy makes these recommendations regarding disposal of unused medications[112]:

- Remove the prescription medication from its original container.
- Mix the drugs into an undesirable substance such as kitty litter or used coffee grounds.
- Place the mixture in a disposable container with a lid or a sealable bag.
- Conceal any personal identification.
- Place the sealed disposable container in the trash.

Recommendations for Managing Chronic Pain with Opioids

The dual public health concerns of (1) escalating numbers of persons with inadequately treated chronic moderate to severe pain and (2) the misuse, abuse, and diversion of prescription opioids must be addressed in a comprehensive fashion. These recommendations are offered as key components of addressing these problems.

Professional Educational Recommendations

1. Improve education for healthcare practitioners about chronic pain; pain management; and opioid use, misuse, abuse, diversion, and addiction.

Core curricula in HCP educational programs must include the prevalence and pathophysiology of chronic pain, appropriate management of pain, proper prescribing of opioids, and risks for opioid misuse, abuse, and diversion. Content should include information about addictive behaviors, drug-seeking patterns, and co-dependency.

2. Develop and implement a standardized curriculum in pain management and opioid prescribing. This curriculum should be required to secure accreditation for all HCP educational programs.

A similar knowledge base for safe prescribing is required for members of all healthcare professions. A standardized curriculum will promote a set of core competencies for prescribers across disciplines. Linking this effort to accreditation will ensure that programs implement the needed curriculum.

3. Implement mandatory outcome-oriented continuing education (CE) for healthcare practitioners on the topics of chronic pain management and opioid prescribing.

Practicing HCPs need access to CE from qualified instructors in pain management with the goal of maintaining currency and expanding knowledge. CE must be based on needs assessment, must provide opportunity for learners to engage in educational activities, and must be outcomes-oriented. CE may be offered in multiple modalities but should be based on a core curriculum developed by the health professions. Testing may be done electronically, as is currently being done in CPR training.

4. Provide education on chronic pain and on opioid use, misuse, abuse, diversion, and addiction for all members of the healthcare team.

Some HCPs may miss subtle clues suggesting opioid misuse, abuse, or diversion by their patients. Nonclinical staff members may pick up these clues; some patients are more likely to confide in a nursing assistant or a receptionist than in their HCP. Educating everyone on staff about chronic pain and opioid use creates an environment that encourages early identification of problematic drug-use patterns and facilitates patient education, referrals, and treatment—with the aim of reducing opioid misuse.

System-wide Recommendations

5. Increase reimbursement for HCPs to accommodate the time needed to provide education, counseling, and low-cost nonpharmacologic interventions for chronic pain sufferers.

Time allocated for care of patients with chronic pain must include reimbursement to cover the extended visits (30-60 minutes) needed to provide education. In many chronic pain cases, insurance companies pay only for nerve blocks and/or opioid treatment, even if a patient's pain is better relieved by another type of medication or by a nonpharmacologic modality. Third-party payers must be encouraged to direct their dollars toward educating chronic pain sufferers about self-management (eg, lifestyle changes, monitored exercise) and away from expensive surgeries and nerve blocks whose promise of sustained pain relief is achieved by only a small fraction of patients.

6. Educate patients, family members, and communities about chronic pain and proper use of opioids.

Patient, family, and community education is vital in preventing opioid misuse, abuse, and diversion. Educational efforts include instructions in safe use of opioids for pain, locking up and storing opioids, implementation of take-back programs for unused prescription analgesics, and review of proper disposal of opioids when take-back programs are not available. Funding these programs locally and nationally will enable communities to educate members to act responsibly.

7. Standardize information systems, databases, and terminology regarding chronic pain and opioid misuse, abuse, and diversion.

Electronic databanks are needed to track and monitor all aspects of chronic pain and of opioid misuse, abuse, and diversion. Terminology regarding various types of chronic pain and regarding opioid use, misuse, dependence, abuse, addiction, and diversion must be standardized. Lack of standardized terminology limits a more informed approach to research and clinical practice. Funding is needed

to bring together HCPs, researchers from different disciplines, and policymakers to develop standardized terminology for both chronic pain and opioid use and to develop methods of measuring these phenomena in a way that can be incorporated into future epidemiologic studies, research, and clinical diagnostic coding.

8. Improve systems for identifying and managing opioid misuse.

Managed care organizations, in collaboration with pharmacy benefit providers, can use prescription software edits to identify potential misuse of prescription opioids and alert HCPs and health plan medical directors of potential problems. Medicare and Medicaid offices could have defined processes for investigating and managing potential prescription misuse.

9. Standardize procedures to identify and manage chronic pain.

Healthcare organizations must have standardized procedures to facilitate appropriate identification and management of pain, including the prescribing of analgesics. Procedures could routinize ongoing pain assessments, universal precautions, and monitoring of medication use. Medication management procedures include opioid management agreements, locking of medications, careful documentation of prescribing and distribution of opioids, and appropriate disposal of opioids. In some cases, HCPs may determine that the best medication is a new opioid product designed to be abuse deterrent or tamper resistant. This type of medication formulation should be available for HCPs to prescribe—*without* arbitrary formulary or insurance company restrictions.

Regulatory and Policy Recommendations

10. Institute appropriate regulatory oversight.

The DEA, state professional boards, and employers who credential prescribers must establish methods to ensure that HCPs have a working understanding of chronic pain and the problems of substance misuse, abuse, and diversion.

11. Facilitate referrals to pain specialists.

Health plan policies and community practice norms must facilitate utilization of board-certified pain specialists and addiction medicine experts for patients with persistent uncontrolled pain and opioid addiction. Pain management/addiction medicine certification for clinicians in medicine and advanced practice nursing is needed. Identification of these specialists in health plan directories should be encouraged.

12. Increase federal support for pain management research and for resources to increase community and practitioner understanding and ability to manage pain appropriately.

Government funding is needed for several well-orchestrated research programs in the area of coexisting addiction and pain.

13. Develop collaboration between law enforcement and the health professions to address misuse, abuse, and diversion of opioids.

Implement a national tracking system to reduce the potential for opioid diversion and to support HCPs treating patients with chronic pain. HCPs and law enforcement officials can work together to address inappropriate prescribing. HCPs have a primary obligation to treat pain and reduce suffering. HCPs must also be aware of the potential for misuse, abuse, and diversion and risks of inappropriate use. Law enforcement officials must do their best to stop diversion but, at the same time, avoid interfering with HCPs' obligation to treat chronic pain. Close communication between the two professional groups will enhance the effort to stop opioid diversion. Current mechanisms, fragmented by state lines, need to be linked via a national tracking mechanism (eg, the Prescription Monitoring Program) as one way to identify persons at risk for diverting drugs and reduce the potential for diversion. This information needs to be accessible in real-time as a prescription is being written.

Conclusion

Responsible pain management incorporates assessment and treatment strategies consistent with national standards, state regulations, and institutional policies. While pain management is of utmost importance, HCPs must institute responsible prescribing practices that keep patients and communities safe from prescription misuse, abuse, and diversion, and support proper disposal of unused medications via take-back programs in communities. By developing electronic databases, HCPs can track trends and outcomes of our efforts with enough accuracy to direct future efforts to treat pain without a corresponding rise in opioid misuse, abuse, or diversion. Finally, HCPs involved in research and/or education can focus on patient-centered approaches to chronic pain management and on improving methods to assess for, prevent, and intervene against substance abuse and addiction.

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