



ASAM

American Society of Addiction Medicine

Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction

Background

The diversion of prescription drugs from the person to whom they were originally prescribed, and the non-medical, sometimes lethal use of these drugs, are components of our nation's overall drug problem, and they are of special concern to physicians. The last two decades have seen dramatic increases in the use of and addiction to potentially addictive pharmaceuticals. Although the non-medical use of prescription drugs is not a new phenomenon, increases in cases of diversion, misuse, and overdose deaths have been striking and have drawn the attention of public health officials, regulatory agencies, and public policy makers on the state and national level. Notable among the proposed responses to these problems is the published strategy of the White House Office of National Drug Control Policy, addressing educational, rehabilitative and disciplinary approaches to the problem it discusses under the term "prescription drug abuse."

Two of the most commonly misused classes of prescription medications are opioid analgesics and sedative hypnotics, both of which are considered "controlled substances" in that they appear in schedules for pharmaceuticals under the federal Controlled Substance Act.

According to the Centers for Disease Control and Prevention, the number of opioid analgesic prescriptions filled at pharmacies has increased from 175 million in 2000 to 254 million in 2009. Prior to that, however, the use of these same drugs to assist patients with pain was considered too low. The medical literature described "under prescribing" as a problem, and that it was based on evidence that physicians--fearful that they would face rebuke from their peers or sanctions from licensure bodies for being "too liberal" in the prescribing patterns--were declining to offer prescriptions for controlled substances even when patients were in significant pain. Well intentioned researchers demonstrated, in short term studies, that the benefit: risk ratio was positive when terminally ill patients with painful conditions were treated with what had heretofore been considered high-dose levels of opioid analgesics. This research was embraced by policy analysts who influenced bodies such as the Federation of State Medical Boards to issue "reformed" guidelines supporting the use of opioids, even in high doses, for palliative care, for oncology care, for acute injury care, and even for the treatment of chronic non-cancer pain. These guidelines assure practitioners that, when they act in good faith, conduct thorough evaluations, document their rationale well, and monitor their patients carefully, they will not be sanctioned by their state licensing board for providing appropriate medical care. Elements of the pharmaceutical industry engaged in well-documented efforts to increase the utilization of

opioid analgesics as the preferred, if not first-line treatment for chronic pain, including chronic non-cancer pain; and financial incentives from industry drove endorsements by recognized physicians and thought leaders of the use of high-dose opioids as a treatment for non-malignant pain. The recommendation that physicians and other medical personnel probe for cases of pain and intervene lest pain go undertreated, culminated in accreditation requirements, such as the often-cited "Pain Standard" of the Joint Commission, which would find health care organizations to be sub-standard if, on accreditation site visits, they could not demonstrate that they had in place a formal process to proactively extract from patients comments about their perceived level of pain at essentially every clinical encounter.

Knowing that many patients with pain also experience anxiety or sleep disturbances, clinicians have often added sedative hypnotics to a regimen of chronic opioid analgesic therapy, leading to instances of oversedation, chronic use of benzodiazepines, tolerance, withdrawal, and even addiction to benzodiazepines among some chronic pain patients. Physician comfort with prescribing benzodiazepines (some of the most frequently prescribed of all medications in the 1980s) and patient liking for these agents made the co-prescribing of opioids and benzodiazepines a not uncommon clinical scenario.

Pain management is an important component of high-quality compassionate medical care. There remains great controversy about the place of opioid medications in the treatment of pain, and little education of the non-pain specialist related to the differences in various types of pain. The fact that acute pain from a fracture or surgery is different from "failed back syndrome," or from chronic stable pain of musculoskeletal origin, is infrequently stressed as physicians consider whether to prescribe opioids for complaints of back pain. Differences between nociceptive pain (the somatic pain commonly resultant from injury or surgery), neuropathic pain (injury to the nerve itself), and central pain (as seen in fibromyalgia, some cases of chronic headaches, or complex regional pain syndrome) and differences in recommended clinical and pharmacologic approaches for these different presentations, are not often appreciated by prescribing physicians. Furthermore, the understanding of iatrogenic injury that can arise from the prescription of scheduled medications to patients with chronic stable pain of musculoskeletal origin has been hampered by the exclusion of persons with drug misuse histories from research studies. No clear recommendation for attention to the co-occurrence of addiction in these patients has been forthcoming, and they have been routinely recommended for exclusion from services rather than referral to treatment.

Similarly, studies have shown that physicians have not received adequate education about the potential psychiatric and addiction consequences of the decision to prescribe scheduled medication. Most practicing physicians have had little if any formal training in addiction. Few physicians demonstrate understanding of the etiology of addiction. Although issues of tolerance and withdrawal are understood to exist, most physicians are not aware of the mechanisms and the behavioral consequences of these phenomena, or the relationship of these phenomena to addiction. Confusion still exists whereby some clinicians mistake physical dependence (tolerance and withdrawal) for addiction. Rarely are craving and reward seeking behaviors appreciated by prescribers as being potential consequences of their prescribing of opioid and sedative medications. And while most physicians are skilled in the initiation of prescriptions for opioid analgesic therapy (a notable exception being the safe initiation of methadone as a

chronic pain treatment), most physicians are not comfortable with or skilled in discontinuation of opioid analgesic therapy or outpatient management of opioid withdrawal when opioid discontinuation results in abstinence symptoms.

The evidence that physician education about addiction would modify prescribing practices is controversial. Different medical specialties have argued that the educational needs of physicians within a given specialty must be tailored to that specialty, and broad, all-licensee educational mandates would be a waste of educational resources and practicing physicians' time. Others have argued that basic concepts on how to recognize addiction, how to recognize physical dependence and withdrawal syndromes, and how to safely taper and discontinue opioid analgesics and sedative hypnotics are so misunderstood by physicians, dentists, and other licensed independent practitioners, that basic education for all persons granted a federal registration to prescribe controlled substances is necessary. It is possible that education that only addresses basic science aspects of pharmacology and neuroscience will not improve patient outcomes unless it is paired with clinical education that addresses strategies for the management of pain, withdrawal, and addiction, clinical drug testing and other diagnostic approaches; as well as functional assessment and basic concepts regarding occupational medicine and disability determination. But there is emerging data to suggest that when primary care physicians are targeted for focused education regarding pain, pain medication prescribing, and assessing patients for risk prior to the initiation of opioid analgesic therapy, trends in opioid overdose deaths can be reversed.

What is clear is that the current situation is untenable. Governmental agencies and the public expect the health system to be responsible, to respond to current clinical and epidemiological challenges, and to be "part of the solution" to reverse trends regarding prescription drug diversion, misuse, addiction, and overdose deaths. The "secondary use" of controlled substances in potentially lethal ways (e.g., by persons who obtain supplies of pharmaceuticals that originated from a legal prescription, but was written for someone else) must be addressed through improved education and practice. All health professionals who can prescribe scheduled medications must be included in any educational efforts to improve patient outcomes and public health. The general public needs to understand better the risks associated with controlled substances and their role in safe medication storage and disposal, and physicians have a key role they can play in patient education regarding these topics.

Recommendations:

The American Society of Addiction Medicine recommends that the following components be included in any public policy response to the growing problem of prescription drug addiction, diversion, misuse and overdose deaths.

A. Prescriber Education

1. Mandatory Prescriber Education

- a. Mandatory education of physicians and all other health professionals licensed to prescribe, dispense or administer prescription drugs is a key strategy in modifying the epidemic of misuse of and addiction to scheduled medications. The Controlled Substances Act should be amended to require all DEA registrants to obtain training on the use of controlled substances. Mandatory prescriber education should be required for all classes of controlled substances and for all schedules.

- b. Education should include the general principles of prescribing drugs that are commonly associated with misuse, dependence and addiction. This education should include how to recognize and appropriately intervene in the case of such findings.
- c. Education should also include recognition of addiction, assessment of the risk potential for the development of addiction, and referral to appropriate addiction treatment colleagues when addiction is identified or strongly suspected to be present.
- d. Education for prescribers should also address how health professionals can provide education to patients about the potential harms associated with the use of controlled substances and about the safe storage of and disposal of supplies of controlled substances.

2. Specific Drug (Class) Education

- a. Specific education should be required about the controlled drugs used in the particular practice of the prescriber where prescribing scheduled drugs is an integral part of that prescriber's practice. DEA registrants should be permitted to select educational modules that are relevant to the classes of medications they frequently prescribe in their practice.

3. Quality Indicators

- a. Quality Indicators for clinical practice should be developed regarding these topics, addressing practices such as of the use of periodic and random urine drug testing, the use of pill counts, the use of treatment agreements, the use of screening tools for the development of addiction and other adverse effects when controlled substance are used, and the patient education activities of prescribers, where the prescription of controlled substances is an integral part of the services provided.

4. Guidelines for Prescriber Education

- a. Content for mandatory training should be evidence-based and focused on symptom reduction, functional impairment, and careful management of the risks associated with the controlled substances being prescribed. Physician education modules and patient education materials should be developed with input from professional societies; not only those that represent primary care and medical/dental/surgical prescribers, but also those that represent addiction medicine, addiction psychiatry, pain medicine, occupational medicine and physiatry.
- b. Professionals with significant pharmaceutical industry relationships (as defined by the AMA's Council on Ethical and Judicial Affairs) should not be involved in developing educational content for mandated prescriber training.

B. Patient Education

1. Guidelines for Patient Education

- a. Prescribers of controlled substances have a responsibility to educate the patient at the time of issuing a prescription, about safe drug storage and disposal practices by patients. Practitioners need to be educated on how to inform patients about locking medication supplies in the home (akin to locking firearms and ammunition, and locking toxic chemical supplies in the home) as a means of prevention of unauthorized use, theft, or accidental overdose by children. Physicians, dentists and others need to be part of the solution to the prescription drug overdose epidemic by helping patients (who may be parents or grandparents) become part of the solution to the public health crisis of prescription drug misuse and addiction.
- b. Physicians should provide educational materials about chronic pain and the risks vs. benefits of long-term use of medications as part of their prescribing practices.

C. Medical School and Residency Education

1. Training for Medical Students and Residents

- a. Training should include curricula topics that focus on pain medicine, addiction medicine, safe prescribing practices, safe medication storage and disposal practices, functional assessment of patients with chronic conditions, and the role of the prescriber in patient education.

D. Prescription Drug Monitoring Programs (PDMP)

1. Recommendations for full use of PDMP

- a. Prescription drug monitoring programs can be effective clinical tools in medication management involving controlled substances. In 2005, President Bush authorized the federal National All Schedules Prescription Electronic Reporting (NASPER) program to issue grants to state interested in establishing or enhancing prescription drug monitoring programs (PDMP). However, funding for NASPER has been inconsistent, not all states have an operational PDMP, and few state PDMPs are interconnected. NASPER should be permanently authorized and adequately funded.
- b. PDMPs developed by various states should be available for review by clinicians across state boundaries.
- c. PDMP data should be available in real-time by clinicians considering a decision to authorize a prescription for a controlled substance.

- d. PDMP data should be considered health information, and should be protected from release outside of the health care system (e.g., to law enforcement, the courts, employers, family members or others) unless there is a specific authorization from the individual patient to release personal health information (see ASAM Public Policy Statement on Confidentiality of Patient Records and Protections Against Discrimination).
- e. Medical examiners, public health authorities, quality assurance agencies, and state licensure boards, should have the same access to PDMP data that they have to other personally identifiable health information, for the purposes of assessing trends and assuring that standards of professional practice are met. But law enforcement, the judiciary, corrections professionals, employers, and others outside of the health care system should not be granted access to PDMP data except via the means available to them to secure access to other personally identifiable health information.
- f. Every prescribing clinician should be familiar with the process of accessing and utilizing information from PDMP's so that they can incorporate this information in their practices.

E. Better Data Through Research

1. Recommendations for continuing research

- a. Epidemiological research conducted by the Centers for Disease Control and Prevention and others should be expanded to provide the best quality data on patterns of manufacture, distribution and sales of psychoactive drugs which have the potential for diversion and misuse. Better data is also needed on patterns of diversion and involvement of specific classes of scheduled drugs in being the direct and contributory causes of overdoses and drug-related mortality. Health services research which profiles the prescribing patterns of individuals and classes of practitioners is an appropriate approach to learning more about how to reduce the incidence of prescription drug diversion, misuse, addiction, and overdose deaths.

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