Opioid Prescribing: Guidelines, Laws, Rules, Regulations, Policies, Best Practices

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"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[1]

ABSTRACT

Prescription drug abuse, misuse and unintentional overdose deaths are major public health concerns and have captured the attention of regulators at every level. There is no shortage of guidelines, laws, rules, regulations, and policies regarding opioid prescribing. Physicians struggle with their duty to treat pain, and yet balance this against the risk to patients as well as the potential for diversion. There are gaps in policy and resources such as lack of interdisciplinary pain clinics, addiction treatment, and education for prescribers and patients.

KEYWORDS: Prescription drug abuse, accidental deaths, www.health.ri.giov/saferx, www.health.ri.gov/painmeds

INTRODUCTION

Physicians struggle with the duty to treat pain, specifically non-cancer related pain and the growing problem of diversion of prescription drugs. The statistics on prescription drug abuse are sobering if not shocking. In 2009, there were over 15,500 deaths from prescription drugs and 30% of those involved methadone.[2] 2010 data from the Substance Abuse and Mental Health Administration (SAMSHA) reveals 13.7% of individuals over age 12 have used prescription pain killers for non-medical reasons in their lifetime.[3] The most common pharmaceuticals people use for non-medical purposes are: hydrocodone, oxycodone, and fentanyl.[4]

This has all occurred during a time when efforts have been increased from multiple entities to assess pain as a "5th vital sign,"[5] and to treat pain more aggressively, and when direct advertising to consumers for pain medication has increased.[6]

Regarding controlled substances, the World Health Organization *"considers the public health outcome to be at its maximum (or balanced) when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse."*[7] This balance is elusive and underscore's the relationship between analgesic efficacy and its potential for abuse[8]. It is important to emphasize that the opiate drugs that are most effective in relieving pain are also the ones with the highest risk of abuse. It is no secret this entire issue is a dilemma for clinicians and represents a significant challenge to the every day practice of medicine.

What's out there?

The Rhode Island Board of Medical Licensure and Discipline is concerned about prescription drug misuse, dependence and related deaths. We should further explore what can be learned from existing efforts of policymakers, and what common ground and gaps in policy exist.

Federal Entities	State Governments	Professional Societies	Pharmaceutical/ NGO
DEA[9]	Washington[10]	American Pain Society[11] American Academy of Pain Management[12]	Federation of State Medical Boards[13]
CDC[14]	Ohio[15]	American Academy of Pain Management[16]	Cares Alliance[17]
FDA Blueprint[18]	Colorado[19]	American Society of Anesthesiologists[20]	Endo Pharmaceuticals[21]
White House[22]	Iowa[23]	American Academy of Family Physicians[24]	American Chronic Pain Association[25]
DOD/VA[26]	Arizona[27]	American College of Physicians[28]	Purdue Pharmaceuticals Pain education[29]

The extensive variety of guidelines, toolkits, regulations, etc., highlights the significance and pervasiveness of this issue. Clearly, from the perspective of prescribers, patients, regulators, payers and government this is one of the most important issues of our day. Each entity above has addressed this issue to some extent; the State of Washington took the unique step of creating very specific legislation focusing on prescribers.

Washington Pain Rules

The Washington pain rules were enacted into law 7/1/2011 in response to the epidemic of prescription drug abuse in this state[30] yet recognizing the important role in the appropriate treatment of pain. These pain rules are specific to non-cancer treatment of pain and specifically address several aspects of chronic pain management. These include:

1. evaluation of the patient
2. detailed documentation requirements
3. treatment goals/plan
4. informed consent
5. highly detailed written agreement for treatment of pain and monitoring
6. periodic review of the patient
7. appropriate treatment for episodic care
8. recommendations for when to obtain consultation, including a mandatory threshold based on morphine equivalent dose
9. defines who can be considered a pain management specialist
10. strongly recommends use of prescription monitoring program

The Washington Pain Rules are specifically addressed to prescribers and attempt to balance the need for appropriate pain management while recognizing the public health threat from diversion, dependence and addiction.

The pain rules are not without their critics with some expressing that patients with legitimate pain needs are not having these needs addressed.[31] The American Academy of Pain Management has supported these rules, yet highlighted that confusion, misinterpretation and clarification is needed.[32]

Although the Washington pain rules were initially a practice guideline,[33] the main criticism of the pain rules is they were ultimately enacted as law. It has been suggested that physicians leery of the legal burden and expense of this law on their practice have chosen not to treat chronic pain in their patents, leaving the patient caught in the middle.[34] Some physicians have chosen to interpret these rules as so restrictive as to stop prescribing narcotics.[35] This may be an unintended consequence of this legislation, although the legislation clearly highlights as one of its goals that patients with chronic pain be appropriately treated.

The Washington Pain Rules have not been around long enough for a thorough evaluation, yet were constructed in a collaborative manner and with an evidenced-based[36] approach. Time will tell if such a legislative approach has effectively turned the tide in Washington.

Common themes among many regulators

After a review of many of these guidelines and statements, there are several common themes which should be noted.

1. Recognition of balance and responsibility to appropriately treat pain while also recognizing that opioid medications are addictive and subject to diversion.
2. The morbidity and mortality from opioid medications is a national epidemic.
3. There are standard practices that reflect responsible opioid prescribing.
4. There are accepted tools that reflect responsible monitoring of patients who take opioid medications.
5. There is often a need for an interdisciplinary/multidisciplinary approach to pain management.

Role of Regulatory Agencies

Regulatory agencies, like the Rhode Island Board of Medical Licensure and Discipline (BMLD), are charged with a specific mission: "*To protect the public through enforcement of standards for medical licensure and ongoing clinical competence.*"[37] Establishing and enforcing regulations, promoting and conducting education and ensuring a competent workforce reflect the major activities of the BMLD.

Limitations on regulatory agencies and the problem of prescription drug abuse highlights one of our most significant limitations. Regulatory agencies do not get in the exam room with the prescriber, their reach is from a different level and their regulation or guidance is expected to be interpreted in the context of a legitimate prescriber-patient relationship. Regulatory agencies are counting on the prescriber to have exercised sound professional judgment and made the best effort to construct the most appropriate treatment decisions for the individual patient.

Unique Challenges

Opioid addiction/dependence/abuse presents several challenges due to the addictive nature of the medication and the unpleasantness of pain. Additionally, accumulating evidence indicates that opiates may cause an additional problem, opioid induced hyperalgesia (OIH).[38] Paradoxically, this therapy which alleviates pain has the potential to make patients more sensitive to pain and may make matters much worse for the individual patient.[39] Patients with OIH typically experience this after escalating doses of opiates which are not controlling their pain and often report the pain to be different in character than previously reported pain.[40]

What Can Rhode Island Learn From All of This?

Policy Gaps and Bridges

There are gaps that exist when it comes to the appropriate management of pain. Patients with chronic pain and prescribers perceive our health care marketplace lacks an alternative for pain control with opioid medications. Although there is debate on the business case for interdisciplinary pain clinics, they have been shown to be cost effective; yet uncertainty exists on the optimal combination of professionals in an interdisciplinary pain clinic.[41] It should be noted that an interdisciplinary clinic differs from a multidisciplinary clinic in that in the former, all professionals share the patient and collaborate with the patient on treatment goals and outcomes. There is a place in the health care system for an interdisciplinary non-pharmacologic approach to chronic pain.

Another gap is the relative shortage of resources for patients with addiction and reluctance of some in viewing addiction as a chronic disease. Effective treatment for

addiction does exist yet is not effective for all patients. Additionally, addiction is a chronic disease and relapse is part of the disease process. Addiction is a complex disease that requires time, collaboration and perseverance not just for the patient, but the treating team.

Although many resources exist for providers in managing chronic pain, what is missing is a simple tool kit specific to various common clinical settings. Providers need practical tools they can easily implement and incorporate into their work flow.

Additionally, prescribers would benefit from targeted training in conflict resolution, bullying and how to handle manipulative patients. Patients who are addicted or dependent often exhibit aberrant behavior and physicians are generally not prepared to handle this in the time- constrained, busy and complex clinical milieu.

Additionally, there is a profound lack of patient education regarding this public health epidemic. Patients are not typically informed of the risk of taking opioid medication and do not have an opportunity to do their own risk/benefit analysis. This suggests the need for more explicit regulation which defines the terms when informed consent shall be obtained when prescribing opiates. It is difficult to reliably assess which patients are at risk for addiction; therefore many have advocated an approach which incorporates "universal precautions."[42] This approach destigmatizes the issue of addiction and allows for a frank discussion of the risks and benefits of the proposed treatment for pain.

CONCLUSIONS

The complex issue of pain, opioid dependence, addiction and abuse represents a multifaceted and difficult issue. There is no rapid solution forthcoming and the clinical landscape for this is uncertain and problematic. This issue reflects one of the largest barriers to patients with chronic pain achieving a state of optimal health. There are plenty of policy gaps and opportunities to address for the foreseeable future.

The prescription drug abuse epidemic cries out for collaboration from prescribers, policymakers, payers, law enforcement, behavioral health, complementary and alternative medicine providers, educational professionals and more. Each generation has its mountains to climb; this issue will not be solved with Herculean efforts by any single entity; rather a combined and coordinated approach that may redefine health care as we know it to accomplish a sustainable solution.

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