Health Care Safety Net Series:

Opiate Use for Chronic, Non-Cancer Pain (CNCP)

First Edition - October 2011
Health Care Safety Net Series: Opiate Use for Chronic, Non-Cancer Pain

About MPCA

Maine Primary Care Association (MPCA) is a membership organization representing the collective voices of Maine’s community, tribal, migrant and homeless health centers - referred to as Maine’s health care safety net.

For 30 years, MPCA has provided technical assistance and training, housed relevant programs and services and advocated on behalf of Maine’s safety net and the hundreds of thousands of patients it serves.

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Executive Summary

Opiate prescriptions are now the class of analgesic drugs most often prescribed in the US. According to International Medicine News in 2006, with a rate of 87–200 defined daily doses prescribed per 1,000 Medicaid beneficiaries Maine ranks among the 9 states with the highest rates¹ of opioid prescribing. The eight states with the lowest rates prescribed 0 to 39 defined daily doses per 1,000 Medicaid beneficiaries. While access to and use of opioids has increased so has the number of Maine people seeking treatment for substance abuse. From 1998 through 2008, there was a 400% increase in the number of patients admitted for substance abuse treatment for opiates, other than heroin. Maine has the highest opiate treatment rate in the nation; with 386 people per 100,000 admitted².

Despite the wide-spread prescribing of opiates, studies on the effectiveness of opioids as a pain reliever are quite varied in duration, population/sample size and validity. This lack of a widely accepted body of research has resulted in significant variation in the prescribing and monitoring practices associated with opioid-based medications. The fields of pain management, substance abuse treatment and primary care all have their own historical perspective on the use and abuse of opiates and how best to treat those patients seeking to manage chronic, non-cancer pain.

However, it is time to set dissenting opinions, practice and experience aside. It is in the best interest of Maine’s patient population, and the primary care system to focus efforts to improve chronic pain management while impacting the increasing trend of the non-medical use of opiates on the following four high leverage points:

- Increase the active use of Maine’s Prescription Drug Monitoring Programs (PMPs)
- Use opiate trials when initiating opioid therapy
- Application of Universal Precautions for Chronic Opioid Therapy (COT)
- Utilization of an equitable discontinuation process within the care setting

To locate common ground, the Maine Primary Care Association has engaged in extensive research and collaboration to identify resources, educational opportunities and best practices being utilized across Maine’s Federally Qualified Health Center system, with a goal of better utilizing and monitoring the use of opiates for chronic, non-cancer pain.

The purpose of this white paper is to identify high leverage points to change how opiates are prescribed for the treatment of chronic, non-cancer pain.

The elements identified within this paper will support Maine’s patient-centered, primary care safety net to shift the focus of opiate prescribing for chronic, non-cancer pain (CNCP) from analgesia to function, ultimately resulting in treatment goals that become objective and verifiable and improve the quality of life and care experienced by Maine’s patient population.
Historical Perspective -
Medicinal, Recreational, Commercial & Regulatory Origins of Opiates

The use of opioids has a historical presence in medical innovation, economic and diplomatic history, legal and regulatory influence as well as altering the social consequences associated with recreational and illegal drug use. There is significant variation in the management of chronic pain, utilizing opiate-based pharmacology. Historically, the relationship with opiates as medicine and fear of addiction often led to the under treatment of pain and the cautious prescribing of opiates. The variability in the “best practices” associated with the use of opiates for pain control lacks uniform acceptance from the research and medical communities. As evidenced by the key moments in more recent history outlined below, both fields have been pushed and pulled between the competing interests associated with opiates and how these medications are integrated into appropriate patient assessment and care.

1995: The American Pain Society proposes a set of guidelines using a standardized pain scale of 0-10 based on a patient's self report. Pain is declared the 5th vital sign, with the expectation that pain would be assessed with the same frequency as the standard set of vital signs.

1996: Purdue Pharma brings a semi-synthetic opioid analgesic named OxyContin to market. Its active ingredient is OxyCodone. While OxyCodone is also found in medications like Percodan and Tylox, both pain relievers also contained Tylenol or aspirin, which limited their abuse potential. Purdue Pharma markets OxyContin for relief from chronic or long-lasting pain. Unlike Percodan and Tylox, OxyContin contains OxyCodone at 10-80 mg per pill in a time-release capsule. It was seen as an effective pain control agent for cancer patients allowing them to ingest a larger amount of pain reliever in two pills per day, resulting in 24-hour pain management. As in the past with morphine and heroin, Purdue aggressively markets OxyContin as less addictive and less subject to abuse than other pain medications. Despite warnings to the contrary from physicians, the media, and members of its own sales force the company markets the drug as non-addictive³.

1998: The Federation of State Medical Boards (FSMB) aligns with the American Pain Society guidelines and sets out a Model Policy for the Use of Controlled Substances for the Treatment of Pain. The goal of the initiative being the appropriate use of controlled substances in the management of chronic cancer and non-cancer pain. The guidelines outline expected essential components of care: patient evaluation, a treatment plan, informed consent and agreement for treatment, periodic review, consultation, maintenance of medical records, and compliance with state and federal controlled substance laws⁴.

Alongside the historical perspective presented here and in Appendix A, the disciplines of pain management, substance abuse treatment and primary care all have their own historical viewpoint on the use and abuse of opiates and how best to treat those patients seeking to manage chronic pain. Although uniform acceptance of a best practice associated with opiate prescribing may still be in the future there is an immediate need for dissenting opinions, practice and experience to be set aside.

Currently, in Maine momentum is building to decrease access to opiates while improving patient care for chronic, non-cancer pain. Stakeholders from across the medical, business, political, legal and regulatory communities are taking action to do what is in the best interest of Maine’s patient population.

The primary care system is pivotal in the exploration of how opiates are currently used as a chronic pain management tool and identifying common ground to shift the function of opiate prescribing from analgesia to functionality.
How State policy will support this shift will be outlined by the findings and recommendations of the LD 1501 Workgroup. The bill intended to establish protocols for the health care provider community to follow in prescribing opioid drugs for chronic non-cancer pain. It includes provisions on physical examinations, health records, periodic review of patient health and consultations with and referrals to pain management specialists. It requires the Department of Health and Human Services to review and evaluate the efficacy of comprehensive pain management, including physical therapy and cognitive behavioral therapy, and report back to the Joint Standing Committee on Health and Human Services no later than December 7, 2011. (Appendix B)

**Current State of Opiate Use for the Treatment of CNCP**

**National Perspective**

An estimated 50 million Americans have chronic pain and, 41% of patients with chronic pain report that their pain is not controlled. Chronic pain is the most common cause of long-term disability and is associated with reduced physical, psychological, and social well-being resulting in increased use of health services.

The annual cost of chronic pain in the United States, including healthcare expenses, lost income and lost productivity, is estimated to be $100 billion annually (based upon 2005 estimates). It is the second leading cause of medically related work absenteeism, resulting in more than 50 million lost workdays each year. The high prevalence of chronic pain affects health care costs and premiums, and is the leading cause of disability in the working age population, with both private disability plans and the Social Security system being significantly affected.

Parallel to the rising cost of chronic pain and increasing opiate prescribing rates is the financial impact of the dependence, diversion, addiction and subsequent treatment needs associated with prescription opiate abuse. The National Survey on Drug Use and Health (NSDUH), conducted annually, showed in 2009 that 20.6% of respondents have used psychotherapeutics (prescription drugs) for nonmedical purposes in their lifetimes. In 2001 this form of abuse cost $8.6 billion. Of this amount, $2.6 billion were healthcare costs, $1.4 billion were criminal justice costs, and $4.6 billion were workplace costs.

The presence of chronic pain is also associated with a spectrum of determinants, both physiological and socioeconomic. The 2006 Trends for Pain in America, a review conducted by the National Center for Health Statistics found that non-Hispanic, white adults (27.8%) reported more pain more often than adults of other races and ethnicities (as compared to 22.1% of black adults and 15.3% of Hispanic adults). Nationally, more women (27.1%) than men (24.4%) report that they are in pain. While Maine is a disproportionately Caucasian state, it is important to note that the need for chronic pain treatment transcends race and ethnicity.

The public health impact of opiate abuse should not be underestimated. Based on a variety of reports from the Government Accountability Office (GAO), Drug Abuse Warning Network (DAWN), the SA Treatment Advisory within the Substance Abuse and Mental Health Services Administration (SAMHSA) the abuse and misuse of opiates and narcotic-based pain relievers is on the rise. From 1999 to 2002, there was an increase in deaths from prescription opiates of 91.2%. Subsequently, the number of Emergency Department visits involving non-medical use of narcotic pain relievers rose 111% from 2004-2008.
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National morbidity and mortality statistics related to pain relievers reflect what primary care providers across Maine are seeing daily in their practice patterns and patients seeking treatment for CNCP.

- In the US, the proportion of primary care office visits during which opiates were prescribed for chronic pain doubled from 8% (in 1980) to 16% (in 2000).
- From 1980 – 2000 the prescribing of opiates increased from 2 - 9%
- The top prescribed opiates were hydrocodone, with 120 million prescriptions dispensed in 2007 and oxycodone, with 400 million prescriptions dispensed that same year.

2009 data captured by the Maine Prescription Drug Monitoring Program bring these national statistics home; the top five prescription drugs of abuse in Maine are:

1. Hydrocodone/APAP (26.4 million tablets dispensed)
2. Oxycodone HCl (17.3 million tablets dispensed)
3. Oxycodone/APAP (10.6 million tablets dispensed)
4. Alprazolam (9.2 million tablets dispensed)
5. Diazepam (4.0 million tablets dispensed)

The number of persons aged 12 or older who reported that the most recent treatment they received in the past year was for pain relievers was:

- 360,000 in 2002
- 415,000 in 2003
- 424,000 in 2004
- 466,000 in 2005
- 547,000 in 2006
- 558,000 in 2007
- 601,000 in 2008
- 739,000 in 2009
- **754,000 in 2010**

The differences between the 2010 estimate and the 2002-2006 estimates were statistically significant.
State Perspective

Similar to the National trend, the number of Maine people seeking treatment for substance abuse has increased significantly. From 1998 through 2008, there was a 400% increase in the number of patients admitted for substance abuse treatment for opiates, other than heroin. Maine has the highest opiate treatment rate in the nation; with 386 people per 100,000 admitted for treatment. It should be noted that the number of substance abuse treatment admissions is bound by both the need and the capacity for treatment. Therefore, this prevalence data is handicapped by the minimal treatment resources available in rural areas where the need is greatest. It does, however, provide an indication of service usage and the impact of substance use on the behavioral healthcare system.

Maine’s statewide response to the opiate abuse and diversion epidemic is lead by the Office of Substance Abuse (OSA). Their response is guided by local data and a body of substance abuse prevention research that has identified certain groups of factors that “cause” or have an impact on substance use and the consequences related to use. That is, they appear to influence the occurrence and magnitude of substance use and its related consequences. Generically, these causal factors (also known as contributing factors) are categorized into groups which include:

- Social Access (e.g., over supply of prescription drugs, getting drugs from friends or family)
- Retail Availability (e.g., retailer not carding properly, confirming prescription validity)
- Pricing & Promotion (e.g., two-for-one specials, industry sponsorships or signage)
- Social/Community Norms (e.g., parental/community attitudes and beliefs)
- Enforcement (e.g., monitoring process with consequences clearly defined, lack of compliance checks)
- Perceptions of Harm (e.g., individuals’ belief that deviating from the intended purpose of prescription drug or sharing with others is harmful)
- Perceived Risk of Being Caught (e.g., individuals’ belief that s/he will be caught by provider, parents or law enforcement)\textsuperscript{11}.

The above contributing factors indicate that the primary care system is but one influence on the current opiate abuse epidemic plaguing communities statewide. However, the primary care system can positively impact the factors of social access, social and community norms, perception of harm and perceived risk of being caught when abusing an opioid-based medication. This system is pivotal in bending the trend illustrated by recent data found in the 2011 Substance Abuse Trends in Maine report, the need for primary care interventions across these contributing factors is urgent.

- Mainer are increasingly using available prescription drugs, including stimulants and opiates, instead of illegal drugs to get high.

- **Adults ages 21-29 are the most represented age group when it comes to adult prescription drug users in 2009, making up 45% of all reported adults ages 18 and older.** Young adults who are between the ages of 18 and 20 followed with 24% while 30-34 year olds constituted 17 percent.

- The highest reported nonmedical use of pain relievers among Mainers (age 12 and older) was among 18-25 year olds at 12% in 2007-2008. Those ages 26 and older were consistent at 3% across all years (2003-2008).
Since 2005, the percent of women who were admitted primarily due to synthetic opiates has increased by 33%.

Both inpatient and outpatient hospital admissions related to substance use are an indication of injury sustained through substance use and the resulting impact on Maine’s healthcare system.

- Inpatient admissions and outpatient visits related to opiates increased sharply in 2008.

- Opiates (defined as prescription narcotics, methadone & heroin) are the second group of substances most associated with inpatient admissions (367 cases between 2006-2008).

- Opiates were indicated as the substance of concern nearly twice as often as alcohol, increasing from 23,742 visits in 2007 to 30,451 in 2008.

- Overdose deaths associated with pharmaceuticals – including methadone, oxycodone, and benzodiazepines – are considered to be on the rise across the state.

- By 2009, 165 of total overdose deaths (92%) were attributed to pharmaceuticals, compared to 19 overdose deaths related to illicit drugs.

- Estimates in 2009 showed a decrease in the proportion of drug deaths involving methadone to 27%, while the proportion involving oxycodone (28%) & benzodiazepine (31%) appeared to be rising.

- Synthetic opiates are the second most frequent substance for which treatment is sought in Maine. The number of treatment admissions related to synthetic opiates has been increasing since 2005.

- The overall number of Mainers seeking treatment for substance abuse has been declining since 2007, from 14,159 to 12,351 in 2010. Mainers continued to seek out treatment for abuse involving a wide array of substances besides alcohol; in 2010 there were 3,594 admissions for synthetic opioids.

- In 2009, synthetic opiates were the primary substance for which treatment was sought in 29 percent of all treatment admissions; they were listed the secondary substance in 28 percent of admissions that listed a second substance.
Primary Care Perspective

The intention of the primary care system is to provide care that is responsive to the whole patient. Providers working within this system assess the patient through both a clinically trained eye and their own practice style. The current state of opiate prescribing and increased rates of prescription analgesic addiction, diversion and requests for treatment illustrate the fragmentation of care experienced by patients seeking care for CNCP and present an opportunity to actualize comprehensive pain management concepts in primary care.

Across the health care safety net there is a call for a decrease in opiate prescribing variation; system-wide monitoring of the opiates prescribed and enhanced educational resources for both prescribers and patients. Simultaneously, across this system providers are seeking to enhance their own skill set in treating chronic pain. They are looking for a solution that will decrease the variation in opiate prescribing practices while improving the care experienced by CNCP patients. The issue is complex and the ideal solution will be just as intricate. However, in this time of evolving patient-centered care many PCPs are ready to take action.

Patient Centered Prescribing:
How Do We Shift from Analgesia to Functionality

Identifying a medical home for patients on chronic opioid therapy, not necessarily to prescribe the chronic opioid therapy, but to coordinate consultation and communication among all of the involved clinicians. At the same time, the medical home clinician should identify when a patient needs further consultation or resources that the medical home cannot provide, and refer these patients appropriately12. To best assess the functional benefit of prescribing opiates, the PCP relies upon team-based care. The use of a team approach will also mitigate the risk of prescribing opiates by presenting a united and consistent prescribing practice across each care site within Maine’s health care safety net.

From a population perspective the application of team care to patients prescribed opiates meets National guidelines for the patient-centered medical home model of care. Although opiate therapy is not equally effective for all patients or for all types of pain the use of an interdisciplinary care team will increase the likelihood of better managing chronic pain using a patient centered approach, with or without the use of opiate therapy.

Chronic pain is a major health concern and for care providers can present as a treatment enigma. It has a tremendous negative impact on patients’ well being both directly and due to its sequela such as sleep disturbance, depression, and anxiety13. Treatment is often based upon the acute pain symptom(s) presented.

Historically, care providers have utilized the standard pain scale of 0-10 endorsed by the American Pain Society’s 1995 guidelines. This treatment approach aligned with the call for pain to be assessed as the 5th Vital Sign and has resulted in opiate prescribing being focused upon analgesia, or pain relief as opposed to improved, long term functionality.

In response to the current state of prescription drug abuse at the National, State and local levels the easiest solution for the primary care clinician might seem to be to avoid the use of opioids when treating chronic pain altogether, and utilize alternative measures that exclude their use. In reality, this is an unrealistic and untenable solution as the incidence of chronic pain is rising annually14.

However, there are key changes that can be undertaken to achieve more effective chronic pain management than we currently achieve today.
More effective chronic pain management includes assessing the patient from both pain relief and life functioning perspectives. Improved functionality is often an assumption associated with pain relief. However, over time, the brain changes in response to daily exposure to opiates. One condition associated with long-term use is hyperalgesia. Hyperalgesia is an increased response to a stimulus which is normally painful. In other words, patients can develop a heightened sense of pain while taking the prescribed opioid-based medication. While the complete mechanism for this phenomenon is unknown, it is known that regular exposure to opiates causes the brain to decrease the number of dopamine receptors (Appendix D). Therefore, increased opioid levels and increased opioid potency are necessary to generate the same relief effect. This increased dosage often results in lower levels of functionality and increased dependency.

Primary care prescribers can stem the supply of these medications by implementing safeguards within their system of care that evaluate the patient for potential risk of abuse benefits of opiate-based therapy. Moving forward, “benefits” should be defined as both improved functionality and pain relief. To instill this risk-benefit culture the PCP within the practice will need to utilize a team approach to care while shifting the focus of opiate prescribing for CNCP from analgesia to function. This shift will ultimately result in decreasing potential diversion and addiction while providing treatment that is objective and verifiable and improves the quality of life and care experienced by Maine’s patient population.

The primary care system is encouraged to consider the following four recommendations to achieve more effective chronic pain management and more appropriate use of opiate-based therapy the primary care system is encouraged to consider the following four recommendations.

Increase the Active Use of Maine’s Prescription Drug Monitoring Program

Maine is one of 38 states utilizing a prescription drug monitoring program (PMP). For a PMP to be successful, clinicians need to know what it is, how it works, how to determine if it is effective, and how to get detailed information about it. The definition of a PMP, according to the US Department of Justice, Drug Enforcement Administration (DEA), following the National Alliance for Model State Drug Laws (NAMSDL), is a statewide electronic database that collects designated data on substances dispensed in the state. PMP data are housed in a specified statewide regulatory, administrative, or law enforcement agency. The agency distributes the information from the database to individuals authorized under state law to receive it for purposes of their profession. Active use of a PMP includes the integration of data entry, report usage and routine monitoring of the PMP being present in practice patterns and workflows.

As the existence of Prescription Drug Monitoring Programs is relatively new, there is little quantiative, longitudinal evidence that they directly impact the aberrant behaviors of doctor shopping, provider hopping and duplicative prescribing. However, a review by the Journal of Pharmacoepidemiological Drug Safety conducted an analysis of Schedule II opioid prescription data in Massachusetts from 1996-2006, concluding that PMPs can become a useful public health surveillance tool to monitor the medical and non-medical use of the prescription opioids and to inform public health and safety policy. In addition, anecdotal evidence suggests that individual health care providers have found PMPs to be helpful with clinical decision-making.

When integrated into practice patterns, a PMP can provide objective information to integrate into treatment planning, problem solving and goal setting. Active use of the prescription monitoring program will aid in establishing a statewide, systematic approach to manage the patient population (ab)using opiates. To more effectively integrate PMP use into existing practice outreach providers may benefit from additional education on the “ins-and-outs” of Maine’s PMP and how it can enhance patient care. As a tool, the PMP notification report will support communication across providers, both medical and pharmacy thus insuring greater continuity of care for the patient while mitigating the risk incurred by their practice.
Use Opiate Trials When Initiating Opioid Therapy

An appropriate trial of opioid therapy with adjunctive therapy is a method to assess what care is most appropriate to the patient. The appropriate combination of agents, including opioids and adjunctive medications, may be seen as “Rational Pharmacotherapy”. This approach incorporates opioid trials into comprehensive pain management. The effectiveness of stand-alone trials, without supplemental, alternative therapies and ongoing risk-benefit analysis has not been proven, but may be considered a form of “promising practice”19 (Appendix E). The use of an opioid trial will provide a stable therapeutic platform while stemming the epidemic of opiate abuse by decreasing the rate of new addicts and prescription drug diverters.

There is wide variation in the practice of COT. Chronic Opioid Therapy is defined as the ongoing use of opiate medication for chronic non-cancer pain. However, there appear to be two accepted definitions of “ongoing”. Ongoing use is defined by the American Pain Society as 30 days or more. Other research defines it as daily or near daily use of opioids for at least 90 days, often indefinitely20. Prior to the initiation of long term opioid therapy, an opioid therapy trial includes the following elements:

• Any Provider may write a one-time prescription for acute pain
  - This prescription could be short-term (21 day maximum)
  - Could have no refill
  - Could be for a short acting opiate that contains aspirin or Tylenol to limit abuse potential

• Patient could sign an informed consent acknowledging that this is a trail period and consenting to screening for substance abuse potential, mental health illness and ongoing assessment of daily life functioning

• At close of trial the provider reviews initiation of COT with care team or peer provider to determine next steps.

The use of opioid therapy trials could dramatically improve the effectiveness of opiates for chronic, non-cancer pain. The screening and assessment components of a trial would result in patients receiving the most appropriate care. The systematic use of a trial process, supported by health center policy and protocols will result in more equitable prescribing practices thus mitigating both provider and administrative risk.

Apply Universal Precautions for Chronic Opioid Therapy (COT)

The term "universal precautions" originated from an infectious disease model that addressed an approach to patients when there was a deficiency of significant risk assessment information. In such instances past behavior or practices were not reliable indicators of safe and reasonable approaches, especially with at-risk patients. The “universal precautions” approach to the pain patient was first proposed by a group of researchers from Mount Sinai Hospital. Their research was undertaken under the belief that the pain management model is very similar to the infectious disease model in that the “at-risk” population is hard to identify, incorrect assessment can lead to patient and practitioner harm, and all elements of the model currently exist21.
By utilizing Universal Precautions chronic pain management would become more patient-centered and utilize more promising practices in both the monitoring and prescribing of opiates. The ten elements within the Universal Precautions for Pain Management are:

1. **Diagnosis with reasonable differential**
2. **Psychological assessment including risk of addictive disorders**
3. **Obtain informed consent accompanied by patient education materials**
4. **Patient Pain Treatment Agreement (PPTA or PPA) that identifies both the patient & provider’s responsibilities**
5. **Pre and post-intervention assessment of pain level and function**
6. **Appropriate trial of Opioid Therapy +/- Adjuvant Meds and therapies**
7. **Reassessment of pain score and level of function**
8. **Regularly assess the “4 A’s” of pain medicine:**
   - Analgesia (pain relief)
   - Activities of daily living (ADLs; functional outcomes)
   - Adverse effects (side effects)
   - Aberrant drug-related behaviors (appropriate use and adherence vs. misuse or addiction-related outcomes).
9. **Periodically review pain diagnosis and co-morbid conditions including addictive disorders**
10. **Maintain objective, verifiable, ongoing documentation**

Undertaking the application of these Universal Precautions is a daunting task. Due to limited system (EMR) capability to efficiently house the above elements in a centralized location, the limited time resources available for medication reconciliation and health record maintenance and the need for redesigning the scope of work to include all ten Universal Precautions. **For this approach to positively impact the care provided for CNCP and reduce the risk of aberrant behaviors it needs to be part of a comprehensive, mindful opioid prescribing program.**
Utilize Equitable Discontinuation Process within the Primary Care Setting

The discontinuation of opiate-based therapy is anxiety producing for both the patient and the primary care provider. The patient may fear withdrawal, loss of perceived functionality such as work absenteeism or in cases of addiction and diversion, loss of social connections or income. However, this anxiety is actualized for a minority of patients receiving long term opiate therapy. A review conducted by the University of Washington of patients receiving COT from 2000-2005 who were in commercial and Medicaid insurance plans found that 64-67% remained on opiates indefinitely. This statistic elicits two questions; 1) what, if any, differential is being applied to determine when the discontinuation of opiates is appropriate, and 2) what processes and decision tools are available to support discontinuation?

Discontinuation may be considered if the provider does not see an improvement in function and quality of life, when they may feel that the risks of the therapy outweigh the benefit. Providers may consider tapering opioids due to patient non-compliance with the medication regimen or violation of the patient’s contract or agreement. When discontinuation is deemed appropriate, either due to improved condition or suspected/confirmed abuse, providers may fear negative ramifications such as harassment, law suits or the patient perceiving they are being abandoned in a time of need. These biosocial implications for both patients and providers are significant motivators behind the “status quo” of opiate prescribing.

When faced with this process, providers may have concerns about the efficacy of opiate discontinuation or tapering. There is a significant gap in information and guidance for switching or stopping opioid medications. There is no single strategy that can be applied to all patients and each situation must be handled on an individual basis. Many practitioners have their own formulas for managing conversions and tapers. With patients who are non-compliant each provider may also have their own “breaking point” when it becomes clear that no amount of contracting is going to result in medication compliance. This fragmented care results in inequitable treatment of CNCP patients and furthers Maine’s opiate addiction and diversion epidemic.

Based on a review of the literature and current practice it is recommended that an opioid discontinuation “decision tree” be utilized. To alleviate the perceived subjective nature of opiate discontinuation this decision tree would identify key “milestones” in the patient’s chronic pain care. The decision tree acts as an exit strategy guide. As an algorithm it would provide guidance on the following patient scenarios:

- Patient appears to have a problem with drug addiction
- No apparent addiction problem. Patient able to cooperate with office-based taper.
- Patient unable or unwilling to cooperate with outpatient taper

Using a decision tree or defined algorithm establishes an equitable response to patients who are either not responding to opiate-based care, both from an analgesic or functional perspective and/or engaging in aberrant behavior (drug seeking for addiction or diversion purposes).
Policy Recommendations

Impactful change in the primary care treatment of chronic, non-cancer pain using opioid therapy will have many layers: regulatory, administrative, provider, community and patient. Each layer of the response to Maine’s opiate addiction and diversion epidemic will have its own policy needs. Both factors, such as increased education for both providers and patients and enforcement factors, such as prescription monitoring and medication discontinuation and disposal are central to supporting the shift of opiate prescribing for chronic, non-cancer pain from analgesia to function, ultimately resulting in treatment goals that become objective and verifiable.

The following policy recommendations and resources will support the implementation of the promising practices for chronic pain management encouraged within this paper.

• Set a threshold of continuing education required of all prescribers of opioid-based medications.

• Create a directory of resources specific to pain management available to any prescriber of opiate medications; Suboxone providers/locations, opportunities for training in Suboxone care and ongoing licensure requirements, pain clinic and experts and locations of alternative therapy options.

• Encourage provider prescribing opiates to be a part of the Maine Prescription Drug Monitoring Program. Promote Primary care practice standards of care that support the active use of the PMP.

• Encourage the State Medicaid agency to explore and identify barriers to Comprehensive Pain Treatment and remove them. Example barrier: two physical therapy visits are reimbursable by Medicaid, but reimbursement for this service as needed would result in greater potential for improved functionality and decreased reliance upon opiate-based analgesia.

• Consider State and primary care system collaborations to increase access to comprehensive pain care through the establishment of Pain Clinics throughout Maine.

Conclusion

Primary care providers working across Maine’s patient-centered, health care safety net each have their own practice style. The autonomy of the provider should not be neglected; however the call to maintain individual practice styles should not discount the need for equitable treatment for patients struggling with chronic pain. If undertaken, the four leverage points will support the shift of using opiates for chronic, non-cancer pain from analgesic benefit to functionality:

• Increase the active use of Maine’s Prescription Drug Monitoring Programs (PMPs)

• Use opiate trials when initiating opioid therapy

• Application of Universal Precautions for Chronic Opioid Therapy (COT)

• Utilization of an equitable discontinuation process within the care setting

Maine is poised to lead the way in curbing the current opiate addiction epidemic that is spreading across the nation. Taking a proactive, comprehensive stance on the treatment of chronic pain and the more appropriate use of opiates for CNCP will result in better care for all.
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1. California, Minnesota, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, and Vermont
9. GAO Report 9/30/09
10. DAWN Report, 6/18/2010
Appendix A: Historical Timeline

Through looking at the historical use of opiates, the public health implications, and the new scientific evidence around the impact opiates have on the body, we will be able to better understand why Primary Care Providers (PCP) have an influential role in the prescribing of opiates for chronic non-cancer pain.

C. 3400 B.C.: The opium poppy is cultivated in lower Mesopotamia. The Sumerians refer to it as Hul Gil, the 'joy plant.' The Sumerians would soon pass along the plant and its euphoric effects to the Assyrians. The art of poppy-culling would continue from the Assyrians to the Babylonians who in turn would pass their knowledge onto the Egyptians.

C.460 B.C.: Hippocrates, "the father of medicine", dismisses the magical attributes of opium but acknowledges its usefulness as a narcotic and styptic in treating internal diseases, diseases of women and epidemics.

1500: The Portuguese, while trading along the East China Sea, initiate the smoking of opium. The effects were instantaneous as they discovered but it was a practice the Chinese considered barbaric and subversive.

1527: During the height of the Reformation, opium is reintroduced into European medical literature by Paracelsus as laudanum. These black pills or "Stones of Immortality" were made of opium thebaicum, citrus juice and quintessence of gold and prescribed as painkillers.

1600's: Residents of Persia and India begin eating and drinking opium mixtures for recreational use.

1680: English apothecary, Thomas Sydenham, introduces Sydenham's Laudanum, a compound of opium, sherry wine and herbs. His pills along with others of the time become popular remedies for numerous ailments.

1803: Friedrich Sertuerner of Paderborn, Germany discovers the active ingredient of opium by dissolving it in acid then neutralizing it with ammonia. The result: alkaloids--Principium somniferum or morphine. Physicians believe that opium had finally been perfected and tamed. Morphine is lauded as "God's own medicine" for its reliability, long-lasting effects and safety.

1819: Writer John Keats and other English literary personalities experiment with opium intended for strict recreational use--simply for the high and taken at extended, non-addictive intervals.

1827: E. Merck & Company of Darmstadt, Germany, begins commercial manufacturing of morphine.

1840: New Englanders bring 24,000 pounds of opium into the United States. This catches the attention of U.S. Customs which promptly puts a duty fee on the import.

1843: Dr. Alexander Wood of Edinburgh discovers a new technique of administering morphine, injection with a syringe. He finds the effects of morphine on his patients instantaneous and three times more potent.

1890: U.S. Congress, in its earliest law-enforcement legislation on narcotics, imposes a tax on opium and morphine.

1895: Heinrich Dreser working for The Bayer Company of Elberfeld, Germany, finds that diluting morphine with acetylcs produces a drug without the common morphine side effects. Bayer begins production of diacetylmorphine and coins the name "heroin." Heroin would not be introduced commercially for another three years. The product is promoted commercially as having the pain relieving properties of morphine without the addictive qualities and as a step down drug for morphine addicts.

1902 – 1904: In various medical journals, physicians discuss the side effects of using heroin as a morphine step-down cure. Several physicians would argue that their patients suffered from heroin withdrawal symptoms equal to morphine addiction. Heroin addiction rises at alarming rates across the U.S.

1906: Several physicians experiment with treatments for heroin addiction. Dr. Alexander Lambert and Charles B. Towns tout their popular cure as the most "advanced, effective and compassionate cure" for heroin addiction. The cure consisted of a 7 day regimen, which included a five day purge of heroin from the addict's system with doses of belladonna delirium.
U.S. Congress passes the Pure Food and Drug Act requiring contents labeling on patent medicines by pharmaceutical companies. As a result, the availability of opiates and opiate consumers significantly declines.

December 17, 1914: The passage of Harrison Narcotics Act which aims to curb drug (especially cocaine but also heroin) abuse and addiction. It requires doctors, pharmacists and others who prescribed narcotics to register and pay a tax.

1965 – 1970: U.S. involvement in Vietnam is blamed for the surge in illegal heroin being smuggled into the States. To aid U.S. allies, the Central Intelligence Agency (CIA) sets up a charter airline, Air America, to transport raw opium from Burma and Laos. The number of heroin addicts in the U.S. reaches an estimated 750,000.

1980: Dr. Hershel Jick of the Boston Collaborative Drug Surveillance Program at Boston University Medical Center publishes a letter that summarizes a surveillance study of 40,000 hospitalized patients in the New England Journal of Medicine. Of the study population a sample of 12,000 patients received one or more narcotic preparations and of these, only 4 cases of reasonably well-documented addiction in patients with no previous history of addiction were found. Dr. Jick then concluded, "Despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."

1986: The World Health Organization (WHO) begins a campaign to improve cancer pain relief by increasing the availability and use of opiates for the control of pain in underdeveloped countries. Basing their endorsement on consumption indicators that show that in nearly half of the countries in the world, there is little or no use of morphine. Almost all of the morphine that is produced for medical purposes is consumed in developed countries. Although these countries also use other opioid analgesics, consumption of morphine continues to be used as an indicator, because morphine is widely accepted and used throughout the world and because reasonably good data are available.

1991: The global consumption of morphine has increased by 272% over 1984 consumption. As of 1991, the 10 countries with the highest consumption of morphine used 57% of the world supply (in alphabetical order): Australia, Canada, Denmark, Iceland, Ireland, New Zealand, Norway, Sweden, the United Kingdom, and the United States. The top 20 consumer countries, all of which are developed countries, consumed 86% of the morphine in the world. The remaining amount was consumed by countries that have the majority of the world’s population.

1995: The American Pain Society proposes a set of guidelines using a standardized pain scale of 0-10 based on a patient's self report. Pain was declared the 5th vital sign, with the expectation that pain would be assessed with the same frequency as the standard set of vital signs. Historically, the relationship with opiates as medicine and fear of addiction often led to the under treatment of pain and the cautious prescribing of opiates.

1996: Dr. Russell Portenoy’s, a recognized expert in chronic pain management and then president of the American Pain Society, publishes a review and guidelines of the WHO policy. In the late 1990s and early 2000s, The American Pain Society and state Medical Boards actively lobby state legislatures for the relaxation of opiate prescribing laws, frequently citing Dr. Russell Portenoy's 1996 review and guidelines.

1996: Purdue Pharma brings a semi-synthetic opioid analgesic named OxyContin to market. Its active ingredient is OxyCodone. While OxyCodone is also found in medications like Percodan and Tylox, both pain relievers also contained Tylenol or aspirin, which limited their abuse potential. Purdue Pharma markets OxyContin for relief from chronic or long-lasting pain. Unlike Percodan and Tylox, OxyContin contains OxyCodone at 10-80 mg per pill in a time-release capsule. It was seen as an effective pain control agent for cancer patients allowing them to ingest a larger amount of pain reliever in two pills per day, resulting in 24-hour pain management. As in the past with morphine and heroin, OxyContin was aggressively marketed by Purdue as less addictive and less subject to abuse than other pain medications. Despite warnings to the contrary from physicians, the media, and members of its own sales force the company continues to market the drug as non-addictive.
1998: The Federation of State Medical Boards (FSMB) aligns with the American Pain Society guidelines and sets out a Model Policy for the Use of Controlled Substances for the Treatment of Pain. The goal of the initiative being the appropriate use of controlled substances in the management of chronic cancer and non-cancer pain. The guidelines outline expected essential components of care: patient evaluation, a treatment plan, informed consent and agreement for treatment, periodic review, consultation, maintenance of medical records, and compliance with state and federal Controlled substance laws.

References


Appendix B: LD 1501, 125th Maine State Legislature

Health Care Safety Net Series: Opiate Use for Chronic, Non-Cancer Pain

RESOLVE Chapter 81, LD 1501, 125th Maine State Legislature
Resolve, To Reduce Opioid Overprescription, Overuse and Abuse

PLEASE NOTE: Legislative Information cannot perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

Resolve, To Reduce Opioid Overprescription, Overuse and Abuse

Sec. 1 Work group on prescribing opioid drugs for chronic, noncancer-related pain. Resolved: That the Substance Abuse Services Commission, as established in the Maine Revised Statutes, Title 5, section 12004#G, subsection 13#C and referred to in this resolve as "the commission," shall convene a work group of commission members and public and private stakeholders, referred to in this resolve as "the work group," to review and make recommendations for improvements in how physicians and other prescribers treat patients in chronic, noncancer-related pain without causing addiction or diversion.

1. Tasks. The work group's tasks include, but are not limited to:
   A. Review of current efforts in the State aimed at preventing addiction and diversion;
   B. Examination of similar efforts in other states, including Washington State, which in 2010 enacted comprehensive legislation on this subject;
   C. Consideration of additional tools that could lead to decreased abuse while not unduly restricting access to adequate pain control; and
   D. Consideration of enhancements to the Controlled Substances Prescription Monitoring Program established in the Maine Revised Statutes, Title 22, section 7248.

2. Chair; membership. The commission shall appoint a chair of the work group from among the work group members. The membership of the work group must include representatives appointed or invited to participate by the commission from all of the following state agencies, advocacy organizations and the public:
   A. Licensing boards of licensees who prescribe narcotics;
   B. Representatives of professional associations representing the major health professions that prescribe controlled substances;
   C. The Maine Hospice Council, established in the Maine Revised Statutes, Title 22, section 8611;
   D. Representatives of licensed pharmacies; and
   E. Representatives of the Department of Health and Human Services, Office of MaineCare Services, the Maine Hospital Association, specialists in substance abuse treatment and services, specialists in the treatment of addiction and specialists in the treatment of pain.

3. Funding. The commission shall fund the work of the work group from within existing resources.

4. Report. The commission shall report the findings and any recommendations of the work group to the Joint Standing Committee on Health and Human Services not later than December 1, 2011.
Appendix C: State & National Resources

Maine Resources:

Maine Prescription Monitoring Program
Office of Substance Abuse, Maine Department of Health and Human Services
Trish Lapera, PMP Coordinator
Patricia.Lapera@maine.gov 207-287-2595
Website: http://www.maine.gov/dhhs/osa/data/pmp/index.htm
Resources: http://www.maine.gov/dhhs/osa/data/pmp/resources.htm
Contact Information: 207-287-2595, or email osa.ircosa@maine.gov
Helpdesk: 1-866-792-3149

Office of Substance Abuse - Treatment Services
Medication Assisted Treatment
Office of Substance Abuse, Maine Department of Health and Human Services
Tracy Weymouth, State Opioid Treatment Authority
Tracy.Weymouth@maine.gov 207-287-2595

Finding Substance Abuse Treatment Providers
SAMHSA Treatment Directory: http://findtreatment.samhsa.gov/
Buprenorphine Physician Finder (SAMHSA): http://buprenorphine.samhsa.gov/bwns_locator/

List of Maine Opioid Treatment Programs:
New England Chapter of American Society Addiction Medicine

ASAM is a professional society representing close to 3,000 physicians dedicated to increasing access and improving quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addictions.

www.asam.org

Northern New England ASAM Chapter (Maine, New Hampshire, Vermont)
President: Dr. Mark Publicker
Mercy Recovery Center
50 Park Road
Westbrook, ME 04092
(207) 857-8383
publickerm@mercyme.com

National Resources:
The Substance Abuse and Mental Health Services Administration’s Center for Substance Abuse Treatment sees this as a valuable resource to implementing best practice. OSA has copies of this book available in its Information and Resource Center for loan (http://www.maine.gov/dhhs/osa/irc/index.htm).

The University of Wisconsin offers an online course with CMEs at http://trc.wisc.edu/. This course is coordinated and supported by the Federal of State Medical Board (FSMD) with purchase of the book through their website: http://www.fsmb.org/pain-overview.html.

Substance Abuse Mental Health Services Administration (SAMHSA) website for information on Opiates and MAT, and DATA waived physician info:
Website: http://www.samhsa.gov/

http://buprenorphine.samhsa.gov/waiver_qualifications.html

U.S. Drug Enforcement Agency (Diversion resources)
Office of Diversion Control: http://www.deadiversion.usdoj.gov/

All websites accessed 10/19/11
Known as opioids and chemically related to opium, opioids are obtained from the seed of the poppy flower. Synthetic derivatives include: hydrocodone (Vicodin), oxycodone (Percodan, OxyContin), hydromorphone (Dilaudid) and heroin. Some synthetic opiates with a different chemical structure but similar effects on the body and brain are propoxyphene (Darvon), meperidene (Demerol) and methadone.

Opiates bind to the µ-opioid receptors to reduce the sensation of pain. Each person has individual variations in their µ-pain receptors and may also have other genetic factors at play.

Opiates are regulated by the US Drug Enforcement Agency (DEA) under 5 schedules (I-V);

<table>
<thead>
<tr>
<th>DEA Schedule</th>
<th>Short-acting Equivalent</th>
<th>Long-acting Equivalent</th>
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<tbody>
<tr>
<td></td>
<td>Codeine (generics)</td>
<td>None</td>
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<tr>
<td>Schedule II</td>
<td>None</td>
<td>Fentanyl transdermal</td>
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<tr>
<td></td>
<td>Hydromorphone (generics,</td>
<td>(generics, Duragesic)</td>
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<tr>
<td></td>
<td>Dilaudid)</td>
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<td></td>
<td>Meperidene (generics,</td>
<td>None</td>
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<td></td>
<td>Demerol)</td>
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<tr>
<td></td>
<td>Oxycodeine (generics,</td>
<td>Oxycontin</td>
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<td></td>
<td>roxicodone, OxyFast)</td>
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<td></td>
<td>Oxycodone/acetaminophen</td>
<td>None</td>
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<td></td>
<td>(generics, Endocet,</td>
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<td></td>
<td>Magnacet, Percocet,</td>
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<td></td>
<td>Primalev, Roxicet, Tylox)</td>
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<tr>
<td></td>
<td>Oxycodeine/NSAIDS</td>
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<tr>
<td></td>
<td>(generics, Combunox)</td>
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<tr>
<td></td>
<td>Oxycodone/ASA (generics,</td>
<td>Opana</td>
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<td></td>
<td>Percodan)</td>
<td>Opana ER</td>
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<td></td>
<td>Tapentadol (Nucynta)</td>
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<tr>
<td></td>
<td>Oxymorphone (Opana)</td>
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</tr>
<tr>
<td>Schedule III</td>
<td>Codeine/acetaminophen</td>
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<td>(generics, Tylenol #3,</td>
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<td></td>
<td>Tylenol #4)</td>
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<tr>
<td></td>
<td>Hydrocodone/acetaminophen</td>
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<td></td>
<td>(generics, Vicoprofen,</td>
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<tr>
<td></td>
<td>Reperxain, Ibudone)</td>
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<tr>
<td></td>
<td>Buprenorphine transdermal</td>
<td>Butrans patch</td>
</tr>
<tr>
<td>Non-Scheduled</td>
<td>Tramadol (generics,</td>
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<td></td>
<td>Ultram, Rybic, ODT)</td>
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<tr>
<td></td>
<td>Tramadol/acetaminophen</td>
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<td>(generics, Ultracet)</td>
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Opioid-based medication suppresses pain, reduces anxiety and at high doses induces euphoria and pleasure. When smoked, snorted or injected intravenously, it causes a strong and rapid high followed by several hours of milder pleasure. But there is a serious downside to its long term use or abuse. Over time and with regular use, opiates create a physical dependence, which creates severe withdrawal symptoms when the drug is not taken. The symptoms include: a strong craving for the drug, diarrhea, nose running, eye watering, shivering, nausea and vomiting, sleeplessness, restlessness, tremor, abdominal and bone pain and diffuse muscle aches.
Appendix E: Comprehensive Pain Management - Alternative Therapies

Pharmacologic non-opiate pain control:

- Anticonvulsant Agents
- Muscle Relaxants
- Antidepressant Agents
- Alpha Adrenergic Agents
- Topical Agents
- Address Vitamin D deficiency

Non-pharmacologic pain control:

- Heat
- Prosthetic supports
- Physical therapy
- Exercise
- Cognitive-behavioral therapy
- Orthopedic Consultation for structural problems requiring intervention
- Chiropractic Care
- Yoga
- Relaxation Therapy
- Meditation
- Interventional pain therapy
- Tens Unit
- Vocational Rehab
- Recreational Therapy

Behavioral Health Treatment

As Chronic Non-Cancer Pain is often a complex biopsychosocial condition, clinicians who prescribe COT should routinely integrate psychotherapeutic interventions, functional restoration, interdisciplinary therapy, and other adjunctive non-opioid therapies.

It should be noted the availability of these alternative therapies is limited across much of Maine due to financial and geographic barriers.

*Pain therapies list from Dr. Ilene Robeck, Section Chief, Primary Care Pain Clinic, James A. Haley VA Hospital, St. Petersburg, FL. Obtained during interview in October 2011.