



Nurse Practitioner Healthcare Foundation

Improving Health Status and Quality of Care through Nurse Practitioner Innovations

Managing Chronic Pain with Opioids: A Call for Change, 2017

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 policy makers. In that spirit, NPHF periodically addresses relevant healthcare issues.

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Chronic pain is a serious, prevalent, complex, and costly public health problem that usually requires individualized multimodal treatment plans that are refined over time.¹ Increased use of opioids as the primary treatment has contributed to the growing public health crisis of opioid addiction and overdose deaths.^{2, 3} These are serious, but separate, public health problems that may co-occur, demanding changes in the way we treat chronic pain when opioids are deemed appropriate. Denying appropriate care to people with chronic pain, whether or not opioids are used, is unethical and can lead to physical, mental, and/or socioeconomic harm and premature death. The complex public health problems of chronic pain and the epidemic of overdose deaths produce tremendous human suffering at great individual and societal costs. This paper addresses the need for judicious use of opioids when used to treat chronic pain while minimizing the risk of treatment-related harm. Changes are needed in the areas of Clinical Practice, Education, Research, and Public Policy.

The Convergence of Two Major Public Health Problems

The health and well-being of United States citizens are threatened by two separate, yet related, public health crises: chronic pain and substance use disorders (SUD). To date, efforts to prevent, identify, and treat these conditions have lagged behind other advances in medical care. These problems have now grown to proportions where they can no longer be ignored. The prevalence of chronic pain has been largely unnoticed by most public health campaigns despite statistics showing 126 million adults have had recurrent pain in the past three months, and 25 million adults endure daily chronic pain.⁴ The traditional narrowly focused biomedical approach to treating chronic pain likely contributed to the problems of today. In the 1990s, prescribers used non-opioid medicines for mild pain, weak opioids for moderate pain, and prescribed strong opioids with no ceiling dose limit for persistent severe cancer pain.^{5, 6} The belief that prescription opioids used for pain, even at high doses, had little or no risk of iatrogenic addiction promoted widespread use of higher dose opioids, even for chronic non-cancer pain. Psychosocial, environmental, and cultural factors that made non-medical use of both licit and illicit drugs more prevalent since the 1960's, combined with genetic predispositions, resulted in more patients than anticipated developing Opioid Use Disorders (OUD). Furthermore, SUDs, including non-medical use were not emphasized as risk factors, and pain could be feigned by those seeking drugs to abuse. Payer policies and administrative initiatives designed to cut costs with shorter healthcare visits and simple solutions to complex health problems also contributed to favoring a prescribed opioid over an integrated multidisciplinary approach to treating pain.⁷ These, and other health system incentives, contributed to prescribing opioids for more types of pain, such as low back pain, headache, and other non-cancer chronic pain problems. The availability and use of higher dose products appear to have resulted in a dramatic rise in OUD prevalence involving prescription opioids. Overdose deaths from prescription opioids, heroin, and synthetic drugs (e.g. non-pharmaceutical

fentanyl) are occurring in epidemic proportions and are a leading cause of accidental injuries.^{8,9} The suffering that results from opioid-related morbidity and mortality is widespread, affecting individuals, families, and friends in virtually every community. Public attention generated by these deaths has led to increased scrutiny of OUD and subsequent public policy changes placing restrictions on opioid prescribing. However, this approach has put an undue burden on those with chronic pain who have benefited from opioids, calling for a more balanced, holistic approach to treating chronic pain in a sustainable, compassionate way.

Chronic Pain as a Public Health Crisis

Chronic pain is an under-recognized and under-resourced public health crisis with a devastating impact. The World Health Organization (WHO) ranking of 310 ailments places low back and neck pain as the leading “Global Burden of Disease” worldwide, with painful musculoskeletal conditions (e.g. arthritis) a major threat to mobility that compromises the health of individuals and societies around the world.¹⁰

In America, of the 25 million adults who endure daily chronic pain, 23 million report pain so intense they are unable to work or care for themselves.⁴ More are added to this growing cohort daily as up to half of those who have an acutely painful serious illness or major injury go on to develop chronic pain. Those at highest risk are older adults, people with a history of childhood trauma, and those who have experienced suboptimal pain control and/or have psychosocial risk factors.¹¹ Based on the impact of their daily or frequently recurring pain, 40 million adults have “high-impact chronic pain,” a term used to describe pain that is associated with substantial restriction of participation in work, social, and self-care activities for six months or more.¹² For many, this is a permanent condition with no available cure. High impact chronic pain degrades health, increases healthcare utilization, and results in more disability than those with less severe pain.⁴ The most notable pathological changes are structural and functional changes in the nervous system.¹³ Brain remodeling and loss of gray matter occurs, producing changes in the brain similar to those observed with 10-20 years of aging. These pathological changes can explain some of the learning, memory, and emotional difficulties endured by many with ongoing pain.^{14, 15} These are partially reversible with effective treatment, however, significant biopsychosocial problems often persist and frailty develops.^{16, 17, 18} Chronic pain represents more years lost to disability than cancer, heart attacks, and diabetes combined.¹⁹ Low back pain has topped this list for over 35 years, with disabling arthritis pain becoming an increasingly prevalent affliction that disproportionately affects women and minorities.^{10, 20}

Chronic pain has a distressing impact that shortens life for many. Patients with persistent severe pain are twice as likely to attempt suicide than those without pain. Its intensity, mental defeat, functional limitations, insomnia, and being perceived as a burden to others is strongly associated with suicidal ideation and attempts.^{21, 22, 23} Even after controlling for life-limiting diseases, those with severe chronic pain die at a 50% higher rate (especially from cardiovascular events) over 10 years than those without pain.²⁴ Data from the 1999-2004 NHANES (National Health and Nutrition Examination Survey, n=15,311) also revealed that chronic pain was associated with increased mortality risk among adults in the US. This was attributed to limitations in physical functioning.²⁵

In addition to the physical and emotional consequences of chronic pain, spirituality is beginning to be identified as an important component in the care of individuals with chronic pain. This is an area of care that is not being addressed, yet it contributes to the fundamental experience of suffering of those with persistent pain.⁷ One study found that spirituality played an important role in patients’ coping with chronic pain; that same study reported that patients with pain and SUD experienced a loss of spirituality.²⁶ Addressing spirituality as an integral component of care validates the complexity and significant impact pain has on one’s life. Incorporating spirituality into a biopsychosocial – spiritual approach is key to planning care that addresses the existential suffering that patients experience from pain and SUD.²⁷

Adding to the serious health and possible spiritual consequences, chronic pain drains enormous financial resources from affected individuals and our society. Individuals with chronic pain incur \$10,000 per year in medical expenses, costing our nation at least \$600 billion per year in healthcare and disability costs.⁷ Those with chronic pain are often unable to be financially independent, retiring early with a wealth accumulation of under \$4,000 by age 65, compared to individuals without pain who have saved over 50 times that amount.²⁸ Indirectly, these costs accumulate to place a \$2,000 per year financial burden on each U.S. citizen in the form of increased insurance premiums and taxes and \$10,000 per year for those with chronic pain.^{7, 29}

Chronic Pain Treatment and the Rise of Opioid Use Disorder

Although personalized, multimodal, and interdisciplinary treatment is considered best in the treatment of pain, it is not widely available outside of research and demonstration projects. Instead, because of inadequate payment system design and lack of integrated care, there is an overreliance on opioid therapy. Despite evidence that over 75% of chronic pain patients do not develop an opioid use disorder and overdose deaths rarely occur when opioids alone are used at low stable doses, all patients prescribed opioids are at risk for these serious concerns.^{12, 30, 31, 32, 33}

In the United States, 20 million individuals are identified with a SUD, which is defined as the recurrent use of alcohol and/or drugs that cause significant clinical and functional impairment such as health problems, disability, and failure to meet major social roles.^{34, 35} Of these, in 2014, two million Americans are estimated to have OUD.³⁶ Opioid Use Disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by behaviors such as unsuccessful efforts to cut down, impaired control, social impairment, tolerance, a great deal of time spent obtaining and using, and withdrawal symptoms after stopping or reducing (physical dependence).^{35, 37} It is important to recognize that two factors – physical dependence and tolerance – are not considered indicators of OUD for people who are taking opioids as prescribed. However, many people are engaged in various degrees of non-medical use of opioids, which would be contributors to the diagnosis of OUD.

Failing to identify nonmedical drug use while treating pain with opioids can lead to a trajectory of misuse and biopsychosocial harm or death. In a study of patients treated for OUD, some participants started overusing prescription opioids when treated for pain, and when this overuse behavior was identified, the opioids were stopped; some were discharged from medical practices, leading them to self-treatment with illicit substances, most commonly, heroin.³⁸ Buying heroin on the street was cheaper, more accessible, and easier to misuse, leading many to a pattern of escalating heroin use.^{36, 38, 39, 40}

The failure to secure proper treatment for an emergent OUD, when prescription overuse is identified, is also concerning. In a large study of Substance Abuse and Mental Health Services Administration admission and discharge date drawn from the Treatment Episode Datasets, researchers found that less than 10% of patients admitted to treatment for prescription opioid abuse were referred by their healthcare provider.⁴¹ Healthcare providers who prescribe opioids while treating pain without identifying and referring those with emerging OUD for treatment are failing to meet patient safety obligations and have added to the opioid problem. Additionally, when treating pain is blamed for the rise in OUD and overdose deaths, there are misplaced and negative consequences for patients in need of help for a very complicated problem.^{42, 43} When pain and OUD co-occur, both conditions need to be treated simultaneously.

The Resultant Rise in Opioid Death

The tragic rise in opioid overdose deaths has quadrupled over a 9-year period between 1999 and 2008.^{9, 44} There has been a 13.1% decline of opioid prescriptions since 2012, and a significant decline in high dose prescriptions (41%) since 2010.⁴⁵ In general, prescriber data shows lower doses and fewer pills prescribed than in 2008.^{34, 46} Yet opioid deaths continue to soar annually through 2016. This rise in deaths during a fall in prescription rates appears to be driven by non-pharmaceutical fentanyl and other synthetic opioids illegally manufactured and distributed.⁴⁷

Many deaths can also be linked to drug interactions of opioids with tranquilizers, antidepressants, antipsychotics, physical and mental health comorbidities.⁴⁸ Over 5,000 deaths per year are attributed to the combination of opioids and benzodiazepines (tranquilizers). In a study of over 2 million patients prescribed opioids, the risk of death from opioid overdose does not substantially increase until the dose exceeds 200 morphine milligram equivalents (MME), unless the patient receives benzodiazepines, which increases the overdose risk 10-fold.⁴⁹ Patients with co-morbid mental health disorders are particularly vulnerable to overuse or overdose.⁵⁰ Recognizing and safeguarding individuals with these risk factors and ensuring they receive treatment for mental health disorders as well as pain, is a necessary step in reducing these heartbreaking losses.

What's in a Name? The Problem of Unclear Terminology

For decades, examples of overgeneralizations from select studies have resulted in the overtreatment or undertreatment of pain. Some studies have concluded that addiction rarely occurs and others show opioid misuse is a frequent occurrence. A 2014 comprehensive review of over 4,200 research studies found 10 uncontrolled studies examined patients prescribed opioids for at least one year. Rates of opioid abuse ranged from 0.6-8%, rates of dependence ranged from 3.1-26%, and rates of aberrant drug-related behaviors ranged from 5.7-37.1%.³³ The conclusion was these variable findings resulted from different settings and a lack of standardized definitions and methods used. Lack of standardization of terminology can lead to data misinterpretation. In 2010, we stated the need for databases to track chronic pain and the treatment effects of chronic opioid therapy, including unintended prescription opioid misuse, abuse, and diversion.⁵¹ Before tracking can be accomplished, there needs to be standardized terminology.³³ Clarification of terms such as non-medical use, prescription opioids, OUD, and high impact chronic pain follow.

Nonmedical use: The term *nonmedical use* is defined as “use without a prescription of the individual’s own or simply for the experience or feeling the drugs caused,” and describes behavior that may include non-adherence, taking someone else’s medication, manipulating the prescription opioid to pursue euphoria, or use of prescription opioids obtained from illicit sources.⁵²

Prescription opioid: The term *prescription opioid* is not the same as *prescribed opioids*. *Prescribed opioids* are pharmaceutical opioids legitimately manufactured and prescribed by the healthcare provider for that patient’s symptom management. This is in contrast to the *prescription opioid* that may be diverted from the intended patient. The term *illicit opioid* describes the non-pharmaceutical opioid, such as heroin and illegally manufactured fentanyl or its analogs. There are a growing number of illicit drugs that are copied from pharmaceutical opioids. It has been difficult for medical examiners to distinguish between overdoses from illicit versus legitimately prescribed opioids.^{8, 9, 53, 54}

Opioid Use Disorder (OUD): The term *Opioid Use Disorder* was created with the revised DSM-5 (a standard classification guide for diagnosis of diseases of mental health for use by healthcare professionals) to be less stigmatizing and marginalizing to patients with pain and substance use disorders than the previous term of “addiction” or “opioid abuse.”³⁷ Primary care providers and specialists who treat patients with chronic pain and/or a substance use disorder involving opioids are not yet consistently using the term OUD.

High impact chronic pain: The term *high impact chronic pain* allows differentiation from pain associated with minimal impact on life. This term will lay a foundation for a public health approach (e.g. primary, secondary and tertiary prevention) to the problem of high impact chronic pain.¹²

Federal Response

In the wake of rising public awareness around the issues of the high number of individuals being diagnosed with OUD and the rising death toll related to opioid overdoses, the federal government and some states have taken action. Some of the responses are:

Centers for Disease Control & Prevention (CDC) Guidelines. The CDC’s *Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* is a laudable effort to address the growing public health concern of opioid overdose deaths in America.⁵⁵ These guidelines were issued as a voluntary guide for primary care providers who treat adults with chronic noncancer pain. However, payers, professional training programs, and state regulators adopted these as hard rules that must be followed. The CDC guidelines were consensus-based recommendations, supported by low quality evidence, with a primary focus on opioid harms, using population-level data. Policymakers must be cautious in adopting rules to limit access to prescription opioids by limiting dose and duration of treatment. These actions will not solve the public health problem of addiction and overdose deaths that continue to rise despite these reductions.^{34, 45, 46} In a growing number of cases, these new guidelines and regulations make it difficult for healthcare professionals to provide individualized care to meet a patient’s specific needs. For example, patients who have had cancer cured, but live with severe post-treatment chronic pain or others with persistent high-impact pain following major trauma, may not fit the new guidelines.^{56, 57} This prevents professionals from providing evidence-based, compassionate, and patient-centered care.⁵⁸

Blending Initiative. The core mission of the Blending Initiative is to accelerate the dissemination of research-based drug abuse treatment into clinical practice. The National Institute on Drug Abuse (NIDA), the Substance Abuse and

Mental Health Services Administration (SAMHSA), and the Addiction Technology Transfer Center Network (ATTC) joined together to create the Blending Initiative in 2001 to reduce the gap that exists between the publication of research results and the implementation of new research in clinical practice. This proactive initiative incorporates collaboration among clinicians, scientists, and experienced trainers to create user-friendly treatment tools and products and facilitate the adoption of research-based interventions in clinical settings. For example, one effort identified strategies for enhancing education and support for Nurse Practitioners, Physician's Assistants, and Nurses for managing patients with a SUD while expanding their access to the safe, effective treatment of pain.⁵⁹

Food and Drug Administration Risk Evaluation and Mitigation Strategies. In 2007, the Food and Drug Administration (FDA) was given expanded authority to require a Risk Evaluation and Mitigation Strategy (REMS) from drug manufacturers to ensure that the benefits of a medication outweigh its risks. The FDA has committed to expand their focus to include public health risk-benefit concerns by requiring additional types of research, using an expert advisory committee before approving any new opioid, and adding new warnings to the labels. The new labels will have stern black box warnings and REMS will be required for all opioid formulations, including those approved for pediatric use. These strategies have also led the FDA to develop an educational “blueprint” detailing the knowledge that a prescriber should have in order to prescribe extended-release and long-acting opioid analgesics.⁶⁰

Overall, REMS strategies have provided a positive step in healthcare, by driving healthcare professionals to examine their practices, and adopt new “best practice” habits. Hospitalizations and overdose deaths by ER/LA opioids declined 25% since REMS training began. When asked, patients did not indicate any limitation on access to opioid medications attributable to REMS.⁶¹

Prescribing Naloxone with Opioids. Public policy is rapidly evolving to make the opioid overdose antidote naloxone readily available to all first responders, clinicians, patients, family members and interested community members. Naloxone is a medication used to counter-act respiratory depression and has a track record of saving lives from opioid overdose.⁶² Several states either encourage or mandate naloxone with opioids (co-prescribing) for high risk patients.^{62, 63, 64, 65} Co-prescribing requires prescribers to educate their patients and families or loved ones about the risk for opioid overdose, including how to recognize signs and intervene should this life-threatening emergency occur; and a conversation about risk of OUD. This includes training to ensure the patient and significant others can recognize signs of overdose and act accordingly. Its use is now part of standard basic life support (CPR) training; and is carried by most firefighters and police officers. The FDA is to be commended for rapidly improving access to naloxone, thus meeting an important public health need.

State-based Prescription Drug Monitoring Programs. State-based prescription drug monitoring programs (PDMPs) have been developed to facilitate appropriate prescribing of controlled prescription drugs and prevent the diversion of opioid pain relievers for nonmedical use, abuse, and criminal purposes. These programs primarily serve prescribers and dispensers (e.g. pharmacists) of opioids to prevent inappropriate access. The data is available and sometimes distributed via unsolicited reports to these professionals as well as practitioner licensure boards, law enforcement and drug control agencies, medical examiners, drug courts, addiction treatment programs, public and private third-party payers, and possibly others. Although the rationale for these systems is logical, there are many barriers to their optimal use and evidence supporting them is anecdotal and not well documented. Even so, experience has identified strengths and limitations to this valuable tool that must be optimized and integrated into a real-time, nationalized system that provides easily accessible data. The value of these programs must be weighed against concerns about compromising patient privacy, adding to regulatory burdens, and restricting access to medications that clinicians believe are beneficial for the patient.^{66, 67}

Food and Drug Administration approval of abuse deterrent/tamper resistant opioids. There are now a half-dozen FDA approved abuse deterrent/tamper resistant opioids that prevent manipulation by chewing, dissolving, smoking, snorting or injecting prescription opioids.⁶⁸ Their chemical and physical properties either prevent alteration or utilize aversion technologies that release sequestered chemicals that make attempted misuse ineffective or unpleasant.⁶⁹ Legislation has been enacted in some states to make these expensive products more accessible but they are still not routinely being used for patients at high risk of aberrant behaviors. These advances do not prevent drug misuse by other means such as swallowing high doses, however, they do address the issue of drug tampering, and there are new options emerging.⁷⁰

Current Research Environment

Lack of high quality evidence to guide policy and care. Recent efforts by the CDC, FDA, Agency for Healthcare Research and Quality (AHRQ), and the Cochrane Collaboration (an independent global research network) have failed to establish the existence of high quality research needed to guide practice on the treatment of chronic pain, in part because of the heterogeneity of this population. Given the complexity of research needed and seemingly unending number of variables to be analyzed, population-based registries may be needed. Another major limiting factor of various studies is the heterogeneity of outcome measures used, however, standardization of outcome measures in future studies will expedite advancing the science. An international group of scholars, referred to as IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) developed key recommendations for a) understanding the transition from acute to chronic pain, b) measurements to use when developing new pain treatments, including abuse-deterrent formulations of opioids, and c) uniformly measuring the effectiveness of chronic pain treatments.^{71, 72, 73, 74, 75, 76} These recommendations are a step towards standardized outcome measures in clinical trials.

Promoting research in other medical arenas has proven success. In the areas of cancer and heart disease, there have been significant treatment advances and a decline in deaths over the past 10 years with NIH funding of cancer research reaching \$5.4 billion per year and heart disease research at \$1.2 billion per year. In contrast, there is \$0.4 billion annually for pain research, despite the escalation of the opioid epidemic and the greater burden to patients, families, and society.^{19, 77} Through increased funding and showcasing successful innovations, the bar can finally be raised in providing high quality research in pain and SUD.

National Pain Strategy. In 2011, the National Academy of Sciences published the Institute of Medicine (IOM) report on *“Relieving Pain in America”* describing “the unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right.”⁷ This document was a blueprint for the major transformations needed in healthcare, education, and research to better understand and treat chronic pain. The National Pain Strategy, released in March 2016, is the comprehensive plan delineating short-, medium, and long-term tactics needed to make the cultural transformational changes called for by the Institute of Medicine report.^{7, 12} The strategy calls for population-based research and public health principles to prevent pain, assess and treat pain effectively before becoming chronic, and implement chronic disease management strategies in the chronic pain population to prevent and treat high-impact chronic pain. This research strategy will balance efforts to lessen the burden of chronic pain while reducing the abuse and overdose deaths related to opioids, rather than pitting the interests of helping one vulnerable population against another.

The plan calls for creating public-private partnerships in areas of population research: prevention and care, disparities, service delivery and reimbursement, professional training, and public education. The vision of success is research aimed to identify treatment options that result in a lower prevalence of pain across the life span and a lower prevalence of chronic and high-impact types of pain. If successful, patients with pain will be treated with respect and compassion, while those treating them will provide safe, effective, evidence-informed care that is aligned with the patient’s values and preferences.

Impact of Health Payment Policies

The public health issue of treating chronic pain and preventing SUD and OUD is complicated further by the current health system payment and delivery systems. Barriers occur with restrictive health plan coverages and “fail first” strategies.

Health plan coverage. Current payment structures work against comprehensive, responsible treatment of chronic pain and SUD/OD. The initiation of treatment plans, in partnership with the patient, should be performed using a structured approach that includes informed decision-making based on risks, benefits, and alternatives. In general, healthcare provider time with patients is limited; extended visits are not reimbursed adequately to allow healthcare professionals to conduct full health assessments, to educate patients on proper medication use, and to monitor for emerging OUD. Opioid therapy alone is inappropriate in most cases because of limited effectiveness that appears to wane over time and growing evidence of harm when high-dose, long term prescribing occurs. Therapies, whether opioids, non-opioids, or non-pharmacologic, work best in concert with each other.⁷⁸ Treatment of pain is complicated,

takes time, and office visits are insufficiently reimbursed creating a disincentive to take an individualized approach to treatment.

Furthermore, labeling changes are underway for all opioids to reflect the current push to use them only for severe pain, when other non-opioid treatments are unlikely to help. This move will likely result in payers adopting a “fail first” policy to control costs. Prescribers are often required to try less expensive options in “safer” drug classes for a period of time; then wait for those drugs to fail before access can be considered for treatments the clinician believes would be best for the patient. Thus, even if clinicians believe a low dose opioid could provide relief within a day, patients may need to incur additional costs and endure discomforts for weeks or months of multiple medication trials, surgery, invasive procedures and non-pharmacologic interventions before that treatment can be provided. Circumventing clinical judgment through proscriptive payment policies is not aligned with the goals of patient-centered, ethical, cost-effective care.⁷⁹

Payers are also addressing ways to identify and minimize risky practices. Claims-based health plans can identify individuals receiving multiple pain medication prescriptions from multiple prescribers. Claims data mining can flag suspicious utilization patterns that can be the basis for more scrutiny and intervention as necessary. Unfortunately, this approach leads to onerous prior authorizations, denials of access to medically necessary therapy, and arbitrary dose and/or duration limits on prescriptions. This may drive some patients to secure their supply of pain medications from illicit sources or use illegal drugs out of desperation to achieve pain control.⁴⁰

Health Professional Response

Interprofessional pre-licensure education. All health professionals need to develop core competencies including: understanding the multidimensional nature of pain, using valid, reliable pain assessment methods; and taking a collaborative approach to pain management across the lifespan and the continuum of care.^{80, 81, 82} When first-line pain treatment fails or interferes with biopsychosocial functioning, patients need an expanded interprofessional team that engages physical therapists, psychologists, social workers, addiction specialists, chaplaincy and/or other team members as appropriate to the setting and circumstance. The Centers of Excellence in Pain Education (CoEPEs) are creating these types of programs focused on core competencies identified by the International Association for the Study of Pain (IASP).^{80, 83} Over 40 inter-professional case studies are being developed, some already in the public domain, to be incorporated into professional training programs (https://painconsortium.nih.gov/nih_pain_programs/coepes.html). As envisioned, case-based classroom content, combined with interprofessional group discussions should take place to hone skills in planning team-based, patient-centered care for complex, standardized pain patients. This training model will boost health professional collaboration on assessments, and emphasize critical thinking about pain to best meet their patients’ biopsychosocial comfort needs.⁸⁴

Interprofessional training will stimulate collaboration and the innovative thinking needed to turn today’s challenges into opportunities to improve team-based pain treatment in the future.⁸⁵ There are major challenges to overcome before fully implementing this strategy; including funding these trainings, overcoming stigmas and biases against those with OUD, and creating a broader view of pain treatment beyond the current opioid controversies.

Thus, it is clear that both chronic pain and SUD are complex major public health problems in America that will continue to impart great human suffering and drain national resources. We must invest in our educational programs to develop high-performance interprofessional teams in order to solve these problems. This will require federal funding, interprofessional collaboration, and institutional support to eliminate the current educational silos and create interprofessional educational experiences. This educational approach can successfully deliver quality education that fosters best clinical practices to aid our country in eliminating the threats these problems pose to our society.

RECOMMENDATIONS

Renewed efforts are needed to develop safe, effective treatments and to improve our systems for providing care to those suffering from chronic pain. When we continue to ignore the harmful effects of severe persistent pain, we are denying humane care to people with chronic pain. This is unethical and can lead to unnecessary suffering, depression, disability, and even premature death. One of the most vexing challenges of our time is finding ways to minimize morbidity and mortality related to both severe chronic pain and opioid therapies. This is a serious public health problem that demands major changes in the way we offer treatment to those with chronic pain and how we prescribe

opioids. Compassionate treatment for people suffering from chronic pain and substance use disorder should embrace a biopsychosocial spiritual model.

There are gaps in education of our healthcare providers on appropriate screening and care; gaps in reimbursement for counseling and routine screens for risk; and gaps in availability of providers skilled in co-occurring mental health, pain, and OUD. Both chronic pain and OUD require more than brief visits. We must screen often, treat unrelieved pain through multimodal therapies, identify the emergence of OUD early, and refer to appropriate treatment when identified. Public policy initiatives have recognized these shortcomings, resulting in legislation designed to improve training and access to mental health and addiction services. Other legislation, practice guidelines, and payer policies are also changing to reduce unnecessary exposure of individuals and the public to opioids. Time will tell if these measures will benefit both populations affected by the public health problems of OUD and chronic pain in a balanced fashion, or if they produce an unbalance situation of solving one problem only to worsen the other. In addition to the policy initiatives noted herein, the following recommendations are offered as key components of addressing the dual problems of treating chronic pain and safe prescribing of opioids.

Recommendations for Clinical Practice

Public health leaders and the health professional community must lead the way out of this population health problem by providing care that prevents and treats pain responsibly while acknowledging the risks of OUD.

Effective chronic pain care requires four essential elements:

- 1. Comprehensive assessment:** Assessment requires gathering a detailed history of the individual's pain from a biopsychosocial-spiritual standpoint, including a history of medication use, prescribed and illicit drug use, and a history of mental illness. A full review of prior responses to disease-modifying treatments, non-pharmacologic therapies, and non-opioid analgesic medications should be conducted. The physical exam should focus on painful areas, or can include a comprehensive physical exam.⁸⁶
- 2. Patient education:** Clinicians should offer concise information that balances concerns for safe use of medically necessary opioids when indicated while avoiding the harms to individuals, families and society resulting from nonmedical use, OUD and opioid overdose deaths. Patients and families need counseling and information on realistic expectations regarding the limits and potential harm of opioids.
- 3. Utilization of a wide range of treatment options:** Healthcare providers must individualize chronic pain treatment plans based on the comprehensive biopsychosocial-spiritual assessment that considers the risk of harm from unrelieved pain balanced against treatment-specific risks. Options should include biomedical, behavioral health, and complementary treatments. Clinicians must establish realistic treatment goals for pain and function. Treatment plans should include informed patient consent, with mutually established patient-centered goals aligned with patient values and preferences, tempered by the clinical guidelines and the physical assessment. Opioid use should be considered a trial only for as long as benefits outweigh the risks, because opioids will not effectively relieve pain and improve functioning in all people, and OUD can occur even in patients initially deemed as "low risk."
- 4. Vigilant follow-up to mitigate risks:** When opioids are used, health team members should conduct an initial screen of drug-related risks, and vigilantly monitor for the emergence of OUD as manifested by a pattern of problematic behaviors creating significant impairment or distress. Evaluation of benefits and potential harms require extended visits during the first few months of treatment and every three months for the duration of therapy. Patients who show evidence of OUD should receive comprehensive care that includes biomedical therapies, such as medication-assisted treatment; and behavioral health treatment approaches such as counseling, coping skills training, behavioral therapy, support groups, and recovery coaching.

Recommendations for Research

Access to medically necessary chronic pain treatments is limited as is research to develop new forms of therapy.^{7, 12} Deaths from cancer, HIV and heart disease have declined over the past 10 years but those related to pain medications have increased. In 2015 the NIH spent \$5.4 billion per year on cancer research, \$3.7 billion on HIV research, \$1.2

billion on heart disease research and \$0.4 billion on pain research, despite chronic pain being more prevalent than all those other diseases combined.⁷⁶ Increased research funding for molecular to population-level research is needed to better understand, evaluate and treat chronic pain as it exists, with and without concurrent SUDs. A critical need exists for translational research to provide safer and more effective treatment options. Targeting that funding to quality research programs is also needed. Research should:

- **Focus on underlying neural mechanisms:** Research should focus on the underlying neural mechanisms that develop and maintain chronic pain and substance use disorders and distinct and sometimes co-existing chronic diseases. Once this underlying pathology is understood, targeted therapies that maintain their effectiveness and safety over time can be developed.

- **Support novel non-addictive analgesics and abuse-deterrent opioid development:** Support the development, testing, and use of novel non-addictive analgesics, as well as opioids with the strongest abuse deterrent formulations, to maximize effectiveness and lower the risk of analgesia. Abuse deterrent formulations show promise of changing abuse patterns that need further study.⁸⁷

- **Improve measurements of desirable and undesirable effects of pain interventions:** Well-designed large-scale, multisite comparative-effectiveness and cost-effectiveness trials are needed to better measure effectiveness of current therapies available to treat pain. All trials should use uniform measures recommended by the IMMPACT group. Given the heterogeneity of chronic pain conditions, many areas need study: the underlying mechanisms of chronic pain (ischemic, inflammatory, neuropathic, etc.), transitions over time (acute, chronic, high impact chronic), disease-specific pain (cancer, low back pain, arthritis, diabetes, and pain that follows medical/surgical treatments) and symptom-modifying approaches to pain treatment.

- **Distinguish those with chronic pain from those with OUD:** To reveal true, rather than implied causation, large-scale multisite, well-designed clinical trials are needed. These trials will need the ability to distinguish patients with chronic pain from those with OUD, and those with both conditions concurrently.

- **Use standardized definitions:** Standardized pain items should be included as part of national health surveys, Electronic Health Records, and large datasets. This population level of data about chronic pain and OUD will provide essential information to better understand the distinct versus overlapping scope of these problems and the impact of programs designed to prevent/treat them.

- **Evaluate the effectiveness of risk-mitigation strategies to prevent opioid-related harm:** These measurements would include screening methods, abuse-deterrent formulations, dose caps, naloxone co-prescribing, treatments for patients with both chronic pain and concurrent SUD.

Recommendations for Education

All members of the healthcare team require specific education and training on chronic pain and SUD to create an environment that facilitates: patient/family education; use of opioid risk-mitigation strategies; early identification of problematic drug-use patterns; referrals and treatment of OUD that may emerge. Education on treatment of pain makes up a very small part of traditional healthcare professional education and testing. Continuing education, especially as treatment innovations emerge, will help close the gap of knowledge in pain treatment across settings.

- **Imbed core competencies in chronic pain and SUD in all health professional curricula consistent with the FDA blueprint and the National Pain Strategy.** Core curricula in all healthcare professional educational programs must include the content and competencies needed to prevent and treat the major public health problems of chronic pain and SUDs. This mandate should be tied to attaining/maintaining program accreditation status. The competencies should address:
 - preventing and effectively treating acute pain while avoiding unnecessary exposure to opioids (primary prevention);
 - early identification and effective treatment of chronic pain and/or SUD (secondary prevention)
 - preventing morbidity and mortality from “high-impact chronic pain” and/or SUDs (tertiary prevention).^{12,80, 88}

- **Implement mandatory outcome-oriented continuing education for healthcare professionals who prescribe, dispense, or administer opioids.** Topics should include assessment and management of chronic pain and SUD as a requirement for license renewals. “Outcome-oriented” education that assesses how acquired knowledge or skills learned in these programs improve patient outcomes should be prioritized.
- **In settings where opioids are prescribed for pain management, systems should be in place to include:**
 - **educational resources on pain and safe use of opioid, non-opioid, and non-drug therapies;**
 - **protocols and quality measures specific to pain and opioid prescribing appropriate for their population and setting;**
 - **a referral directory for those needing additional pain expertise or opioid treatment programs.**

Employers of opioid prescribers (skilled nursing facilities, hospitals, clinics) should ensure all health professionals understand the multidimensional (biopsychosocial and spiritual) nature of chronic pain and SUDs, are competent in screening for and assessing persons with these conditions, and know resources to manage these conditions in a collaborative way across the lifespan and the continuum of care. Setting-specific knowledge should be responsibility of the employer, as different patient cohorts present different care challenges.

- **Increase public education:** Promote public education, as outlined in the National Pain Strategy. Clear and frequent messaging must focus on efforts to reduce misinformation about chronic pain and pain medication use. Content would emphasize pain management coping skills, identifying support systems, and avoiding reliance on drugs to soothe physical or emotional discomforts. Explaining the role of opioids and when opioids are indicated for pain control is important for the public to understand. Education should also inform the public about using non-medicine treatments, such as acupuncture or acupressure. When medication is needed, education about the importance of close monitoring by the healthcare team to evaluate benefits (improved pain level and function) and potential harms (side effects, non-medical use, emergence of OUD, and overdoses) is critical. Strategies for this increase in public education about pain and cautious medication use can mirror the strategies used in smoking cessation campaigns.

Recommendations for Public Policy

Chronic pain is both an under-recognized and under-resourced public health crisis with devastating personal, social, and economic impacts. It requires team-based, patient focused individualized care to balance concerns for safe, effective care that cannot be provided given existing public policy barriers. Policy changes should include:

- **Reimbursement reform for healthcare encounters for people with pain.** Reimbursement reform is needed to ensure access to cost-effective therapies that support the judicious use of opioids when appropriate and a full range of non-opioid and non-drug therapies. Providers should be compensated for the extra time needed to support this approach, including payment for extended visits (30-60 minutes) to provide education, counseling, low-cost nondrug interventions, self-management and coping skill training, and monitoring treatment effects.

- **Payment system reform to ensure access to care for people with pain requiring multimodal analgesia and integrative approaches to their pain.** Payment system reform is necessary to support an integrated, multimodal, interdisciplinary approach to care for those who have not been successfully treated with initial therapy and specialist-advised care, particularly those with high impact chronic pain. Multimodal approaches employ a deliberate combination of medications and nondrug methods with different mechanisms of action and side effect profiles to improve patient outcomes.⁸⁹ Supporting patient access to this integrated approach allows them to avoid repeated invasive procedures or sequential visits to multiple specialists.

- **Elimination of policies that restrict access to care and supersede clinical judgment.** Restrictive policies at the federal, state, and payer levels must not supersede clinical judgment and should be based on a careful analysis of root causes of OUD and SUD. Policies should include metrics that evaluate desired and potential unintended consequences. Consideration must be given as to how policies may adversely affect patients with chronic pain who now face barriers to access pain-relieving treatment. Additionally, regulations and policies related to opioid access need to be periodically reviewed and revised to keep up with rapidly expanding scientific knowledge.

- **Integration of REMS training as outlined by the FDA to ensure safe opioid prescribing practices.** REMS training, as outlined in the “FDA Blueprint,” should be a required element for DEA licensure and renewal to ensure safe opioid prescribing practices by all providers. This recommendation is based on overdose deaths by ER/LA opioids declining 25% since REMS training started.⁶¹

- **Support for a strong public education campaign:** State and Federal funding is needed to support a robust public education campaign to counter stigma and correct common misperceptions about chronic pain. Public education should also provide information about potential benefits, harms and uncertainties regarding individual responses to opioids.

- **Funding for a National Prescription Drug Monitoring Program:** Formation of a national Prescription Drug Monitoring Program is needed to support effective collaboration between law enforcement and the health professions. The program must be user-friendly, real-time, with components known to effectively reduce diversion in a way that doesn’t interfere with prescribers’ obligation to treat chronic pain while protecting patient privacy. Although all states, except Missouri, have a state monitoring program, interoperability and access is inconsistent across state lines.

- **Align federal funding of pain research with the prevalence and societal burden of chronic pain.** Federal funding of pain research through the National Institutes of Health needs to be better aligned with the prevalence and societal burden of chronic pain. Deaths related to opioids do need high priority attention, but the focus needs to more clearly separate chronic pain patients from those with a substance use or mental health disorder.⁷⁷

Conclusion

Increased public awareness and attention to the problems related to OUD gives us an opportunity to responsibly address the complex public health issue of chronic pain and its treatment. As public health officials, clinicians, and affected individuals and families grapple with the intricacies of effective pain treatment and the risk of OUD, this paper offers a multipronged approach to address the issues. Improving clinical practice, increasing and strategically targeting research dollars, and creating an effective public education campaign will help. Equally important is a considered and thoughtful public policy approach that supports reimbursement policies that allow the judicious use of opioid treatment while recognizing that OUD is a risk factor in such treatment. Chronic pain affects the lives of millions of Americans. It is our ethical and moral responsibility to relieve that pain in a socially responsible way.

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Thank you to Patricia Kelmar, Esq., PDKelmar Associates, LLC for her assistance in the preparation of this paper.



This publication in the public interest was supported by the Nurse Practitioner Healthcare Foundation (NPHF). NPHF is a nonprofit 501(c)(3) philanthropic organization. To obtain information about the NPHF or to order documents, contact NPHF by phone (425) 861-0911, or e-mail (mail to: info@nphealthcarefoundation.org). This document may be viewed on the NPHF website: nphealthcarefoundation.org