

Prescription Opioid Abuse: A Modern Day Public Health Epidemic

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Abstract

The abuse of prescription opioids has been increasing since early 2000 and currently represents a significant public health crisis. In 2008, opioids contributed to one death every 36 minutes in the United States (Manchikanti et al., 2012). The mortality and morbidity associated with prescription opioid abuse represents a substantial financial burden on society, especially on the health care system. The objective of this paper is to examine the drivers of this epidemic and the prevention strategies that have already been employed in order to recommend a successful intervention aimed at curbing prescription opioid abuse and overdose. These prevention strategies include patient and provider education, the creation and use of evidence-based guidelines for pain management, implementation of state prescription drug monitoring programs, increased access to substance abuse treatment, expansion of take-home naloxone, the creation of abuse deterrent drug formulations, and supportive legislation.

Successful interventions based on these strategies have been utilized at both the state and community level. Through improved data collection, continued research on effective prevention strategies, improved interstate prescription drug monitoring programs, support and maintenance of the workforce treating patients suffering from chronic non-cancer pain, and continued state and federal support, a greater impact can be achieved. A continued effort must be made to address the multiple determinants of prescription opioid abuse. Although a national problem, collaborative public health leadership at the community level needs to be cultivated to provide a foundation for an evidence-based, “bottom up”, multidimensional intervention that will elicit the changes needed to combat this epidemic.

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Prescription Opioid Abuse: A Modern Day Public Health Epidemic

Introduction

The misuse and abuse of prescription opioids is a growing epidemic in the United States¹. Nearly three out of four fatal prescription drug overdoses are caused by prescription opioids. In 2008, prescription opioid overdoses accounted for 14,800 deaths, more than cocaine and heroin combined (Centers for Disease Control, 2012a). Forty percent of all poisoning deaths were caused by prescription opioids. For the first time since at least 1980, poisonings, including unintentional and intentional drug overdoses, and poisonings resulting from other toxic substances, gases, or vapors, have become the leading cause of death from injury in the United States, surpassing motor vehicle traffic deaths (CDC, 2011a).

Over twelve million Americans, age 12 and over, reported nonmedical use of prescription opioids in 2010 (CDC, 2011b). In 2009, the nonmedical use of prescription opioids was responsible for 416,458 emergency department visits, an increase of 141% from 2004 (Substance Abuse and Mental Health Services Administration, 2011). The direct health care cost for health insurers due to the nonmedical use of prescription opioids amounts to \$72.5 billion annually (CDC, 2011b). The prevalence, morbidity and mortality, and cost of prescription opioid abuse on an already strained health care system make this epidemic an important public health priority.

¹ Misuse is defined as use of a medication for nonmedical use or for reasons other than prescribed. Abuse refers to misuse with consequences and use of a substance to modify or control mood or state of mind in a manner that is illegal or harmful to oneself or others (American Psychological Association, 2000; Katz et al., 2007). In this paper, "abuse" refers to both abuse and misuse.

Opioid Epidemic History

The present day epidemic of prescription opioid abuse is not unique in U.S. history. Although opioids have been used throughout history as pain medications and antianxiety drugs, opioid addiction was not documented until the U.S. Civil War (Hentoff, 1965). The commercial marketing of heroin as a “wonder drug” contributed to addiction in middle age, middle class women and returning soldiers (Courtwright, 1992). Relief from pain with liberal doses of opioids was one of the few treatments an army medic could offer a wounded soldier, and those who survived found themselves physiologically dependent on this new “wonder drug”. During the post-Civil War era, an estimated 4% of American adults used opioids regularly (Kosten & Hollister, 2001).

In 1914, just before World War I, Congress passed the Harrison Narcotic Act to help address the problem of opioid abuse, use, and dependence that arose over the preceding fifty years. The Harrison Narcotic Act was "*an Act to provide for the registration of, with collectors of internal revenue, and to impose a special tax upon all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or cocoa leaves, their salts, derivatives, or preparations, and for other purposes*" (Public Law No. 223, 1914). The courts interpreted this to mean that physicians could prescribe opioids to patients in the course of normal medical treatment but not for the treatment of addiction. It was not until the 1970's that the Controlled Substance Act (CSA) replaced the Harrison Narcotic Act. The CSA consolidated numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. The major purpose of the CSA was to enable the United States to comply with the requirements of two international

treaties: the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances. These treaties set to classify controlled substances into schedules in accordance with scientific and medical findings by public health authorities (Van Dusen & Spies, 2007).

Intravenous heroin use intensified in the United States after World War II, reaching epidemic proportions in urban centers during the 1950s and 1960s (Joseph, Stancliff, & Langrod, 2000). Heroin use also increased during the early 1970s and between 1995 and 2002 (SAMHSA, 2005). By 2003, heroin usage was stable at low levels with 96,000 people of all ages using for the first time (SAMHSA, 2005).

Opioid Pharmacology

Opioid drugs are psychoactive chemicals that work by binding to opioid receptors found in the central and peripheral nervous systems and gastrointestinal tract. Analgesia is produced by the binding of these chemicals to receptors in the brain and spinal cord involved in the transmission and modulation of pain (Kosten & Hollister, 2001). These substances were originally derived from the opium poppy (*Papaver somniferum*). Prescription opioids are characterized as natural, semi-synthetic, or fully synthetic. Common natural opioids include morphine and codeine. Common semi-synthetic opioids include oxycodone, hydrocodone, and heroin, and common synthetic opioids include methadone, fentanyl, and tramadol.

Opioids are available in both long-acting and short-acting formulations. Although they confer similar total systemic opioid concentrations and equivalent pain control, long-acting formulations cause less fluctuation in plasma concentrations and are amenable to dosing schedules that may improve treatment adherence (Argoff & Silvershein, 2009).

Historically, abuse and aberrant behaviors were thought to be more associated with short-acting opioid formulations; however, several studies have shown that the abuse of both long- and short-acting opioids is a problem. Additionally, many long-acting formulations can be turned into short-acting formulations through physical tampering (Argoff & Silvershein, 2009).

In 2005, hydrocodone was the most commonly cited opioid responsible for emergency department (ED) visits, and in addition to extended-release oxycodone, it was the most commonly abused opioid when the rate was based on the total population. When calculated based on the number of cases of abuse per prescriptions filled, extended-release oxycodone was more often abused (Cicero, Surratt, Inciardi, & Munoz, 2007). OxyContin, an extended-release oxycodone developed by Purdue Pharma in 1996, was aggressively marketed and promoted upon release. As a result, sales reached \$1.1 billion in 2000 and by 2004, OxyContin became the leading drug of abuse in the United States. Contributing factors related to its success included the extraordinary amount of money spent on marketing, prescriber profiling, and the patient starter coupon program which provided a free 7- to 30- day supply (Van Zee, 2009).

In addition to their analgesic and euphoric properties, opioids also cause sedation and respiratory depression. Opioid-induced respiratory depression is the major limiting factor for the provision of effective analgesia and the mechanism through which opioid overdoses cause death. The fundamental drive of respiration is generated in the brainstem. This drive is modulated by inputs that include conscious inputs from the cerebral cortex and central and peripheral chemoreceptors that sense changes in the chemical constituents in the blood (Pattinson, 2008). Opioids cause respirations to become slower and more

irregular through depression of both central and peripheral chemoreceptors. These effects are further modulated by drug interactions, sleep, pain, and genetics. Specifically, the concurrent use of ethanol and benzodiazepines have a synergistic effect on respiratory depression (Pattinson, 2008). Opioid-induced central sleep apnea is another etiology of opioid-related death when opioids are taken at nighttime (Geller, 2011).

Demographics of Prescription Opioid Use

The demographics of opioid use in the United States can be divided into three main populations; the approximately 9 million persons who report long-term medical use of opioids, the approximately 5 million persons who report the nonmedical use of opioids in the past month, and those who use opioids for a short period of time for acute painful conditions (Boudreau et al., 2009; SAMHSA, 2010). Nonmedical use is defined as the taking of prescription drugs, whether obtained by prescription or otherwise, other than in the manner or for the reasons or time period prescribed, or by a person for whom the drug was not prescribed (United Nations Office of Drug and Crime, 2011b). Long-term medical use of opioids is most commonly seen in patients with chronic noncancer pain (CNCP). CNCP is defined as pain that has been present for at least six months; pain lasting longer than the expected time of tissue healing or resolution of the underlying disease process; or pain due to a condition where there is ongoing nociception or neuropathic pain (Jovey et al., 2003).

Among adolescents, nonmedical use of prescription medications occurs more often in white females in their late teens. Specifically, lifetime use of prescription opioids is higher among white 12th grade students (24.9%) than Hispanic (17.3%) or black (11.5%) students (Johnston, O'Malley, Bachmann, & Schulenberg, 2012). Nonmedical use of prescription medications in adolescents is also associated with low academic performance,

school dropout, and lack of “school bonding.”² Other individual-level correlates include residential instability, rurality, poor self-reported health, recent major depressive episode, post-traumatic stress disorder, mood disorder, mental health service utilization, and emergency room use. Sexual victimization is specifically associated with prescription opioid and sedative use (Young, Glover, & Havens, 2012).

Based on data from the National Household Survey on Drug Abuse, Simoni-Wastila, Ritter, & Strickler (2004) demonstrated that being female rather than male increased the likelihood of nonmedical use of opioids by 41%. Other statistically significant predictors of opioid abuse included being white, 12-17, 18-34, or 25-34 years old relative to middle age, poor or fair health status, daily alcohol use, and past-year illicit drug use. Elders are 31% as likely as middle age adults to misuse opioids. Alternatively, many more men than women die of prescription opioid overdoses, and middle age adults have the highest overdose rate. Whites, American Indians or Alaska Natives, and people living in rural counties are also more likely to overdose on prescription opioids (CDC, 2011b). People on Medicaid are prescribed opioids at twice the rate of non-Medicaid patients and are at six times the risk of overdose. People with mental illness are over-represented in both those who are prescribed opioids and those who overdose on them (CDC 2012a). Back pain, multiple pain complaints, and substance abuse disorders are common among patients at high-risk for abuse. As with the adolescent population, a history of mood disorders, psychological problems, and psychosocial stressors increases the risk for prescription opioid abuse in adults (Sehgal, Manchikanti, & Howard, 2012). The acceptance of

² School bonding was based on students’ reports that they liked going to school, that their school work was meaningful, that classes were important and interesting, and that teachers praised their work.

prescription drugs to treat a myriad of life's problems in the modern world has also likely contributed to the nonmedical use of prescription opioids.

Although a distinct entity, the issue of CNCP adds a complicating factor to the opioid epidemic. CNCP affects approximately 100 million U.S. adults, costing \$560 to \$635 billion annually (Institute of Medicine, 2011). The increased prevalence of CNCP can be attributed to the aging U.S. population, which is likely to experience more diseases associated with CNCP. Additionally, obesity, the progress in saving the lives of people with catastrophic injuries, and a higher percentage of outpatient surgical procedures, which play a role in inadequate pain control, are contributing to the increase in CNCP. The greater public understanding of chronic pain syndromes may have caused these patients to reenter the health care system after years of separation (IOM, 2011).

Opioids are one of the most prescribed medications used to treat CNCP, and their use for CNCP has increased dramatically over the last 20 years (Sullivan et al., 2008). Chronic pain is a complex condition shaped by the interplay of genetic factors, childhood pain, nerve pathways, the brain, and emotional and cognitive context (IOM, 2011). Despite their increased use, limited data exists on the effectiveness of opioids in the long-term management of CNCP (Noble et al., 2010). In an effort to address evidence suggesting the under-treatment of pain, the Joint Commission on Accreditation of Health Care Organizations (JCAHCO) mandated new pain management standards effective January 1, 2001, and state medical boards liberalized their guidelines regarding the treatment of CNCP (Solanki, Koyalagunta, Shah, Silverman, & Manchikanti, 2011). Changes in regulations, consensus from professional societies, availability of longer acting opioid formulations, aggressive marketing by drug manufacturers, and disregard for the lack of

evidence showing long-term effectiveness have all led to an increase in the number of opioids being prescribed from CNCP (Sehgal, Manchikanti, & Howard, 2012). Although difficult to accurately estimate, the rates of addiction for those with CNCP range from 3.2% to 18% (Pohl & Smith, 2012). A review of the literature reporting addiction, dependence, aberrant drug taking, abuse, misuse, and problematic opioid use among patients with CNCP reported a range of 0-50% (Højsted & Sjøgren, 2007).

The Prescription Opioid Supply Chain

Opioid drug distribution through the pharmaceutical supply chain has increased greater than 600% from 1997 to 2007 (CDC, 2012a). In 2007, approximately 700 mg of morphine was prescribed per person. This equated to enough for everyone in the United States to take five milligrams of Vicoden (hydrocodone and acetaminophen) every four hours for three weeks (CDC, 2012a). Among patients who are prescribed opioids, approximately 80% are prescribed low doses by a single practitioner (<100 mg per day morphine equivalent) which accounts for ~20% of all prescription drug overdoses (Edlund et al., 2010). Ten percent of patients are prescribed high doses of opioids (>100 mg per day morphine equivalent) by a single provider and account for ~40% of opioid overdoses (Bohnert et al., 2011). The remaining 10% seek care from multiple doctors, are prescribed high daily doses of opioids, and account for another 40% of opioid overdoses (Hall et al., 2008). This group is also likely to be diverting their drugs to others (CDC, 2012a).

Over 90% of patients receiving care in the pain management setting received opioid prescriptions for CNCP management. However, the majority of opioid prescriptions were provided from outside this setting. In 2009, the top specialties prescribing short-acting opioids were family medicine (26.7%), internal medicine (15.4%), anesthesiology (3.2%),

and physical medicine and rehabilitation (2.7%). Family medicine and internal medicine physicians also prescribed more long-acting opioids at 27% and 16.8%, respectively (Manchikanti et al., 2012).

Despite the fact that primary care physicians prescribe the most opioids, studies have demonstrated that these physicians feel they have inadequate training in pain management. Additionally, they report limited confidence in their ability to provide effective treatment, a low level of satisfaction with the care they provide, and fear of scrutiny by regulatory agencies (Upshur, Luckmann, & Savageau, 2006; Ponte & Johnson-Tribino, 2005). Primary care physicians also voice concern about over-prescription, abuse, and diversion of the opioids they prescribe for the treatment of CNCP (Olsen & Daumit, 2004).

Although physicians consider the role of medical schools and residencies in teaching about the management of CNCP essential, 40% rated their preparation in dealing with CNCP as unsatisfactory and 45.7% rated their preparation in addressing opioid dependence as unsatisfactory (Keller et al., 2012). However, no evidence-based practice guidelines exist for the care of coexisting CNCP and opioid addiction (Volkow, McLellan, Cott, Karithanom, & Weiss, 2009).

The ED represents an important source of opioid prescriptions for patients seeking pain relief and prescription opioids for nonmedical use. A study conducted in a Colorado ED showed that 30% of patients were discharged from the ED with prescriptions for opioid analgesics. The most common diagnoses associated with an opioid prescription were abdominal pain, cold and flu symptoms, back pain, flank pain, and motor vehicle crash (Hoppe, Houghland, Yaron, & Heard, 2013). Additionally, approximately 11% of patients

seeking treatment in the ED have CNCP as their presenting complaint (Cordell et al., 2002). Forty-two percent of ED visits are related to painful conditions in general (Pletcher, Kertesz, Kohn, & Gonzales, 2008). Many ED physicians believed that CNCP had to be treated in the ED because of their role as “safety net” providers. In many cases, a prescription of 20-30 pills of short-acting Schedule III opioids was given to provide a bridge until the patient could see their primary care physician (Wilsey, Fishman, Crandell, Casamalhuapa, & Bertakis, 2008). However, given the time constraints in a busy ED, physicians have little time to search medical records for evidence of previous ED visits or access electronic prescription monitoring systems. These issues create an environment that promotes “doctor shopping” due to a lack of continuity, longitudinal care, and a biopsychosocial focus (Wilsey, Fishman, Ogden, Tsodikov, & Bertakis, 2008).

Almost all prescription drugs involved in overdoses originate from prescriptions. However, after being dispensed, they are frequently diverted. Of those who abuse prescription opioids, 55% obtain them from friends or relatives, 17.3% are prescribed by a doctor, 11.4% are bought from a friend or relative, 4.8% are taken from a friend or relative without asking, 4.4% are obtained from a drug dealer or stranger, and 7.1% are from other sources (SAMHSA, 2010).

Manufacturers and distributors are also an important element in the supply chain. Between 2006 and 2012, the Drug Enforcement Agency (DEA) suspended registrations and filed regulatory charges against at least 10 drug distributors for failing to report suspicious orders of controlled substances received from their customers (Coleman, 2012). Manufacturers are also required to report suspicious orders that may indicate drug diversion. The payment system employed at this level in the industry is thought to

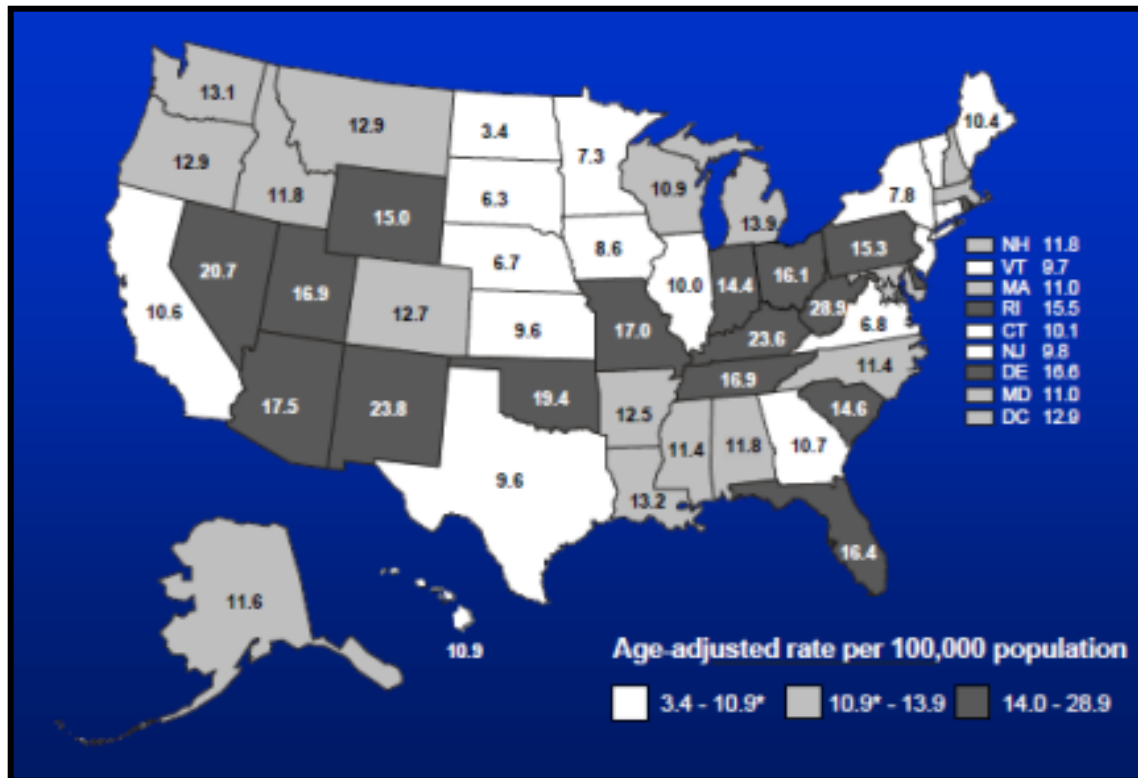
encourage unlawful commerce (Coleman, 2012). Manufacturers negotiate sales with buying groups, and prices are set based on an anticipated volume that the customer is expected to purchase over time. Once a sale has been completed, the manufacturer provides a retroactive discount to the distributor representing the difference between the full price paid for the drug and the discounted price received for the drug. Because the current operating margins and returns on investment in drug wholesaling are not attracting significant capital or new entrants into the marketplace, new avenues for competitive advantage may include filling suspicious orders (Coleman, 2012).

State Variation in Prescription Opioid Abuse

Although prescription opioid abuse is a national problem, not all states are affected equally. The drug overdose epidemic is most severe in the Southwest and Appalachian region. The highest overdose rates were seen in New Mexico and West Virginia. These rates were almost three times that of Nebraska, the state with the lowest rate (CDC, 2012b). Figure 1 shows the drug overdose rates by state in 2010.

Prescription sales per person were the highest in Florida, which was more than three times higher than the lowest rate found in Illinois. In 2008 and 2009, the nonmedical use of prescription opioids (age 12 or older) in the past year ranged from 1 in 12 people in Oklahoma to 1 in 30 in Nebraska (CDC 2011b). In general, states that demonstrate higher sales of opioids per person and more nonmedical use tend to have more overdose deaths (CDC 2011b).

Figure 1. Drug Overdose Rates by State, 2010 (L. Paulozzi, personal communication, March 13, 2013)

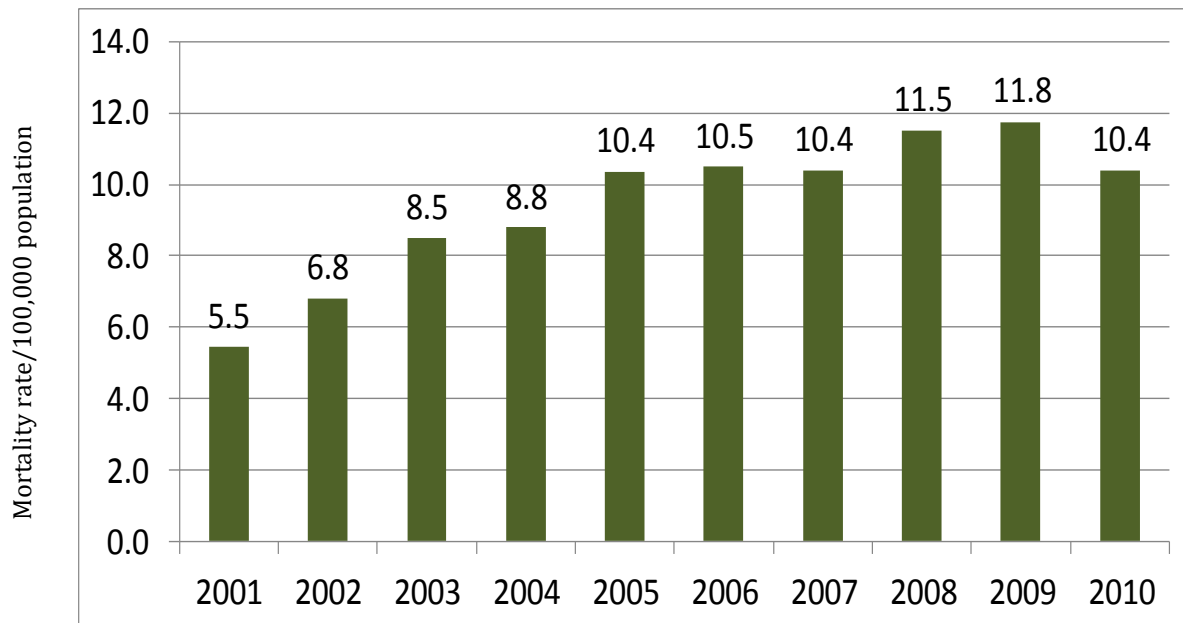


The drug overdose rate for North Carolina in 2010 was 11.4 per 100,000. Statistics from the North Carolina Center for Health Statistics demonstrated a significant increase in mortality rates due to both unintentional and undetermined intent poisonings from 2001 to 2010 as shown in Figure 2. In 2011, this rate increased to 12.1 per 100,000 population (Lancaster, 2012).

The economic burden caused by the cost of hospitalizations due to unintentional poisonings in North Carolina is staggering. In 2008, the estimated cost was \$98,986,010 with an average cost of \$16,980 for inpatient hospitalization due to an opioid poisoning, excluding substance abuse hospitalizations. Unintentional and undetermined intent poisonings resulted in 5,833 hospitalizations in 2008 (Community Care of North Carolina,

2013b). In 2009, the statewide rate for dispensed prescriptions of controlled substances was 185,234 per 100,000 (as cited in CCNC, 2013b). In 2011 and 2012, the rate jumped to 187,889 and 195,043 per 100,000, respectively (Bill Bronson & Scott Proescholdbell, personal communication, March, 25, 2013)

Figure 2. North Carolina Mortality Rates, Unintentional and Undetermined Intent poisonings, 2001-2010 (CCNC, 2013b)



The lack of complete and accurate information that is required to produce the national, state, and local data needed to address prescription opioid abuse deserves mentioning. Data on the number of prescriptions written for a specific drug or class of drugs may only be available for a cost. SDI Health (Plymouth Meeting, PA) receives nationally representative data from approximately 35,000 of the 62,000 pharmacies in the United States. For a price, their *Vector One: Market Pharmacy* database can provide monthly reports that are specific to products, geography, and payment type (SDI, 2013;

Volkow et al., 2011). Adverse reaction reports provided to the U.S. Food and Drug Administration are not publicly available. Additionally, hospitals and mortality databases use ICD-10 codes that do not specifically identify the opioid involved in overdose cases or hospitalizations. The opioids are grouped into “methadone”, “heroin”, “other opioids”, “other synthetic narcotics”, and “other narcotics”. Information on contextual factors leading to adverse events is also lacking (Maxwell, 2011).

Global Burden of Prescription Opioid Use and Abuse

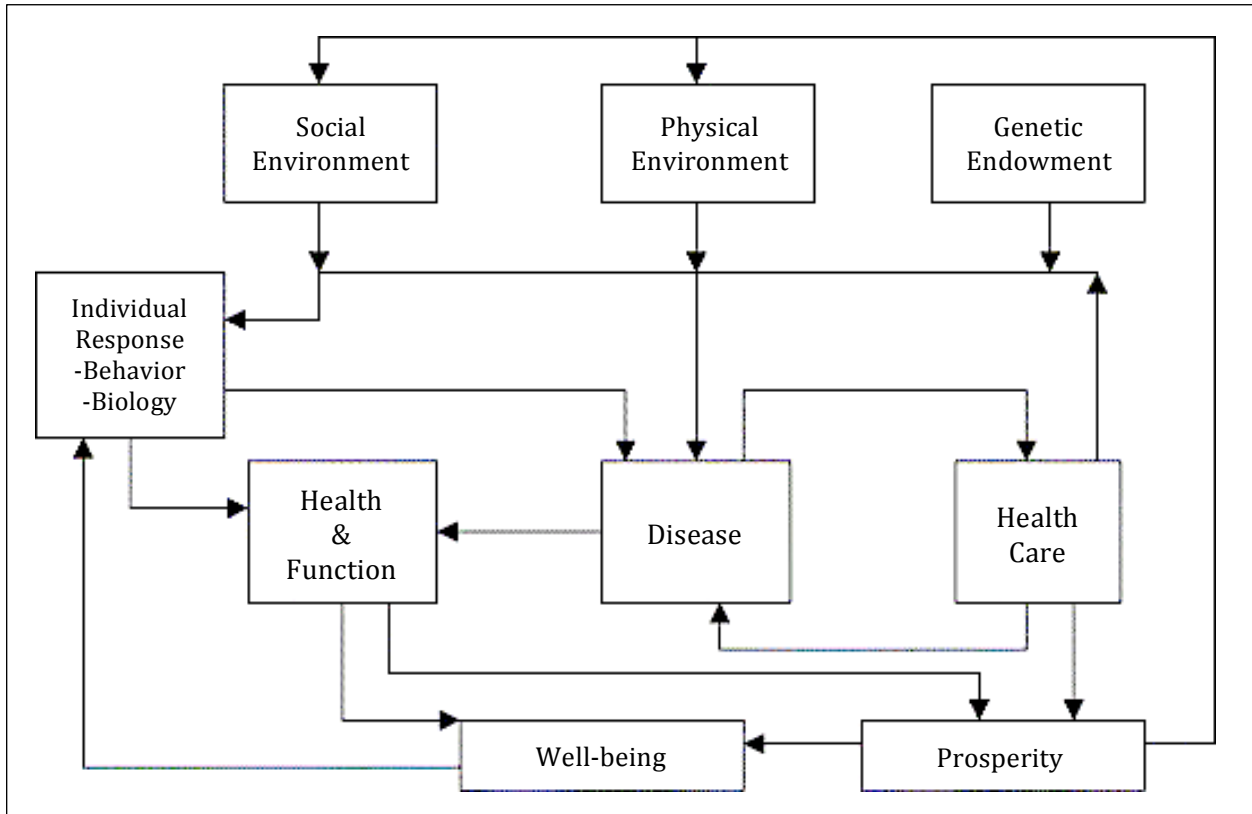
In an evaluation of the world’s supply of opioids, the United Nations Office on Drug and Crime showed that 90% of the global consumption of morphine, fentanyl, and oxycodone registered in 2009 occurred in the United States, Australia, Canada, New Zealand, and several European countries (UNODC, 2011a). In 2003, six developed countries accounted for 79% of global morphine consumption, whereas developing countries, representing 80% of the world population, accounted for only 6% of global morphine consumption (Milani & Scholten, 2011). The United States used 99% of the world’s supply of hydrocodone and 83% of the world’s supply of oxycodone in 2007, while millions of patients in many other countries with moderate to severe pain may not have been adequately treated to alleviate their suffering in part due to the inadequate supply of needed opioid pain medication (International Narcotics Control Board, 2008). Although beyond the scope of this paper, the equally pressing public health issue of untreated pain related to the limited access of prescription opioids in developing countries due to barriers such as limited medical knowledge, overly restrictive regulations and lack of enabling policies, and supply challenges needs to be appreciated and acknowledged (World Health Organization, 2010).

Although studies on the prevalence and patterns of nonmedical use of prescription drugs are limited in many regions of the world, such as Africa, the Middle East, and Asia, available data clearly demonstrates a cause for alarm (UNODC, 2011b). Because these regions do not monitor the nonmedical use of prescription drugs, studies have focused on the use of illicit drugs. In the Philippines, nalbuphine, a semi-synthetic prescription opioid, and codeine-containing cough preparations are being used for nonmedical purposes (UNODC, 2011b). In Bangladesh, Pakistan, India, Nepal, and Singapore, nonmedical use of injected buprenorphine, a semi-synthetic prescription opioid, is common. In South and Central Asia, up to one third of illegal opioid users report using prescription drugs for nonmedical purposes, of which 10% admit to using prescription opioids and barbiturates (UNODC, 2011b). In Afghanistan, the prevalence of prescription opioids is 0.5% (UNODC, 2011b).

A Model to Address the Determinants of Prescription Opioid Abuse

Addressing the prescription opioid epidemic requires a multilayered approach involving individual, community, state, and federally directed interventions. The factors associated with an increase in prescription opioid abuse, dependence, and death discussed above provide the foundation for which these prevention strategies are based. The field model of health determinants described by Evans and Stoddart (1994) provides a broad conceptual framework for considering the factors that influence prescription opioid abuse. This model identifies the major influences in health and well-being and the dynamic relationship among them. Figure 3 shows Evans and Stoddart's model of the determinants of health, which identifies nine health determinants and their interactions.

Figure 3. Evans and Stoddart’s Model of the Determinants of Health (Evans and Stoddart, 1994)



These determinants include the social environment, physical environment, genetic endowment, individual response, health care, disease, health and function, well-being, and prosperity. Among the elements in the social environment that are linked to health are family structure, the educational system, social networks, social class, work setting, and level of prosperity. Genetic factors contribute to a greater or lesser risk of health outcomes, and the physical environment, such as poor housing conditions, may contribute to mental health problems. Behavior is viewed as an individual response to these determinants (IOM, 1997).

This model demonstrates the complex interactions of determinants on health outcomes. Additional features of the model that lend itself to addressing prescription opioid abuse include its emphasis on considering the origins and underlying causes of this epidemic, and the interdisciplinary and multisectorial efforts required to achieve health improvement in a community (IOM, 1997). Although this model operates on an individual level, Patrick and Wickizer (1995) applied Evans and Stoddart's framework to the community level. They demonstrated how the social and physical environment are affected by cultural, political, policy, and economic systems and in turn, influence community response, activation, and social support. In addition to the role of policy in shaping the social and physical environment, local, state, and Federal level policies also affect individual behavior and health care. Given the interrelationship between policymaking and the other health determinant described by Evans and Stoddart, it represents an additional important target for community-based interventions. Combining both Evans and Stoddart's model and the community framework created by Patrick and Wickizer provides an excellent structure for designing prevention strategies aimed at curbing prescription opioid abuse and overdose.

Prevention Strategies

Education is a crucial first step in addressing prescription opioid abuse and aims to change individual behavior. Parents and youth need to be better educated about the dangers of prescription drugs, specifically that they can be as dangerous as the use of illegal drugs. This education also includes the risks associated with sharing medications and proper storage and disposal. Proposed strategies include evidence-based education campaigns and the promotion and dissemination of public education materials to increase

awareness of prescription drug abuse by local anti-drug coalitions and other organizations (Office of National Drug Control Policy, 2011).

Healthcare provider education directed at prescribing practices and the management of CNCP is an important strategy to curb opioid abuse and misuse (ONDCP, 2011). Healthcare provider education also addresses individual behavior, as well as health care. Proposed strategies include mandatory training on responsible opioid prescribing for those who request DEA registration to prescribe controlled substances. Other recommendations include collaborating with appropriate medical boards to institute educational curricula in health professional schools and using continuing medical education programs to teach the safe and appropriate use of opioids (ONDCP, 2011). Evidence-based guidelines are needed for all medical specialties. Given that primary care providers and emergency department physicians are the gateway to the health care system and at the forefront of opioid prescribing, these evidence-based guidelines should start with these specialties.

As a way of addressing the health care and policy component of the determinants of health, the American College of Emergency Physicians, in consultation with the Center for Disease Control (CDC) and the Food and Drug Administration, developed a clinical policy aimed at addressing the critical issues in prescribing opioids to adult patients treated in the ED (Cantrill et al., 2012). The questions addressed in this policy are:

- (1) What is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse in the adult ED patient population with noncancer pain for whom opioid prescriptions are considered?

(2) Are prescriptions for opioids more effective during the acute phase than other medications in the adult ED patient with acute low back pain?

(3) Are short-acting schedule II opioids more effective than short-acting schedule III opioids in the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain?

(4) Do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms in the adult ED patient with an acute exacerbation of noncancer chronic pain?

Based on the available evidence-based medicine and consensus of panel members, this policy provides a focused examination of these issues that can be used as a guide while recognizing the importance of the individual physician's judgment.

Crucial to evidence-based guidelines is the use of screening for opioid abuse potential and monitoring for adherence. Although screening tools have not been fully validated in a variety of settings and populations, screening patients prior to beginning opioid therapy is considered good practice. The same issues are present for screening tools used to identify aberrant drug-related behavior in patients already on opioid therapy. Urine drug testing is considered one of the mainstays of adherence monitoring in conjunction with screening tools and prescription drug monitoring programs (discussed below). Despite evidence favoring the use of urine drug testing, this method is not routinely used in monitoring opioid therapy (Sehgal, Manchikanti, & Smith, 2012). An algorithmic approach to urine drug testing has been developed to aid in the integration of this method into adherence monitoring (Christo et al., 2011). Although opioid treatment agreements are both suggested and mandated by some states, evidence that they are

effective in reducing opioid abuse is weak. Observational studies showed a modest reduction in opioid misuse ranging from 7-23%, with and without urine drug testing (Starrels et al., 2010). Opioid treatment agreements have not been proven to improve adherence, enhance patient care, or protect the rights of patients or physicians (Sehgal et al., 2012). Both screening for opioid abuse and adherence and the use of opioid treatment agreements are examples of prevention efforts that address the health care component of the determinants of health.

Prescription drug monitoring programs (PDMP) are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs. PDMP are an important tool to help detect abuse and diversion and allow prescribers and pharmacists to identify high-risk patients who would benefit from early interventions. The CDC recommends that PDMP focus their resources on not only patients at highest risk, but also prescribers that clearly deviated from accepted medical practice in regards to their prescribing practices (CDC, 2012b). In 2005, the National All Schedules Prescription Electronic Reporting Act (NASPER) was signed into law, which required states to collect prescription information for Schedule II, III, and IV medications. The aim of this law was to encourage information sharing between states (Sehgal et al., 2012). This law significantly increased the number of states with physician-friendly PDMP. As of October 2012, 42 states have operational PDMP, but only Oklahoma has real-time reporting (Alliance of States with Prescription Monitoring Programs, 2012a; ASPMP, 2012b). Registration for access to PDMP databases is voluntary in all states except Arizona, Kentucky, Tennessee, Utah, and Vermont (Morgan, Weaver, Sayeed, & Orr, 2012).

Although evidence suggests that PDMP can play a critical role in helping to reduce opioid abuse, diversion, and overdose, further studies are necessary to elucidate its direct role in curbing the prescription opioid epidemic. In a 2010 prospective study of clinical records reviewed in Ohio's database, real-time access to PDMP changed practitioners' opioid prescription patterns in 41% of interactions, resulting in a decrease or no opioid prescriptions in 61% of queries and an increase in opioid prescriptions in 39% of queries (Baehren et al., 2010). This study demonstrates that the use of PDMP does not universally decrease the prescription of opioids. Additionally, Paulozzi et al. (2011) demonstrated that PDMP were not significantly associated with lower rates of opioid overdose or consumption of opioid drugs.

In conjunction with PDMP, state benefit programs (i.e. Medicaid), private insurance companies, and workers' compensation programs can provide restrictions that will lock a patient in with one medical provider. These "lock in" programs help prevent "doctor shopping" and reduce the inappropriate use of opioids. This concept includes limiting reimbursement claims to a designated doctor and pharmacy. Insurance company data can also help identify inappropriate use of certain opioids for certain diagnoses (CDC, 2012a). Both PDMP and "lock in" programs are examples of prevention strategies that also address policymaking and health care.

State laws regulating the distribution of controlled prescription drugs at for-profit pain clinics have been successful, but are limited. In Florida, 447 illegal pain clinics have been shut down in the last 2 years. Louisiana has instituted its own guidelines for pain clinics under a Pain Management Clinic Law and violations can result in a fine up to \$50,000 or a 5-year prison sentence. Florida and California both have legislation with stiff

penalties directed at physicians who over-prescribe opioids (Chakravarthy, Shah, & Lotfipour, 2012).

Effective and accessible substance abuse treatment programs can help address prescription opioid dependence and addiction and reduce overdoses in this population. To increase access, the Affordable Care Act requires coverage for substance abuse services by health insurance plans (ONDCP, n.d.). Expanding funding for substance abuse treatment is also mentioned in the Presidential report on the prescription drug abuse crisis (ONDCP, 2011). New legislation also exists that has increased accessibility to Naltrexone and buprenorphine (both medications used to treat opioid dependence) by both providers and patients (Chakravarthy et al., 2012). Naloxone is a safe, inexpensive opioid receptor antagonist that can reverse the respiratory depression caused by opioid overdoses via intramuscular injection or nasal spray. Multiple programs exist that distribute naloxone to opioid users and their friends and families in the United Kingdom, Italy, Germany, Australia, and the United States. Despite compelling findings of harm reduction and the successful implementation of programs around the world, objections still exist, and in the United States programs are limited and local (Bazazi, Nickolas, Zaller, Fu, & Rich, 2010).

The pharmaceutical industry is under growing pressure to develop abuse deterrent formulations of opioids. Some abuse deterrent formulations employ physical barriers that resist common methods of tampering like crushing and chemical manipulation to produce extracts that can be snorted or chewed. However, these methods do not decrease abuse in those who consume the drug intact. Opioid agonist and antagonist combinations have also been developed, but this combination decreases its efficacy in treating pain (Solanki et al., 2011). In February 2012, a new formulation of Opana ER (extended-release

hydromorphone) designed to inhibit crushing and dissolving tablets for snorting and injection, respectively, was released on the market. By the end of October 2012, fifteen cases of thrombotic thrombocytopenic purpura (TTP)-like illness were reported in Tennessee and later determined to be associated with dissolving and injecting tablets of Opana ER (CDC, 2013). TTP is a life-threatening blood disorder characterized by thrombosis in arterioles and capillaries in the setting of microangiopathic hemolytic anemia and thrombocytopenia (CDC, 2013).

The growth of prescription drug abuse as a public health problem has stimulated much discussion and legislation at the federal level that is supportive of these prevention strategies. In 2007, the Food and Drug Administration Amendments Act was passed, increasing the agency's authority over pre- and post-market drug safety. This Act required post-marketing studies and clinical trials, safety labeling changes, and Risk Evaluation and Mitigation Strategies (REMS). Their goal for opioid REMS was to reduce the adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of opioids while maintaining access (Maxwell, 2011).

In April of 2011, the Office of National Drug Control Policy, along with the Food and Drug Administration and the DEA, released a national action plan to fight prescription drug abuse entitled, "Epidemic: Responding to America's Prescription Drug Abuse Crisis" (ONDCP, 2011). The major goals of this plan are:

- (1) Expand awareness and education to physicians, researchers, and the public.
- (2) Expand efforts to ensure that all states have effective prescription drug monitoring programs
- (3) Increase the disposal of prescription drugs and prevent diversion

(4) Reduce doctor shopping and shut down pill mills or sites where practitioners illegally prescribe and dispense controlled substances

In support of this action plan, the FDA developed an opioid REMS which would require manufacturers of long-acting and extended-release opioids to provide educational programs to prescribers of these medications as well as materials prescribers can use when counseling patients about the risks and benefits of opioid use. This REMS was approved on July 9, 2012, and also included required assessment and auditing of REMS implementation by companies (U. S. Food and Drug Administration, 2012).

During the 112th Congressional session (January 1, 2010 to March 30, 2012), ten bills were introduced to offer a comprehensive solution to prescription opioid abuse. Table 1 summarizes these ten bills.

Table 1. Proposed Legislation Addressing Prescription Opioid Abuse (Phillips, 2012)

Number	Name	Provisions
H. R. 886	National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act of 2011	Amends the National All Schedules Prescription Electronic Reporting Act (NASPER) of 2005 to foster the establishment of state-administered controlled substance monitoring systems
S. 507	Prescription Drug Abuse and Treatment Act of 2011	Addresses prescription drug abuse-mandatory provider education, supporting public education on safe use and disposal of painkilling drugs, basic clinical guidelines for safe dosage and recognition of high-risk populations, increasing federal support

		for state prescription drug monitoring programs, and supporting comprehensive reporting of opioid deaths
H. R. 1925	Prescription Drug Abuse Prevention and Treatment Act of 2011	House companion bill identical to S. 507 bill
H. R. 1065	Pill Mill Crackdown Act of 2011	Amends the Controlled Substances Act to provide more penalties for pill mill operators, reclassifies hydrocodone combination drugs as Schedule II drugs, making them more difficult to prescribe and obtain
H. R. 1316	Stop Oxy Abuse Act of 2011	Directs the FDA Commissioner to approve drugs containing oxycodone to use for severe pain only vs. current use for moderate to severe pain
S. 882	STOP Act	Amends Medicaid of Social Security Act and Part D of Medicare to help prevent the misuse, overuse, and trafficking of prescription drugs by high-risk Medicaid and Medicare beneficiaries
H. R. 1266	Fraudulent Prescription Prevention Act of 2011	Amends the Controlled Substances Act to improve the detection of fraudulent abuse of controlled substances II and III
H. R. 2119	Ryan Creedon Act of 2011	Amends the Controlled Substances Act to require practitioners to obtain approved training/special certification on addiction to and abuse of controlled substances and appropriate and safe use of controlled substances II, III, IV, or V
S. 1251	Medicare and Medicaid FAST Act	Seeks to combat Medicare and Medicaid fraud and abuse by encouraging the

		establishment of state prescription drug monitoring programs and updating DEA databases of controlled substance providers
H. R. 3339	Medicare and Medicaid FAST Act	As above

Project Lazarus and Community Care of North Carolina

In response to some of the highest drug overdose death rates in the country, Project Lazarus developed a successful community-based overdose prevention program in Western North Carolina (Albert et al., 2011). Project Lazarus was initiated in Wilkes County, which is a county with a history of substance abuse, high unemployment rates, and with a labor force that is dependent on physically demanding jobs. The unintentional poisoning mortality rate in Wilkes County was quadruple that of North Carolina (46.6 vs. 11 per 100,000 in 2009) and due almost exclusively to prescription opioids. Those who were dying were using opioids for both medical and nonmedical reasons (Albert et al., 2011). The average age of death was in the late 30s, and decedents had considerable comorbid health conditions, including respiratory, circulatory, and metabolic disorders. More than half of the overdose deaths occurred in the home setting as a result of emergent medical care not being activated or activated too late (Albert et al., 2011).

Project Lazarus created a model for preventing opioid overdose deaths that included five components: community activation and coalition building, monitoring and surveillance data, prevention of overdoses, use of rescue medication for reversing overdose by community members, and evaluating project components. Other coalitions and

organizations involved in this initiative were the Substance Abuse Task Force from Wilkes Health Carolinians Council, Chronic Pain Initiative from Northwest Community Care Network, and Wilkes County Health Department (Albert et al., 2011). This model is based on prior research on community activation for health promotion suggesting the following organizations are important for successful public health campaigns: health departments, schools, governmental agencies, hospitals, primary care clinics, churches, newspapers, television stations, health-related nonprofit agencies, substance abuse treatment centers, and colleges (Van Kroff et al., 1992). The overdose prevention activities are outlined in Table 2. These activity components are drawn from successful public health campaigns in injury prevention and were developed by community coalitions.

Table 2. Activities and Timeline of Community-Based Prevention of Opioid Overdose in Project Lazarus (Albert et al., 2011)

Activity	Years of Operation
<i>Community organization and activation</i>	
Town hall meetings	2006-present
Specialized task forces	2005-present
Community-based leadership	2005-present
Coalition building	2005-present
“Managing Chronic Pain” tool kit assembled	2007-2008
<i>Prescriber education and behavior</i>	
One-on-one prescriber education on pain management	2008-2010
Continuing medical education sessions on pain management	2008-2010

Licensing actions against prescribers by state medical boards	2008
Promotion of controlled substances reports systems	2007-present
<i>Supply reduction and diversion control</i>	
Hospital ED opioid dispensing policy modified	2008-present
Unused medication take-back events by sheriff and police department	2009-present
Fixed medicine disposal sites at law enforcement offices	2011
Hiring and training of drug diversion specialized law enforcement officers	2009-present
<i>Pain patient services and drug delivery</i>	
Medicaid policy change: mandatory use of patient-prescriber agreements and pharmacy home	2010
Support groups for pain patients	2008-2009
ED case manager for Medicaid beneficiaries with chronic pain	2008-present
Vetting of local pain clinics and facilitation of specialized pain clinic referrals	2008
<i>Drug treatment and demand reduction</i>	
Drug detox program	2000-present
Negotiation and support for opening of satellite office-based treatment clinic (buprenorphine)	2009
<i>Harm reduction</i>	
Naloxone prescription	2010
<i>Community-based prevention education</i>	
School-based education, including pledge cards	2009-present
Red Ribbon campaign—warnings not to share attached to dispensed prescription packages	2010
Billboards containing messages against sharing medications	2010
Presentations at colleges, community forums, civic organizations, churches, etc.	2007-present
Radio and newspaper spots	2006-present

Due to this multifaceted intervention and the complex relationships that affect opioid overdoses at the community level, it is difficult to conclude the individual impact of each intervention. However, preliminary unadjusted data from Wilkes County suggests that the overdose death rate decreased from 43 per 100,000 in 2008 to 29 per 100,000 in 2010. Further evaluation demonstrated a 42% decrease in overdose deaths and stabilization in the number of opioid prescriptions in the three years after implementing Project Lazarus (Project Lazarus, 2013). Additionally, in 2011, not a single overdose death occurred in a patient receiving an opioid prescription from a Wilkes County prescriber (Albert et al., 2011). The all cause poisoning mortality rate per 100,000 decreased 69% from 2008 to 2011 and the hospital ED visits for substance abuse and overdose decreased by 15% from 2008 to 2010. Project Lazarus is now working in more than 30 counties and recently received \$2.5 million from the State of North Carolina and the Kate B. Reynolds Charitable Trust to take this program statewide (Project Lazarus, 2013).

Intimately tied to Project Lazarus, the Chronic Pain Initiative (CPI) is funded by Community Care of North Carolina (CCNC) and partners with the North Carolina Hospital Association, local hospitals and emergency departments, primary care doctors, faith-based programs, and law enforcement (CCNC, 2013). The CPI, modeled after Project Lazarus, is a set of inter-related programs designed to improve the medical care received by CNCP patients and reduce the misuse, abuse, potential for diversion, and overdose from opioid medications (Lancaster, 2012). The key clinical components are the Primary Care Physician Toolkit, the Emergency Department Toolkit, and the Care Management Toolkit (CCNC, 2013). The community focus is on educating on the danger of opioids, taking only ones own medications, and keeping medications in a safe place (Lancaster, 2012).

Important clinical and community-based components of the CPI include a focus on treating CNCP patients appropriately, encouraging the use of pain treatment agreements with CNCP patients, encouraging the use of the Controlled Substance Reporting System, and encouraging the assignment of a single pharmacy home for CNCP patient as a means to change individual behavior that may contribute to opioid abuse. Additional elements include ongoing case management for Medicaid patients with opioid prescriptions above threshold levels, case management for identified CNCP patients visiting the ED, and ED policies that restrict the dispensing of narcotics (Lancaster, 2012). The goal for the CPI is to provide a tool that would produce results similar to Project Lazarus on a statewide level.

Washington State's Opioid Dosing Guidelines

Washington State provides an additional example of a successful intervention aimed at addressing the increase in prescription opioid overdoses that began in the late 1990s. In 2006, the Agency Medical Director's Group, representing Washington's public payers (Medicaid, workers' compensation, corrections, health, and public employees) convened an advisory group of clinical and academic pain experts to develop an Interagency Guideline on Opioid Dosing. This guideline was introduced in 2007 as a web-based educational pilot. In addition to widely agreed upon best practices, these guidelines included a "yellow-flag" warning at an opioid dose of 120 mg/day morphine equivalents and a recommendation that prescribing providers seek consultation from a pain medicine expert for patients receiving opioid doses greater than 120 mg/day morphine equivalents (Franklin et al., 2012). In addition to these guidelines, the web-based tool provides two hours of free continuing medical education, use of a patient-prescriber agreement, and recommends judicious use of random urine drug screening.

In response to data suggesting that the majority of prescribers were not using all the best practices, patient questionnaires were added to the web resources (CDC, 2012a). Additionally, Washington State is focusing on improving access to pain specialists by developing a program to offer “pain proficiency” to primary care providers. The University of Washington has made twice-weekly pain consultations with specialist available (CDC, 2012a). In 2010, the Washington State legislature repealed the prior prescribing rules for opioids and instituted new rules reflective of these dosing guidelines (CDC, 2012a).

A study of opioid dosing for patients covered by the Labor and Industries program found that since the state implemented the prescribing guidelines in 2007, the percentage of workers receiving long-acting opioids has fallen by 27%. The proportion of patients that were prescribed doses of 120 mg/day morphine equivalents or more has fallen by 35%. Deaths linked to prescription opioids have also dropped 50% in 2010 (Franklin, 2012).

In conjunction with Washington’s dosing guidelines, Group Health, a Seattle-based non-profit health plan, implemented a multifaceted program addressing opioid prescribing in 2010. Group Health has more than 600,000 members in the Pacific Northwest, and through lean quality improvement techniques, was able to not only affect prescribing patterns, but also improve patient care (McCarthy, 2012). Their innovative strategy included a comprehensive guideline covering care and monitoring focused on single provider oversight, standardized care plans, early review and refill request, and monitoring and drug screens. Additional activities included online provider training, peer support for prescribers, EMR-based tools (treatment agreement forms, patient handouts, dose calculators), and financial incentives for care plans (Agency for Healthcare Research Quality, 2013).

Collaborative Leadership

The interventions used to address prescription opioid abuse in North Carolina and Washington State required strong public health leadership. Elements of both efforts point toward a collaborative leadership model. Collaborative leadership embraces a process in which people with differing views and perspectives come together, put aside their self-interests, and discuss issues openly and supportively in an attempt to solve a larger problem or achieve a broader goal and encourage systems change (Turning Point, 2006). This type of leadership has proven effective in public health planning where multiple stakeholders have an interest and when issues are so complex that no one person or entity has either the information or power to address these issues adequately (Work Group for Community Health and Development, 2013).

The six fundamental practices of collaborative leadership as identified by the Turning Point Leadership Development National Excellence Collaborative are assessing the environment, creating clarity, building trust and safety, sharing power and influence, developing people, and self-reflection (Turning Point, 2006). Assessing the environment refers to understanding the context for change before acting through recognizing other perspective, identifying beneficial change for all participants, setting priorities, and identifying barriers. Clarity is developed by creating a shared vision, helping others develop confidence to mobilize, providing guidance through ethical standards, and developing commitment to a cause. Creating a safe place for developing shared purpose and action hinges on communication skills and a trustworthy leader, and participants need to be empowered and goal focused to develop the synergy required to accomplish the goal. In order to develop people, their talents need to be maximized. Through mentoring and

power sharing, power can be build and some ownership can be relinquished (Turning Point, 2006). Finally, a collaborative leader needs to embody emotional intelligence.

Based on the fundamental practices of collaborative leadership, several advantages exist. Table 3 outlines both the advantages and difficulties of collaborative leadership.

Table 3. Advantages and Difficulties of Collaborative Leadership (WGCHD, 2013)

Advantages	Difficulties
Buy-in	Time-consuming
More involvement in implementation	Demands the ability to face conflict directly and mediate it to a resolution acceptable to all
Trust building	Need to overcome resistance to collaborative leadership
Elimination of turf issues	May lead groups down the a path that differs form the ideas of the leader
Access to more and better information and ideas	Leaders must subordinate their egos
Better opportunity for substantive results	
Generation of new leadership	
Community or organization empowerment	
Fundamental change for the better in the ways communities and organizations operate	

Timing is a key element in choosing to employ collaborative leadership.

Collaborative leadership is well suited when problems are complex and require the attention of diverse stakeholders with varied interests. When issues affect a whole community or when other attempts to find a solution have failed, this style of leadership can prove effective. Collaborative leadership yields itself to situations where inclusiveness

and empowerment are goals of the process. Additionally, developing collaborative leaders within a community contributes to the social capital of the public health community, which can be considered an essential element in public health infrastructure (Baker, 2000; Turnock, 2012).

Collaborative Leadership is an ideal method for guiding coalitions. Coalition building was an important component that contributed to the success of project Lazarus. Evidence suggests that coalitions may be useful in reducing the harm of prescription opioid abuse while improving access to pain medications. Counties with coalitions had a 6.2% lower rate of ED visits for substance abuse than counties with no coalitions, and this increased to 23% lower rates when the coalitions was lead by a health department. Despite lower rates of ED visits, 1.7% more residents received opioids in counties with coalitions. This data suggest that increasing coalitions ideally lead through collaborative leadership may have an important role in reducing prescription opioid harm (CCNC, 2013c).

Summary of Findings

For every one of the 14,800 prescription opioid deaths in 2008 nationwide, there were ten treatment admissions for abuse, 32 emergency department visits for misuse or abuse, 130 people who abused opioids or were dependent on them, and 825 nonmedical users (SAMHSA, 2010). Nonmedical use of prescription opioids represents a significant financial burden on health care, adding to an already staggering economic cost of CNCP and its associated risk of opioid abuse. Those affected by prescription opioid abuse exhibit a vast demographic profile, but the Medicaid population appears to be more at risk.

Today's epidemic of prescription opioid abuse is not unique to American history. Just as historical events precipitated this problem in the past, the present day situation can be linked to concerns about untreated pain in the 1990s. In response to this concern, JCAHO mandated new pain management standards, which likely contributed to increased nonmedical and legitimate use of opioids. Most prescription opioids involved in overdoses originate from prescriptions written by either primary care or emergency physicians, and these opioids are diverted after being dispensed.

The multifaceted arsenal of prevention strategies aimed at addressing prescription opioid abuse includes patient and provider education, the creation of evidence-based guideline for pain management, and implementation and utilization of state PDMP. Additional strategies include increased access to substance abuse treatment, expansion of take-home naloxone, and the creation of abuse deterrent drug formulations. State and federal policies are being developed that support these strategies. These prevention strategies encompass several of the determinants of health discussed by Evans and Stoddart and elaborated by Patrick and Wickizer including individual behavior, health care, social behavior, and policymaking. Some of the individual strategies address multiple determinants of health. For example, increasing access to substance abuse treatment address both health care and policymaking given the increased funding required for such efforts. Implementation and utilization of state PDMP also addressed both policymaking and health care given the role that health care provides play in employing PDMP.

The gravity of prescription opioid abuse had prompted the introduction of a number of bills during the 112th Congressional session that address PDMP, high-risk Medicaid and Medicare populations, prescriber training, and amendments to the Controlled Substance

Act. The Obama administration released a plan for addressing prescription drug abuse in April 2011 that focused on many of the prevention strategies discussed above, however, this plan falls short of adequately addressing multiple determinants of prescription opioid abuse.

Although the prevention strategies discussed show promise in curbing the prescription opioid epidemic, several concerns warrant mentioning. The practice of medicine by physicians has a strong historical foundation of autonomy. Mandated guidelines of care represent an erosion of that autonomy. This threat to autonomy, which is already being witnessed with pay for performance standards, has the potential to create strong resistance among the profession, especially in the setting of lacking evidence in regards to opioid prescribing and abuse prevention. The practice of medicine is variable and unpredictable, and creating a “one size fits all” guideline may not ultimately be in the best interest of all patients. PDMP show promise in addressing prescription opioid abuse, however, several studies have demonstrated little benefit. These systems are expensive to operate and maintain, and a continued revenue source is required for adequate functioning of a system that may not be producing the desired outcome.

Prescription opioid abuse is becoming more recognized as a problem in developing countries. At the same time, there is limited access to these medicines for legitimate medical use. Infrastructural and socio-political issues represent significant barriers to addressing this growing problem on an international level.

Washington State and North Carolina’s Project Lazarus and CCNC have demonstrated successful implementation of a multidimensional approach that addresses prescription opioid abuse and overdose, with the later focusing efforts at the community

level. The success of Project Lazarus relates to its focus on multiple determinants of prescription opioid abuse as described in Evans and Stoddart's framework and in the community level focus added by Patrick and Wickizer. For example, health care is addressed through the creation of drug detoxification programs and support of office-based drug treatment programs. Additionally, the interventions directed towards emergency department policies, pain patient services, and toolkits for managing chronic pain appropriately also address issues related to health care. Individual behavior is addressed through the community-based prevention education and provider education. As a community-based project, many strategies address the social environment, including community organization and activation, creating a police force with specialized law enforcement officers, providing support groups and case managers for pain patients, and providing naloxone to family and friend of those at high risk for overdose. Emergency department opioid prescribing policies and Medicaid "lock in" policies address an additional determinant of opioid abuse.

The initiatives that were implemented in Washington State predominantly addressed the policymaking element of the determinants of health through their opioid dosing guidelines and legislation. However, their success stemmed from the incorporation of other strategies that addressed the determinants of individual behavior and health care through provider education, pain treatment agreements, and drug testing. The social behavior within the medical profession was also addressed through improved collaboration with pain specialists.

The leadership within both projects shares similarities with collaborative leadership. Collaborative leadership provides a style of leadership that is conducive to

finding solutions to complex problems involving multiple stakeholders and whole communities, such as prescription opioid abuse. Collaboration between the Substance Abuse Task Force of Wilkes Health Carolinians Council, the CPI of Northwest Community Care Network, the Wilkes County Health Department, and Project Lazarus created a common purpose and citizenship that facilitated a successful community-based health improvement process. Through this collaborative leadership that was based in community coalition building, Project Lazarus was able to devise “bottom up” interventions that leveraged existing resources and raised awareness and funds for new programs. As a secondary gain, this collaborative leadership also helped build the public health infrastructure within the community.

Conclusion and Recommendations

There is no doubt that prescription opioid abuse has reached epidemic proportions in the United States and constitutes an important and emerging public health problem. Although a theoretical distinction exists between those who use prescription opioids for nonmedical reasons and those who require them for CNCP, delineating these two groups is an exercise in futility, which may prevent the success of interventions aimed at curbing abuse. Creating a distinction may block those most at risk of overdoses from receiving prevention messages and appropriate interventions. Addressing both the CNCP element and the abuse and dependency element of prescription opioid use is imperative given their intimate relationship. Curbing prescription opioid abuse must be accomplished while at the same time ensuring access to prescription opioids for legitimate use.

Given the breadth of this problem, several Healthy People and Healthy North Carolina 2020 objectives address prescription opioid use and abuse. Medical Product

Safety (MPS) Objective 2 aims to increase the safe and effective treatment of pain. MPS 2.1, MPS 2.3, and MPS 2.4 are all developmental objective with goals to reduce the proportion of patients suffering from untreated pain due to a lack of access to pain treatment, reduce serious injuries from the use of pain medicines, and reduce the deaths from the use of pain medications, respectively (U. S. Department of Health and Human Services, 2012b). Injury Prevention Objective 9 and 10 aim to prevent an increase in poisoning deaths and prevent an increase in nonfatal poisonings (USDHHS, 2012a). Reducing the unintentional poisoning mortality rate is also one of Healthy North Carolina 2020's key performance indicators (North Carolina Department of Health and Human Services, 2013). Both Healthy People 2020 and Healthy North Carolina 2020 provide an objective setting process aimed at mobilizing federal and state stakeholders towards a common goal. A foundation for monitoring and evaluating health improvement programs is set but falls short in directly addressing prescription opioid abuse. Although addressed more comprehensively with developmental objectives on a federal level, states need to ensure that objectives aimed at addressing prescription opioid abuse are explicitly stated in their public health agendas to provide the publicity needed to guide community-based prevention efforts.

Multiple prevention strategies are discussed in this paper. Many of these strategies lack clear and strong evidence to link them to a decrease in opioid abuse or overdose. However, they do provide a collection of promising practices. This issue is further complicated by a lack of accurate and available information. In order to respond effectively to the increase in prescription opioids abuse, more thorough data needs to be easily available, specifically related to prescribing and contextual factors. Further breaking down hospital and mortality data into opioid-specific causes would be helpful but would require

modifying the current ICD-10 coding system or exhaustive record reviews and abstraction projects. This data would be helpful in determining local trends of abuse and help guide intervention development and implementation. The current limits in data collection also prevent the development of objectives and indicators aimed specifically at the elements of prescription opioid abuse.

Pain is a subjective phenomenon. Although the current evaluation tools, questionnaires, and scales attempt to translate this subjective experience into an objective answer, they fall short due to the complex and idiosyncratic nature of pain. This characteristic of pain also makes it difficult to draw a distinction between those who use prescription opioids as prescribed for pain and those who use them for nonmedical reasons. Thus, researching pain as it relates to opioid uses and abuse is challenging. Continued research is needed in both neurotechnology and other fields to develop better tools for measuring pain while keeping in mind individuality and the limitation of these tools. Despite evidence suggesting that diversion plays a large role in opioid overdoses, more evidence is need, especially in the setting of increases in CNCP given the opioid tolerance experienced by this population.

PDMP have not been as successful as anticipated in preventing prescription opioid abuse or mortality. Limited use by prescribers due to a lack of real-time reporting and difficulty in use, as well as poor state support and lack of universality across states, has likely contributed to its marginal success. Mandatory registration of all prescribers seeking licensure, implementation and improvement of real-time reporting, and federal support of an interstate reporting platform can improve the effectiveness of this prevention strategy.

Provider education is a prevention strategy that has been universally discussed as a way to combat the prescription opioid epidemic. These education strategies focus on appropriate prescribing based on evidence-based guidelines, screening for addiction potential, and monitoring for abuse. However, there is limited information regarding physician burnout as it relates to the increased responsibility in managing CNCP that falls upon primary care physicians. As a result of the complexities associated with managing CNCP, many primary care physicians are opting to defer pain management to specialists. In many rural communities where prescription opioid abuse is a significant problem, access to these specialists may be limited or non-existent, especially to the Medicaid population. Additionally, these specialists may provide care that is limited to the procedural rather than medical management of pain. These issues need to be addressed to maintain the workforce necessary for the appropriate treatment of CNCP and decrease in prescription opioid abuse. The creation of a multifaceted program similar to the one implemented by Group Health in the Pacific Northwest is one step that can help address physician satisfaction while also addressing patient satisfaction.

Significant strides are being made at the national and state level to curb prescription opioid abuse. Legislation provides an excellent foundation for addressing this issue, but given the regional variation of opioid abuse and the unique qualities and attitudes within a community, prevention strategies are best suited to be applied at the community level. Project Lazarus and Community Care of North Carolina provide an example of a successful community-based intervention aimed at decreasing the number of overdose deaths from prescription opioids by addressing virtually all the prevention strategies discussed in the paper. This case study also adds credence to the importance of a multifaceted approach.

Implementation of only one or two strategies alone will not have the breadth to successfully address this problem.

Evans and Stoddart's framework helps identify several determinants of prescription opioid abuse that are not addressed in Project Lazarus. People with mental illness are over-represented in both those who are prescribed opioids and those who overdose on opioids, and both mental health care and even the built environment that contributes to mental illness should be considered in future interventions. In many of the rural communities most affected by the prescription opioid epidemic, mental health services are marginal and must be bolstered independently from substance abuse treatment programs in order to combat prescription opioid abuse. Social behavior is the health determinant that is not adequately addressed by the prevention strategies discussed in this paper. Project Lazarus does address some elements of social behavior at a community level, but socioeconomic conditions, educational opportunities and living wages are not addressed. Prescription opioid abuse is more prevalent in the rural poor, and although economic structure is largely shaped at the global and federal level, improving local economies will likely positively affect this epidemic.

As with any intervention, unintended consequence must be considered. Specifically, pain needs to be treated. If interventions aimed at addressing prescription opioid abuse create a system that makes opioid prescribing too difficult for prescribers, pain will be undertreated and these individuals may choose to obtain opioids illegally.

Although prescription opioid abuse is considered a problem of the developed world, it is becoming more recognized in developing countries. Epidemiological data is lacking and the exact extent of the problem worldwide remains unknown. Governments need to

take action to address the nonmedical use of opioids through the creation of infrastructure to support the collection of epidemiological data. These countries must also construct legislation that balances the control of substance abuse and access to essential opioid analgesics necessary for achieving and maintaining a good quality of life. In order for public health to address both the excessive consumption of prescription opioids in the United States as well as the paucity of availability in developing countries, efforts should be focused on the control of opioid demand rather than supply (“Non-medical Use,” 2011). The concept of “One World” rings true even for prescription opioid abuse, and public health professionals need to add this problem to the global agenda.

The strategies and legislation aimed at combating the prescription opioid epidemic are present and growing. Data demonstrating the seriousness of the problem are available, and although incomplete, likely underestimates the extent of the epidemic. Successful implementation of a multifaceted, community-based intervention that addresses multiple determinants of prescription opioid abuse has been demonstrated and should be replicated. Public health leaders, in collaboration with community leaders, need to step forward and make this issue a community priority. Once identified, collaborative leadership provides an ideal strategy for addressing the complex issue of prescription opioid abuse on a community level in a “bottom up” fashion to create sustainability. These programs need to be continuously evaluated and expanded in order to make continued strides. Although a national epidemic, community mobilization and action is necessary and required to successfully curb the epidemic of prescription opioid abuse.

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