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Laurie Geddes

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Exploring the Opioid Epidemic: Barriers to Adequate Patient Care

Laurie Geddes

University Of North Dakota

Abstract

With current evidence supporting the continued rise in morbidity and mortality rates related to the nonmedical use of opioid pain relievers and the proven safety and efficacy of the use of buprenorphine/naloxone for the treatment of opioid use disorders, the lack of patients receiving adequate patient care indicates the presence of multi-level barriers that contribute to this major public health concern. The purpose of this study was to comprehensively review the literature and examine potential barriers to treatment for patients with opioid use disorders. Articles were included if they were English-language studies, peer-reviewed journals, and published between 2002 and 2016. A total of 15 articles were examined, including 2 related to prevalence, 3 related to morbidity and mortality rates, 4 related to treatment recommendations, and 6 related to barriers to treatment, including physician supply, limitations of the Drug Addiction Treatment Act of 2000, and perceived barriers to implementing access to buprenorphine/naloxone for the treatment of opioid use disorders. Findings from the review indicate that a variety of barriers exist including lack of physician supply to meet patient demand, lack of supportive resources for providers and patients, lack of administrative support within the clinic setting to treat patients with opioid use disorder, and generalized stigma surrounding co-occurring disorders. These findings support the need for policy changes at the state and local government level, practice changes within primary care settings, educational changes that aim to increase knowledge and awareness of the current opioid epidemic, and changes to the current perception of substance use disorders to minimize stigma. By implementing strategies to eliminate these barriers, we will begin to address the current opioid epidemic and provide patients with treatment consistent with other chronic health conditions.

Exploring the Opioid Epidemic: Barriers to Adequate Patient Care

In 1999, when adequate pain management received national attention, the US Joint Commission initiated the assessment of pain during all clinical encounters and introduced pain as the fifth vital sign (Mularski et al., 2006). This led to an increase in use of opioid pain relievers, resulting in quadrupled sales by 2010 (Hasegawa, Brown, Tsugawa, & Camargo, 2014). With an increase in accessibility, the non-medical use of opioid pain relievers grew from 11 million to 12.5 million people in the United States alone (Meyer, Patel, Rattana, Quock, & Mody, 2014). In a survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), non-medical use of opioid pain relievers is the second most prevalent type of drug abuse, after marijuana (Meyer et al., 2014).

The continued rise of opioid use has led to an increase in prevalence of opioid use disorder (OUD) and greater risk for morbidity and mortality. According to Knudsen (2015), over 2 million Americans meet criteria for OUD in a given year. This has led to an increase in emergency room visits from 82.5 per 100,000 in 2004 to 184.1 per 100,000 in 2011 and deaths involving opioid pain relievers more than tripled from 1.4 per 100,000 in 1999 to 5.1 per 100,000 in 2013 (Han, Compton, Jones, & Cai, 2015). These statistics highlight the significance of this public health concern and support the need for improved treatments for OUD. Although buprenorphine/naloxone, a partial agonist medication, is highly effective for the treatment of OUD and dramatically reduces morbidity and mortality, “the demand for treatment remains consistently above available capacity in many areas of the country” (Sigmon, 2015, p. 32).

In 2000, The Drug Addiction Treatment Act (DATA) initiated a certification process that enabled qualifying physicians to receive a waiver to prescribe buprenorphine/naloxone for the treatment of OUD. Despite its efficacy, few physicians use this clinical tool and report a wide

range of barriers that have dissuaded them from prescribing buprenorphine/naloxone (Hutchinson, Catlin, Andrilla, Baldwin, & Rosenblatt, 2014). Exploring the barriers that prevent patients with OUD from receiving adequate patient care may promote a greater understanding, discussion, and collaboration among providers to improve access to care and greatly reduce morbidity and mortality related to OUD.

Purpose

With the initiation of DATA, the proven efficacy of buprenorphine/naloxone for the treatment of OUD, and the concern that the United States has reached epidemic proportions for opioid abuse and dependence, concerns persist about the underutilization and limited availability of this particular treatment. Patients are often placed on extensive waitlists to enter treatment or continue maintenance therapy following discharge from an inpatient treatment program. During this delay in treatment, patients are at greater risk for continued substance use, criminal activity, infectious disease, overdose, and mortality (Sigmon, 2015).

The purpose of this research paper is to explore potential barriers that may contribute to patients with OUD from receiving adequate patient care. Identifying the barriers will create awareness and dialogue about clinical changes that would aim to improve the quality of care for individuals and policy changes that would aim to improve the quality of care for communities as a whole. The results of this research project will be presented to peers within the psychiatric mental health nurse practitioner track to increase knowledge of the barriers related to adequate care for patients with OUD. By increasing awareness, providers within the field of psychiatry and co-occurring disorders may be influence the initiation of change, positively contribute to the opioid epidemic, and greatly reduce morbidity and mortality rates related to OUD.

Significance

The increase in prevalence of OUD and the lack of access to adequate patient care indicates the significance of the problem. According to Meyer et al., (2014), 12.2 million people reported using opioid pain relievers non-medically for the first time within the past 12 months while treatment admission rates for individuals with OUD increased 414% between 2002 and 2007. This has led to a growing clinical and economic burden associated with prescription opioid abuse.

The unintentional opioid overdose deaths within the United States rose 124% between 1999 and 2007, while the Center for Disease Control and Prevention (CDC) reported that opioid-related deaths tripled between 1999 and 2009 (Meyer et al., 2014). To highlight the continued rise in opioid-related deaths, the National Center for Health Statistics reported in 2012 that more drug-related deaths occurred as a result of opioid pain relievers than any other drugs, including heroin and cocaine (Meyer et al., 2014). This increase in unintentional deaths related to overdose fundamentally contributes to the clinical burden that remains evident.

Prescription opioid abuse creates a substantial cost to society and was estimated at \$55.7 billion in 2007 (Meyer et al., 2014). Factors that contribute to the economic burden include health care costs, criminal justice costs, and workplace costs. According to Hasegawa et al., (2014) emergency department (ED) visits related to opioid overdose increased 183% from 2004 to 2011, leading to an increase in hospitalizations related to opioid overdose, resulting in direct medical costs of \$1.3 billion. The increase in ED visits for opioid overdose represent a failure of treatment and are considered preventable through changes in long-term management of OUD.

The DATA permits qualifying physicians to obtain a special waiver to prescribe buprenorphine/naloxone for the treatment of OUD. Despite its efficacy, only 2.2% of American physicians have obtained the waiver, 90.4% of which report practicing in urban counties, leaving 53.4% of US counties without access to a provider that is certified to treat patients with OUD (Rosenblatt, Andrilla, Catlin, & Larson, 2015). Gaining insight into specific barriers that directly impact access to buprenorphine/naloxone treatment, may promote the implementation of supportive resources for providers, the commitment of institutions to address the opioid epidemic, and policy changes that would grant prescribing authority to other health care professionals.

Theoretical Framework

Nancy Milio, a nurse leader in public health policy and public health education, developed a theoretical framework of prevention in the 1960's that focused on community-oriented, population focused care. The framework states that behavioral patterns of populations and individuals who make up populations are a result of habitual selection from limited options. It describes neglected areas of community health care to determine areas in need for improvement that can be used to influence public policy (Current Nursing website, 2013). There are four levels of prevention; primordial, primary, secondary, and tertiary. This framework was developed to influence public health practices and aims to maintain health and prevent disease or injury to populations as a whole. The concepts within the theoretical framework of prevention highlight that history of disease is on a continuum with health at one end and advanced disease at the other and that three levels of prevention can be used to promote health and arrest the disease process at different points along the continuum.

The different levels aim to intervene at different points along the continuum. Primordial prevention aims to prevent the emergence of a disease or development of risk factors in populations where the disease is not yet present. Primary prevention aims to intervene before the onset of disease and focuses on encouraging communities to achieve an acceptable level of health and maintain that. Secondary prevention aims to intervene after the disease has become evident, halt progression of the disease, and prevent further complications from occurring. Tertiary prevention aims reduce impairment, minimize further suffering, and promote health for the patient as they adjust to the realities of the chronic illness (Current Nursing website, 2013).

When viewed as a potential solution to the problem, Milio's theoretical framework of prevention can be used to guide the exploration into potential barriers for populations with OUD while ensuring they have access to adequate patient care. As barriers become evident, clinical changes, institutional changes, and policy changes can be initiated to prevent the continued rise of morbidity and mortality rates among this vulnerable population. By increasing access to buprenorphine/naloxone for patients with OUD, secondary and tertiary prevention strategies are being implemented to minimize and prevent further complications as a result of this chronic illness.

Definitions

Nonmedical- An intervention not guided by medical theory or practice.

Opioid use disorder- A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period: 1) Opioids are often taken in larger amounts or over a longer period of time than was intended. 2) There is a persistent desire or unsuccessful efforts to cut down or control opioid use. 3) A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or

recover from its effects. 4) Craving, or a strong desire or urge to use opioid. 5) Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home. 6) Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. 7) Important social, occupational, or recreational activities are given up or reduced because of opioid use. 8) Recurrent opioid use in situations in which it is physically hazardous. 9) Continued opioid use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance. 10) Tolerance as defined by either of the following: a) A need for markedly increased amounts of opioids to achieve intoxication or desired effect, b) A markedly diminished effect with continued use of the same amount of an opioid. 11) Withdrawal, as manifested by either of the following: a) The characteristic opioid withdrawal syndrome, b) Opioids are taken to relieve or avoid withdrawal symptoms (American Psychiatric Association [APA], 2013).

Buprenorphine/Naloxone- A combination drug formulation of buprenorphine, an opioid receptor partial agonist, and naloxone, an opioid receptor silent antagonist, in a 4:1 ratio that is used to treat opioid use disorders.

Epidemic- When the negative effects of a health condition spreads rapidly among a large population of people.

Waivered Physicians- Qualified physicians who have completed the training and obtained the waiver to prescribe buprenorphine.

Interim Treatment- A temporary treatment for OUD, using medication alone, without accompanying psychosocial services.

Illicit Opioid Use- Use of opioid pain relievers that is not permitted or authorized.

Taper Therapy- A medical therapy that is designed to slowly decrease the dose of buprenorphine/naloxone to avoid severe withdrawal symptoms that may lead to illicit drug use.

Maintenance Therapy- A medical therapy that is designed to help a primary treatment, such as the use of buprenorphine/naloxone, succeed.

Abstinence- Restraining from the illicit use of opioid pain relievers.

Rural Opioid Addiction Management Project- a project established in 2009 in Washington State to address the opioid epidemic.

Narcan Kit- An injection of naloxone hydrochloride used to counteract and reverse the effects of an opioid related overdose.

Review of the Literature

Using data from the National Surveys on Drug Use and Health (NSDUH), which was conducted by SAMHSA from 2003-2013, Han, Compton, Jones, & Cai (2015), conducted a trend analysis and examined national trends specific to nonmedical use of opioid pain relievers, trends specific to opioid use disorders, and trends related to mortality rates among patients with OUD. Participants included adults between the ages of 18-64 years old who willingly participated in the survey collection. Persons who were homeless, active in the military, or institutionalized were not included in the survey. The annual response rate of the 2003-2013 survey was 66.3% and the sample consisted of 472,200 participants.

Additional data was examined from the Multiple Cause of Death Files from the National Vital Statistics System from 2003-2013. Overdose deaths related to opioid pain relievers were assigned specific ICD-10 codes and were limited to adults between the ages of 18-64 years old. Prevalence data focused on a 12-month period and was defined by the NSDUH as “the nonmedical use of opioid pain relievers within the past 12 months without a prescription or

obtained with a prescription but used simply for the feeling caused by opioids (Han et al., 2015, p. 1469).” Participants who reported use of nonmedical use of opioid pain relievers were asked to state the number of days they used opioids. Han et al., (2015) defined frequent users as those who reported using 100 days or more of nonmedical use of opioid pain relievers within the past 12 months, while high frequent users were defined as participants who reported using 200 days or more within the past 12 months.

The results of this study highlighted some interesting statistics. Surprisingly, the 12-month prevalence of nonmedical use of opioid pain relievers decreased from 5.4% in 2003 to 4.9% in 2013. However, the 12-month prevalence of OUD among users, increased from 11.9% in 2003 to 17.8% in 2013 and the 12-month prevalence of high frequency use among users increased from 5.0% in 2003 to 8.2% in 2013. These statistics would support the increase in overdose death rates related to the use of opioid pain relievers which was found to jump from 4.5 per 100,000 in 2003 to 7.8 per 100,000 in 2013 (Han et al., 2015). Although this data displays a decrease in prevalence of nonmedical use of opioid pain relievers, the increase in prevalence of high-frequency use and opioid use disorders among users highlights the severity of the problem and warrants the concern as a major public health issue.

A similar study conducted by Wang, Becker, and Fiellin (2013) examined data specific to prevalence rates of nonmedical use of opioid pain relievers among urban and rural residents. Using the NSDUH from 2008-2009 and limiting the sample to participants ages 18 and older, 75,964 residents contributed to the data collection, with 16.6% of the sample residing in rural counties. The prevalence rate of nonmedical use of opioid pain relievers among residents in urban and rural counties were similar with 4.7% noted among urban residents and 4.3% noted among rural residents. This is important to note as research specific to the distribution of

physicians across U.S counties that are trained to treat OUD, found that waived physicians are highly concentrated in urban counties leaving any rural communities without access to treatment for OUD.

These types of studies have some limitations. The NSDUH is a self-report survey and is subject to recall bias. However, the survey items are administered using computer-assisted self-interviewing to maximize validity, have been evaluated extensively, and refined multiple times for accuracy and reproducibility. The actual prevalence rates may underestimate true prevalence rates with the exclusion of participants who were institutionalized, homeless, or active military members. We know that substance use disorders are more prevalent among people with co-occurring mental health disorders and that individuals who were excluded due to the above mentioned criteria are known to have higher prevalence rates of mental health disorders. In addition, prevalence rates may have been underestimated due to the fact that participants voluntarily completed the survey. However, participants were compensated for completing the survey which may have improved the number of people willing to participate (Wang, Becker, & Fiellin, 2013).

In order to highlight the severity of the problem, 3 articles were reviewed to examine the clinical burden and the increase in mortality related to the nonmedical use of opioid pain relievers. A review of the literature conducted by Meyer et al., (2014), was conducted to gain a better understanding of the clinical and economic burden of prescription opioid use. Articles were limited to a date range between 2002 and 2012 and included all articles specific to opioid abuse, overdose deaths, quality of life, health care utilization, and overall costs. This inclusion criteria generated 23 articles for review and included 4 reports, 5 retrospective studies, 1 observational study, 1 trend analysis, 4 claims analyses, 1 literature review, 1 longitudinal study,

1 historical case control study, 4 cost studies, and 1 cost and utilization study (Meyer et al., 2014). One study reported overdose-related deaths as a result of nonmedical use of opioid pain relievers increased from 37% in 2002 to 41% in 2008 while another study reported a 129.2% increase in deaths related to opioid overdose between 1999 and 2002. Interestingly, while a study showed that only 10% of patients are prescribed high doses of opioid pain relievers, these patients accounted for 40% of the deaths related to overdose (Meyer et al., 2014).

In a retrospective cohort study conducted by Hasegawa et al., (2014), data was collected using the Healthcare Cost and Utilization Project (HCUP), State Emergency Department Databases (SEDD), and State Inpatient Databases (SID) from California and Florida in 2010 and 2011. Frequency of emergency department (ED) visits related to the nonmedical use of opioid pain relievers were examined over a 12-month period for 19,831 adult patients ages 18 years and older. Examination of data sets measured the frequency of ED visits, hospitalizations, near-fatal events, in-hospital mortality, and charges of service for opioid overdose. Results indicated that 7% of patients had frequent ED visits and accounted for 15% of all ED visits for opioid overdose. In addition, 53% of the ED visits resulted in hospitalization and 10% led to a near-fatal event. These statistics align with the results from Meyer et al., (2014) which highlights an increase in resource utilization among patients with a history of nonmedical use of opioid pain relievers. According to the Drug Abuse Warning Network (DAWN), the number of ED visits involving nonmedical use of opioid pain relievers increased 183% from 2004 to 2011 and patients who overuse opioid pain relievers were found to be 4 times more likely to use the ED, 11 times more likely to have a co-occurring mental health diagnosis, and 12 times more likely to require inpatient hospitalization related to a near-fatal event (Meyer et al., 2014). These statistics

directly impact the \$1.3 billion cost of healthcare examined by Hasegawa et al., (2014) as a result of the increase in resource utilization among this population.

A final report that highlights an increase in morbidity and mortality related to the use of nonmedical opioid pain relievers specifically from 2013 to 2014 was written by Rudd, Aleshire, Zibbell, and Gladden (2016). Examining the National Vital Statistics System multiple cause-of-death mortality files, special attention was paid to deaths classified as a drug overdose using the *International Classification of Disease, Tenth Revision* (ICD-10). In 2014, 47,055 deaths occurred as a result of a drug overdose, with 61% of those involving some type of opioid, including heroin. This data indicates a 14% increase in overdose death related to opioid pain relievers within a 12-month period, from 2013-2014. This highlights the continued rise in mortality rates related to nonmedical use of opioid pain relievers and supports the concern that we are currently experiencing an epidemic.

Several limitations were noted in the literature review and the retrospective cohort study. The review that examined clinical and economic burden included studies and reports varying in quality. Although every attempt was made to ensure high quality studies were used, some reports included a discussion on the topic of opioid use. In addition, the use of *International Classification of Diseases, Ninth Revision* (ICD-9) codes for opioid abuse are often not utilized, which may lead to underreporting of true prevalence rates of opioid use disorders in a given population. In contrast, the clinical and economic burden of opioid use on the health care system and payers from the government and private sectors, indicates the magnitude of costs and impact sustained to treat patients with OUD.

The retrospective cohort study examined administrative data, which can lead to potential errors in documentation and misclassification of patient encounters. In addition, only patients

with overdose codes used in the primary or secondary diagnosis fields were used, which may have led to an underestimated rate of actual opioid overdose encounters. Although the data was not obtained from a random sample of the entire nation, California and Florida are diverse states and the data obtained from ED visits and hospitalizations within these two states account for nearly 18% of US adults. This data related to age, race, and ethnicity associated with opioid overdose mirrored a national study of ED visits supporting its findings to be generalized nationally (Hasegawa et al., 2014).

With the evidence highlighting the increase in morbidity and mortality related to opioid abuse, 4 articles were reviewed that focused on treatment recommendations for patients with OUD. A systematic review conducted by Mattick, Breen, and Davoli, (2014) included 31 randomized controlled trials of buprenorphine maintenance treatment versus placebo or methadone in management of patients with OUD. An additional randomized clinical trial conducted by Fiellin et al., (2014) was completed to determine the efficacy of a buprenorphine taper versus ongoing maintenance therapy in the primary care setting for patients with OUD. The systematic review, which included 31 studies, yielded 5,430 participants and generated a variety of high to moderate quality studies. The evidence indicated that buprenorphine was superior to placebo medication in retention of participants in treatment and that high dose buprenorphine (greater than or equal to 16mg) was more effective than placebo in suppressing illicit opioid use. In contrast, low dose and medium dose (less than 16mg) buprenorphine did not suppress illicit opioid use in participants. Both buprenorphine and methadone produced similar results related to retention and suppression of illicit drug use at moderate (8-16mg) and high doses. In contrast, low dose methadone produced greater results related to retention than participants on low dose buprenorphine (2-8mg). This data is consistent with the results from the

randomized clinical trial conducted by Fiellin et al., (2014). This study included 113 patients randomly assigned to buprenorphine taper or buprenorphine maintenance therapy within the primary care setting. Patients assigned to the taper therapy were stabilized for six weeks, tapered for 3 weeks, and offered naltrexone for maintenance therapy. Patients assigned to the maintenance therapy received ongoing buprenorphine therapy for the 14-week trial, and all patients were monitored with urinalysis for illicit opioid use. Results indicated that patients in the buprenorphine taper group displayed a higher percentage of positive urinalysis indicating higher incidence of illicit opioid use during treatment. In addition, patients in the taper group had fewer weeks of consecutive abstinence compared to those in the maintenance group. This parallels the results from the systematic review by indicating that patients who maintain a steady state of buprenorphine are more likely to maintain abstinence from illicit opioid use.

Although the limitations of this study include the fact that the participating physicians had more experience with addiction medicine and the use of buprenorphine, and that the primary care setting had on-site drug counseling available, which is not standard in the majority of primary care clinics, the results do highlight the efficacy of the use of buprenorphine for the treatment of OUD. In addition, the knowledge of the physicians as well as the access to supportive resources, such as counseling indicates the value of increased training for the use of buprenorphine and increased access to additional services for patients receiving treatment for OUD.

A systematic review conducted by Sigmon (2015) evaluated the use of interim treatment for patients with OUD who are on a waiting list to enter a traditional treatment program. A search was conducted and inclusion criteria included the interim use of methadone or buprenorphine for patients awaiting entry into a comprehensive treatment program, only peer-

reviewed journals, randomization, and a research design where treatment effects would be attributed to the interim condition. Four randomized controlled trials were used to evaluate the use of interim treatment and found that patients who received methadone or buprenorphine while awaiting entry into a treatment program were more likely to maintain abstinence from illicit opioid use at 1-month follow-up and 4-month follow up. In addition, patients who participated in interim treatment were more likely to enter a traditional treatment program than the control group and were retained longer in the treatment program than the control group. The results from this review add to the growing knowledge base that the use of medications like buprenorphine consistently display high efficacy rates for the treatment of OUD.

A clinical consultation article written by Boothby and Doering, (2007) reviewed the clinical issues surrounding the use of buprenorphine for the treatment of OUD. The dosing and administration of buprenorphine was reviewed based on relevance to this paper and the results from 3 clinical trials indicated that the recommended target dose for buprenorphine is 16mg daily. The clinical trials used to support this recommendation date back to 1992, 1998, and 2000, indicating that research has supported the use of buprenorphine for the treatment of OUD for over 20 years. With the knowledge of the efficacy of buprenorphine over the past two decades, the continued rise in morbidity and mortality related to OUD indicates that barriers exist related to access to recommended treatment for patients with OUD.

To gain a better understanding of the potential barriers, 6 articles were reviewed that focused specifically on identification of barriers that may be contributing to the current opioid epidemic. Two articles focused on the supply and distribution of physicians who obtained the waiver, two articles focused on limitations of the DATA of 200, and two articles examined reported barriers from primary care providers prescribing buprenorphine.

Two articles were reviewed that examined the supply and distribution of physicians waived to prescribe buprenorphine for the treatment of OUD. In a retrospective cohort study conducted by Knudsen (2015), data was integrated using secondary sources to examine state-level variation in the supply of waived physicians who are authorized to prescribe buprenorphine. Data regarding waived physicians was purchased, and the independent variables were publicly available from the Henry J. Kaiser Family Foundation, the U.S. Census Bureau, the Center for Disease and Control (CDC), and SAMHSA (Knudsen, 2015). Independent variables explored included political control at the state level, demographic composition of each state, physician supply, demand for opioid treatment, and geographic region. The U.S. Drug Enforcement Agency maintains the Controlled Substances Act (CSA) registrants database and in 2013, 23,629 physicians in the U.S. held the waiver to prescribe buprenorphine. This study revealed that physician supply varied considerably between states and that geographic location was found to contribute to the most variance. Northeastern states had a greater supply of waived physicians compared to other regions, yet are geographically smaller, suggesting a higher concentration of physicians in that region. Interestingly, buprenorphine physician supply was greater in states under Democratic political control compared to states under Republican control highlighting the continued differences in beliefs regarding the role of the state in providing social services. States with a larger overall supply of physicians were associated with a higher rate of waived physicians indicating that physician supply was positively associated with access to a physician waived to treat OUD. States with higher overdose rates were also positively associated with waived physicians indicating that some providers may have experienced the burden of the opioid epidemic first-hand influencing their decision to obtain a waiver to treat OUD.

A retrospective cohort study conducted by Rosenblatt et al., (2015) examined the geographic and specialty distribution of U.S. physicians trained to treat OUD. Using the July 2012 DEA DATA waived physician list and determining the providers age, specialty, rural-urban status, and location, physicians were mapped to examine their supply for all U.S. counties. Results from this study indicated that only 2.2% of all U.S physicians obtained a waiver to prescribe buprenorphine. Within that 2.2%, 41% of all physicians who obtained a waiver were psychiatrists and practiced primarily in urban areas, while only 3.6% were family practice physicians. The most alarming statistic found that 90.4% of these physicians were practicing in urban counties, which leaves 53.4% of U.S. counties without access to a physician with a DEA DATA waiver, ultimately denying patients with OUD who reside in any of those counties, access to the recommended treatment.

Two articles reviewed, analyzed the Drug Addiction Treatment Act of 2000 to explore potential barriers that may contribute to the underutilization of buprenorphine as a new treatment modality. O'Connor (2011) and Fornili and Burda (2009) initiated the analysis to identify limitations of the DATA and discuss the possible benefits of granting Nurse Practitioners (NPs) the authority to prescribe buprenorphine. The DATA 2000 is worded to permit "physicians" to complete a minimum of eight hours of training for the treatment of OUD if they currently have a Drug Enforcement Administration (DEA) license and have the capacity to refer patients to counseling. Initially, physicians were only allowed to treat a maximum of 30 patients with OUD, however, in 2006 an amendment allowed physicians to submit a request to prescribe for a maximum of 100 patients following a 12-month period since initial prescriptive authority was obtained (O'Connor, 2011). According to Fornili and Burda (2009), buprenorphine is the only schedule III medication that existing laws permit only physicians to prescribe and there are no

documents providing the rationale for restricting NPs from prescribing buprenorphine.

However, “a congressional aide who participated in preparing DATA 2000 recalled a general concern about the diversion of buprenorphine and the majority believed that psychiatrists, rather than primary care providers were better prepared to treat patients with addiction” (O’Connor, 2011, p. 543).

Both Fornili and Burda, (2009) and O’Connor (2011) hypothesize that the continued inequality between physicians and nurse practitioners contributes to the law being written to allow physicians-only to prescribe buprenorphine for the treatment of OUD. An article written by Brewington (2009) discussed the role of nurse practitioners in health care reform and utilizing them to reduce costs while keeping patients healthier, quoted Dr. Ronald C. Sroka, the president of The Maryland Medical Society, as saying “nurse practitioners don’t have the expertise to handle the load” (p. 14). The evidence of the safety and efficacy of the use of buprenorphine for the treatment of OUD combined with the requirements necessary to obtain a waiver don’t introduce any differences from other treatment modalities that would indicate the NP’s inability to safely prescribe buprenorphine for the treatment of OUD. Many states allow NPs to practice independently already and are often the sole provider in rural, underserved communities, so restricting their ability to prescribe buprenorphine directly impacts access to treatment and likely contributes to the alarming statistics related to morbidity and mortality. Fornili and Burda, (2009) examined one study that found that 48.6% of NPs were interested in prescribing buprenorphine and some had even reported completing the certification process with the hope that they would be granted prescribing authority in the future.

Although the information in these articles is valuable, limitations exist when analytical articles are written that aim for policy changes. Both articles are written with the intent to

provide data that supports the authors' belief that NPs should be granted prescribing authority for buprenorphine in order to effectively treat patients with OUD. Although the intention highlights their own personal opinion, the use of moderate and high quality evidence to support their opinion strengthens the position in their papers.

With the knowledge that buprenorphine is an effective treatment for OUD, the concern remains as to why more physicians haven't obtained the waiver to prescribe the medication. A descriptive study conducted by Hutchinson et al., (2014) was conducted as part of the Rural Opioid Addiction Management Project to determine what percentage of trained physicians began prescribing buprenorphine and identify potential barriers to implementing this approach into outpatient practice. The study consisted of 78 physicians who trained between October 30, 2010 and November 5, 2011 and was conducted 7 months after the November course to allow physicians time to receive their DEA waiver and begin prescribing buprenorphine. A 10-minute questionnaire was administered that focused on demographic information, practice characteristics, and perceived barriers as well as rating their clinical opinion on the effectiveness of buprenorphine for the treatment of OUD on a scale of 1 to 5, with 1 being very unfavorable and 5 being very favorable.

Results indicated that of the 78 participants, 50 were verified as obtaining the waiver by checking the DEA list for waiver status and 22 of those who obtained the waiver had prescribed buprenorphine to 1 or more patients (Hutchinson et al., 2014). Practice characteristics displayed that 64% of providers practiced in an urban setting compared to 36% practicing in a rural setting and 77% report being affiliated with a single specialty clinic, such as family medicine. Common barriers reported include lack of on-site mental health support, time constraints, lack of specialty backup, resistance from practice partners, lack of institutional support, and concerns for adequate

reimbursement. 92% of all respondents would recommend buprenorphine for the treatment of OUD due to the average favorable rating of 4.3 out of 5.

Physicians who did not obtain the waiver or who chose not to prescribe buprenorphine were asked the same questions regarding barriers that may have influenced their decision to not treat patients with OUD. This sample consisted of 56 physicians, 28 who obtained the waiver and 28 who did not. Having another provider with a waiver available in the same practice was greatly associated with a provider's decision to obtain a waiver. Concern was reported that being the only provider would be overwhelming and greatly affect the provider's ability to manage their time. Providers who had not obtained a waiver reported a greater lack of institutional support than those who obtained the waiver, which may indicate their organization didn't support their decision to become certified.

According to Fornili and Burda, (2009), a national poll, conducted in 2002, to assess qualified physicians' perceptions of barriers to widespread use of buprenorphine found that a number of physicians reported they "didn't treat addicts." In addition, a physician survey conducted by Olsen, Bass, McCaul and Steinwachs (2004), found that 17% of unwilling physicians believed that addiction was a habit instead of an illness, that opioid addiction was beyond their scope of practice, and that "opioid dependent patients are undesirable too have in the clinic setting" (p. 221). These statements highlight the presence of stigma and judgment that continues to surround patients with substance use disorders. These views are evidence that barriers continue to exist that impact patients with OUD and hinders their ability to receive adequate treatment.

Methods

With the increased significance in clinical and economic burden related to OUD and the evidence that supports the use of buprenorphine/naloxone for the treatment of OUD, a review of the literature was conducted to highlight the severity of the problem and identify barriers that affect patients with OUD from accessing the recommended treatment. An online search was conducted through the University of North Dakota Harley E. French Library of the Health Sciences. Three databases were accessed, including Cochrane Library, CINAHL, and PsycInfo. According to Fineout-Overholt, Mazurek Melnyk, Stillwell, and Williamson (2010), the presence of a systematic review provides the strongest evidence for clinical decision making. The Cochrane Library is a database that consists of reviews that are considered to have the strongest level of evidence based on rigorous study designs. A search using the words “treatment for opioid use disorder” yielded 37 results. Following assessment of the displayed titles, one systematic review was specific to the use of buprenorphine/naloxone for the treatment of OUD and consisted of the review of 31 randomized controlled trials of buprenorphine/naloxone maintenance treatment versus placebo or methadone in the management of patients with OUD.

A further search within CINAHL and PsycInfo was completed to strengthen the literature review. Initial search terms included “prevalence of opioid use disorder.” This returned 218 articles in CINAHL and 151 articles in PsycInfo. With the addition of search terms such as “prevalence of overdose in opioid use disorder,” “barriers to treatment for opioid use disorder,” and “buprenorphine for the treatment of opioid use disorder,” articles were reduced to 16 in CINAHL and 17 in PsycInfo. Inclusion criteria included English-language sources, peer-reviewed journals, and articles within the date range of 2005-2016. Upon review of the relevant

articles, the review of the literature consisted of fifteen articles related to the significance of the problem, treatment recommendations, and barriers to treatment for patients with OUD.

To highlight the increased concern with the opioid epidemic, stress the importance of access to treatment for patients with OUD, and highlight current barriers that are contributing to the significance of the problem, a power point presentation (refer to Appendix A) was presented to fellow psychiatric mental health nurse practitioner students and family nurse practitioner students from The University of North Dakota College of Nursing. By reaching out to providers who are just entering the field, the significance of the problem may influence their decision to improve access to treatment in the organization where they pursue employment, lobby for policy changes that expand prescribing authority to NPs and obtain the waiver if policies do change, or challenge their own attitudes about patients with substance use disorders before providing patient care.

Results

Of the 15 studies included in this review, 2 examined prevalence rates of nonmedical use of opioid pain relievers, 3 discussed the clinical burden of prescription opioid abuse, including resource utilization and overdose rates related to the use of opioid pain relievers, in addition to mortality rates, 4 discussed treatment recommendations for patients with OUD, and 6 examined physician supply and distribution of waived physicians that are certified to treat patients with OUD, limitations of the DATA 2000, and perceived barriers to implementing access to buprenorphine/naloxone in outpatient practice. Studies included 3 trend analyses, 1 literature review, 3 retrospective cohort studies, 1 observational study, 3 reports, 2 systematic reviews, and 2 randomized controlled trials.

The evidence related to the prevalence of nonmedical use of opioid pain relievers and its increase in morbidity and mortality rates supports the current public health concern as it relates to the opioid epidemic. Although national trends have shown a recent decline in the 12-month prevalence of nonmedical use of opioid pain relievers, the prevalence of high frequency use has increased, likely contributing to the increase in prevalence of OUD among users, as well as the increase in overdose death rates related to opioid pain relievers. The impact has led to an increase in utilization of resources, such as frequent ED visits and hospitalizations. The trends related to prevalence were similar among residents in urban and rural counties indicating the widespread impact the opioid epidemic has had on the United States.

The evidence related to the treatment recommendations for patients with OUD consistently supports the use of buprenorphine/naloxone to suppress illicit opioid use. Buprenorphine/naloxone is shown to be superior to placebo medication, similar to methadone, and is shown to display greatest efficacy when administered in doses greater than or equal to 16mg as a maintenance therapy. When used as a maintenance therapy, at the recommended target dose of 16mg daily, buprenorphine/naloxone is shown to suppress cravings that lead to illicit opioid use and support longer periods of abstinence for patients with OUD.

The evidence related to potential barriers to treatment access highlighted state-level variation in the supply and distribution of physicians authorized to prescribe buprenorphine/naloxone. Results indicated that only 2.2% of all U.S. physicians obtained a waiver and even less reported ever prescribing the medication. In addition, the majority of waived physicians practice in urban communities, leaving rural communities without access to treatment for OUD. The DATA 2000 likely contributes to the shortage of waived providers as it is written to limit prescribing authority to physicians-only, failing to utilize the services of

nurse practitioners (NPs) and physician's assistants (PAs) who have displayed interest in prescribing buprenorphine/naloxone for the treatment of OUD. The perceived barriers among waived and non-waived providers indicated that many institutions and practice partners do not support the treatment of OUD in the outpatient setting. Providers reported concern that patients with OUD would be more time-consuming and disrupt the clinic environment. Providers reported that on-site psychosocial services and access to specialty backup providers would influence their commitment to prescribe buprenorphine/naloxone and treat patients with OUD.

Discussion

With the review of the literature supporting the detriments of opioid abuse as a major public health concern, actions aimed at secondary and tertiary prevention are necessary measures to halt the rise in morbidity and mortality rates among patients struggling with OUD. Implications for nursing practice include expanding treatment to the use of maintenance therapy in primary care settings and targeting daily dosing to a minimum of 16mg per day. In addition, recommendations include expanding access to providers by providing institutional training and ensuring that all primary care settings have a minimum of 2 waived-physicians per clinic to share the load of patients with OUD and utilize one another for back-up. To support the treatment of patients with OUD, it is recommended that all primary care settings initiate the integration of additional resources aimed to support mental health and provide social support services. To support the waived-physicians, it is recommended that all primary care clinics ensure access to addiction specialists for case consultation and support staff for the potential of challenging patients. To support patients and their families, it is recommended that all patients

being treated for OUD and their family members receive a Narcan kit as a precautionary measure to the potential for overdose-related death from the use of opioid pain relievers.

To increase awareness and reduce morbidity and mortality rates for patients with OUD, educational recommendations aimed at patients and families include training and access to the use of a Narcan kit in the event of a potential opioid-related overdose. To improve access to quality care, educational recommendations include mandated training for all providers, clinic staff, and administrators on the opioid epidemic, the current treatment recommendations, and the existing barriers to treatment access. Education should aim to explore participant's bias towards substance use disorders, provide evidence of the nature of substance use disorders as a chronic health condition, and highlight that no other chronic health condition, such as asthma or diabetes allows for providers to decide whether they choose to treat the condition or not. In order to ensure that mandated training occurs within clinic settings, educational recommendations specific to administrators should focus on obtaining an organizational commitment to train teams of providers with the intent to increase waived-physician supply within all primary care settings. In an attempt to change the culture and perceived bias of patients with OUD, additional recommendations include the incorporation of education on OUD as a chronic health condition and treatment recommendations into residency programs to standardize treatment and increase physician supply.

To ensure that practice and educational recommendations are implemented, policy changes are necessary to improve the quality of care for patients with OUD. Examination of the DATA 2000 highlights the need for policy recommendations that include increasing the maximum number of patients that waived-physicians are allowed to treat. In addition, based on the reported interest, extending prescriptive authority to NPs and PAs would increase provider

supply and increase access to care for patients with OUD. In addition to ensuring adequate supply of trained providers, increased funding for state and local governments is recommended to prevent further detriments of opioid abuse, expand treatment options, provide patients with access to additional resources, such as mental health and supportive services in the primary care setting, and provide waived-providers supportive services that support the need for case consultation and ensure high-quality care for patients with OUD.

Although the evidence in this literature review highlights the severity of opioid abuse and the increase in concern related to the lack of access to quality care for patients with OUD, additional research is recommended to expand the knowledge of the current opioid epidemic. The literature used in this review only contained data among adults ages 18 years of age and older. Additional research is necessary to explore the potential for nonmedical opioid use among adolescent populations. It is known that substance use disorders typically evolve from experimentation with substances during the adolescent phase of development, therefore understanding the prevalence of nonmedical use of opioid pain relievers among the adolescent population may highlight national trends and additional information that may influence prevention strategies and treatment recommendations for people who report nonmedical use of opioid pain relievers and patients with OUD. In addition, more research is recommended that focuses on ways to improve adherence to treatment and overall treatment outcomes for patients struggling with OUD. With the evidence suggesting that urban settings are saturated with waived-physicians and access to methadone clinics compared to rural settings, additional research recommendations include conducting more research on rural communities and exploring the need for prevention strategies, implementation of supportive services, and education on the community perceptions of the use of opioid pain relievers and their potential for

abuse. By gathering more data beyond prevalence rates of OUD within rural communities, the development of strategies aimed at prevention, education, and treatment of OUD can be implemented to improve access to care for patients with OUD living in rural communities.

Conclusion

Since the Joint Commission's initiation of pain as the fifth vital sign, the use of opioid pain relievers for the treatment of pain has led to over 12 million people reporting the use of opioids for nonmedical purposes. This has led to a rise in prevalence of high-frequency use, OUD, and increased morbidity and mortality rates related to the nonmedical use of opioid pain relievers. The use of buprenorphine/naloxone for the treatment of OUD has been on the forefront for nearly twenty years and has displayed consistent evidence for its safety and efficacy. In response to the increased prevalence of opioid abuse, the DATA 2000 initiated a certification process to increase physician supply and expand access to treatment for patients struggling with OUD. However, research continues to highlight that only 2% of American physicians have completed the certification process and obtained the waiver, while even less report actually treating patients with OUD. This has resulted in a steady rise in prevalence of OUD and morbidity and mortality rates associated with the nonmedical use of opioid pain relievers, leaving over 70% of patients with OUD no access to the recommended treatment.

By exploring barriers to treatment, policies and procedures can be implemented to increase awareness of the detriments of nonmedical use of opioid pain relievers, educate providers on the importance of access to treatment for patients with OUD, educate policy makers on the importance of increasing provider supply to expand access to treatment, and implement strategies that aim to decrease stigma surrounding substance use disorders. The knowledge

obtained through this literature review has highlighted the need for a systematic change to address OUD as a chronic health condition, increase clinical support within primary care settings to meet the needs of waived-providers and provide patients with integrated care that focuses on mental health and supportive services, and utilize anti-relapse medications, such as buprenorphine/naloxone, which have been proven safe and effective for the treatment of OUD.

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Appendix A

