

A Reality Check: The Need for a Deeper Understanding of Opioid Abuse Treatment Options: A Policy Statement From the American College of Clinical Pharmacology

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Lorraine M. Rusch, MSc, PhD

Most clinical pharmacologists agree that prescription drug abuse is no longer just a trending topic; it has reached epidemic levels in the United States. Although the United States makes up less than 5% of the global population, 80% of the opioids and 99% of the hydrocodone used in the world are used by people in the United States.¹

Members of the American College of Clinical Pharmacology (ACCP) are intimately involved with the development of novel drugs, many for the treatment of chronic pain. The ACCP is uniquely positioned to serve both its membership and the public by providing scientific knowledge to optimize research, development, and the utilization of medication for the benefit of all, which is the vision of the organization.

This position paper asserts that increased physician, pharmacist, and scientific researcher education is the best way to create a better understanding of opioid abuse and dependence as well as its treatment. Understanding, acceptance, and the promotion of supervised treatment options such as combined psychotherapy with Suboxone treatment paradigms provide rapid and significant lifesaving options as compared to programs relying on complete abstinence. Additionally, the FDA's recent guidances^{2,3} supporting the development of abuse deterrent formulations of opioids and the thorough evaluation of the potential of a new chemical entity (NCE) to be abused has been proposed to prevent the widespread tampering that currently occurs through both patient abuse and general diversion of the supply.

Overview

According to the Substance Abuse and Mental Health Service Administration (SAMHSA), the number of people 12 years or older who used pain relievers, tranquilizers, stimulants, or sedatives nonmedically for

the first time in 2013 was 2.0 million. This averages to be about 5500 initiates each day.⁴ Additionally, the most often misused prescription drugs by youths aged 12 to 17 were pain relievers.⁵

It is estimated by the Centers for Disease Control and Prevention (CDC) that 2.2 million people in the United States abuse opioids, and 1.8 million are dependent on them and unable to stop taking them without going through withdrawal.⁶ There are approximately 4 million Americans who are either abusing or addicted to opioids, roughly the population of Oregon.

In the midst of this unprecedented epidemic, overdose death rates in the United States have increased 5-fold since 1980, and 60% of the drug overdose deaths in 2010 were from opioid analgesics (as opposed to 30% in 1999).^{7,8} Currently opioid-related overdose deaths outnumber deaths from heroin and cocaine combined.⁹

DSM-V Definition of Substance Use Disorder

The spiral from use to abuse, dependence, and addiction follows a general path. Susceptible people (ie, those who may have a potential for addiction risk) are exposed to opioids; this includes patients with prescriptions and those obtaining drugs via diversionary practices for

Public Policy Committee of the American College of Clinical Pharmacology, Ashburn, VA, USA

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Corresponding Author:

Lorraine M. Rusch, MSc, PhD, American College of Clinical Pharmacology, PO Box 1758, Ashburn, VA 20146

recreation. Subsequently, tolerance develops over time in some people who are recreationally using an opioid, leading to increased misuse/abuse via swallowing. Eventually, subjects begin chewing the pills to release the drug more rapidly, which leads to other forms of drug release including crushing, snorting, and intravenous use; ultimately a substance use disorder develops.

The *Diagnostic and Statistical Manual of Mental Disorders* (DSM-V), published in May 2013, defines substance use disorder as the presence of at least 2 of 11 criteria, which are derived from 4 categories (impaired control, social impairment, risky use, and pharmacological dependence).¹⁰

Current Treatment Options

There appears to be a dichotomy in the medical treatment of substance dependence in the United States. On one hand, there is significant evidence of overprescribing in certain medical circles, resulting in diversion into the general population for recreational use, which eventually may become substance use disorder, often leading to overdose and death. On the other hand, treatment options for substance abuse are extremely limited. Currently, there is significant governmental and medical resistance to utilize the best medical treatment available, Suboxone (buprenorphine/naloxone). There is a pervasive view, held by members of the general public, the legal and justice system, as well as many in the mental health sector that abstinence is the preferred treatment. It should be noted that the latter includes physicians as well as addiction counselors, who may have little formal training in addiction treatment. The *Huffington Post* recently highlighted the challenges that treatment-seeking substance abusers face when evaluating their medical options in a compelling article titled “Dying to Be Free,” in January 2015.¹¹

The author elucidated that the popular abstinence-only route is based on different iterations of the 12-step program first created by Alcoholics Anonymous. However debatable in its effectiveness for the treatment of alcoholism, the model is wholly insufficient for opiate addicts, where normal brain function has altered over time and through opioid use patterns.^{12,13} The time has arrived to reject the stigma associated with addiction, accept scientific and medical aspects of the disease, and remove the criminal aspects of addiction, which are a symptom and/or a by-product of the disorder.

Although the National Institute on Drug Abuse (NIDA) has taken measures to urge the increased use of Suboxone and Methadone programs, many states have pushed back, limiting the number of physicians certified to prescribe Suboxone.¹⁴ The stringency of maintaining their prescribing license for these treatments is a major factor that has driven physicians out

of this therapeutic area. Currently, physicians certified to offer these treatments can prescribe for no more than 30 patients during their initial year of certification and then a maximum of 100 per year thereafter. In some states the doses to be administered to individual patients are also tightly regulated. The Drug Enforcement Agency (DEA) closely monitors these limits and can suspend a physician’s medical license for infractions.¹⁵ Finally, physicians are limited to a period of no more than 3 years to prescribe Suboxone to an individual patient, with little data to support that this time frame is adequate. Considering the excessive regulation, constant fear of being out of compliance with state and federal regulations, and inadequate reimbursement for physicians practicing addiction medicine as compared to other practices in the psychiatry space, it is hardly surprising that a shortage of prescribing doctors exists in this area despite the clear need. Recent data from SAMHSA indicates that there are approximately 29,000 physicians with prescribing privileges for Suboxone, while according to a 2013 SAMHSA report there are an estimated 2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin.¹⁶

Even some in law enforcement are beginning to question the criminalization of substance abuse disorder. In May, a local police department in Gloucester, MA announced that they would no longer arrest addicts who turn themselves and their drugs in to authorities. With this enlightened program, the Chief of Police has taken the unprecedented step of ignoring the criminal aspects of addiction and is working with those actively seeking medical treatment via local hospital partners.

“Instead we will walk them through the system toward detox and recovery,” Gloucester Police Chief Leonard Campanello said in a Facebook post announcing the new policy. “We will assign them an ‘angel’ who will be their guide through the process. Not in hours or days but on the spot.”

It will be interesting to evaluate the progress of this new policy fighting the addiction challenge; credit is due for the courage of this police department to innovate in an area fraught with social, medical, and ethical discord.

The Future of Substance Use Disorder Research and Treatment: ACCP’s Role

Substance use disorder (“addiction” as a lay term) is similar to other diseases, which, once defined, accepted, and understood, can be effectively treated. At this time it is impossible to imagine a future free of opioid addiction, but realistically there are ways to reverse it from its current status as an unofficial epidemic to

a treatable disease. Once this is initiated, clarification around whether it is classified as acute or chronic can be addressed with appropriate research tools.

The main proponent of both prevention and treatment in the United States continues to be government agencies, specifically NIDA. NIDA has committed to conducting research supporting the understanding of addiction and in many instances works in a public-private relationship with innovator pharma companies. ACCP encourages further outreach to NIDA in this forum. To support this effort, the College should create a section within the organization dedicated to substance abuse disorders that would highlight new clinical pharmacology research opportunities toward understanding the pathways and mechanisms of human addiction.

Although there are societies dedicated to the study of addiction in general (eg, College of Pain and Drug Dependency) and those that evaluate the regulatory aspects of abuse liability (eg, Cross Company Abuse Liability Consortium) as well as the neuroscience aspects of addiction as they relate to clinical studies (eg, International Society for CNS Clinical Trials and Methodology), the clinical pharmacology of substance use disorder and its respective treatments, emerging pharmaceuticals and their side effects are not well integrated for education to medical, scientific, and law enforcement professionals.

In support of the ACCP mission, it is suggested that continuing education programs in the form of workshops and roundtable panels including NIDA and the Controlled Substance Section (CSS) be routinely included as a section of the Annual Meeting. Highlighted developments in both the evaluation of NCEs for abuse potential as well as the evolving aspects of abuse deterrent formulation technology should be evaluated from both the clinical and clinical pharmacology perspectives. This approach would serve the membership of ACCP (pharmacists, physicians, and researchers, among others) well, providing an annual update on emerging clinical research and treatment aspects of the disease.

Additionally, the active support of the US Department of Health and Human Services (HHS) may be available as an avenue for research and educational activities. As recently as March 2015, the HHS has published its intentions to address the needs in prescribing practices and treatment to reduce opioid and heroin use disorders.¹⁷ The President's budget for 2016 now includes \$133M in new funding for (1) "providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions," (2) "increasing the use of naloxone," and (3) expanding the use of medication-assisted treatment, including "exploring bipartisan policy changes to increase use

of buprenorphine and develop the training to assist prescribing."

This announcement from the HHS encapsulates the current thinking of the ACCP, highlighting that currently the most effective treatment option is considered to be the combination of the use of medication with counseling and behavioral therapies as the main paradigm for substance use disorder.

ACCP can and should take a leading role in safe prescribing education as well as offering pain management alternatives to physicians, pharmacists, and scientists within the setting of our Annual Meeting as well as Continuing Medical and Pharmacy Education options. Possibly in coordination with the HHS, ACCP is in a position to provide basic and current thinking around alternate and new naloxone products as well as sharing the therapy-based psychiatric practices with the same audiences that will go far to reduce the stigma around this malady and address the treatment options of the disease in a more logical and rational approach.

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