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Opioid Crisis Challenges

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Abstract

RF is a 31-year-old single Caucasian male who was incarcerated six times in the past thirteen years for possession of tetrahydrocannabinol (THC), manufacture with intent to deliver THC, possession of drug paraphernalia, and possession of heroin. He has struggled with addiction since the age of sixteen beginning with alcohol, THC, progressing to heroin and methamphetamines. RF continues to struggle with his addiction to heroin despite supportive family, various county services, attending alcoholics anonymous and narcotics anonymous meetings, and medication assisted treatment. During his last incarceration he was started on Vivitrol before he was released. An overview of the literature investigates the introduction of naltrexone (Vivitrol) into the fight against the opioid crisis and how it has become the medication of choice in the criminal justice system.

Background

The financial and social burdens of substance use disorders (SUDs) in the United States are exorbitant. The cost in dollars of alcohol, illicit drug, and tobacco use is estimated to top $740 billion annually, with the crime, health care costs, and lost productivity resulting from SUDs responsible for this stunning economic toll (National Institute on Drug Abuse (NIDA), 2015).

Although SUDs can result in criminal behavior with significant financial and social costs, there is an increasing awareness that the criminal justice system, as it currently operates, cannot adequately address these illnesses. During the 1980s there was an increase in harsh sentencing laws which caused a great increase in incarceration for SUDs. This did not "fix" the issue of substance use. (Phillips, Eikenberry, Beeler-Stinn, & Silver Wolf, 2018).

Increasing access to medication for opioid use disorder (MOUD) is one way to address the opioid epidemic. Opioid agonist maintenance (methadone and buprenorphine) are effective interventions and are the most commonly prescribed MOUD treatments in the community (Phillips, Eikenberry, Beeler-Stinn, & Silver Wolf, 2018). Most correctional facilities do not offer these treatments. Consequentially, most opioid and heroin users involve jail detained and sentenced inmates experiencing opioid detoxification upon jail admission. They also face high rates of relapse, opioid overdose, and death following release (Alex et al. 2017). Extended-release naltrexone (Vivitrol) is a long-acting, injectable, full opioid receptor antagonist. The use of Vivitrol has recently increased in US jail-to-community reentry programs (Phillips, Eikenberry, Beeler-Stinn, & Silver Wolf, 2018).

Case Report

RF is a 31-year-old single Caucasian male who resides with his mother and 5-year-old daughter of whom his mother has temporary guardianship. He is seen in the office due to concerns that he is not doing as well. He has relapsed three times on methamphetamine since his last appointment. RF indicates that one thing that may be contributing to his relapse is he stopped all his medications. He reports that he felt like he no longer needed them and could get through this with "Jesus." He realizes now he should not have done this and restarted his medications five days ago. He has been feeling a little off since restarting his medications. Review of medications with him included discussion that restarting his medications at previous doses could cause increased anxiety.

Some of RF's relapses may be due to a combination of school, lack of structure, and going off his medications. RF is working to get back on track. He has a good plan of remaining on his medications, going to aftercare groups, AA meetings, and meet with his counselor. He feels that he was not connected recently because of focusing on school and he feels he needs groups and meeting in his life.

RF was born and raised locally. He had a difficult childhood. He reports that he was molested. His father died when he was 12 years old. He has had numerous losses when he was younger that directly affected his health. RF has a strong personal and family history for addiction. He also has a learning disability for which he had an individualized education plan (IEP) in school and attention deficit hyperactivity disorder (ADHD). He did however graduate from high school in 2006.

Psychiatric history for RF includes one hospitalization which he described was a way to get put on Methadone. He does not endorse any suicide attempts but has had six episodes of heroin overdoses. RF reports having used numerous drugs in the past with his drug of choice being

heroin. He used methamphetamine during his time in jail and has since struggled with its continued use since his release in May 2018. He has not had any psychiatric providers per se but has been in treatment for alcohol and other drug abuse (AODA) since May 2018 and has seen a therapist.

RF has followed with this organization's services since April 2018 after he was released from jail for narcotic possession. During this time, he has been placed at three different sober houses and has either chosen to leave to find different housing or been evicted due to substance use. He is now living with his mother and assists with care taking of the motel she owns. RF has applied to twenty-three apartments openings but has not heard back from a single one in the past month. He had a job interview with a snow shoveling service he worked for last year after his appointment today. He knows his recidivism plays a role in the struggle to find both an apartment and employment.

RF visit diagnoses include: Major depressive disorder (MDD), recurrent; polysubstance use, drug of choice is heroin; and methamphetamine use. His current medication regimen is fluoxetine (Prozac) 40mg daily, bupropion (Wellbutrin) 450mg daily, naltrexone (Vivitrol) 380mg IM every 23 days, and lisdexamphetamine (Vyvanse) 50mg daily. He reports over the years he has been prescribed stimulants amphetamine and dextroamphetamine (Adderall), methylphenidate (Concerta), and lisdexamphetamine (Vyvanse) since his diagnosis of ADHD in sixth grade, approximately nineteen years ago. This case study will review the treatment of Vivitrol for opioid addiction and the decision to begin treatment while still incarcerated. RF reports he was prescribed paroxetine (Paxil) while in jail, but it was too sedating and caused affect flattening. RF began Vivitrol treatment shortly before his release date of his last incarceration at the suggestion of the judge in drug court.

Literature Review

The above case prompted a thorough research investigation on the use of naltrexone (Vivitrol) and its use on inmates. The databases CINAHL, ClinicalKey, and PubMed were utilized. The search terms, alone or in combination, "opioid," "crisis," "methadone," "suboxone," "naltrexone," and "incarceration" or "jail" were entered. Filters included full-text articles and those published within the past 8 years. CINAHL yielded 14 results, ClinicalKey yielded 30, and PubMed yielded 26. Eventually, 18 articles were selected that were found to be the most relevant for the chosen topic.

Prior to concentrating on the research, approval, and marketing of Vivitrol, an understanding of the opioid crisis and treatment options is essential. The prescription opioid epidemic started in the 1990s when pain was recognized as the "fifth vital sign" (Lyapustina & Alexander, 2015). Pharmaceutical companies who were looking for new pain killers began to push synthetic and semi-synthetic opioids to doctors. This created an increase in the use of opioids for non-malignant pain management, namely OxyContin (Oxycodone). Not only did sales representatives visit doctors across the United States and leave them free patient samples, gifts, and invitations to all-expenses- paid symposia but they also downplayed the addictive potential of opioids, saying the drugs were either less-or non-addictive in comparison to morphine and had no dangerous side effects. Pharmaceutical company Purdue spent $200 million in 2001 to promote the use of opioids in general and OxyContin in particular (Van Zee, 2009).

According to the Center for Disease Control and Prevention (CDC, 2018) more than 700,000 drug overdose deaths have occurred from 1999 to 2017. Approximately 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid (CDC. 2018). The deaths in 2017 that involved prescription opioids and illegal opioids like heroin was 6 times higher than in 1999

(CDC, 2018). On average, 130 Americans die every day from opioid overdose (CDC, 2018). Between 2010 and 2017, the rate of heroin-related overdose deaths increased by almost 400% (CDC, 2018).

The opioid crisis isn't just about overdose deaths. Incarceration is another staggering result of this crisis. Every 25 seconds, someone in America is arrested for drug possession (Sawyer & Wagner, 2019). The number of Americans arrested for possession has tripled since 1980, reaching 1.3 million arrests per year in 2015—six times the number of arrests for drug sales (Sawyer & Wagner, 2019). One-fifth of the incarcerated population—or 456,000 individuals—is serving time for a drug charge (Sawyer & Wagner, 2019). Incarcerating people for drug-related offenses has been shown to have little impact on substance misuse rates (Sawyer & Wagner, 2019). Instead, incarceration is linked with increased mortality from overdose. In the first two weeks after their release from prison, individuals are almost 13 times more likely to die than the general population (Sawyer & Wagner, 2019). The leading cause of death among recently released individuals is overdose (Sawyer & Wagner, 2019). During that period, individuals are at a 129 percent greater risk of dying from an overdose than the general public (Sawyer & Wagner, 2019).

The opioid epidemic costs the United States an estimated $504 billion per year (Pearl, 2018). This includes the costs to the health care and justice systems as well as the economic impact of premature fatalities. In 2015, the federal government spent an estimated $9.2 million every day to incarcerate people charged with drug-related offenses—that's more than $3.3 billion annually (Pearl, 2018). With staggering numbers like these, the question of how to treat opioid addiction is one of the most pressing and difficult questions facing our nation.

Treatment for opioid addiction currently consists of three main medications. Methadone, buprenorphine/naloxone (Suboxone), and extended-release naltrexone (Vivitrol).

Russolillo, Moniruzzaman, & Somers (2018) report that methadone is the oldest, most rigorously well-tested and highly regulated medication that has been safely used to treat opioid addiction in the United States for more than 40 years. Originally it was synthesized in Germany, in 1937, for severe chronic pain relief, after the Allies cut off supplies of imported opium. The first use for withdrawal symptoms from heroin and morphine occurred about 1950. Methadone works by blocking the craving for opioids and withdrawal by maintaining a safe level of opioids in the body for 24 – 36 hours (Russolillo, Moniruzzaman, & Somers, 2018). Methadone also blocks the effects of administered heroin if a patient would attempt to get high while on methadone. Methadone does not cause euphoria, intoxication, or sedation. Methadone maintenance treatment (MMT) is one of the best evidence-based opioid substitution treatments (OSTs) and has been shown to work best when used for long periods of time, often years (Russolillo, Moniruzzaman, & Somers, 2018). Patients receiving methadone are required to comply with daily witnessed ingestion under the supervision of a licensed provider unless authorized to hold 'carry' privileges. Patients are generally weaned off the medication slowly over time, if possible. According to NIDA (2018), methadone treatment, including medication and integrated psychosocial and medical support services (assumes daily visits): $126.00 per week or $6,552.00 per year.

Suboxone's main ingredient, buprenorphine, was first marketed in the 1980s in the US, as an opioid pain reliever (Substance Abuse & Mental Health Services Administration (SAMHSA), 2019). In October 2002, the Food and Drug Administration (FDA) approved suboxone for detoxification and long-term maintenance therapy in opioid dependency (SAMHSA, 2019).

Suboxone contains a combination of buprenorphine and naloxone. Buprenorphine is a semi-synthetic opioid that partially activates receptors in the brain that crave opioids (SAMHSA, 2019). Naloxone is a special narcotic drug that works as an opiate antagonist that will fill the opiate receptors in the brain and it won't let other drugs activate these receptors, but unlike buprenorphine (which fills and activates receptors) naloxone will not activate opiate receptors (SAMHSA, 2019). The naloxone is added to buprenorphine to decrease its abuse potential and discourage the injection use of suboxone for purposes of achieving euphoria. Due to this decreased risk of abuse and diversion, doctors have greater freedom to prescribe suboxone in take-home doses. Buprenorphine for a stable patient provided in a certified opioid treatment program (OTP), including medication and twice-weekly visits costs $115.00 per week or $5,980.00 per year (NIDA, 2018).

Vivitrol, is a monthly injection of a μ-opioid receptor antagonist for the prevention of relapse to opioid dependence following opioid withdrawal (Saxon et al., 2018). Vivitrol is an antagonist that blocks receptors in the brain so they can't be activated by opioids (Saxon et al., 2018). First available as a pill, oral naltrexone, wasn't a huge success because it didn't completely reduce cravings for opioids, and it was hard to get addicts to adhere to taking it daily. In 2006, an injectable version of naltrexone (Vivitrol) was approved to treat alcohol dependence and later, in 2010, the FDA approved the Vivitrol shot in 2010 to help prevent relapse in opioid addicts (Saxon et al., 2018).

The FDA authorized use of Vivitrol for opioid addiction using a single study in Russia, a country where opioid agonists such as methadone and buprenorphine are not available. The study was a "double-blind, placebo-controlled, randomized", 24-week trial with "250 patients with opioid dependence disorder" at "13 clinical sites in Russia" on the use of injectable naltrexone

(XR-NTX) for opioid dependence (Krupitsky et al. 2011). The study was funded by the Boston-based biotech Alkermes firm. A 2011 article reported that this single trial of Vivitrol was performed not by comparing it to the best available, evidence-based treatment (methadone or buprenorphine), but by comparing it with a placebo (Tanum et al. 2017). A subsequent RCT in Norway did compare injectable naltrexone to buprenorphine and found them to be similar in outcomes (Tanum et al. 2017).

Vivitrol requires full detoxification to use (usually seven to ten days of no opioid use). This full detox period can create a significant barrier and is one of the reasons Vivitrol is being introduced in prisons. NIDA (2018) reports Vivitrol provided in an OTP, including drug, drug administration, and related services costs $1,176.50 per month or $14,112.00 per year.

The first two weeks after a drug user is released from jail, the risk of a fatal overdose is much higher than at any other time in his addiction. After months or years in confinement, theoretically without access to illicit drugs, an addict's tolerance for drugs is low but his craving to get high can be as strong as ever (Vestal, 2016).

About two-thirds of the nation's 2.3 million inmates are addicted to drugs or alcohol, compared to 9 percent of the general population, according to a study by the National Center on Addiction and Substance Abuse at Columbia University. There are over 1.5 million state and federal prisoners, in the US, with an estimated 12%-15% having a history of opioid dependence (Gordon, Kinlock, Vocci, Fitzgerald, Memisoglu, & Silverman, 2015).

Vestal (2016) states numerous studies show that punishment simply does not solve the problem of addiction; in fact, 70% of those released from prison return to drug use. The punitive approach has produced disastrous societal and economic consequences for our communities. Drug courts are often touted as the single most successful intervention in US history for leading

people struggling with serious addiction out of the justice system and into lives of health and long-term recovery. The first drug court in the US occurred in 1989 as a response to the growing crack cocaine problem plaguing the city of Miami (Vestal, 2016). According to the National Association of Drug Court Professionals in 2014, there were 3,057 drug courts representing all 50 states, the District of Columbia, Guam, Puerto Rico, Northern Mariana Islands, and various tribal regions (Vestal, 2016).

More than 130,000 Americans will go through drug courts, according to the National Association of Drug Court Professionals (Harper, 2017). Drug courts are designed to allow some people whose crimes stem from addiction to get treatment instead of jail time. But the treatment that is offered varies from court to court and is entirely at the judge's discretion. Some courts offer participants a full range of evidence-based treatment, including medication-assisted treatment. Others don't allow addiction medications at all. And some permit just one: Vivitrol (Harper, 2017).

Harper (2017) reports one reason for this preference is that Alkermes, Vivitrol's manufacturer, is doing something nearly unheard of for a pharmaceutical company: It is marketing directly to drug court judges and other officials. The strategy capitalizes on a market primed to prefer their product. Judges, prosecutors and other criminal justice officials can be suspicious of the other FDA-approved addiction medications, buprenorphine and methadone, because they are themselves opioids. Alkermes promotes its product as "nonaddictive" (Harper, 2017).

Alkermes goes beyond marketing to judges. It also lobbies state and national policymakers to write laws that favor Vivitrol — and in some cases, hamper access to other addiction

medications. The company has said it supports the use of all medications for addiction, but in practice, it doesn't (Harper, 2017).

Harper (2017) reports the company supported one law in Indiana that encourages the use of Vivitrol in drug courts. Signed in 2015, the bill allows judges to require medication as a condition of participating in a drug court, and the language specifically highlights Vivitrol treatment.

Many treatment specialists say allowing judges and other criminal justice officials with no medical training to exert influence over medical decisions is problematic. The power makes them prime targets for Vivitrol marketing (Harper, 2017). Basia Andraka-Christou, who researches drug courts at the Fairbanks School of Public Health at Indiana University says "What this is implying is that the judges in these cases are actually making a lot of the medical decisions, and that should be very concerning to everyone" (Harper, 2017).

Adriane Fugh-Berman, who researches pharmaceutical marketing at Georgetown University, says she has not heard of another drug company going after judges. She says it's not just unique — it's inappropriate and could ultimately be damaging to patients. "They're not health care providers. They don't know data. They don't know research," she says (Harper, 2017).

Vivitrol is far from a one-size-fits-all solution. It's not ideal for patients who are dealing with chronic pain on top of their addiction, or for pregnant women (Harper, 2017).
Furthermore, relapse rates for all kinds of opioid addiction treatment are high, and after a period of not using, tolerance for opioids is low (Harper, 2017). Treatment with Vivitrol, which contains no opioid ingredients, could make someone more likely to overdose if they relapse, addiction specialists warn (Harper, 2017).

Dan Mistak, an attorney with Community Oriented Correctional Health Services, says courts should allow all medication options and let doctors make treatment decisions — including whether someone should use medication in their recovery (Harper, 2017). "We rely on outside experts all the time in the judicial system. We don't ask a judge to come in and be an expert in arson," (Harper, 2017).

Harper (2017) reports the federal government and the National Association of Drug Court Professionals agree that courts should allow all three FDA-approved opioid addiction medication options. “Especially with this exploding opioid use epidemic, we have to make available, as much as we can, whatever interventions are out there that are likely to be effective," says Terrence Walton, chief operating officer for the NADCP, which lists Alkermes as one of its biggest donors (Harper, 2017).

Harper (2017) reports Alkermes declined repeated interview requests. In a written statement, the company defended the practice of marketing in criminal justice settings by noting that judges don't actually prescribe their product.

Implications

Dealing with opioid addiction is one of the most significant issues the U.S. health system faces today, and while health care providers should be the ones providing a key role in the nation’s efforts to deal with the crisis, pharmaceutical companies and drug court judges are playing roles as well.

Treatment specialists recognize that addiction is a complex biobehavioral disorder; in curing addiction, people often experience many relapses into drug use as they attempt to break their pattern of abuse.

A host of treatment/deterrence options are available to health care practitioners when working with individuals suffering from a SUD including medication-assisted treatments, prescription drug monitoring programs, and voluntary monitoring programs. An understanding of the methodologies, benefits, and drawbacks of each approach is of critical importance.

Pharmaceutical companies and drug court judges are not health care providers or treatment specialists, yet they are influencing and making treatment decisions for individuals in the criminal justice system every day.

Conclusion

Pharmaceutical companies generate millions of dollars in profit and influence in the US in various ways every day. When faced with the decision to prescribe a medication, a health care provider must continue to utilize sound judgement and weigh the benefits versus the risk ratios prior to prescribing medications. Health care providers should not be swayed in their personal practice by the influence that millions of dollars can buy.

References

Alex, B., Weiss, D.B., Kaba, F., Rosner, Z., Lee, D., Lim S., …MacDonald, R. (2017). Death after jail release: Matching to improve care delivery. *Journal of Correctional Health Care*; 23(1):83–87. https://doi.org/10.1177/1078345816685311

Centers for Disease Control and Prevention (2018). Understanding the epidemic. Retrieved from https://www.cdc.gov/drugoverdose/epidemic/index.html

Gordon, M. S., Kinlock, T. W., Vocci, F. J., Fitzgerald, T. T., Memisoglu, A., & Silverman, B. (2015). A phase 4, pilot, open-label study of VIVITROL® (Extended-Release Naltrexone XR-NTX) for prisoners. *Journal of Substance Abuse Treatment, 59*, 52–58. https://doi-org.ezproxylr.med.und.edu/10.1016/j.jsat.2015.07.005

Harper, J. (2017). To grow market share, a drug maker pitches its product to judges. Retrieved from https://www.npr.org/sections/health-shots/2017/08/03/540029500/to-grow-market-share-a-drugmaker-pitches-its-product-to-judges

Krupitsky E, Nunes EV, Ling W, Illeperuma A, Gastfriend DR, Silverman BL. (2011). Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicentre randomised trial. *Lancet*, 377 (9776): 1506–13. *doi:10.1016/s0140-6736(11)60358-9. PMID 21529928.*

Lyapustina, T. & Alexander, C. (2015). The prescription opioid addiction and abuse epidemic: How it happened and what we can do about it. Retrieved from https://www.pharmaceutical-journal.com/opinion/comment/the-prescription-opioid-

addiction-and-abuse-epidemic-how-it-happened-and-what-we-can-do-about-it/20068579.article?firstPass=false

National Institute on Drug Abuse (NIDA). (2015). Trends & statistics. Retrieved from https://*www.drugabuse.gov/* related-topics/trends-statistics#costs

National Institute on Drug Abuse (NIDA). (2018). Medications to treat opioid use disorder. Retrieved from https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addictions/how-much-does-opioid-treatment-cost

National Institute on Drug Abuse (NIDA). (2019). Heroin. Retrieved from https://www.drugabuse.gov/publications/drugfacts/heroin

Pearl, B. (2018). Ending the war on drugs: By the numbers. Retrieved from https://www.americanprogress.org/issues/criminal-justice/reports/2018/06/27/452819/ending-war-drugs-numbers/

Phillips, S., Eikenberry, J., Beeler-Stinn, S., & Silver Wolf, D. A. P. (2018). Substance use treatment in jails: Current issues and recommendations. *Counselor: The Magazine for Addiction Professionals, 19*(4), 22–32. Retrieved from https://search-ebscohost-com.ezproxylr.med.und.edu/login.aspx?direct=true&db=ccm&AN=131074804&site=ehost-live

Russolillo, A., Moniruzzaman, A., & Somers, J. M. (2018). Methadone maintenance treatment and mortality in people with criminal convictions: A population-based retrospective

cohort study from Canada. *PLoS Medicine, 15*(8), 1–19. https://doi-org.ezproxylr.med.und.edu/10.1371/journal.pmed.1002625

Sawyer, W. & Wagner, P. (2019). Mass incarceration: The whole pie. Retrieved from https://www.prisonpolicy.org/reports/pie2019.html

Saxon, A. J., Akerman, S. C., Liu, C., Sullivan, M. A., Silverman, B. L., & Vocci, F. J. (2018). Extended-release naltrexone (XR-NTX) for opioid use disorder in clinical practice: *Vivitrol's Cost and Treatment Outcomes Registry. Addiction*, 113(8), 1477–1487. https://doi-org.ezproxylr.med.und.edu/10.1111/add.14199

Substance Abuse & Mental Health Services Administration (2019). Buprenorphine. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine

Tanum, L., Solli, K. K., Latif, Z. E., Benth, J. Š., Opheim, A., Sharma-Haase, K., … Kunøe, N. (2017). Effectiveness of injectable extended-release naltrexone vs daily buprenorphine-naloxone for opioid dependence: A randomized clinical noninferiority trial. *JAMA psychiatry*, *74*(12), 1197–1205. doi:10.1001/jamapsychiatry.2017.3206

Van Zee A. (2009). The promotion and marketing of oxycontin: commercial triumph, public health tragedy. *American Journal of Public Health*, 99(2), 221–227. doi:10.2105/AJPH.2007.131714

Vestal, C. (2016). Helping drug-addicted inmates break the cycle. Retrieved from https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/13/helping-drug-addicted-inmates-break-the-cycle