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Opioid Use Disorder Petition- Section 3

Consideration of whether conventional medical therapies are insufficient to treat or alleviate the disease or condition.

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Opioid Use Disorder is a complex condition that is not easily treated successfully. The patient usually has other associated mental and/or physical issues. According to NIDA the relapse rate for patients going through drug addiction treatment ranges from 40% to 60%. Twelve Step Facilitation programs have mixed success and are not well documented. The indisputable fact that we have such a tremendous number of overdose deaths indicates that conventional medical therapies are insufficient.
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<u>Consideration of whether conventional medical therapies are insufficient to treat or alleviate the disease or condition.</u>

Opioid Use Disorder is a complex condition that is not easily treated successfully. The patient usually has other mental and/or physical issues associated with the condition. According to NIDA the relapse rate for patients going through drug addiction treatment ranges from 40% to 60%. A popular treatment method is the replacement of one opiate with a different one (i.e. Methadone, Suboxone, and Buprenorphine). These carry their own risk of addiction, problematic withdrawal, illicit distribution and even overdoses. Twelve Step Facilitation programs have mixed success and are not well documented.

The fact that we continue to have the increasing number of overdose deaths despite the existence of conventional therapies suggests that conventional medical therapies remain insufficient in addressing the complexities associated with opioid use disorder.

One aspect of this condition is that for many people, opioid use disorder represents a chronic lifelong condition. Therefore for many, opioid use disorder / opiate addiction is a condition which requires strategies that are long term, and perhaps life-long. The longer one is in some form of treatment, the more likely the addicted individual will be successful in dealing with the negative effects of their addiction.

Below are a series of conventional therapies used today with mixed success.

- **Medication assisted treatments: Methadone, Suboxone and Subutex (agonist/partial agonist therapies); Naltrexone and Vivitrol (antagonist therapies).**
- **Varying levels of care ranging from inpatient detoxification, residential treatment, intensive outpatient treatment and outpatient treatment.**
- **The legal system administered programs including drug court programs.**
- **Sober support programs including 12 step programs and faith-based programs.**

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Note: Each subject area is separated by a dashed (-=-=) line and has Hyperlink(s) to the full/original article from which the summary quotes or relevant sections were obtained. Note if petition reviewers are use unable to use the Hyperlink provided to obtain the reference document, Ohio Patient Network can obtain an original copy upon request. Also note any excerpts or copies of the referenced articles text are in *non bolded italics***.**

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Medication Assisted Treatments

Methadone treatment for addiction is only available through strictly regulated opioid treatment programs accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA). Persons with OUDs initially attend the opioid treatment program daily before receiving take-home doses.

"According to the National Institute on Drug Abuse publication Principles of Drug Addiction Treatment: A Research-Based Guide – 2012, the length of methadone treatment should be a minimum of 12 months. Some patients may require treatment for years. Even if a patient feels that they are ready to stop methadone treatment, it must be stopped gradually to prevent withdrawal"

Reference Source: Substance Abuse and Mental Health Services Administration. 2015. Medication and Counseling Treatment: Methadone. https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone).

-=-=- and from Mattick et al -=-=-

Due to the nature of how Methadone works it places patients in a situation where they are essentially committed to a daily-dose, long-term replacement program. If an individual chooses to go off Methadone, the withdrawal syndrome persists for an extended period of time and is mentally and physically taxing. Patients come off of their Methadone for numerous reasons, and the associated physical and psychological withdrawal symptoms serve as significant relapse triggers leading some patients back to the dangerous behaviors associated with heroin use. Hence, having insight as to who will be compliant with a Methadone program from those who will not commit to the requirements of a Methadone program, is important and carries important safety implications. Many opt not to consider Methadone as a treatment alternative because of these limitations, making this option insufficient in meeting the overall needs of those with Opioid Use Disorder.

BACKGROUND:
Methadone maintenance was the first widely used opioid replacement therapy to treat heroin dependence, and it remains the best-researched treatment for this problem. Despite the widespread

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use of methadone in maintenance treatment for opioid dependence in many countries, it is a controversial treatment whose effectiveness has been disputed.

MAIN RESULTS:
Eleven studies met the criteria for inclusion in this review, all were randomized clinical trials, two were double-blind. There were a total number of 1969 participants. The sequence generation was inadequate in one study, adequate in five studies and unclear in the remaining studies. The allocation of concealment was adequate in three studies and unclear in the remaining studies. Methadone appeared statistically significantly more effective than non-pharmacological approaches in retaining patients in treatment and in the suppression of heroin use as measured by self report and urine/hair analysis (6 RCTs, RR = 0.66 95% CI 0.56-0.78), but not statistically different in criminal activity (3 RCTs, RR=0.39; 95%CI: 0.12-1.25) or mortality (4 RCTs, RR=0.48; 95%CI: 0.10-2.39).

AUTHORS' CONCLUSIONS:
Methadone is an effective maintenance therapy intervention for the treatment of heroin dependence as it retains patients in treatment and decreases heroin use better than treatments that do not utilise opioid replacement therapy. It does not show a statistically significant superior effect on criminal activity or mortality.

Reference Source:
Mattick RP1, Breen C, Kimber J, Davoli M.
Author Info : National Drug and Alcohol Research Centre, University of New South Wales, National Drug and Alcohol Research Centre, University of New South Wales, Sydney, New South Wales, Australia, 2052. 2009. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence.
Cochrane Database Syst Rev.;(3):CD002209.
doi: 10.1002/14651858.CD002209.pub2.
https://www.ncbi.nlm.nih.gov/pubmed/19588333

=-=-=-=- and from NIDA =-=-=-=-

"Relapse rates for addiction resemble those of other chronic diseases such as diabetes, hypertension, and asthma."

Reference Source #2
2- National Institute of Drug Abuse. 2018. How effective is drug addiction treatment? Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition)
https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/how-effective-drug-addiction-treatment

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Suboxone

The use of Suboxone to help patients with Opioid Use Disorder has become very common and with this replacement therapy comes some understandable and predicted problems associated with misuse, abuse and diversion. Johanson, Arfkena, di Menza and Schuster (2012) describe the abuse potential with Suboxone; they comment on how abuse and diversion problems grow in parallel with the increasing number of prescriptions written for Suboxone. This conclusion was supported by earlier work that appeared in the British Journal of Addiction.

While Suboxone has provided a tool for physicians to help patients with Opioid Use Disorder it faces similar challenges comparable to those faced by the Methadone programs.

Abstract

Background: Since 2003, buprenorphine has been approved for the treatment of opioid dependence in office-based practice. Diversion and abuse can be a threat to its continued approval under these conditions.

Methods: As part of a national post marketing surveillance program, applicants to substance abuse treatment and physicians certified to prescribe buprenorphine were surveyed about their perceptions of buprenorphine/naloxone diversion and abuse. These surveys were supplemented by information from national databases. Availability of buprenorphine/naloxone was measured by number of tablets dispensed.

Results: Measures of diversion and abuse of buprenorphine/naloxone increased from 2005 to 2009. The results from the applicant survey showed that the perceptions of the extent of diversion and abuse were lower than positive controls, methadone, oxycodone and heroin, but higher than the negative control, amitriptyline. By 2009, 46% of the physicians believed that buprenorphine /naloxone was diverted but 44% believed illegal use was for self-management of withdrawal and 53% believed the source of the medication was substance abuse patients. Other measures from national databases showed similar results. When adjusted for millions of tablets sold per year, slopes for measures of diversion and abuse were reduced.

CONCLUSIONS:
The increases in diversion and abuse measures indicate the need to take active attempts to curb diversion and abuse as well as continuous monitoring and surveillance of all buprenorphine products. However, these increases parallel the increased number of tablets sold. Finding a balance of risk/benefit (i.e. diversion and abuse versus expanded treatment) remains a challenge.

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Reference Source
Diversion and abuse of buprenorphine: findings from national surveys of treatment patients and physicians.
Drug Alcohol Depend. 2012 Jan 1;120(1-3):190-5. Epub 2011 Aug 21.
Johanson CE , Arfken CL, di Menza S, Schuster CR.
https://www.ncbi.nlm.nih.gov/pubmed/21862241
DOI 10.1016/J.DRUGALCDEP.2011.07.019

-=-= and from the British Journal of Addiction -=-=

Summary
Buprenorphine has been described as a potent analgesic with low abuse potential. Sporadic reports in the world literature would seem to contradict this view. A retrospective study of all opiate addicts first presenting over a 12-month period showed an increasing level of buprenorphine abuse.

Reference Source
2 - Buprenorphine Abuse Among Opiate Addicts
British Journal of Addiction Volume 83, Issue 9
JOHN J. O'CONNOR M.B., M.R.C.Psych. EAMONN MOLONEY M.B. RAYMOND TRAVERS M.B. AISLING CAMPBELL M.B.
https://doi.org/10.1111/j.1360-0443.1988.tb00536.x

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Vivitrol and Naltrexone

Vivitrol is one of the newest medical interventions to assist with treating Opioid Use Disorder. Unlike the opiate-based agonists, Vivitrol is an injectable form of Naltrexone that works as an antagonist, or "opiate blocker." Vivitrol has shown to be of value in helping patients avoid relapse on opiates (Sullivan, 2012). It appears that Vivitrol is superior to oral dose naltrexone with respect to treatment compliance, as measured by retention rates in treatment (Tucker, Ritter, Maher & Jackson, 2004; Chang et. al, 2018).

Some significant concerns and limitations facing both oral dose and injectable forms of Naltrexone (Vivitrol) have to do with initiation and subsequent adherence. The addicted heroin user must first go through withdrawal and be opiate free before beginning treatment with either form of Naltrexone. This deters some from considering this as an option.

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Interestingly, Raby et al. (2009) found that patients who used marijuana while also being treated with Naltrexone remained in treatment an average of 100 days longer. This novel approach to treating Opioid Use Disorder is an alternative and a promising strategy in helping individuals recover from their dependency to opiates.

Reference Sources

CHANG, G. et al. Adherence to extended release naltrexone: Patient and treatment characteristics. American Journal on Addictions, [s. l.], v. 27, n. 6, p. 524–530, 2018.
https://onlinelibrary.wiley.com/doi/abs/10.1111/ajad.12786

RABY, W. N. et al. Intermittent Marijuana Use Is Associated with Improved Retention in Naltrexone Treatment for Opiate-Dependence. American Journal on Addictions, [s. l.], v. 18, n. 4, p. 301–308, 2009.
https://www.tandfonline.com/doi/abs/10.1080/10550490902927785
Online DOI: 10.1080/10550490902927785

SULLIVAN, M. A. et al. Naltrexone treatment for opioid dependence: Does its effectiveness depend on testing the blockade? Drug & Alcohol Dependence, [s. l.], v. 133, n. 1, p. 80–85, 2013.
https://www-sciencedirect-com.proxy.libraries.uc.edu/science/article/pii/S0376871613002160
https://doi.org/10.1016/j.drugalcdep.2013.05.030

TUCKER, T. K. et al. Naltrexone maintenance for heroin dependence: uptake, attrition and retention. Drug & Alcohol Review, [s. l.], v. 23, n. 3, p. 299–309, 2004.
https://www.ncbi.nlm.nih.gov/pubmed/15370010
DOI: 10.1080/09595230412331289464

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Drug Courts/ Compulsory Treatment

Results
Of an initial 430 potential studies identified, nine quantitative studies met the inclusion criteria. Studies evaluated compulsory treatment options including drug detention facilities, short (i.e. 21-day) and long-term (i.e., 6 months) inpatient treatment, community-based treatment, group-based outpatient treatment, and prison-based treatment. Three studies (33%) reported no significant impacts of compulsory treatment compared with control interventions. Two studies (22%) found equivocal results but did not compare against a control condition. Two studies (22%) observed negative impacts of compulsory treatment on criminal recidivism. Two studies (22%) observed positive impacts of compulsory inpatient treatment on criminal recidivism and drug use.

Conclusion
There is limited scientific literature evaluating compulsory drug treatment. Evidence does not, on the whole, suggest improved outcomes related to compulsory treatment approaches, with some studies suggesting potential harms. Given the potential for human rights abuses within compulsory treatment

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settings, non-compulsory treatment modalities should be prioritized by policymakers seeking to reduce drug-related harms.

Reference Source
D Werb, A Kamarulzaman, MC Meacham, C Rafful, B Fisher, SA Strathdee, and E Wood. 2016.
THE EFFECTIVENESS OF COMPULSORY DRUG TREATMENT: A SYSTEMATIC REVIEW.
International Journal of Drug Policy.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4752879/

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12 step programs

One of the more difficult "therapies" to discuss are the 12 step programs. At a basic level they are not scientific or medicine based, but some have more of a moral basis underpinning. Thus there is a lot of heated rhetoric and blowback when the effectiveness is assessed or challenged.

Below are some examples of some of the critical evaluation. Note these are primarily based on the alcohol, but note the Narcotics Anonymous is based upon the same basic model.

A 2006 Cochrane systematic review reviewed studies published between 1966 and 2005 that investigated the efficacy of AA and twelve step facilitation (TSF) found no significant difference between the results of AA and twelve-step participation compared to other treatments, stating that "experimental studies have on the whole failed to demonstrate their effectiveness in reducing alcohol dependence or drinking problems when compared to other interventions." This conclusion was based on a meta-analysis of the results of eight trials involving a total of 3,417 individuals.

Source Ferri, Marcia; Amato, Laura; Davoli, Marina. 2006. Alcoholics Anonymous and other 12-step programmes for alcohol dependence. Cochrane Database of Systematic Reviews (3): CD005032. *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005032.pub2/full*

-=-=- And by Gabrielle Glaser. -=-=-=

Dr. Lance Dodes, a retired psychiatry professor from Harvard Medical School, book "The Sober Truth: Debunking the Bad Science Behind 12-Step Programs and the Rehab Industry" looked at Alcoholics Anonymous's retention rates along with studies on sobriety and rates of active involvement (attending meetings regularly and working the program) among AA members. Based on these data, he put AA's actual success rate somewhere between 5 and 8 percent.

The late G. Alan Marlatt, a respected addiction researcher at the University of Washington, commented on the controversy in a 1983 article in American Psychologist. "Despite the fact that the basic tenets of [AA's] disease model have yet to be verified scientifically," Marlatt wrote, "advocates of the disease

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model continue to insist that alcoholism is a unitary disorder, a progressive disease that can only be arrested temporarily by total abstention.

Source: Gabrielle Glaser. 2015. *The Irrationality of Alcoholics Anonymous.* The Atlantic.
https://www.theatlantic.com/magazine/archive/2015/04/the-irrationality-of-alcoholics-anonymous/386255/

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