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Increasing Access to Medication to Treat Opioid Addiction – Increasing Access for the Treatment of Opioid Addiction with Medications

July 2, 2014

Introduction

The American Association for Treatment of Opioid Dependence represents more than 950 Opioid Treatment Programs in the United States and Mexico. AATOD has worked with our European partners (EUROPAD) in forming the World Federation for the Treatment of Opioid Dependence.

This policy paper is being written against the backdrop of a public health crisis with regard to increasing opioid addiction in the United States. More than 100 Americans are dying each day of opioid related overdoses based on a number of recent reports. First responders such as police are being given opioid overdose prevention kits as a method of reversing the trend of opioid overdoses. This is a critical first step in confronting this public health crisis; however, this intervention also needs to be connected to additional healthcare interventions and addiction treatment, as needed. More Opioid Treatment Programs (OTPs) and more DATA 2000 practices are needed, especially in rural and underserved areas.

Recent published reports have also indicated that the increased use and abuse of prescription opioids has served as a gateway to injecting heroin. Additionally, greater supplies of inexpensive heroin are being shipped into the U.S. by Mexican drug cartels.

This paper also addresses a current policy debate in addiction treatment. Should we view treating chronic opioid addiction as a public health intervention where the principal component of care is prescribing a federally approved medication (methadone, buprenorphine, and Vivitrol/Naltrexone) to treat chronic opioid addiction; should we devote resources to treating chronic opioid addiction with medications and other ancillary services; should we better coordinate organized service delivery models to treat opioid addiction through a continuum of different service delivery components? Illustratively, should harm reduction be the first opportunity of engaging untreated addiction either through syringe exchange programs or Naloxone overdose prevention kits? Should patients be able to access care in physician offices where there is an initial diagnosis of opioid addiction and the prescription of a federally approved medication (buprenorphine/Naltrexone/Vivitrol)? At the present time, DATA 2000 practices appear to be fulfilling this mission. Should there be a better connection between DATA 2000 practices and opioid treatment programs, where there are interfacility referrals from one practice to the next?



It is also important to point out that effective addiction treatment policy begins with effective prevention initiatives and consistent public education.

Medication Assisted Treatment for Opioid Addiction

The federal government recently shifted its characterization of treating opioid addiction to Medication Assisted Treatment (MAT) for opioid addiction. The key phrase is “Assisted Treatment”, since medication alone is not viewed as being sufficient in and of itself to treat this complex disease. NIDA’s *Principles of Drug Addiction Treatment*, which was published in 2009, underscores this point as does the SAMHSA *Treatment Improvement Protocol #43 (2005)*, *Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. These perspectives are also reflected in SAMHSA’s recent draft *Federal Guidelines for Opioid Treatment*, which were published in a Federal Register Notice on May 16, 2013 and are still under federal review.

Federal Guidance/Clinical Treatment Recommendations

NIDA’s *Principles of Drug Addiction Treatment* (2009) discusses a number of important points which are relevant to this paper. NIDA clearly indicates that “Medications are an important element of treatment for many patients, especially when combined with counseling and other behavioral therapies. For example, methadone and buprenorphine are effective in helping individuals addicted to heroin or other opioids stabilize their lives and reduce their illicit drug use. Naltrexone is also an effective medication for some opioid addicted individuals and some patients with alcohol dependence.”

NIDA also makes an important point in one of their agency’s principles in underscoring the fact that “effective treatment attends to multiple needs of the individual, not just his or her drug abuse. To be effective, treatment must address the individual’s drug abuse and any associated medical, psychological, social, vocational, and legal problems.” These statements represent some basic foundations for the treatment of this complex illness; however, the question is how often are such principles put into actual practice in treating this chronic illness outside of the OTP setting?

It is useful to reference an early perspective on this matter through Dr. Vincent Dole, who with his associates, Dr. Marie Nyswander and Dr. Mary Jeanne Kreek, developed the foundation of Methadone Maintenance Treatment at Rockefeller University in the mid 1960s. Dr. Dole’s point on this matter is captured in a book, *Addicts Who Survive: An Oral History of Narcotic Use in America, 1923-1965*. Dr. Dole indicated that “The problem was one of rehabilitating people with a very complicated mixture of social problems on top

of a specific medical problem, and that [practitioners] ought to tailor their programs to the kind of problems they were dealing with. The strength of the early programs as designed by Marie Nyswander was in their sensitivity to individual human problems. The stupidity of thinking that just giving methadone to solve a complicated problem seems to me beyond comprehension.” We agree with this perspective and AATOD’s policymaking recommendations have reflected these principles since our founding in 1984.

The Value of Providing Comprehensive Treatment Services to Treat a Complicated Illness

SAMHSA’s Treatment Improvement Protocol #43 (published 2005) develops an important discussion about opioid addiction as a medical disorder. “Discussions about whether addiction is a medical disorder or a moral problem have a long history. For decades, studies have supported the view that opioid addiction is a medical disorder that can be treated effectively with medications, administered under conditions consistent with their pharmacological efficacy, when treatment includes comprehensive services, such as psychosocial counseling, treatment of co-occurring disorders, medical services, vocational rehabilitative services, and case management services.”

NIDA also makes the evidence-based point for having a comprehensive array of services to treat chronic opioid addiction in *Principles of Drug Addiction Treatment*, as referenced above. “Many drug addicted individuals also have other mental disorders. Because drug abuse and addictions – both of which are mental disorders – often co-occur with other mental illnesses, patients presenting with one condition should be assessed for the other(s). And when these problems co-occur, treatment should address both (or all), including the use of medications as appropriate.”

It is recognized that effective treatment interventions are ideally provided at a single site, especially in treating a stigmatized patient population with a complex disorder. It is understood that Health Care Reform initiatives will have a major dynamic effect on this approach to treating chronic opioid addiction. Obviously, this paper is written at an extremely challenging time in the United States as federal and state agencies are confronting the fact that increasing opioid addiction is a major public health challenge. Governor Shumlin of Vermont went so far as to indicate that opioid addiction is the major public health crisis affecting this society at the present time.

There are numerous reports about the increasing public health crisis of Americans becoming dependant and subsequently addicted to prescription opioids. It has also been reported that an increasing number of individuals are using heroin when their preferred prescription opioids are no longer available. This is still a developing issue so it is too early to refer to this as a trend. The

reason for referencing these data and changes in the public health view of opioid dependence and addiction is related to how effectively we treat the illness.

NIDA also makes the point that “treatment programs should assess patients for the presence of HIV/AIDS, Hepatitis B and C, Tuberculosis, and other infectious diseases as well as provide targeted risk reduction counseling to help patients modify or change behaviors that place them at risk for contracting or spreading infectious diseases.” There have been recent published reports expressing concern about how such services are targeted, specifically in Opioid Treatment Programs, in addressing these infectious diseases. The criticism basically forms along the line that some OTPs are not providing sufficient access to either diagnose or treat such illnesses either through the OTP or through case management referral to other settings. This matter is also discussed in SAMHSA’s *TIP #43*, as referenced above. “Entry into comprehensive maintenance treatment provides an opportunity to prevent, screen for, and treat diseases such as HIV/AIDS, Hepatitis B and C, and Tuberculosis, and to increase compliance with medical, psychiatric, and prenatal care.”

In this particular case, it is reasonable to conclude that such critiques could be applied to both OTPs and DATA 2000 practices, however, we know more about what happens to the patient in the Opioid Treatment Program.

There is another important point to make in the discussion of providing ancillary services to the patient in addition to a medication. There have been papers about phases of care and patient matching. Such references have underscored that not all patients need access to counseling services indefinitely. A number of OTPs have offered intense and comprehensive treatment interventions for newly admitted patients, which continue during the early stabilization phase of care. We have also learned that patients will need treatment interventions specifically geared to their needs at different points in time throughout the treatment experience. Additionally, treatment personnel need to be well trained and compassionate; otherwise the patient will not feel that the care they are receiving is helpful.

Current Policy Debates

OTPs

At the present time, there are two significant provider opportunities to treat chronic opioid addiction. Opioid Treatment Programs, which have been in existence since the mid 1960s, principally utilize methadone as a medication to treat chronic opioid addiction. SAMHSA provided an expanded opportunity for OTPs to use buprenorphine on December 6, 2012, when it published federal guidelines to use buprenorphine with greater clinical flexibility with regard to take-home medication. All of the other requirements for operating OTPs remained in effect, which were consistent with the SAMHSA regulatory

requirements of 2001. As most readers know, OTPs have been under federal regulation since 1972 when Congress bifurcated regulatory oversight between the Department of Justice/DEA and the Department of Health and Human Services/FDA. The FDA subsequently transitioned its regulatory oversight authority to SAMHSA in 2001 with the approval of the Department of Health and Human Services. The governing regulations of the DEA remained in effect.

SAMHSA also has promulgated the Treatment Improvement Protocol guidelines as referenced above, first through *TIP #1, State Methadone Guidelines*, (1993) which were subsequently updated in an expanded version of *TIP #43* in 2005, as referenced above.

In the SAMHSA trilogy of oversight to OTPs, it also published *Accreditation Guidelines for OTPs* in 2007. These guidelines provided a greater depth of clinical guidance to OTPs, expanding on the SAMHSA regulations of 2001 and reinforcing the clinical guidelines contained in *TIP #43*. In effect, the OTPs are required to provide the services as delineated in the SAMHSA 2001 regulations in addition to being guided by the principles of treatment in *TIP #43* and the *Accreditation Guidelines*. The regulations also specify that all certified OTPs in the United States must be reviewed by accrediting entities as approved by SAMHSA. There is no opt-out provision for this regulatory oversight. Additionally, OTPs also operate under the regulatory aegis of the State Opioid Treatment Authorities (SOTAs).

At the present time, approximately 1,270 OTPs are certified to treat patients in the United States. Approximately 325,000 patients receive treatment through these OTPs. The most recent available N-SSATS data from SAMHSA indicates that approximately 300,000 patients receive methadone through the OTPs while the remaining 25,000 receive buprenorphine. We have also learned that there are considerable impediments to the use of buprenorphine in OTPs. Illustratively, very few states have Medicaid reimbursement for the use of buprenorphine in OTPs. There are also third party insurance restrictions in some states and through some commercial insurers with the use of buprenorphine in DATA 2000 practices and the use of Naltrexone/Vivitrol as well. This policy issue was the foundation of ASAM's (American Society of Addiction Medicine) groundbreaking report of July 2013.

DATA 2000 Practices

The Drug Abuse Treatment Act of 2000 was approved by Congress in 2000 and focused on the use of Schedule III, IV, V opioids to treat chronic opioid addiction through DATA 2000 practices. The Congressional legislation did not reference Opioid Treatment Programs and was exclusive to certified physicians who would qualify to prescribe such medications to treat chronic opioid addiction through an eight hour training course. The limitation was in treating 30 patients for the first year and subsequently treating 100 patients (amended

Act 2006), should the DATA 2000 practitioners wish to do so after they had demonstrated expertise in treating the patient population. It is estimated that approximately 400,000 – 450,000 patients are treated through DATA 2000 practices at any point in time, depending on the data source. Approximately 7,500 certified DATA 2000 physicians have the approval to treat 100 patients. This is the ceiling on the number of patients that can be treated through any singular DATA 2000 practice. There are also group DATA 2000 practices, where physicians can treat up to 100 patients per physician in a group practice model. There is no published restriction on the number of physicians who form such a group medical practice in treating such patients.

As a point of reference, there is no restriction on the number of patients that can be treated in the OTP as far as federal regulations go. There are statewide regulations, which can limit the number of patients in treatment based on licensing standards. It is also important to point out that in some states, an OTP cannot increase the number of patients it would like to treat without passing through a review by the state.

It is important to reference the history of why Congress incorporated the initial restrictions of the 30 patient cap on DATA 2000 practices and the subsequent 100 patient restriction, as referenced above. Federal agencies and Congressional representatives repeatedly indicated that they wanted to “normalize addiction medicine” by having a significant number of physicians treat a limited number of opioid addicted individuals as part of their private medical practices. They also did not wish to create more hub settings, such as Opioid Treatment Programs, which attract community attention in such centralized sites. Such federal authorities and Congressional representatives also repeatedly indicated that they wanted to avoid creating large medical practices, which would be treating several hundred patients at a single site, since they did not want to promulgate regulatory oversight standards for DATA 2000 practices, which had been in place for OTPs since 1972. The point, which was repeatedly expressed at the time of the initial DATA 2000 legislation, was that in limiting the number of patients that a DATA 2000 practice could treat, there would be limited negative public reaction in questioning why such physicians were treating opioid addicted individuals and there would not be any need for regulatory oversight.

At the present time, it would appear that such admonitions have been forgotten given the current climate of urgency in needing to increase access to care in DATA 2000 practices.

Reports of Medication Diversion

Reports of Methadone Diversion through OTPs

There has always been a concern about medication diversion from addiction treatment facilities since the early 1970s when methadone maintenance

treatment was the exclusive medication used to treat chronic opioid addiction in the United States. This point is made in the 1995 report “Federal Regulation of Methadone Treatment” as published by the Institute of Medicine. “The concern for methadone diversion preceded the issuance of FDA methadone regulations in 1972, influenced the views of policymakers writing the regulations, and continues to shape the regulations today as thoroughly as does the concern for the medical use of methadone to treat opioid addiction.” The Institute of Medicine report described how such diversion concerns influenced federal regulation in the use of methadone to treat opioid addiction, in developing a “closed model” of treatment programs licensed by the federal government in addition to specifying strict time tables and criteria for granting and rescinding take home doses to patients. As many readers know, the FDA transitioned its oversight of the nation’s Opioid Treatment Programs to the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2001. SAMHSA did change the regulations in order to provide greater clinical flexibility to OTPs; however, SAMHSA preserved the eight-point criteria which would govern the provision of take home medication to patients. These eight criteria remain fully intact from the FDA regulations and continue in force at the present time.

There were significant reports of methadone diversion from the nation’s Opioid Treatment Programs in the 1970s and 80s. This raised concerns in enforcement agencies, including the DEA and a number of state regulatory authorities. One observer might argue that the maturation of the treatment system, the greater vigilance in adhering to the promulgated federal and state regulations, governing the provision of take home medication, reduced the diversion of methadone through the nation’s OTPs. Federal and state published reports about methadone diversion from OTPs during the late 1990s decreased significantly.

There was an unanticipated development relating to reports of methadone diversion and mortality, which was related to the prescribing of methadone to treat chronic pain. This phenomenon came to surface in 1997 and continues to the present day. The issue of methadone diversion and methadone related mortality during this period of time has little to do with the nation’s Opioid Treatment Programs. The clear distinction relates to the mechanisms that limit how take home medication is restricted through the OTP setting versus the unrestricted use of methadone through a physician’s office. This has been documented in five national reports on this particular topic.

It is useful to cite the United States Government Accountability Office Report to Congressional Requestors (published March 2009), “Methadone Associated Overdose Deaths – Factors Contributing to Increased Deaths in Effort to Prevent Them”. “Federal officials and experts of epidemiology, pain management, and addiction treatment at SAMHSA’s National Assessment of Methadone Associated Mortality of 2003 also acknowledged a correlation between the increased distribution of methadone through pharmacies for pain management with the increase in methadone associated overdose deaths and reached

consensus that the increase in these deaths was not associated with addiction treatment in OTPs. Additionally, in 2006, CDC researchers suggested that the increase in deaths involving methadone was related to physicians increasingly prescribing the drug for pain. The researchers reported that the increase in deaths track the increase of methadone used for pain management rather than its use in OTPs.” SAMHSA’s published reports on methadone related mortality in 2007 and 2010 drew similar conclusions.

Reports of Buprenorphine Diversion through DATA 2000 Practices

There have been increasing reports concerning the diversion of buprenorphine products as a greater number of patients have received access to buprenorphine in DATA 2000 practices. The major difference in how methadone and buprenorphine diversion is viewed is based on the pharmacologic properties of the medications. Methadone is a full agonist and as a noted pain management specialist has pointed out, it is an excellent medication when used properly and an unforgiving medication when used improperly. The result of methadone diversion and its improper use has caused a significant number of methadone related mortalities each year since 1997.

On the other hand, buprenorphine is a partial agonist/antagonist and while it is diverted for non-therapeutic use, it rarely results in an overdose when used alone. There is also a current policy debate about the fact that such diverted buprenorphine is being used therapeutically by people who cannot gain access to treatment. This perspective takes the view that the nation and its officials should not be concerned about reports of buprenorphine diversion because it is being used safely by such individuals. There are no published reports to support this point of view, although a number of people who are using buprenorphine through illicit means may be doing so to prevent withdrawal until they are able to access their preferred opioid. It is also true that a number of individuals who use buprenorphine, which is obtained through illicit means, are abusing the medication. It is a complex topic which needs further evaluation.

Future Policy Considerations

At the present time, there is an interest on the part of some parties to remove existing patient caps from DATA 2000. Some legislators and professional medical associations are interested in increasing the existing 100 patient cap to a larger number of patients. The argument is that no medical practice should be restricted to any number of patients that a practitioner can treat. After all, no other practice limitation applies to the treatment of any other illness which uses medications to treat a chronic disorder. In this argument, there should be no distinction in the provision of treating chronic opioid addiction as compared to the treatment of other chronic diseases. The question that comes to mind in this policy arena is should the treatment of opioid addiction be seen as a specialized treatment for a specific disorder? The SAMHSA and NIDA publications, as

referenced above, would appear to lead one to take this perspective, which is why such agencies repeatedly discuss the importance of “comprehensive service delivery”.

What should we know before the existing patient caps are removed or changed in treating patients with buprenorphine in DATA 2000 practices? What do we know about what goes on in a DATA 2000 practice? What percentage of physicians refers patients for counseling and other services? How many DATA 2000 practices are organized to provide such counseling to the patient on site? What percentage of physicians uses any sort of toxicology testing to guide therapeutic dosing and decision making? How long do patients remain in treatment through DATA 2000 practices? What other services are being provided at or through DATA 2000 practices?

This is not meant to be an exhaustive list of questions but represent some of the essential questions that should be asked and answered before any major shift in federal policy is promulgated.

There are Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (*TIP #40*) also published and disseminated by SAMHSA. The difference here is that the clinical standards of *TIP #40* are not reinforced by either regulation or accrediting guidelines. We are not suggesting that this change, because we understand the value of having different levels of service for the patient population. The question is how different the levels of care should be based on what we know in treating this particular illness.

The point here is that we should not forget about the research that has been conducted over the course of the past 50 years and the many policy reports and published federal recommendations that have followed. There is much discussion about evidence based practice and good medical care to treat this illness. Some representatives even go on to state that we all know that treating chronic opioid addiction requires a comprehensive treatment intervention that goes beyond writing a prescription. Soon after, the statement typically follows that we cannot afford to turn any patient away from care in spite of the fact that we are not able to provide such comprehensive services. If we know that there are medical standards in treating such an illness, they should be followed. When quality treatment interventions are sacrificed at the hands of quantity, the integrity of the treatment intervention is inevitably questioned.

Summary

Our country is in a dynamic period of Health Care Reform and we anticipate that a greater number of people will access medical care to treat their illnesses, including opioid addiction. The questions raised here also relate to what quality of care is provided to the patient and over what period of time.

Another dynamic is dealing with increasing prescription opioid addiction in both OTPs and DATA 2000 practices. AATOD has been managing one of the Signal Detection Systems within the RADARS™ System, managed by the Denver Health and Hospital Authority, since January 2005. We have learned a great deal over this period of time about changing patient characteristics as people are admitted to treatment. At the time of this paper, over 70,000 patients have completed survey instruments as they are admitted to OTPs. Of this group, 45% have indicated that they are addicted to prescription opioids at the time of admission. AATOD has provided guidance to OTPs in accessing statewide Prescription Drug Monitoring Programs, where they exist, as the patient is beginning treatment and throughout the course of the patient's care. We agree with SAMHSA's correspondence on this policy topic, as reflected by Dr. Westley Clark's letter to the field of September 2011. AATOD subsequently published its own guidelines in support of Dr. Clark's correspondence since we believe that accessing such PMP databases will improve treatment outcome.

There is also an evolving treatment issue with regard to recovery oriented systems of care. The draft SAMHSA *Accreditation Guidelines for OTPs* references this important evolution, especially in referencing recovery oriented care. The guidelines provide two important reference points, "Medication Assisted Treatment for opioid addiction reflects many elements of the chronic care treatment model. Instead of brief interventions, crisis linked timing, and a focus on abstinence characterized by the acute care treatment model, Medication Assisted Treatment focuses on treatment retention, stabilization, and medication maintenance and tapering." The guidelines go on to make a second important point. "Within the recovery management framework, recovery from addiction is viewed as a voluntary, self directed, ongoing process where patients access formal and informal resources; manage their care and addiction; and rebuild their lives, relationships, and health to lead full, meaningful lives. While recovery is patient-directed, recovery management is comprised of clinically based structured processes used to coordinate and facilitate the delivery of recovery support services after the acute stage of treatment." This recovery based treatment intervention is referenced here only as a means of suggesting that any significant philosophical change in treating chronic opioid addiction, whether in the OTP or DATA 2000 practice, be taken into account.

This policy paper is not intended to answer all the questions that are raised, since current data do not allow for a full and reasonable exploration of such matters. These are questions that are raised given the current dynamics of the system and the fact that state legislatures and regulatory bodies are implementing a number of statutes and regulations affecting how patients gain access to care.

There is also increasing interest in developing new models of addiction treatment in an era of Health Care Reform and parity legislation. It is expected that a greater number of people will need to access treatment for their opioid

addiction in the coming years. This is already in evidence as states are responding to treating this population. Illustratively, Vermont has developed a “hub and spoke model”, which is increasing access to different levels of care through a number of treatment resources, including DATA 2000 practices and OTPs. Rhode Island and Maryland are developing models where OTPs are integrated with health homes and creating different treatment models, which also reflect greater amounts of reimbursement to treat the patients more holistically.

There are also alternatives to increasing the existing cap for currently certified DATA 2000 practices. One potential and significant policy change would be to include mid-level practitioners under the aegis of DATA 2000. Another option is to provide DATA 2000 practitioners, who are treating 100 patients, with the option of converting to Opioid Treatment Programs, which would function under the aegis of SAMHSA’s regulations. Illustratively, if DATA 2000 practices would like to treat 250-500 patients at a single practice site, they could do so with an approval from SAMHSA. In this way, a physician in a DATA 2000 practice would employ other professionals to provide access to different services in addition to the prescribing of a medication.

There are additional federal considerations to be made by the existing oversight agencies within the Department of Health and Human Services with regard to adjusting the cap of existing DATA 2000 practices. Rather than execute any across the board change, some consideration could be given to experts in addiction medicine who have been found to successfully coordinate the treatment of 100 patients in their DATA 2000 practices. This would be a far more considered approach and based on evidence that has been gathered in understanding how effectively such individualized DATA 2000 practices have operated in treating this patient population and based on the established evidence of good quality practice standards.

As was stated earlier in this paper, harm reduction models are increasingly being used, such as syringe exchange programs and Naloxone opioid overdose prevention kits as a method of keeping people alive. The key to making these early interventions successful will be connecting the individuals to other treatment interventions to prevent future opioid overdoses. One of the most important points to make is to support the use of the three federally approved medications to treat opioid addiction and to educate the public about the realities of opioid use/dependence/addiction so that people better understand when they are getting into trouble.

The point of this paper is to recommend careful consideration on such policy issues so that we can effectively increase access to care for all individuals who need treatment for their opioid addiction in an era of increasing prescription opioid abuse, increasing heroin use, and the need to provide the best level of care that can be offered to treat such illnesses effectively. In spite of the fact that

we are clearly facing a public health crisis of opioid addiction, we need to develop thoughtful solutions based on what research and clinical practice have demonstrated over the past 50 years. We also need a major public education campaign about opioid use, dependence, abuse, and addiction. It will need to be sustained over the course of many years with a consistent message readily embraced by a wary public.