Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Recovery-Oriented Methadone Maintenance

July 2014



Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Recovery-Oriented Methadone Maintenance

June 2014 | Community Care Behavioral Health Organization | www.ccbh.com

Contact: Marge Hanna

Senior Director, Substance Use Disorder Initiatives, Community Care

<u>hanname@ccbh.com</u> | 412.454.2120

Contents

Exe	cutive Summary	. 4
l.	Introduction	. 4
II.	Background	. 7
III.	Recovery-Oriented Methadone Maintenance (ROMM)	. 12
IV.	Scope and Purpose	. 13
V.	Intended Audience	. 14
VI.	Limitations and Clarifications	. 14
VII.	Community Care Guiding Principles for Medication-Assisted Treatment (MAT) for Opioid Addiction	. 15
VIII.	Organization of Best Practice Guidelines for Recovery-Oriented Methadone Maintenance	. 17
	VIII.A. Phase 1: Recovery Initiation and Stabilization	. 17
	VIII.B. Phase 2: Early Recovery and Rehabilitation	. 24
	VIII.C. Phase 3: Recovery Maintenance	. 26
	VIII.D. Phase 4: Long-Term Sustained Recovery	. 27
	VIII.E. General Agency Guidelines	. 29
IX.	Summary	. 30
Ac	ddendums	
A.	Methadone: Basic Information and Resources	. 37
B.	Management of Benzodiazepines in Medication-Assisted Treatment: Final Report on the Development of Clinical Guidelines, November 2014	. 39
C.	DSM-V Opioid Use Disorder Diagnostic Criteria	. 47
D.	Tools for Assessing Withdrawal Status	. 49
E.	Bibliography: AATOD	. 53
F.	Patient/Family Information	. 64
G.	Supporting Recovery from Opioid Addiction: Best Practice Guidelines for Buprenorphine and Suboxone®	. 67

Executive Summary

Opioid use disorders are as significant in Pennsylvania as elsewhere in the country—with Pennsylvania reported to have one of the highest numbers of heroin users. Addiction to prescription pain relievers has increased dramatically over the years, fueling the growth in numbers of those needing access to quality treatment options. Methadone Maintenance Treatment (MMT) is one of the best researched treatment options for those with an opioid use disorder and has been a practice since the late 1960s. Despite evidence of good outcomes, there remains some controversy about the use of medication-assisted treatment in general and MMT specifically among the general public, policymakers, treatment experts, and those seeking recovery.

Although there has been insufficient research on the impact of various treatment pathways on long-term recovery outcomes, there is a growing body of evidence indicating that we need to pay more attention to the importance of non-clinical recovery support services (RSS) as an adjunct to clinically-based treatment pathways such as MMT. Recovery support services, including peer-based recovery support services (P-BRSS), made available before, during, and after formal treatment interventions are believed to enhance recovery outcomes, including improving rates of engagement and retention in treatment. The breakthrough monograph *Recovery-Oriented Methadone Maintenance*, by William L. White, MA and Lisa Mojer-Torres, JD, introduced specific support services that can enhance MMT outcomes—rooted in the larger framework of recovery-oriented systems of care (ROSC).

These best practice guidelines serve to blend what is currently known to be best practice in MMT with recovery-oriented strategies proposed by White, Mojer-Torres, and others. Application of these guidelines can enhance the quality of care in MMT and long-term recovery outcomes.

I. Introduction

Addiction to opioids continues to be a significant public health problem in the United States. In 2011 the National Survey on Drug Use and Health (NSDUH) reported that an estimated 22.5 million Americans aged 12 or older (8.7% of this population) were current (past month) illicit drug users. Illicit drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics (pain relievers, tranquilizers, stimulants, and sedatives) used non-medically. Non-medical users of pain relievers are now at an estimated 4.5 million people or 1.7% of the 12 or older group, a figure somewhat lower than 2009 or 2010. The number and percentage of persons aged 12 or older who were past year heroin users (620,000) continued the trend upward—a 60% increase since 2007. There was a 49% increase in the number reporting as dependent on heroin as measured in the past 12 months (369,000) and a 59.5% increase in new initiates to heroin for the same reporting period (178,000). The increase in initiation rates was observed in the 18 to 25 and 26 to 49 age groups. According to Pennsylvania law enforcement officials, Pennsylvania has the third highest number of heroin users in the United States, estimated recently at 40,000 users.²

The Drug Abuse Warning Network (DAWN) is another marker for change in drug use and abuse. The 2011 findings on drug-related emergency room visits indicated that visits involving misuse or abuse of pharmaceuticals increased from 2004 (626,470 visits) through 2011 (1,428,145 visits). The most commonly involved drugs were anti-anxiety and insomnia medications and narcotic pain relievers (160.9 and 134.8 visits per 100,000 population, respectively). There was a 153% increase between 2004 and 2009 in the reported drug related emergency room visits for narcotic pain relievers, with no significant increase reported in the 2011 numbers. In comparison, reported heroin related visits have remained stable since 2004 at 83 visits per 100,000.

The Centers for Disease Control (CDC) reported in February 2013 that three out of four drug overdose deaths in 2010 involved opioids. Between 1999 and 2010 overdose deaths attributable to opioid analysesics have shown an increase of more than 300% with reported deaths at 16,651. This parallels the percentage increase in sales of opioid analysesics for the same period. Pennsylvania is one of the top twelve states for drug overdose deaths. Those most at risk for overdose include 4:

- People who obtain multiple controlled substance prescriptions from multiple providers.
- People who take high daily dosages of prescription painkillers and those who misuse multiple abuseprone prescription drugs.
- Low-income people and those living in rural areas

 people on Medicaid are prescribed painkillers at
 twice the rate of non-Medicaid patients and are at six
 times the risk of prescription painkiller overdose.
- People with a mental health condition and those with a history of substance abuse.

The Treatment Episode Data Set (TEDS) ⁵ report indicated that in Pennsylvania in 2010, there were 19,479 individuals admitted for a heroin or other opioid addiction, 31.3% of all admissions. Although this number also reflects little change in the percentage of heroin users in recent years, since 2006 there has been a 60% increase in the number of individuals admitted to treatment in Pennsylvania reporting addiction to other opioids, which would include narcotic pain relievers.

In the fall of 2013, fueled by the increasing number of drug related deaths and interest in expanding a prescription drug monitoring database, Pennsylvania initiated a series of hearings to determine the extent of what is referred to by state legislators and law enforcement personnel as a heroin epidemic. A recent SAMHSA (Substance Abuse and Mental Health Administration) study indicated a strong association between prior non-medical use of pain medication and initiation of heroin use. Heroin is considered a cheaper and more readily available substitute for prescription pain relievers. ⁶

It is a sad fact that those who have an addiction to drugs do not necessarily seek treatment. The NSDUH 2011 survey noted that only 18.8% of those who needed treatment for an illicit drug use problem received it in a specialty facility in the past year, with 5.8 million not receiving treatment for their abuse or dependency. Of this number, only 488,000 (8.4%) felt that they needed any treatment, with 51% making no effort to obtain treatment for the following reasons:

- Lack of health insurance or could not afford the cost of treatment (37.3%).
- Not ready to stop using (25.5%).
- Had health coverage but did not cover treatment or did not cover cost (10.1%).
- Possible negative effect on job (10.1%).

- No transportation/inconvenient (9.5%)
- Not knowing where to go for treatment (7.3%).
- Concern about negative perceptions by neighbors and the community (7.2%).
- Did not have time (7.1%).

In summary, the rates of dependency and new initiates to heroin continue to trend upwards as does the number of individuals abusing or dependent on the non-medical use of prescription pain relievers. This increase is a factor in admissions to treatment facilities, emergency room visits, and drug overdose deaths. It is also of note that the Medicaid population has a higher percentage of individuals with abuse and addiction⁷, as well as being at higher risk for overdose deaths, as are those with a mental health condition or prior history of substance abuse dependence. Yet only a very small percentage of those who meet the criteria for substance abuse or dependency actually seek treatment for their illness. Studies have indicated that individuals with a drug addiction averaged seven years from initiation of regular drug use prior to entering treatment for the first time. ⁸

Strategies to increase our success in addressing the serious problem of substance use disorders include:

- Routine screenings of individuals in health care and other settings to identify and address risky behavior and identify early patterns of abuse and addiction. 9
- Assertive outreach to those with patterns of abuse and addiction to encourage them to engage in a pathway of treatment and recovery.
- Increased access to evidence-based and promising practices, including medication-assisted treatment (MAT).
- Expansion of community-based recovery supports, including certified recovery specialists, recovery coaches, safe housing options, educational and vocational services, recreational and spiritual supports, and other services that support long-term recovery and are in accordance with the principles and elements of recovery management (RM) and recovery-oriented systems of care (ROSC). 10

Medication-Assisted Treatment (MAT)

Opioid addiction, along with other drug addiction, is a chronic disease, requiring a community-based recovery management approach to increase the likelihood of long-term recovery. Medication-assisted treatment is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. In the United States, MAT (also frequently referred to as Medication-Assisted Recovery MAR) has proven to be effective in the treatment of opioid dependence with the U.S. Food and Drug Administration (FDA) approved drugs of methadone, naltrexone, and buprenorphine.

Research shows that when treating substance use disorders, a combination of medication and behavioral therapies is most successful integrated with addressing physical health issues. Additionally, community-based recovery supports, such as mutual aid groups (e.g., 12-step programs); certified recovery specialists; recovery coaches; safe and stable housing; and attention to educational, vocational, social, and spiritual needs, are important in recovery management. MAT is clinically driven with a focus on individualized patient care. As part of a comprehensive treatment program, MAT has been shown to: 11

- · Improve survival.
- Increase retention in treatment.
- Decrease illicit opiate use.
- Decrease hepatitis and HIV seroconversion.

- Decrease criminal activities.
- · Increase employment.
- Improve birth outcomes with perinatal addicts.

Research indicates medication-assisted treatment as the most effective approach in treating chronic opioid addiction for many individuals. Methadone maintenance treatment (MMT) is the most researched of medications used in the effective treatment of opioid addiction. Buprenorphine treatment was approved by the FDA in 2002 and access to buprenorphine through private physicians certified to prescribe this medication, as well as through OTPs (Opioid Treatment Programs) and other licensed drug and alcohol treatment programs, continues to expand access to opioid addiction treatment. Little data is currently available on the extent of use of naltrexone and its long-acting formulation, Vivitrol®, for treatment of opioid-addicted individuals; although its use is increasing in Pennsylvania, including a pilot program for women incarcerated in Muncy State Correctional Institution. A person-centered and recovery-oriented approach is to offer a range of options for people who present to treatment, including medication-assisted treatment.

Methadone Maintenance Treatment (MMT)

Introduced in the late 1960s with the first federal regulations issued in 1972, methadone maintenance treatment has been well researched and continues to be a very important tool in treatment and recovery from opioid addiction. In the United States, MMT is provided in the context of licensed OTPs and is the most regulated of addiction treatment approaches. In his book *Slaying the Dragon—The History of Addiction Treatment and Recovery in America*¹³, William L. White presents a comprehensive description of addiction and reviews the evolution of treatment approaches, including methadone maintenance treatment. More information about methadone is included as **Addendum A**.

Methadone maintenance treatment in Pennsylvania is provided, for the most part, in free standing licensed treatment agencies—OTPs. Such agencies are licensed to provide MMT and also to (minimally) provide basic outpatient services. There are only a few facilities in Pennsylvania where MMT is integrated within the context of a full range of ambulatory care services including partial and intensive outpatient services. Currently only a few Pennsylvania residential programs will initiate or maintain person(s) in recovery (PIR) on methadone at this higher level of care.

II. Background

Pennsylvania Challenges

Pennsylvania currently has 65 licensed methadone maintenance OTPs, located in 33 counties and serving all 67 counties of the Commonwealth. As of this writing there are 20 MMT programs in the Community Care Behavioral Health Organization (Community Care) network serving individuals in 39 counties. While methadone maintenance treatment with accompanying psychosocial programming is considered a well-researched, evidence-based pathway for many with an opioid addiction, access to MMT continues to be an issue, along with other challenges related to MMT in particular and medication-assisted treatment (MAT) in general.

The Pennsylvania Department of Drug and Alcohol Programs (DDAP) contracts with 47 Single County Authorities (SCAs), representing the 67 Pennsylvania counties, to manage the provision of county-based drug and alcohol prevention, intervention, treatment, and recovery services utilizing federal block grant, state, and local funding. This contract includes a requirement that SCAs contract for methadone maintenance services. As one example of problems with access, a SCA director in a rural region recently stated, "Our clients must travel two hours one way for methadone maintenance and then usually (spend) an hour or two at the facility and then two hours back home. Methadone maintenance treatment consumes almost 8 hours a day and makes it very hard to hold a job. If a client is able to still have a job then it hinders their participation into treatment." ¹⁴

In addition to access, there are other challenges inhibiting provision of quality methadone to individuals screened and assessed as appropriate for this service. In 2010 the Institute for Research, Education & Training in Addiction (IRETA), then Pennsylvania's regional Addiction Technology Transfer Center (ATTC), published *Recovery-Focused Methadone Treatment—A Primer for Practice Today in Pennsylvania* ¹⁵ in which the continued issues of stigma by the general public about MMT was discussed. Recent Pennsylvania legislative initiatives included establishing a specific review panel for methadone-related deaths (the only one of these bills subsequently passed into law) ¹⁶, adjusting transportation reimbursement policies, establishing time limits on methadone treatment availability, and setting dosing standards. Many issues sparked the introduction of these bills including:

- A significant upward trend in the number of methadone related deaths in Pennsylvania. Although the increase in the last decade of overdose deaths parallels the increase in the prescribing of methadone (and other opioid analgesics), there remains a public perception that these deaths are somewhat or largely attributable to methadone dispensed at OTPs and subsequently diverted. Five national reports on the topic of methadone deaths have been published—three by SAMHSA (2003¹⁷, 2007¹⁸, 2010¹⁹), one by the Department of Justice (2007²⁰), and one by the General Accounting Office (GAO) (2009²¹). All came to the inclusion that the primary cause of methadone mortality was methadone prescribed by physicians to treat pain and dispensed through pharmacy channels.
- Well publicized highway deaths attributed to individuals traveling home following MMT clinic visits. These deaths have raised questions of appropriate dosing, adequate monitoring for other medications/alcohol/other drugs that may be in use by the individual at time of dosing, and questions related to the side effects of a methadone dose.
- Accusations that medication take home polices by some programs in Pennsylvania are contributing to both deaths and illegal sales. This continues to be a perception as indicated in a March 2013 article that also quotes the author of several of the bills introduced.²²
- Aggressive marketing practices of select MMT programs to the general public.
- A history of high reimbursement amounts billed to DPW for transportation to and from MMT clinics by some persons in recovery (PIR). Under Pennsylvania's State Medicaid Plan, the Commonwealth must ensure that individuals have transportation to and from their health care providers and uses its Medical Assistance Transportation Program (MATP) to provide non-emergency transportation to those who need it. A performance audit of the state's methadone treatment and transportation program ^{23,24} released in February of 2011 included the recommendation that DPW consider developing "best practice" guidelines for its methadone treatment providers to help ensure that transportation service reimbursements are appropriate. In 2010, DPW did change its policy to restrict reimbursement to clients to the two closest clinics to the client's residence with a maximum reimbursement of 50 miles one way; and local paratransit services for individuals attending MMT similarly changed their polices in 2011.
- Accusations that some for-profit clinics were placing profits over quality services, including concerns that psychosocial services were not being matched to the specific needs of PIR. Some providers and others believe that the Pennsylvania regulations on the number of counseling hours for PIR are misinterpreted and have become the standard number of hours provided to those attending MMT rather than a minimum with additional psychotherapy provided as needed.

PA Code § 715.19. Psychotherapy services.

A narcotic treatment program shall provide individualized psychotherapy services and shall meet the following requirements:

- 1. A narcotic treatment program shall provide each patient an average of 2.5 hours of psychotherapy per month during the patient's first 2 years, 1 hour of which shall be individual psychotherapy. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.
- 2. A narcotic treatment program shall provide each patient at least 1 hour per month of group or individual psychotherapy during the third and fourth year of treatment. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.
- 3. After 4 years of treatment, a narcotic treatment program shall provide each patient with at least 1 hour of group or individual psychotherapy every 2 months. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.

This concern has also been expressed in other states. In a 2013 article ²⁵, Robert Lubran, director of Pharmacologic Therapies at the Substance Abuse and Mental Health Services Administration (SAMHSA), was quoted as saying the "array of legislation reflects concerns that some for-profit clinics, which distribute the synthetic narcotic to help patients beat addictions to heroin and other opiates, don't provide enough services. We know for-profit providers often provide a lower level of service" than nonprofit counterparts. Additionally there have been reports that the "group therapy" provided in some clinics is inconsistent in terms of frequency and may not be appropriately balanced between psychoeducational and psychotherapeutic. There have also been reports of group size sometimes exceeding 50 individuals. Whether substantiated or not, such reports do not bode well for the public perception of MMT and add fuel to a continued controversy on the efficacy of MMT.

Throughout this period of increased focus on MMT many professionals and persons in recovery in Pennsylvania have testified or otherwise commented on the importance of MMT as one pathway to recovery. A March 28, 2013, Bloomberg article entitled "Methadone Deaths Tied to For-Profit Clinics Prompt Bills" presented what are generally perceived as nationwide concerns about MMT that mirrored the remarks of some Pennsylvanians and included these responses:

- Mark Parrino, president of the <u>American Association for the Treatment of Opioid Dependence</u>: "Many of the legislative proposals are misguided and pose a threat to methadone treatment, which is already rigidly regulated and has been used effectively to treat drug addiction for decades."
- Joycelyn Sue Woods, executive director of the <u>National Alliance for Medication Assisted Recovery</u>, a patient advocacy organization: "The system is in need of reform, but good reform. Once you start passing all these laws, you make it impossible for people who need treatment to get treatment."

It is clear that MMT remains somewhat controversial in nature, as do other forms of medication-assisted treatment (MAT). Concerns continue to be voiced about quality as well as whether MMT is the right pathway to recovery for many individuals. These concerns have sparked a number of Pennsylvania legislative hearings and bills, though legislating clinical decisions may not be the best route. In their document "Best Practices in Methadone Treatment" is issued in 2011 and presented at one of the hearings held by Rep. Gene DiGirolamo, the Pennsylvania Community Providers Association (now the Rehabilitation and Community Providers Association—RCPA) remarked that while (the legislation efforts are) well intentioned, treatment decisions are most appropriately left to clinicians rather than legislated. They went on to acknowledge, however, that their members "...do recognize the need to ensure that methadone treatment is conducted in a safe manner that assures quality and responsible stewardship of public funds." PCPA encouraged the development of best practice guidelines and suggested sixteen specific guidelines that should be included in any BPG document. They also presented six areas for further work, including the recommendation that we promote more education about the good outcomes and cost effectiveness of the provision of MMT services.

The early work of Dr. Herman Joseph (1995) helped us understand the impact of stigma associated with methadone maintenance treatment.²⁷ In his paper *Long-Term Strategies to Reduce the Stigma Attached to Addiction, Treatment, and Recovery within the City of Philadelphia (With Particular Reference to Medication-Assisted Treatment/Recovery)*, ²⁸ William L. White describes how stigma remains a factor in the journey to long-term recovery—tied not only to specific treatment approaches such as medication-assisted treatment, but to those with an addiction in general. He further outlines the "Conceptual Underpinnings of the Social Stigma Attached to Medication-Assisted Treatment (MAT):

- Social and professional stigma, particularly stigma associated with methadone treatment, is buttressed by a set of core assumptions or beliefs.
- These assumptions and beliefs include:
 - Compulsive drug use is a choice.
 - Methadone is a "crutch."
 - Methadone simply replaces one drug/addiction for another.
 - Methadone prolongs rather than shortens addiction careers.
- Low doses and short periods of methadone maintenance result in better rates of long-term recovery.
- Methadone maintenance patients should be encouraged to end methadone treatment as soon as possible.
- These propositions have been and are being challenged by a growing body of scientific research on methadone and medication-assisted treatment and recovery.

While continued stigma appears to be at the root of some of the current challenges to methadone maintenance treatment in Pennsylvania, attention is required for many quality of care concerns. Positive strategies include embracing the principles of recovery-oriented systems of care (ROSC), recovery management (RM), and the enhancements to long-term recovery that this can affect.

In July of 2014, the American Association for the Treatment of Opioid Dependence issued a policy statement ²⁹ in which they comprehensively detail the many issues facing the field of medication-assisted treatment. Their list includes many of the issues raised in Pennsylvania, including the importance of quality care and thoughtful solutions to current issues based "…on what research and clinical practice have demonstrated over the past 50 years." Community Care believes that the issuance of these best practice guidelines will assist our field in improving quality care and pathways to long-term recovery.

Community Care Initiatives

Community Care supports the use of medication-assisted treatment in addressing addiction for select candidates, as well as ready access to quality methadone maintenance treatment. As part of quality improvement efforts it endorses the principles and elements of ROSC ³⁰ and RM and their application in the utilization of medication-assisted treatment. To this end Community Care has engaged in efforts to develop standards of care and best practice guidelines to support this recovery pathway. This has included involvement in several initiatives:

1. Recovery-Oriented Methadone Maintenance Standards Collaboration (2012–2013) with Community Behavioral Healthcare Network of Pennsylvania (CBHNP)

Community Care collaborated in the development of a document entitled *Recovery-Oriented Methadone Maintenance Services Standards* ³¹ to address practice of OTPs in six Pennsylvania counties. These standards are being piloted in 2014 by two Pennsylvania OTPs. This document was influenced by the Southwest Behavioral Health Management, Inc. document, *Best Practice Standards 2012 for Providers of Recovery-Oriented Methadone Services*, ³² developed to cover services provided in a nine-county HealthChoices partnership.

2. Recovery-Oriented Systems of Care Collaboration (2011–ongoing) with Pennsylvania Counties, Treatment Providers and Peers—Persons in Recovery (PIR) and Family Members

Community Care is working in partnership with 39 counties to create recovery-oriented systems of care (ROSC), including recovery management service development and enhancement initiatives designed to improve long-term recovery outcomes. This effort includes a multi-stakeholder Advisory Committee; more than 51% of the individuals on the committee are PIR and family members.

3. Methadone and Benzodiazepine Guideline Collaboration (2012-2013) with Philadelphia Department of Behavioral Health and Intellectual disAbility Services (DBHIDS) and Institute for Research, Education and Training in Addictions (IRETA)

Community Care partnered in the development of a document entitled *Management of Benzodiazepines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines.* ³³ This partnership involved a unique expert panel methodology—the RAND/UCLA Appropriateness Method (RAM)³⁴ —and included a comprehensive review of the literature on methadone and benzodiazepines and best practice clinical guidelines, and the development of proposed guidelines and ratings by the expert panel. This document includes (Addendum B) 101 guidelines organized as:

- a. General guidelines
- b. Assessment for MAT
- c. Addressing benzodiazepine use
- d. MAT for patients with concurrent benzodiazepine use

- e. Noncompliance with treatment agreement
- f. Risk management/Impairment assessment
- g. Special circumstances
- h. Benzodiazepine maintenance

4. Buprenorphine Best Practice Guidelines

In January 2013 Community Care published *Supporting Recovery from Opioid Addiction: Best Practice Guidelines for Buprenorphine and Suboxone*®, ³⁵ the result of a consensus process involving an expert panel and partnership with county including persons in recovery. This document introduced our Guiding Principles for Medication-Assisted Treatment.

III. Recovery-Oriented Methadone Maintenance (ROMM)

"Recovery-oriented methadone maintenance (ROMM) is an approach to the treatment of opioid addiction that combines pharmacotherapy and a sustained menu of professional- and peer-based recovery support services to assist patients and families initiating and maintaining long-term addiction recovery—recovery defined here as remission of primary and secondary substance use disorders, enhancement of personal/family health and functioning, and positive community reintegration." ³⁶

William L. White, MA and Lisa Mojer-Torres, JD in their monograph *Recovery-Oriented Methadone Maintenance*,³⁷ describe the evolution of methadone maintenance treatment in the United States and a vision of a return to, and expansion of, sustained recovery-oriented practices designed to enhance long-term recovery outcomes. They build on the foundation of ROSC—a framework for viewing all behavioral health services including substance use, abuse and addiction and prevention, intervention, treatment, and recovery pathways. Their work also supports the principles of recovery management (RM), the chronic disease model approach for addressing substance use disorders (SUD).³⁸

The Federal Guidelines for Opioid Treatment dated April 2013 in support of ROSC and recovery-oriented methadone maintenance (ROMM) includes the following extracted from William White's work:

"Recovery-oriented systems of care" (ROSC) are networks of formal and informal services developed and mobilized to sustain long-term recovery for individuals and families impacted by severe substance use disorders. The system in ROSC is not a local, state, or federal treatment agency but a macro-level organization of a community, a state, or a nation."

Medication-assisted treatment for opiate 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. Applying the concepts of recovery management, which William White defined as "a philosophical framework for organizing addiction treatment services to provide pre-recovery identification and engagement, recovery initiation and stabilization, long-term recovery maintenance, and quality-of-life enhancement for individuals and families affected by severe substance use disorders," to OTPs was a logical step to improve quality of care and outcomes.

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 their 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. ³⁹

IRETA has developed a training program entitled "Effective Risk Management Strategies in Outpatient Methadone Treatment" ⁴⁰ that presents seven areas of practice that will be "profoundly transformed" as OTPs move toward an ROMM.

These Community Care best practice guidelines are significantly informed by the White and Torres monograph and are designed to support the enhancement of recovery-oriented practices within the context of MMT, thus enhancing short- and long-term outcomes for persons in recovery. These guidelines also incorporate the phased-based examples of recovery-oriented methadone maintenance as listed in the document *Recovery-Focused Methadone Treatment: A Primer for Practice Today in Pennsylvania* authored by IRETA. ⁴¹ These guidelines have been reviewed by each of the SCAs in the counties that Community Care works for and by many additional providers and stakeholders.

IV. Scope and Purpose

The best practice guidelines herein encompass the following processes:

- Screening for appropriateness for medication-assisted treatment in general and methadone maintenance treatment specifically.
- Screening, assessing, and concurrent provision of the appropriate psychotherapeutic treatment and psychosocial services utilizing best practice approaches and integrating recovery-oriented principles.
- Screening, assessing, and treatment of co-occurring mental health conditions and physical health issues.
- Provision of a menu of community-based, recovery-oriented support and wellness services, and activities as necessary to enhance and support long-term recovery.

The commonly accepted definition of clinical practice guidelines is "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." ⁴² Clinical protocols can be seen as more specific than guidelines. The phrase "best practice guidelines," however, generally refers to a combination of both clinical and non-clinical guidelines. The term "guidelines" refers to recommendations based on a consensus of what is highly recommended.

With the implementation of health care reform, it is important to pay even more attention to the utilization of evidenced-based practice (EBP) and recovery approaches for MAT including methadone and to attend to fidelity issues associated with EBP. The development of the guidelines herein will serve to: 43

- "...[d]escribe appropriate care based on the best available scientific evidence and broad consensus;
- ...[r]educe inappropriate variation in practice;
- ...[p]rovide a more rational basis for referral;
- ...[p]rovide a focus for continuing education;

- ...[p]romote efficient use of resources;
- ...[a]ct as focus for quality control, including audit; [and]
- ...[h]ighlight shortcomings of existing literature and suggest appropriate future research."

The purpose of this document is to convey a gold standard of treatment and recovery in the practice of methadone maintenance that is based in science, person-centered, person-driven, and focused on long-term recovery within the context of recovery-oriented systems of care (ROSC). 44

V. Intended Audience

These best practice guidelines are issued to guide all physicians, clinicians, agencies, and systems in the Community Care treatment and recovery network. The intent is to educate, improve access to care, promote safe and quality prescribing, and promote quality treatment and recovery practices overall. Specifically, these guidelines are for the following:

- OTPs providing methadone maintenance and other medication-assisted treatment options for persons in recovery.
- Other physicians, clinicians, and individuals in the addiction field and other behavioral health care fields, health care and helping professions who may be screening, assessing, and/or providing treatment and recovery supports to members and/or referring to medication-assisted treatment approaches including MMT.

These guidelines shall also serve to inform and support PIR and their families, thereby reflecting the principles of recovery 45 and focusing on wellness.

VI. Limitations and Clarifications

These guidelines are not intended to supplant any requirement or obligation of law, licensure, regulation, accreditation, or certification. Nor are they to be used in place of sound clinical judgment as may be applied to address the unique needs of PIR.

These guidelines are designed to support existing federal standards for opioid treatment programs, under 42 CFR § 8.12 and subsequent SAMHSA guidelines and updates including:

- Treatment Improvement Protocol (TIP) 43, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.
- Center for Substance Abuse Treatment. (2009). Emerging Issues in the Use of Methadone. HHS Publication No. (SMA) 09-4368. *Substance Abuse Treatment Advisory*, Volume 8, Issue 1.
- Center for Substance Abuse Treatment. *Guidelines for the Accreditation of Opioid Treatment Programs, Revised July 20, 2007.*
- Center for Substance Abuse Treatment. *Federal Guidelines for Opioid Treatment*, April 2013 (in draft at the time of this writing).

Additionally, these guidelines hope to address some of the specific issues and concerns that have been raised in Pennsylvania.

VII. Community Care Guiding Principles for Medication-Assisted Treatment (MAT) for Opioid Addiction

Community Care introduced the following guiding principles for medication-assisted treatment as part of the development process of a prior document entitled Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Buprenorphine and Suboxone®, ⁴⁶ released in January of 2013. All of our best practice guidelines for medication-assisted treatment for opioid addiction are grounded in eleven guiding principles. ⁴⁷

- 1. An individual can be considered a person in recovery (PIR) if free from other drugs and non-prescribed medications while participating in MAT (now often referred to as Medication-Assisted Recovery [MAR]). While abstinence is considered the safest approach for those with substance use disorders, MAT encompasses evidence-based approaches that are proven to help certain individuals initiate or sustain recovery. These principles acknowledge that recovery is most likely to occur within the context of self-directed care and acknowledgment of every individual's right to "define their own life goals and design their unique path(s)" to long-term recovery. ⁴⁸
- 2. Persons in recovery are to be fully informed about substance use disorder (SUD) treatment options (as evidenced by documentation in the medical/clinical record), including FDA approved MATs, such as methadone, buprenorphine, and naltrexone, at all levels of care. For programs that do not have MAT available, appropriate referral should be made and care coordinated for PIR. ⁴⁹
- 3. PIR who are appropriate for and choose a MAT should be offered and provided the appropriate level of care of SUD treatment (in Pennsylvania this determination is based upon the Pennsylvania Client Placement Criteria [PCPC] ⁵⁰ and individual PIR needs as evidenced by documentation in the medical/clinical record). For programs that do not have the recommended level of care available, appropriate referral should be made and care coordinated for the PIR. ⁵¹
- 4. MATs are to be provided in the context of a menu of services available to PIR. This should include concurrently attending to physical and mental health conditions as well as to all presenting SUDs. Psychosocial care should be provided and staged according to the individual needs of PIR.
- 5. PIR receiving MAT and presenting with acute pain or chronic non-cancer pain (CNCP) should be provided with best practice pain management approaches⁵² only in the context of collaboration between PIR's primary care physician, pain clinician, and MAT prescriber.
- 6. Extreme caution should be used when persons in recovery receiving opioid agonist or partial agonist therapy use benzodiazepines or other pharmaceutical products that might put them at the risk for overdose and death. Use of concomitant benzodiazepines should include documentation of informed consent regarding the risk of overdose and death.
- 7. As there are medical risks and other safety issues associated with any MAT, evidence-based tools and best practices should be utilized in concert with sound clinical judgment during the screening, assessment, and induction processes and throughout the duration of MAT, attending to elimination or reduction of risk.

- 8. Community-based recovery support services (RSS), such as certified peer specialists, recovery coaches, alumni mentors, safe housing options, educational and vocational services, recreational and spiritual supports, and other services that support continued recovery are essential components of care to ensure long-term recovery. RSS or other recovery-focused clinical and supportive services should be made available to PIR while involved in MAT—either directly or through referral.
- 9. PIR should be supported in the development of a recovery plan attending to the four dimensions of wellness and recovery:
 - Health: Overcoming or managing one's disease(s) as well as living in a physically and emotionally healthy way.
 - Home: A stable and safe place to live.
 - **Purpose**: Meaningful daily activities, such as a job, school, volunteerism, family care taking, or creative endeavors, and the independence, income, and resources to participate in society.
 - Community: Relationships and social networks that provide support, friendship, love, and hope.
- 10. Prescribing physicians should be encouraged to continue their medical education regarding the use of MAT and to consult specialists certified by the American Board of Addiction Medicine or certified in Addiction Psychiatry by the American Board of Psychiatry and Neurology.
- 11. MAT guiding principles and practice guidelines should change as advanced scientific evidence becomes available. Community Care's Guiding Principles and Best Practice Guidelines will be updated as necessary.

VIII. Organization of Best Practice Guidelines for Recovery-Oriented Methadone Maintenance

These guidelines are organized under categories, acknowledging the early work of Drs. Moolchan and Hoffman (1997) ⁵¹ and the recommendations in TIP 43 (2005) that MMT be conceptualized in terms of phases of treatment—matching the levels of progress of persons in recovery to the intended outcomes. The TIP 43 phases were further advanced based on the work of IRETA⁵³ and their 2010 document, *Recovery Focused Methadone Treatment—A Primer for Practice Today in Pennsylvania*. These guidelines reflect the phase linked recommendations on recovery strategies from this IRETA document, as well as the subsequent evolutions: *Best Practice Standards 2012 for Providers of Recovery-Oriented Methadone Services* ⁵⁴ and more recently, *Recovery-Oriented Methadone Maintenance Services Standards*. They also reflect the position stated in the Federal Guidelines for Opioid Treatment 2013 in support of recovery-oriented systems of care (ROSC) and recovery-oriented methadone maintenance (ROMM). Community Care guidelines are also influenced by the American Association for the Treatment of Opioid Dependence, Inc. (AATOD) document, *Opioid Maintenance Pharmacotherapy: A Course for Clinicians*, November 2013. Additionally they reflect the recommendations of the Rehabilitation and Community Providers Association (RCPA) of Pennsylvania as indicated in their 2011 document *Best Practices in Methadone Treatment*. ⁵⁶

VIII.A. Phase 1: Recovery Initiation and Stabilization

VIII.B. Phase 2: Early Recovery and Rehabilitation

VIII.C. Phase 3: Recovery Maintenance

VIII.D. Phase 4: Long-Term Sustained Recovery

VIII.E. General Agency Guidelines

For ease of reference, the best practice guidelines contained in *Management of Benzodiazepines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines* are included in **Addendum A** in their entirety and referenced in appropriate sections below.

VIII.A. Phase 1: Recovery Initiation and Stabilization

The phase of treatment covering intensive assessment and intervention lasts between three to seven days, with early stabilization spanning from the third to seventh day of treatment through eight weeks.⁵⁷ This phase aligns with the TIP 43 acute phase of treatment with a primary goal of eliminating illicit use of opioids for at least 24 hours and inappropriate use of psychoactive substances.

Recovery-oriented strategy examples have been identified as an important first step in moving towards more recovery-oriented methadone maintenance (ROMM).⁵⁸ Examples of those strategies are listed with each phase.

VIII.A.1. Screening and Assessment

The clinician assessor will conduct an initial screen and assessment to determine the appropriateness of medication-assisted treatment at whatever intake point or treatment level of care the individual first presents. If MAT is found appropriate, the individual is to be provided education on all forms of MAT as well as other treatment options and supported in a decision process as to the best course of treatment and recovery, including the appropriateness of methadone. Clinician assessors are challenged to assess the level of addiction severity, as well as the psychosocial needs and other characteristics of each person in recovery, in order to identify the best MAT approach at the time the individual presents for treatment and continually as this person progresses in recovery.

Use of decision support tools designed to assist individuals as well as clinicians in making a choice for medication-assisted treatment, as well as other forms of treatment, are to be encouraged.⁵⁹

Methadone is recommended for consideration with individuals who have a moderate to severe opioid addiction severity. ⁶⁰ In the case where methadone treatment is not available, buprenorphine should be considered.

Medication-assisted treatment is not to be considered a level of care but an approach that can be provided at every level of care dependent upon results of assessment of individual need and PIR informed choice.

The screening and assessment process will minimally:

- 1. Utilize the ASAM for Opioid Treatment Using Methadone (OTUM) in the initial screening/assessment for appropriateness of methadone (ASAM Criteria, Third Edition).⁶¹
- 2. Determine opioid dependence by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or the International Classification of Diseases and Related Health Problems (ICD) (Addendum C).
- 3. Communicate essential information about MAT with the PIR, including treatment requirements, addiction as a brain disease, and a discussion of the benefits and drawbacks of MAT, to help applicants make an informed decision about treatment.
- 4. Assess withdrawal status utilizing validated tools (Addendum D).
- 5. Assess addiction severity.
- 6. Assess pregnancy status. Methadone is considered the gold standard of treatment for those who are pregnant and addicted to opioids. As noted in the Federal Opioid Treatment Standards: although promising, the level of evidence supporting buprenorphine maintenance during pregnancy is not as compelling as the evidence supporting methadone maintenance for pregnant women. Pregnancy testing is to be considered throughout the treatment process as may prove necessary.

- 7. Assess substance use history and current substance use, including alcohol, over the counter medications, and non-prescribed use of methadone, buprenorphine, and benzodiazepines. Consider consulting the Prescription Drug Monitoring Program (PDMP) if/when this is available in Pennsylvania.
- 8. Provide education regarding the potential adverse consequences of benzodiazepine use, for those testing positive for benzodiazepines or indicating a history of use (Addendum B).
- 9. Assess substance treatment history, including previous treatment episodes with methadone and/or buprenorphine.
- 10. Assess for current drug use by conducting a witnessed urine drug screen (UDS) to include screening for methadone, buprenorphine, and benzodiazepines.
- 11. Conduct a mental status assessment and assess psychiatric history with attention paid to current compliance with medication, actively linking PIR to services as may be needed and agreed upon and collaborating with the mental health provider in medical management and service planning. A letter of agreement with the mental health provider is recommended to ensure effective coordination of care.
- 12. Assess medical condition and history, including conducting a physical exam, with attention paid to liver, cardiac and respiratory status, medications, and seizures—determination if methadone is appropriate, or alternative medication, and if treatment is to be induction, detoxification or maintenance. Referrals are to be made for acute care needs.
- 13. Assess pain.
- 14. Assess trauma.
- 15. Assess motivation and readiness for change.
- 16. Assess psychosocial and recovery needs and supports including needs such as food, safe and stable housing, transportation, employment, criminal justice related, and supports through family, mutual-aid support groups, recovery coaches and certified recovery specialists, etc.
- 17. Utilize the Pennsylvania Client Placement Criteria (PCPC) in determining the recommended level of care (LOC), collaborating with the PIR and Community Care to access the recommended LOC if it is not available at the OTP. If the PIR refuses the recommended LOC care and/or access to that LOC is not readily available, the OTP needs to address how the needs of the individual will be met.
- 18. Involve PIR in the development of initial short-term, person-centered, and PIR-directed treatment service plan that acknowledges the phases of treatment.
- 19. Include initial engagement of family/significant others, as the PIR defines them, in the treatment and recovery process.
- 20. Include involvement of a case manager in the admission process to begin to assist in engaging the PIR in treatment and identification of needs/issues. ⁶⁴

VIII.A.2. Induction

Patients are at most risk during this phase and induction requires sound clinical judgment and critical attention to the individual's history as well as the presenting medical condition. "...deaths during methadone induction occur because the initial dose is too high, the dose is increased too rapidly or the prescribed methadone interacts with another drug" ⁶⁵ (Addendum F). Studies show the greatest risk in the first two weeks of treatment.

It is important that the PIR as well as family members/significant others be informed of the risks during induction, as well as the risk of unintentional overdose with prescribed or street opioids alone or in combination with other prescribed medications or street drugs.

Legislation has been introduced in Pennsylvania ⁶⁶ to expand the availability of naloxone, a drug used to counter the effects of an opioid overdose. The American Society of Addiction Medicine (ASAM) issued a policy statement in 2010 that includes the following: "ASAM supports the increased use of naloxone in cases of unintentional opioid overdose, in light of the fact that naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal side effects, when used at the proper dosage, for preventing the often fatal respiratory arrest which characterizes the advanced stages of prescription or illegal drug overdose. Naloxone can be administered quickly and effectively by trained professional and lay individuals who observe the initial signs of an opioid overdose reaction." ⁶⁷ If this becomes law, opioid users, family members, friends or other persons would be allowed to administer naloxone and programs, including OTPs could distribute naloxone kits to PIRs and family members.

Induction outcomes expected:

- "Preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for at least 24 hours.
- Reducing or eliminating the drug craving routinely experienced by the patient.
- Blocking the euphoric effects of any illicit acquired, self-administered opioids, without inducing undesirable effects experienced by the patient or noticed by observers." ⁶⁸

The induction process will minimally:

- 1. Follow best practice (TIP 43 and/or TIP 40) dosing and timing protocols for induction of MAT. Additional expert panel recommendations are included in the 2013 ASAM article "Safe Methadone Induction and Stabilization—Report of an Expert Panel" ⁶⁹ (Addendum E). Dose caps are not supported by CSAT, AATOD, or ASAM.
- 2. Consider the perspective of the PIR as well as clinical judgment and the use of validated tools.
- 3. If PIR is at risk of withdrawal from alcohol, they should be detoxed before initiating methadone treatment.
- 4. Be aware when inducting a person onto methadone that the long half-life of methadone, possible synergistic effects and drug-drug interactions may alter methadone metabolism.
- 5. Identify risk for QT prolongation prior to dosing. The Federal Guidelines for Opioid Treatment indicate that the "medical assessment should specifically cover the symptoms and risk factors for torsades de pointes and any indicated follow-up tests, which may include an EKG or a more comprehensive electrophysiological assessment. The treatment plan should also address concerns related to the discovery or risk of torsades de pointes."⁷⁰

- 6. Include prior to dosing, and on an ongoing basis, a review of all other medications to identify any potential contraindications ⁷¹ (Addendum F), including interactions between methadone and other medications that also have QT-prolonging properties, or with medications that slow the elimination of methadone (CSAT 2005, p. 35). ⁷²
- 7. The initial first day dose of methadone is typically between 10-30 mg. -10-20 mg. for high-risk situations; e.g., those with medical illness, older adults, and individuals on psychotropic medications ⁷³ (Addendum E).
- 8. Attend to history and current use of prescribed or illicit benzodiazepines and attention to the recent consensus guidelines developed relating to use of methadone and benzodiazepines: ⁷⁴ people who receive/use CNS depressants may need to be inducted on methadone at a lower dose than those who do not receive/use CNS depressants. See **Addendum B** for more information about methadone and benzodiazepines.
- 9. Ensure that PIR has ready access to medical personnel to address all questions and concerns regarding the dose and dosing process including addressing safety concerns.
- 10. Utilize a daily directly-observed administration of methadone dose during the induction period until stabilization, with weekly random drug screens for first 90 days and for patients that relapse.
- 11. Not allow take-homes during the induction and stabilization period.
- 12. Include policies and procedures for assessing and addressing potential impairment of individuals presenting for dosing or post dosing, including patient education and policy regarding driving while impaired.
- 13. Attend to collaboration with PIR's primary care physician and/or pain management specialist for individuals presenting with chronic non-cancer pain.
- 14. Initiate doctor-to-doctor conversation with mental health provider at time of treatment initiation and with all dose changes.
- 15. Request that individuals sign an informed consent form before initiating MAT agreeing that if the person in recovery appears impaired, the treatment center has permission to notify a family member and refuse medication.
- 16. Inform individuals receiving MAT of the treatment setting's policy on impairment. Provide education about impairment, especially about drug-to-drug interactions. Give individuals/family sources of information and encourage them to ask questions.
- 17. Have a policy that prohibits individuals from driving themselves to the treatment setting during the induction phase.

VIII.A.3. Stabilization

In the early stage of stabilization the PIR has been stabilized on a methadone dose, with adjustments made as necessary. A more in depth evaluation has been initiated, with an initial short-term, person-centered, and PIR-directed treatment service plan in place—to be reviewed with the PIR regularly and modified as necessary as further needs and issues are identified.

The stabilization process will minimally:

- 1. Educate the PIR about the treatment and recovery process including the chronic nature of addiction.
- 2. Assess stage of change on an ongoing basis.
- 3. Ensure that the individual has access to and is receiving the correct level of treatment service, coordinating care as necessary if services are off-site. Services are to be culturally competent and trauma-informed.
- 4. Involve the PIR in an ongoing assessment of the appropriateness of their dosage and respond appropriately, ensuring access to medical staff by PIR to discuss concerns.
- 5. Not allow take-homes during induction and stabilization period.
- 6. Conduct weekly random drug screens for first 90 days of treatment. A policy of "collect often/test randomly" is recommended. 75
- 7. Involve the family/significant other, as defined by the PIR, in the treatment and recovery process and provide or refer for family/child education, counseling, and/or therapy as may be necessary to support healing and recovery. Emphasize the importance of family involvement.
- 8. Directly provide or actively collaborate, coordinate, refer, and follow-up to ensure that all medically necessary services, mental health services, and psychosocial and recovery support needs are being met. Direct provision of these services is ideal.
- 9. Directly provide or otherwise ensure that PIR receives testing for HIV, HBV, HCV, and TB.
- 10. Assertively link PIR to available recovery coach or peer recovery specialist services.
- 11. Provide access to case management services, assertively linking persons in recovery to these services and "endorsing the efficacy and value of case management in their dialogue" with the PIR.
- 12. Assertively link PIR to recovery community resources including mutual aid support groups.
- 13. Provide coaching to the PIR around issues of stigma; e.g., attending local mutual aid support groups.
- 14. Provide ongoing collaboration and coordination of care with mental health provider, including doctor-to-doctor conversation with dosage changes.
- 15. Ensure that PIR understands the rules regarding impaired driving and that agency staff are monitoring for impairment before and after dosing.
- 16. Monitor for use of benzodiazepines. Concomitant use of benzodiazepines and opioids should include documentation of informed consent regarding the risk of overdoes and death. Provide alternatives to address the need for benzodiazepines as appropriate. See **Addendum B** for best practice guidelines on use of methadone and benzodiazepines.

Recovery-oriented strategies for Phase 1 include:

- 1. Emergency contact information was provided to the PIR and family.
- 2. The effects of methadone dosage and possible side effects were explained to the PIR.
- 3. All risks and benefits of MAT were explained to the PIR.
- 4. The PIR was offered alternatives to MAT when warranted.
- 5. The PIR's family was educated about opioid addiction, methadone treatment, and recovery.
- 6. The PIR's family was educated about peer-based recovery supports and the family has been actively linked to local resources.
- 7. The PIR has been actively linked to a peer support resource local to where he/she lives.
- 8. The OTP has assessed/assured that the person "feels heard" in addressing his/her needs.
- 9. The OTP has assessed/assured that the person trusts OTP with his/her care.

Indications that a person has reached the goals of Phase 1 can include (adapted from TIP 43):

- Elimination of opioid withdrawal symptoms/cravings and has overall sense of well-being throughout the day.
- Is able to avoid situations that might trigger or perpetuate substance abuse.
- Have acknowledged that their addiction is a problem and are motivated to change.
- Acute medical crises have been resolved and ongoing care for chronic medical conditions have been initiated.
- Basic needs for food, safety, and safe housing and stabilization of their living situation have been met.
- Transportation and child care issues have been resolved.
- Stabilization of financial situation.
- Committed to treatment process, participating in treatment and recovery planning, and regularly attending both therapeutic and educational sessions.
- Positive interaction with treatment staff and other treatment providers.
- Evidence of lifestyle changes and addressing addiction related issues.

VIII.B. Phase 2: Early Recovery and Rehabilitation

Early recovery begins when the PIR is stabilized and comfortable on his/her methadone dose for at least 24 hours, although later adjustments may be necessary, and lasts for an indefinite period. As indicated in TIP 43, the primary goal of this phase is to empower persons in recovery to address the major problems in their life, including their substance use, medical issues, mental health conditions, educational and vocational issues, family problems, and legal issues.

The early recovery and rehabilitation phase will minimally:

- 1. Monitor drug use and progress utilizing urine drug screens (UDS), PIR perception and clinical judgment, adjusting methadone dose as necessary, and addressing relapses in a non-punitive manner.
- 2. Schedule weekly random drug screens first 90 days of treatment, monthly thereafter.
- 3. Continue to monitor use of benzodiazepines (Addendum B.).
- 4. Continue ongoing collaboration and coordination of care with mental health provider, including doctor—to-doctor conversation with dosage changes.
- 5. Complete all necessary and in-depth evaluations within the first 30 days, if not already conducted.
- 6. Directly provide or actively collaborate, coordinate, refer, and follow-up to ensure that all medically necessary services, mental health services, psychosocial, and recovery support needs are being met. Direct provision of these services is ideal.
- 7. Continually reassess and update treatment service plan with PIR.
- 8. Follow-up to ensure that routine testing has taken place for HIV, HBV, HCV, and TB and treatment is initiated as indicated.
- 9. Utilize a global assessment process. In recovery management models, assessment is global—focused on the whole life of the recovering person, asset-based, and is continual over the span of the service relationship.
- 10. Provide regular recovery-based and asset-focused psychosocial services at a frequency based on individual need. During this phase, counseling/psychotherapeutic services are provided at a more intensive level.
- 11. Provide continued educational sessions on issues related to treatment and recovery.
- 12. Provide individualized treatment that is trauma-informed, culturally competent, gender-sensitive, co-occurring competent, and otherwise reflects best practices or promising practices; e.g., attention to the therapeutic alliance, motivational interviewing, contingency management, family therapy, CBT, mutual aid support, recovery supports, etc.
- 13. Monitor for family stability/relationships, providing for or referring to family therapy as necessary.
- 14. Assess educational and vocational needs and provide support to attain goals; e.g., onsite GED program, literacy and vocational training, budgeting and personal finance, and job development opportunities.
- 15. Monitor ongoing legal issues and provide support as necessary.

Recovery-oriented strategies include:

- 1. Actively link person and his/her family to peer-based recovery support activities.
- 2. Assist the PIR in assessing their recovery capital—internal and external assets that can help initiate and sustain recovery.
- 3. Help person in the development of a recovery plan.
- 4. Assess/assure that the person "feels heard" in addressing his/her needs.

Indications that a person has reached the goals of Phase 2 can include (adapted from TIP 43):

- · Discontinuation of opioid and other drug use.
- · Absence of problem alcohol use.
- Repertoire of coping skills.
- Stable medical and mental health status—compliance with psychiatric care as agreed upon.
- · Improved dental health and hygiene.
- Working a recovery plan and connected with recovery support services in the community as available and appropriate.
- Involvement in productive activity: employment (or actively searching for), school, homemaking, or volunteer work.

- Stable source of legal income from employment, disability, or other legitimate sources.
- Social support system in place—absence of major conflict with support system.
- Regular prenatal care.
- · Smoking cessation plan.
- · Ability to identify and manage relapse triggers.
- Increased responsibility for dependents (if relevant).
- Resolution of or ongoing efforts to resolve legal problems.
- Absence of illegal activities and actively involved in resolving legal issues.

VIII.C. Phase 3: Recovery Maintenance

During this phase of treatment, as referenced in TIP 43, the person in recovery continues his/her opioid maintenance therapy, counseling, medical and social services as necessary and indicated, and otherwise resumes primary responsibility for their life. The PIR can receive take-home medication for longer periods and be permitted to reduce their OTP visits. Continued participation in non-clinical recovery support services is essential.

At some point after a period of time in this phase—based on the PIR needs and with evidence of continued abstinence from illicit drugs or abuse of prescription drugs and progress in their recovery goals—consideration is given for continued methadone maintenance or tapering and discontinuation.

The early recovery maintenance phase will minimally:

- 1. Continue to monitor drug use and progress utilizing urine drug screens (UDS), PIR perception and clinical judgment, adjusting methadone dose as necessary, and addressing relapses in a non-punitive manner.
- 2. Continue ongoing assessment and attention to medical, mental health, education, vocational, spiritual, and recovery support needs.
- 3. Continue to monitor use of benzodiazepines (Addendum B).
- 4. Continue ongoing collaboration and coordination of care with mental health provider, including doctor-to-doctor conversation with dosage changes.
- 5. Continue to regularly reassess and update treatment service plan with PIR.
- 6. Continue to regularly reassess and update recovery plan with PIR.
- 7. Continue to provide regular recovery-based and asset-focused psychosocial services at a frequency based on individual need.
- 8. Continue to provide educational sessions on issues related to treatment and recovery at a frequency based on individual need.
- 9. Continue to monitor for family stability, providing/referring for family therapy as necessary.
- 10. Continue to monitor ongoing legal issues and provide support as necessary.

Recovery-oriented strategies:

- 1. Continue to help person and his/her family to assess and build recovery capital.
- 2. Provide ongoing checkups on person's involvement in peer-based recovery supports.
- 3. Continue to assess/assure that the person in recovery "feels heard" in addressing needs.

Indications that a person has reached the goals of Phase 3 can include (adapted from TIP 43):

- Discontinuation of opioid and other drug use.
- · Continued stability in all life domains.
- Stable source of legal income from employment, disability, or other legitimate sources.
- Resolution of legal problems—no new criminal charges for 3 years and no current probation or parole status.

VIII.D. Phase 4: Long-Term Sustained Recovery

In Phase 4 the person in recovery continues to take primary responsibility for his/her life and recovery and moves either to medical maintenance or begins a taper with intent to discontinue medication. The TIP 43 consensus panel recommended at least two years of continuous treatment as a condition of eligibility for this phase, with increased take-homes and fewer clinic visits required. The individuals should be stable in all domains of their life. The medical maintenance phase continues for an indefinite period of time as long as PIR is benefiting from treatment and desires to continue.

VIII.D.1. Medical Maintenance.

The long-term sustained recovery—medical maintenance phase will minimally:

- 1. Note that clinical stability is generally achieved at a dose between 60 and 120 mg per day.
- 2. Continue to monitor drug use and progress utilizing UDS, PIR perception and clinical judgment, adjusting methadone dose as necessary, and addressing relapses in a non-punitive manner.
- 3. Continue to monitor medical and mental health needs including compliance with necessary medications and treatment. Maintain communication and continue collaboration with prescribers and other relevant healthcare personnel, including doctor-to-doctor communication with dosage changes.
- 4. Continue to monitor use of benzodiazepines (Addendum B).
- 5. Continue to monitor family stability, providing/referring for family therapy as necessary.
- 6. Continue to monitor educational and vocational needs and progress.
- 7. Continue to monitor spiritual and recovery support needs.
- 8. Continue to assess/assure that the person in recovery "feels heard" in addressing needs.
- 9. Continue to regularly reassess and update treatment service plan with PIR.
- 10. Continue to regularly reassess and update recovery plan with PIR.
- 11. Continue to provide regular recovery-based and asset-focused psychosocial/educational services at a frequency based on individual need.

Recovery-oriented strategies:

- 1. Provide any needed assistance for person and his/her family to maintain engagement with peer-based recovery supports in his/her community.
- 2. Provide checkups on person's involvement in recovery support services.
- 3. Continue to assess/assure that the person "feels heard" in addressing his/her needs

VIII.D.2. Tapering, Medically Supervised Withdrawal and Discontinuation

A decision to taper is to be made without coercing the person in recovery and considering among other things: the PIR's motivations and wishes, progress in treatment, support systems in place, addiction history, and prior attempts to taper and discontinue treatment. It is not unusual for a PIR to attempt a taper several times after achieving a maintenance dose level, with or without medical advice. It is important to educate the PIR that while many succeed in their taper and live a drug free-life, there is a high risk of relapse with the discontinuation of methadone. Both pathways are to be equally valued in terms achieving recovery goals. Drs. Magura and Rosenblum in their article Leaving Methadone Maintenance: Lessons Learned, Lessons Forgotten, Lessons Ignored.⁷⁷

Following a taper, the PIR will be allowed to choose at any time to return to a higher dose and a higher level of service supports or reenter treatment following discontinuation. Administrative withdrawal refers to the OTP's decision to terminate the PIR non-voluntarily.

Federal guidelines note that, "Relapse prevention may be further supported by the administration of naltrexone in depot formulation upon completion of medically supervised withdrawal and a suitable period of being opioid free in accordance with current clinical guidelines." ⁷⁸

Indications that post taper a PIR needs to return to a previous treatment phase (Tip 43):

- · Relapse or concern about relapse
- · Positive drug screen for illicit substances
- · Unstable health issues
- · Instability in vocational areas; e.g., loss of employment
- · Instability in family, loss or death of a loved one
- · Unstable housing
- New criminal involvement

The long-term sustained recovery—taper, medically supervised withdrawal, and discontinuation phase will minimally:

- 1. Explore motivation of PIR in requesting a taper to address issues of stigma around continued use or other social pressures, etc., not related to their overall health and recovery.
- 2. Follow recommendation of federal guidelines that a "medically supervised withdrawal schedule for administrative withdrawal is generally a minimum of 21 days", with adjustments by the physician or mid-level practitioner, as appropriate, depending on clinical factors.⁷⁹
- 3. Increase psychosocial and recovery supports during a taper period and include case managers in discharge and transfer decisions.
- 4. Inform the PIR of symptoms that may occur during and post taper including physical discomfort.
- 5. Understand that there are no limits to provision of psychosocial supports post-taper and OTPs are to allow for continuation of psychosocial treatment as necessary and requested.

Recovery-oriented strategies:

- 1. Provide ongoing (e.g., monthly, quarterly, or biannually) recovery checkups post-taper.
- 2. Provide any needed assistance for PIR and his/her family to maintain engagement with peer-based recovery supports in his/her community.
- 3. Allow person to return to participate in onsite recovery support groups post-taper.
- 4. Allow person to return to the program to serve as a recovery support for newer recoverees post-taper.
- 5. Continue to assess/assure that the person "feels heard" in addressing his/her needs.

Indications that a person has reached the goals of Phase 4 can include (adapted from TIP 43):

- Discontinuation of opioid and other drug use.
- Continued stability in all life domains for at least two years.
- Stable source of legal income from employment, disability, or other legitimate sources.
- Resolution of legal problems—no new criminal charges for 3 years and no current probation or parole status.

VIII.E. General Agency Guidelines

These general guidelines address issues that have been identified as of concern in Pennsylvania and support the movement to a more recovery-oriented approach in methadone maintenance programming.

Agencies will minimally:

- 1. Complete a strategic planning process to move into alignment with ROMM principles and best practice guidelines noting progress towards full alignment.
- 2. Adhere to all federal and state staff training and credentialing requirements and additionally assure that all staff members receive training in recovery-oriented systems of care (ROSC), principles of recovery-management (RM), and recovery-oriented methadone maintenance (ROMM).
- 3. Have policies and procedures in place to address potential diversion of methadone and related safety issues, with particular attention to on-site monitoring of building and grounds and takehome medication.
- 4. Have policies and procedures in place for agency-wide monitoring of the use by PIR of benzodiazepines and methadone and other opioids and strategies for risk reduction.

- 5. Follow best practice guidelines in utilization of UDS and other testing procedures to monitor for use of alcohol and other drugs, with particular attention to weekly random testing in the first 90 days of treatment and more frequently as might prove necessary.
- 6. Have protocols in place for emergency response to management of overdose including naloxone and support for education of PIR and their families.
- 7. Have policies and procedures in place to ensure that PIR are provided, in addition to their medication, the appropriate level of care and the psychotherapeutic services as needed and individually determined.
- 8. Have policies and procedures in place to monitor for intoxication during induction and at time of each dosing and to address safety issues including impaired driving.

IX. Summary

Community Care issues these guidelines to support provision of more recovery-oriented methadone maintenance. We encourage an ongoing dialogue about these guidelines and the guideline development process. Please address your comments to Senior Director, Substance Use Disorder Initiatives, Marge Hanna at hanname@ccbh.com.

Community Care would like to thank the many who reviewed and contributed to this document including:

- Mark Parrino, President, American Association for the Treatment of Opioid Dependence (AATOD)
- Persons in recovery including representatives from:
 - Pennsylvania Recovery Organization—Achieving Community Together (PRO-ACT)
 - Message Carriers of Pennsylvania, Inc.
 - Walter Ginter, Project Director, Medication-Assisted Recovery Services[™] (MARS), a project of the National Alliance of Medication Assisted (NAMA) Recovery

¹Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication No. (SMA) 12–4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. Retrieved from http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm

² Retrieved from NewsWorks http://www.newsworks.org/index.php/local/item/60847-heroin October 14, 2013

³Centers for Disease Control and Prevention. (2011, November 4). Vital Signs: Overdose of Prescription Opioid Pain Relievers—United States, 1999–2008. *Morbidity and Mortality Weekly Report (MMWR)*, 60(43), 1487–1492. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

⁴Centers for Disease Control and Prevention. (2011, December 19). *Policy Impact: Prescription Painkiller Overdose*. Retrieved from http://www.cdc.gov/homeandrecreationalsafety/rxbrief/

- ⁵SAMHSA, Treatment Episode Data Sets (TEDS). Substance Abuse Treatment Admissions by Primary Substance of Abuse, According to Sex, Age Group, Race and Ethnicity, 2010. Retrieved from http://www.dasis.samhsa.gov/webt/tedsweb/tab_year.choose_year?t_state=PA
- ⁶ Muhuri, P. K., Gfroerer, C. G., Davis, M. C. Associations of Non-Medical Pail Reliever Use and Initiation of heroin Use in the United States. CBHSQ Date Review August 2013, SAMHSA. Retrieved from http://www.samhsa.gov/data/
- ⁷SAMHSA. Behavioral Health Treatment Needs Assessment Toolkit for States. HHS Publication No. SMA13-4757. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013. Retrieved from http://store.samhsa.gov/product/SMA13-4757
- ⁸ DATOS. (n.d.). *Treatment History and Outcomes*. Retrieved from http://www.datos.org/adults/adults-history.html
- ⁹ Erickson, L. K., M.D. (2008, May). The Scope of the Problem and the Case for Screening, Brief Intervention, and Referral to Treatment. *Counter Details: The Educational Difference*. 1-2. Retrieved from http://sbirt.ireta.org/sbirt/PMS-CounterDetailsSBIRT-0608.pdf
- ¹⁰ Sheedy C. K., and Whitter M., *Guiding Principles and Elements of Recovery-Oriented Systems of Care: What Do We Know From the Research?* HHS Publication No. (SMA) 09-4439. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2009.
- ¹¹Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies. (n.d.). *Pharmacotherapy for Substance Use Disorders*. Retrieved from http://dpt.samhsa.gov/medications/medsindex.aspx
- ¹² Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048.Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK64164/
- ¹³ White, W. L., Slaying the Dragon—The History of Addiction Treatment and Recovery in America.
- ¹⁴ Quote June 3, 2013 from Colleen Wilber, MS, Potter County Drug and Alcohol Administrator, Pennsylvania.
- ¹⁵IRETA. (2010, October). *Recovery-Focused Methadone Treatment: A Primer for Practice Today in Pennsylvania*. Retrieved from http://ireta.org/node/348
- ¹⁶ Methadone Death and Incident Review Act-Enactment, Act of Cot. 24, 2012, P.L.1198, No. 148.
- ¹⁷Center for Substance Abuse Treatment, Methadone-Associated Mortality: Report of a National Assessment, May 8-9, 2003. SAMHSA Publication No. 04-3904. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2004. Retrieved from http://atforum.com/SiteRoot/pages/addiction_resources/CSAT-MAM_Final_rept.pdf
- ¹⁸ Summary Report of the Meeting: Methadone Mortality—A Reassessment Sponsored by the Center for Substance Abuse Treatment Substance Abuse and Mental Health Services Administration Washington, DC July 20, 2007. Retrieved from http://www.atforum.com/pdf/Methadone_Draft_Report_101807_Brief-w-attch.pdf

- ¹⁹ Data Summary Methadone Mortality: A 2010 Reassessment Sponsored by the Substance Abuse and Mental Health Services Administration Washington, DC July 29–30, 2010. Retrieved from http://www.dpt.samhsa.gov/pdf/methadone_mortality_data_2010.pdf
- ²⁰US Department of Justice, National Drug Intelligence Center. Methadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rate Product No. 2007-Q0317-001. November 16, 2007. Retrieved from http://www.justice.gov/archive/ndic/pubs25/25930/25930p.pdf
- ²¹Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them GAO-09-341: Published: Mar 26, 2009. Publicly Released: Mar 31, 2009. Retrieved from http://www.gao.gov/products/GAO-09-341
- ²² Freedberg, S. P." Methadone Deaths Tied to For-Profit Clinics Prompt Bills", Mar 28, 2013, Bloomsberg.com http://www.bloomberg.com/news/2013-03-28/methadone-deaths-tied-to-for-profit-clinics-prompt-bills.html
- ²³Resolution 348 introduced by Senator Ward (R-39) approved by the Senate June 29, 2010.
- ²⁴ A Performance Audit of Pennsylvania's Medical Assistance Transportation Program for Methadone Maintenance, Legislative Budget and Finance Committee, A Joint Committee of the Pennsylvania General Assembly, February 2011 www.paproviders.org/Pages/DA_Archive/MATP_Performance_Audit_021011.shtml
- ²⁵ Ibid. "Methadone Deaths Tied to For-Profit Clinics Prompt Bills".
- ²⁶Pennsylvania Community Providers Association—now Rehabilitation and Community Providers Association. (2011, February 22). *Best Practices in Methadone Treatment*, Retrieved from, http://paproviders.org/Pages/DA_Archive/Methadone_Best_Practices_022211.shtml
- ²⁷Joseph H, Medical Methadone Maintenance: The Further Concealment of a Stigmatized Condition. Doctoral thesis, City University of New York, 1995. Retrieved from http://www.doraweiner.org/contents.html
- ²⁸White, W. L. Long-Term Strategies to Reduce the Stigma Attached to Addiction, Treatment, and Recovery within the City of Philadelphia. Philadelphia Department of Mental Health and Mental Retardation, 2009.
- ²⁹ Increasing Access to Medication to Treat Opioid Addiction—Increasing Access for the Treatment of Opioid Addiction with Medications, American Association for the Treatment of Opioid Dependence (AATOD), 2014. Retrieved from http://www.aatod.org/policies/policy-statements/increasing-access-to-medication-to-treat-opioid-addiction-with-medications/
- ³⁰ Sheedy C. K., and Whitter M., *Guiding Principles and Elements of Recovery-Oriented Systems of Care: What Do We Know From the Research?* HHS Publication No. (SMA) 09-4439. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2009.
- ³¹PA Counties of Chester, Cumberland, Dauphin, Lancaster, Lebanon, Perry, Community Behavioral Healthcare Network of Pennsylvania and Community Care Behavioral Health Organization (2013, August). *Recovery-Oriented Methadone Maintenance Services Standards*.

- ³² Southwest Behavioral Health Management, Inc. (2010). *Best Practice Standards* 2011-2012 for Providers of Recovery-Oriented *Methadone Services*. Retrieved from http://www.sbhm.org/methadone.php
- ³³ IRETA—prepared for the City of Philadelphia Department of Behavioral Health and Intellectual disAbility Services (with support from Community Care Behavioral Health Organization). (2013, November). *Management of Benzodiazepines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines*. Retrieved from http://www.ccbh.com/providers/phealthchoices/bestpractice/index.php
- ³⁴Bernstein, F. K., Aguilar M. S., Burnand, B., LaCalle, J. R., Lazaro, P., Kahan, J. P. (2001). *The RAND/UCLA Appropriateness Method User's Manual*. Retrieved from http://www.rand.org/pubs/monograph_reports/MR1269.html
- ³⁵Community Care Behavioral Health Organization, Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Buprenorphine and Suboxone®. January 2013. Retrieved from http://www.ccbh.com/providers/phealthchoices/bestpractice/index.php
- ³⁶White, W. L., & Torres, L. (2010). *Recovery-Oriented Methadone Maintenance*. Chicago, IL: Great Lakes Addiction Technology Transfer Center, Philadelphia Department of Behavioral Health and Mental Retardation Services and Northeast Addiction Technology Transfer Center. Retrieved from http://www.williamwhitepapers.com/pr/_____books/full_texts/2010Recovery_orientedMethadoneMaintenance.pdf
- ³⁷ Ibid. Recovery-Oriented Methadone Maintenance.
- ³⁸White, W. L., (2008) Recovery Management and Recovery-Oriented Systems of Care: Scientific Rationale and Promising Practices, Northeast Addiction Technology Transfer Center, Great Lakes Addiction Technology Transfer Center, Philadelphia Department of Behavioral Health/Mental Retardation Services. Retrieved from http://www.facesandvoicesofrecovery.org/pdf/White/recovery_monograph_2008.pdf
- ³⁹ Ibid. Federal Guidelines for Opioid Treatment, April 2013. Page 28.
- ⁴⁰ IRETA. (2013, January). Effective Risk Management Strategies in Outpatient Methadone Treatment—Trainer's Manual and PowerPoint Slides, Module 7: Recovery-Oriented Methadone Maintenance (ROMM). Retrieved from http://ireta.org/riskmanagementcurriculum
- ⁴¹ Ibid. Recovery-Focused Methadone Treatment: A Primer for Practice Today in Pennsylvania.
- ⁴² National Research Council. (1990). *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: The National Academies Press.
- ⁴³ OpenClinical. (n.d.). *Clinical Practice Guidelines*. Retrieved from http://www.openclinical.org/guidelines.html
- ⁴⁴SAMHSA's Partners for Recovery. (n.d.). *Recovery-Oriented Systems of Care*. Retrieved from http://partnersforrecovery.samhsa.gov/rosc.html
- ⁴⁵SAMHSA Blog.(2011, December 11). SAMHSA's Definition and Guiding Principles of Recovery—Answering the Call for Feedback [Web log message]. Retrieved from http://blog.samhsa.gov/2011/12/22/samhsa%E2%80%93-answering-the-call-for-feedback/

- ⁴⁶ Ibid. Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Buprenorphine and Suboxone®.
- ⁴⁷Ohio Department of Alcohol and Drug Addiction Services. (2011) Adapted from <u>"Medication–Assisted Treatment: Proposed Low Dose Protocol for the Use of Buprenorphine and Suboxone®"</u>
- ⁴⁸ SAMHSA. (2011, December). Working Definition of Recovery.
- ⁴⁹ Ibid. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP) Series 43.
- ⁵⁰ Pennsylvania Client Placement Criteria (PCPC)
- 51 Ibid. TIP 43
- ⁵² SAMHSA. (2011). Managing Chronic Pain in Adults with or in Recovery Form Substance Use Disorders, Treatment Improvement Protocol (TIP) 54. HHS Publication No. (SMA) 12-4671.Rockville, MD.
- ⁵³Hoffman, J. A., Moolchan, E. T., The Phases of Treatment Model for Methadone Treatment. 3rd European Methadone and Other Stabilization Treatments Conference, Ljubljana. 1997. Retrieved from \\\u00edupmc-userso8\\hanname\$\MAT \\Medication Assisted Recovery\\Methadone\Phases.mht
- ⁵⁴ Ibid. Best Practice Standards 2011-2012 for Providers of Recovery-Oriented Methadone Services.
- ⁵⁵ Ibid. Recovery-Oriented Methadone Maintenance Services Standards.
- ⁵⁶ Ibid. Best Practices in Methadone Treatment. RCPA (formerly PCPA)
- ⁵⁷ Ibid. Federal Guidelines for Opioid Treatment, April 2013. Page 26.
- ⁵⁸ Ibid. Recovery-Focused Methadone Treatment: A Primer for Practice Today in Pennsylvania.
- ⁵⁹SAMHSA Decision Support Tool in development at the time of this writing. Contact Cathy Nugent <u>Cathy.Nugent@samhsa.hhs.gov</u>
- ⁶⁰ MAT Cycle of Recovery. (2007, Spring). *Addiction Treatment Forum*, 16(2), 1, 3-4. IRETA
- ⁶¹ American Society of Addiction Medicine. *The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Condition*. David Mee-Lee, MD, Editor. October 2013. ISBN: 978-1-61702-197-8. Retrieved from http://www.asam.org/publications/the-asam-criteria
- ⁶² Ibid. Tip 43. NIH Consensus Panel, 1998., WHO Guidelines for the Psychosocially Assisted Pharmacological Treatment of opioid Dependence 2009. ASAM/ACOG Opinion of the Committee on Health Care for Underserved Women 2012. Pennsylvania Client Placement Criteria (PCPC)
- ⁶³ Guidelines for the Accreditation of Opioid Treatment Programs Revised July 20, 2007, An April 2013 update to this revision was published in the Federal Register Notice of May 16, 2013, seeking public comments. Retrieved from http://dpt.samhsa.gov/regulations/accreditation.aspx

- ⁶⁴ Tschakovsky, K. Chair Advisory Board. Centre for Addiction and Mental Health.(2009). *Methadone Maintenance Treatment Best Practices in Case Management*. Canada. Retrieved from http://knowledgex.camh.net/amhspecialists/specialized_treatment/methadone_maintenance/mmt_case_management/Pages/default.aspx
- ⁶⁵Baxter LE Sr., Campbell A, Deshields M, Levounis P, Martin JA, McNicholas L, Payte JT, Salsitz EA, Taylor T, Wilford BB. J Addict Med. 2013 Nov-Dec;7(6):377-86. "Safe Methadone Induction and Stabilization: Report of an Expert Panel".
- ⁶⁶PA House Bill 2090. March 2014. Retrieved from http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/bt-Check.cfm?txtType=PDF&sessYr=2013&sessInd=0&billBody=H&billTyp=B&billNbr=2090&pn=3140
- ⁶⁷ American Society of Addiction Medicine (ASAM) *Use of Naloxone for the Prevention of Drug Overdose Deaths*, Adoption Date: April 15, 2010. Public Policy Statement on the Use of Naloxone for the Prevention of Drug Overdose Deaths. Retrieved from http://www.asam.org/pressroom/read/2012/06/11/asam-supports-increasing-availability-of-naloxone
- ⁶⁸ Ibid. Federal Guidelines for Opioid Treatment, April 2013. Page 50.
- ⁶⁹ Ibid. "Safe Methadone Induction and Stabilization: Report of an Expert Panel".
- ⁷⁰ Ibid. Guidelines for the Accreditation of Opioid Treatment Programs Revised July 20, 2007, Pg. 14.
- ⁷¹McCance-Katz, e. F. MD, PhD, Sullivan, L. MD, Nallani, S. PhD. "Drug Interactions of Clinical Importance among the Opioids, Methadone and Buprenorphine, and other Frequently Prescribed Medications: A Review". Am J Addict. 2010; 19(1): 4–16. doi:10.1111/j.1521-0391.2009.00005.x.
- 72 Ibid. TIP 43.
- ⁷³Ibid. "Safe Methadone Induction and Stabilization: Report of an Expert Panel".
- ⁷⁴ Ibid. Management of Benzodiazepines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines.
- ⁷⁵ American Association for the Treatment of Opioid Dependence, Inc. (AATOD) (2010, November). *Opioid Maintenance Pharmacotherapy: A Course for Clinicians*.
- ⁷⁶ Ibid. *Methadone Maintenance Treatment Best Practices in Case Management.*
- 77 Magura, S., Ph.D., Rosenblum, A., PhD. *Leaving Methadone Maintenance Treatment: Lessons Learned, Lessons Forgotten, Lessons Ignored.* The Mount Sinai Journal Of Medicine. Vol. 68. No. 1 January 2001. Retrieved from http://www.wmich.edu/evalctr/wp-content/uploads/2012/08/Leaving-Methadone-Treatment.pdf
- ⁷⁸ Ibid. Federal Guidelines for Opioid Treatment, April 2013.
- ⁷⁹ Ibid. *Federal Guidelines for Opioid Treatment*, April 2013.

Addendums

Methadone: Basic Information and Resources

Pharmacology

1. METHADONE HYDROCHLORIDE solution [Roxane Laboratories, Inc.] DailyMed-Current Medication Information includes description, clinical pharmacology, indications and usage, contraindications, etc. Retrieved from http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=8c363f90-c378-48ae-abbc-aeb25c9bf5cb.

Research

1. Fullerton CA, Kim M, Thomas CP, et al. Medication-assisted treatment with methadone: assessing the evidence. Psychiatric Services in Advance. November 18, 2013; doi: 10.1176/appi.ps.201300235. Retrieved from SAMHSA "Assessing the Evidence Base for Behavioral Health Services (AEB)" Retrieved from http://beta.samhsa.gov/health-reform/financing-research-data/aeb-series-behavioral-health-services.

General

- Methadone or Buprenorphine for Maintenance Therapy of Opioid Addiction: What's the Right Duration?
 Question posed by Medscape, February 3, 2014. Response from Michael G. O'Neil, PharmD Professor, Department of Pharmacy Practice; Consultant, Drug Diversion and Substance Abuse, South College School of Pharmacy, Knoxville, Tennessee. Retrieved from http://www.medscape.com/viewarticle/819875. Requires establishing free Medscape account.
- 2. Addiction Treatment Forum resources http://www.atforum.com/addiction-resources/methadone.php

Recovery-Oriented Methadone-Maintenance (ROMM) Treatment

- "Recovery Transformation in Philadelphia OTPs: Person-centered, not Patient-centered"- one perspective on movement to more recovery-oriented MAT. Addiction Treatment Forum, February 20, 2014. Retrieved from http://atforum.com/news/2014/02/recovery-transformation-philadelphia-otps/
- 2. White, W. L., & Torres, L. (2010). *Recovery-Oriented Methadone Maintenance*. Chicago, IL: Great Lakes Addiction Technology Transfer Center, Philadelphia Department of Behavioral Health and Mental Retardation Services and Northeast Addiction Technology Transfer Center. Retrieved from http://www.williamwhitepapers.com/pr/__books/full_texts/2010Recovery_orientedMethadoneMaintenance.pdf
- 3. "Recovery-Oriented Methadone Maintenance: A Coming of Age"—an overview of White and Torres monograph. AT Forum Volume 21, #1. Winter 2011. Retrieved from http://atforum.com/newsletters/2011winter.php#recovery
- 4. IRETA. (2013, January). Effective Risk Management Strategies in Outpatient Methadone Treatment—Trainer's Manual and PowerPoint Slides, Module 7: Recovery-Oriented Methadone Maintenance (ROMM). Retrieved from http://ireta.org/riskmanagementcurriculum
- 5. IRETA. (2010, October). Recovery-Focused Methadone Treatment: A Primer for Practice Today in Pennsylvania. Retrieved from http://ireta.org/node/348

Addendum A 37

Peer Supports for MAT

- "Walter Ginter on the Importance of Peers in Recovery With Medication-Assisted Treatment"—an introduction to MARS. The MARS™ Project is a peer-initiated and peer-based recovery support project sponsored by the National Alliance of Medication-Assisted (NAMA) Recovery Addiction Treatment Forum, February 10, 2014. Retrieved from http://atforum.com/news/2014/02/walter-ginter-peers-recovery
- 2. The MARS Project. Retrieved from http://marsproject.org

Training Tools

- 1. IRETA. (2013, January). Effective Risk Management Strategies in Outpatient Methadone Treatment—Trainer's Manual and PowerPoint Slides, Module 7: Recovery-Oriented Methadone Maintenance (ROMM). Retrieved from http://ireta.org/riskmanagementcurriculum
- 2. Methadone video 22 minutes—State of Connecticut "Methadone in the Fight Against Opiate Addiction" http://www.u1ovideos.com/dmhas/Methadone.wmv
- 3. Medication Assisted Therapy Overview Video/PowerPoint presentation by Pacific Southwest ATTC for the ATTC Network. Training presented on February 17, 2011. http://www.attcnetwork.org/regcenters/general-Content.asp?rcid=10&content=STCUSTOM3
- 4. Addiction Technology Transfer Center (ATTC) resources http://www.atforum.com/addiction-resources/methadone.php
- 5. Medication-Assisted Treatment with Special Populations. Free on-line course designed to enhance treatment professionals' general knowledge of medication-assisted treatment (MAT) and improve providers' skills related to reaching and educating identified special populations about MAT. Developed by the ATTC Network's Workforce Development MAT workgroup with special project supplemental funding from SAMHSA. https://www.thedatabank.com/dpg/423/donate.asp?formid=meetb&c=5478106
- 6. Addiction Messenger series on Medication Assisted Treatment—Northwest ATTC. http://www.attcnetwork.org/regcenters/generalContent.asp?rcid=10&content=STCUSTOM3

38 Addendum A

Management of Benzodiazepines in Medication-Assisted Treatment: Final Report on the Development of Clinical Guidelines, November 2014¹

The following best practice guidelines are extracted ver batim from the document <u>Management of Benzodiaze-pines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines</u>, and are the result of a consensus panel process on which Community Care collaborated.

VII.A.4. Benzodiazepines

General Guidelines

- 1. CNS depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, anti-depressants, or alcohol.
- 2. People who use benzodiazepines, even if used as a part of long-term therapy, should be considered at risk for adverse drug reactions including overdose and death.
- 3. Many people presenting to services have an extensive history of multiple substance dependence and all substance abuse, including benzodiazepines, should be actively addressed in treatment. MAT should not generally be discontinued for persistent benzodiazepine abuse, but requires the implementation of risk management strategies.
- 4. Clinicians should ensure that every step of decision-making is clearly documented.
- 5. Clinicians would benefit from the development of a toolkit about the management of benzodiazepines in methadone treatment that includes videos and written materials for individuals in MAT.

Assessment for MAT

Given the prevalence of benzodiazepine use among the MAT population, MAT assessment should include careful examination of benzodiazepine use and education about benzodiazepine use.

Generally:

- 1. Conduct a full assessment according to best practices outlined in the TIP 40 (for office-based MAT), TIP 43 (for OTPs), Veterans Affairs/Department of Defense (for individuals in the VA/DoD medical system), and other practice guidelines as applicable.
- 2. As outlined in the TIP 43, VA/DoD guidelines and elsewhere, screening and assessment should include a person's prescription drug and over-the-counter medication use, history of co-occurring disorders, a mental status assessment, and an initial drug screen that identifies benzodiazepines.

Patient Education

- One of the goals of the initial MAT assessment is education. The clinician should use the screening and assessment process as an opportunity to communicate essential information about MAT, including treatment requirements, addiction as a brain disease, and a discussion of the benefits and drawbacks of MAT, to help applicants make an informed decision about treatment. The risks of benzodiazepine use may be folded into this educational component of assessment for MAT.
- 2. Provide education regarding the potential adverse consequences of benzodiazepine use that includes:
- 3. "Immediate" effects of benzodiazepine co-intoxication including motor vehicle accidents and risk of overdose death.
- 4. Risk of depression and suicide.
- 5. The potential for a protracted, uncomfortable withdrawal syndrome that can last for months to years. Long-term disturbances in sleep and mood, increased risk of hip fracture, emotional blunting, and substantial and growing literature that suggests long-term use of benzodiazepines (especially large doses) leads to cognitive decline.
- 6. Research on benzodiazepines' negative effects on MAT treatment outcomes.

Addressing Benzodiazepine Use

If assessment for MAT shows benzodiazepine use, determine its context and create a plan to address it.

Generally:

- 1. Individuals must be agreeable to engage in a plan to address their benzodiazepine use before beginning MAT.
- 2. Uncontrolled use of benzodiazepines in a person presenting for MAT with methadone or buprenorphine is contraindicated. It presents an extremely high risk for adverse drug reaction involving overdose and/or death during the induction process.
- 3. CNS depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, anti-depressants, or alcohol.
- 4. Individuals who use benzodiazepines, even if used as a part of long-term therapy, should be considered at risk for adverse drug reactions including overdose and death.
- 5. Many people presenting to services have an extensive history of multiple substance dependence and all substance abuse, including benzodiazepines, should be actively addressed in treatment. People who have a history of benzodiazepine abuse should not be disallowed from receiving previously prescribed benzodiazepines, provided they are monitored carefully and have stopped the earlier abuse.
- 6. If a person presenting for MAT will not allow a clinician to coordinate care, he or she may not be appropriate for methadone and/or buprenorphine.

Coordination of Care

- Obtain information from the prescribing physicians regarding diagnosis, reason for prescribing benzodiazepines, documentation of prescription, physician-observed aberrant behavior, adverse reactions to benzodiazepines, the individual's prior experience (failure, success, inadequate therapeutic trial) with non-benzodiazepine medications or non-pharmacological therapy to address symptoms.
- 2. Clinicians who take on the care of individuals who state that they have been maintained on benzodiazepines should be sure to confirm this history by communicating with the previously prescribing physician.

Determine level of care to address benzodiazepine use in the context of MAT:

- 1. Clinicians should follow PCPC criteria to guide the appropriate level of care for benzodiazepine taper/detoxification. Consider:
 - a. The policy of the treatment setting on concurrent benzodiazepine use with MAT.
 - b. The individual's transportation to the treatment setting and whether he or she will be driving alone.
 - c. The individual's recovery environment, including his or her social network, those living in the residence, stability of housing.
 - d. The individual's experience with tapering/withdrawal in the past, including managing cravings and adverse medical events, such as seizures.
- 2. Physicians should not abruptly cease high-dose benzodiazepines due to the risk of seizures.
- 3. Tapering of benzodiazepines in outpatient settings may be attempted in patients without complications of overdose, seizures, or co-morbid medical or psychiatric disorders.
- 4. Some people may be able to accomplish a self-taper from benzodiazepine, and this should be offered as an option. Frequent monitoring and contingency management models may be considered in this case.
- 5. If applicable, the MAT clinician should contact the prescribing physician requesting that the individual be weaned with instructions and information about the mutually-decided upon goals and timeline of the taper. The prescribing physician should be willing to taper the patient.
- 6. Detoxification in inpatient settings is indicated for pregnant patients.
- 7. Detoxification in the inpatient setting is preferable in patients with overdose, seizures, comorbid medical or psychiatric disorders, as well as patients on high doses of benzodiazepines over a long period of time.
- 8. Detoxification in inpatient settings may be necessary for patients who have had unsuccessful attempts to taper in outpatient settings.
- 9. Depending on capacity, it may be more appropriate for clinical settings to choose not to induct a person in MAT until benzodiazepine use has ceased and not manage a patient's taper from benzodiazepines during MAT induction. This person may be more appropriate for inpatient detoxification.
- 10. It may be appropriate for a clinician to taper benzodiazepines in an outpatient setting if there are no available inpatient facilities.

Patient Education:

- Education should emphasize that symptoms of benzodiazepine withdrawal may persist for weeks after tapering is complete.
- 2. Education should emphasize that symptoms of benzodiazepine withdrawal may persist for weeks after detoxification is complete.

MAT Induction

For anyone in MAT, the induction period carries with it the most risk of harm. Extra care is required when inducting a person who uses benzodiazepines.

Generally:

- Physicians should follow best practice (TIP 43 and/or TIP 40) dosing and timing protocols for induction of MAT.
- 2. Clinicians should be aware when inducting a person onto methadone that the long half-life of methadone, possible synergistic effects and drug-drug interactions may alter methadone metabolism.
- Clinicians should note that highest risk of overdose or death is in first two weeks; therefore people should be monitored extremely closely during the first two weeks of induction.
- 4. High variation among individuals in MAT and unverifiable information warrants highly individualized care in dosing and enhanced monitoring for first five days or until stabilization.
- 5. People who receive/use CNS depressants may need to be inducted on methadone at a lower dose than those who do not receive/use CNS depressants.
- 6. People should receive a daily directly-observed administration of methadone dose during the induction period until stabilization.

Patient Education:

- 1. Clinicians should request that individuals sign an informed consent form before initiating MAT agreeing that if he or she appears impaired, the treatment center has permission to notify a family member and refuse medication.
- 2. Inform individuals receiving MAT of the treatment setting's policy on impairment. Provide education about impairment, especially about drug-to-drug interactions. Give them sources of information and encourage them to ask questions.
- 3. Individuals should be prohibited from driving themselves to the treatment setting during MAT induction until they are stabilized.

MAT for People with Concurrent Benzodiazepine Use

A person's use of benzodiazepines may change over time, or even from visit to visit. Effective, individualized treatment includes ongoing communication, appropriate dosing, and careful monitoring.

Generally:

- 1. For a person with concurrent benzodiazepine use, following best practices outlined in TIP 43, MAT clinician should provide treatment appropriate for a patient in the stabilization phase of MAT.
- 2. A contingency management framework can be incorporated into treatment conditions.
- 3. Avoid prescribing alprazolam to individuals receiving methadone.

Dosing:

- 1. Ensure adequate, appropriate MAT dose. Methadone dosing decisions should be individualized; dose should not be changed for punitive reasons but rather on clinical grounds.
- 2. Take-home doses should be guided by the CSAT 2008 "Dear Colleague" letter, which states that "8-point criteria must be considered and documented for patients even for clinic closures" but "the assessment does allow for a physician to use clinical judgment in determining whether a patient is responsible in handling a take home dose(s) and whether the rehabilitative benefit the patient would gain from reduced attendance for directly observed dosing outweighs the potential risk of diversion."

Tapered withdrawal protocol:

- 1. Clinicians and individuals in MAT need to mutually agree on a period of time they envision tapering the patient from benzodiazepines. A longer and slower detoxification is more successful for most, but not longer than six months.
- 2. Benzodiazepines should be tapered no faster than 10−15% at a time.
- 3. It is advisable that people using or abusing multiple benzodiazepines should have their prescriptions converted to a single benzodiazepine for the purpose of simplifying the taper. Very rarely, if the person in MAT is very anxious, converting to one benzodiazepine can be done over 1–2 weeks.
- 4. If possible, a person who is tapering from benzodiazepines should be seen daily. A higher level of care may be necessary for a patient who is tapering than one who has been detoxified from benzodiazepines.
- 5. Close monitoring of adherence to benzodiazepine tapering protocol with observed urine drug screens is indicated.
- 6. Practice continuous monitoring of symptoms during the taper, and alternative treatments to address these symptoms.
- 7. If the physician is prescribing benzodiazepines while the individual in MAT is tapering and there is a recurrence of lost prescriptions or the individual runs out early too often, discontinue benzodiazepine prescription.
- 8. People should be discouraged from stopping MAT before tapering from benzodiazepine is complete.

Patient Education:

- 1. Frequently re-evaluate the treatment agreement with the individual receiving treatment.
- 2. Clinicians should offer referrals and information regarding twelve-step and other mutual aid groups available within the region.
- 3. Provide education to address the use of benzodiazepines that incorporates a stages of change model, motivational enhancement, and a recovery-orientation.
- 4. For all people in MAT, reductions and withdrawal from benzodiazepines should regularly be proposed.

Monitoring:

- 1. If applicable, work closely with the physician who prescribes benzodiazepines.
- 2. Undertake regular monitoring, including clinical review and urine testing.
- 3. Regularly utilize information from prescription drug monitoring programs.

Noncompliance with Treatment Agreement

Individuals in MAT may deviate from the treatment agreement. Clinical judgment is required to address noncompliance.

Generally:

- 1. MAT should not generally be discontinued for persistent benzodiazepine abuse, but requires the implementation of risk management strategies.
- 2. Retain people in a system of care when possible.
- 3. Physicians have some responsibility to reduce diversion.

In case of noncompliance:

- 1. If an individual uses benzodiazepines illicitly while in MAT, change to daily dose of MAT until benzodiazepines clears.
- 2. Limit or cease all take-home MAT doses if a person uses benzodiazepines illicitly while in MAT.
- 3. Consider providing increased intensity of psychosocial treatment.
- 4. Consider a higher level of care with the goal of eliminating aberrant behavior so that the individual may safely and successfully continue MAT with methadone or buprenorphine.
- 5. If efforts are unsuccessful in elimination of the aberrant behavior that presents serious risks for patient safety, non-MAT alternative therapy may be indicated and advised.

Risk Management/Impairment Assessment

Clinicians should use caution with people in MAT who use benzodiazepines because they have increased risk for adverse drug reactions including overdose and death.

Generally:

- 1. The treatment setting should create an environment where all staff are involved in awareness of impairment. Receptionists and security personnel have opportunities to observe and identify impairment. Dosing nurses and counselors are on the front lines of identifying impairment. Individuals in MAT themselves are underutilized resources in helping to identify others who are impaired or at risk.
- 2. Assess everyone for impairment every time they appear for treatment.
- 3. Routinely explore a person's transportation to receive MAT, where from and whether the patient drives alone. For people who drive long distances to the OTP, risk of loss is higher.
- 4. Particular caution should be used when a benzodiazepine-dependent person on opioid substitution therapy has missed doses as such people may be at high risk for overdose.
- 5. Clinicians should ensure that every step of decision-making is clearly documented.

Impairment Assessment Tools:

- 1. Assessment tools include the Clinical Sobriety Checklist, Standardized Field Sobriety Testing, and DSM-IV diagnostic criteria for sedative, hypnotic or anxiolytic intoxication.
- 2. If an individual appears clinically impaired, a validated instrument may be helpful for assessment, but should not replace clinical judgment.

In case of impairment:

- 1. Always apply a no-tolerance policy for impairment.
- 2. Identifying impairment is typically grounds to support refusing to medicate.
- 3. If the individual has signed an informed consent form before initiating MAT, notify a family member and refuse medication if he or she appears impaired.
- 4. If an individual presents for MAT and appears impaired, examine the MAT dose. A state of withdrawal can bring on impairment. He or she may not be receiving an adequate dose and may therefore be self-medicating.

Special Circumstances: People in MAT-Seeking Benzodiazepines

Giving benzodiazepine prescriptions to people in MAT is controversial. Guidelines specific to the practice of benzodiazepine prescribing in the context of MAT are listed below. Clinicians are advised to use recovery-oriented approaches to education and risk management approaches as detailed in the rest of the guidelines.

Generally:

- 1. People who are maintained on sedative medications, especially opioids, should only receive benzodiazepine prescriptions with extreme caution because of the potential for a fatal drug interaction.
- 2. If a person is stable in long-term recovery on MAT and experiences a major stressful event, a clinician may consider a short-term (i.e. 7–10 days) prescription for benzodiazepines to help stabilize the patient but this treatment should not be considered first line.
- 3. Individuals who claim that "nothing else helps" should have a careful evaluation for addiction. Physicians should be aware that the subjective nature of anxiety allows for dishonest presentations of symptoms. The claim that "nothing else helps" is often a direct demand for benzodiazepines from the physician. A reasonable response is a trial of psychotherapy and medications without addictive potential.
- 4. Benzodiazepines should not be the first-line drug for any disorder.

Psychiatric disorders:

- 1. Clinicians are advised not to use benzodiazepines to treat co-occurring psychiatric disorders.
- 2. Clinicians are advised not to use benzodiazepines to treat co-morbid physical/medical disorder that may mask a person's mental status symptoms for anxiety, depression, and/or insomnia.

Considerations:

- 1. Consider individual's past/current relationship with benzodiazepines.
- 2. Think carefully about the goals the individual in MAT and the clinician hope to achieve before starting a prescription of benzodiazepine, even a short-term reduction.

Guidelines for benzodiazepine prescriptions:

- 1. For people receiving methadone, physicians are advised to prescribe a benzodiazepine with a slow onset and long duration of action, at the lowest dose, and for the shortest duration possible.
- 2. Document education and treatment decisions during the initiation of benzodiazepines.
- 3. Avoid prescribing alprazolam to individuals receiving methadone.
- 4. Benzodiazepines with substantially lower abuse potential (e.g. oxazepam, clorazepate) are strongly preferred over benzodiazepines with a rapid onset, such as diazepam and alprazolam, which should be avoided because of their abuse potential.
- 5. Initiate short-term benzodiazepines with a prescription for no longer than one week.
- 6. For a short-course of treatment, the benzodiazepine prescription should be for less than one month.

Benzodiazepine Maintenance

Benzodiazepine maintenance treatment is controversial. Current best practice guidelines are listed below.

Considerations:

- 1. Long-term maintenance of benzodiazepines is rarely indicated and should be avoided.
- 2. Providing a maintenance benzodiazepine dose in the context of MAT is to be considered a last-resort option after other alternatives have been exhausted.
- 3. One of the few who may benefit from a maintenance dose of benzodiazepine is a person who has long-term opioid and benzodiazepine abuse and is not able to stabilize on opioid substitution medication alone.

Non-MAT alternatives:

- 1. It may be more appropriate for individuals maintained on benzodiazepines to consider non-methadone alternatives than those who are not maintained on benzodiazepines.
- 2. Individuals should be willing to consider non-MAT alternative therapy for opioid dependence if maintained on benzodiazepines.

Guidelines for maintenance treatment:

- 1. Physicians are advised to consider a consultation with a specialist in addiction medicine/psychiatry or utilize a mentor from the Physicians Clinical Support System (PCSS) before commencing a maintenance dose.
- 2. People maintained on benzodiazepines should be monitored more closely than others in MAT.
- 3. If maintained on benzodiazepines, it is strongly recommended that a single, long-acting benzodiazepine is used for people in MAT.

¹ Management of Benzodiazepines in Medication-Assisted Treatment—Final Report on the Development of Clinical Guidelines November 2013. Prepared for the City of Philadelphia Department of Behavioral Health and Intellectual disAbility Services By the Institute for Research, Evaluation and Training in Addictions with Support from Community Care Behavioral Health Organization, Retrieved from http://www.ccbh.com/providers/phealthchoices/bestpractice/index.php

DSM-V Opioid Use Disorder Diagnostic Criteria

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 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 opioids.
- 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.
- Continued opioid use despite knowledge of having a 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 need for markedly increased amounts of opioids to achieve intoxication or desired effect.
- · A markedly diminished effect with continued use of the same amount of an opioid.
- Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.
- 11. Withdrawal, as manifested by either of the following:
- The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal).
- Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.
- Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Specify if:

- In early remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception that Criterion A4, "Craving, or a strong desire or urge to use opioids," may be met).
- In sustained remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion A4, "Craving, or a strong desire or urge to use opioids," may be met).

Specify if:

- On maintenance therapy: This additional specifier is used if the individual is taking a prescribed agonist medication such as methadone or buprenorphine and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone.
- In a controlled environment: This additional specifier is used if the individual is in an environment where access to opioids is restricted.

Coding based on current severity: Note for ICD-10-CM codes: If an opioid intoxication, opioid withdrawal, or another opioid-induced mental disorder is also present, do not use the codes below for opioid use disorder. Instead, the comorbid opioid use disorder is indicated in the 4th character of the opioid-induced disorder code (see the coding note for opioid intoxication, opioid withdrawal, or a specific opioid-induced mental disorder). For example, if there is comorbid opioid-induced depressive disorder and opioid use disorder, only the opioid-induced depressive disorder code is given, with the 4th character indicating whether the comorbid opioid use disorder is mild, moderate, or severe: F11.14 for mild opioid use disorder with opioid-induced depressive disorder or F11.24 for a moderate or severe opioid use disorder with opioid-induced depressive disorder.

Specify current severity:

- 305.50 (F11.10) Mild: Presence of 2-3 symptoms.
- 304.00 (F11.20) Moderate: Presence of 4–5 symptoms.
- 304.00 (F11.20) Severe: Presence of 6 or more symptoms.

Reprinted with permission from the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (Copyright ©2013). American Psychiatric Association. All Rights Reserved.

Tools for Assessing Withdrawal Status

Dependence Syndrome (ICD-10)

The legislation *Protecting Access to Medicare Act* (HR 4302) recently signed into law includes a one year delay in implementation of the ICD-10 codes until October 1, 2015.

Definition

The Tenth Revision of the International Classification of Diseases and Health Problems (ICD-10) defines the dependence syndrome as being a cluster of physiological, behavioural, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value. A central descriptive characteristic of the dependence syndrome is the desire (often strong, sometimes overpowering) to take the psychoactive drugs (which may or not have been medically prescribed), alcohol, or tobacco. There may be evidence that return to substance use after a period of abstinence leads to a more rapid reappearance of other features of the syndrome than occurs with nondependent individuals.

In 1964 a WHO Expert Committee introduced the term 'dependence' to replace the terms 'addiction' and 'habituation'. The term can be used generally with reference to the whole range of psychoactive drugs (drug dependence, chemical dependence, substance use dependence), or with specific reference to a particular drug or class of drugs (e.g. alcohol dependence, opioid dependence). While ICD-10 describes dependence in terms applicable across drug classes, there are differences in the characteristic dependence symptoms for different drugs.

In unqualified form, dependence refers to both physical and psychological elements. Psychological or psychic dependence refers to the experience of impaired control over drinking or drug use while physiological or physical dependence refers to tolerance and withdrawal symptoms. In biologically-oriented discussion, dependence is often used to refer only to physical dependence.

Dependence or physical dependence is also used in the psychopharmacological context in a still narrower sense, referring solely to the development of withdrawal symptoms on cessation of drug use. In this restricted sense, cross-dependence is seen as complementary to cross-tolerance, with both referring only to physical symptomatology (neuroadaptation).

ICD-10 Clinical Description

A cluster of physiological, behavioural, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value. A central descriptive characteristic of the dependence syndrome is the desire (often strong, sometimes overpowering) to take psychoactive drugs (which may or may not have been medically prescribed), alcohol, or tobacco. There may be evidence that return to substance use after a period of abstinence leads to a more rapid reappearance of other features of the syndrome than occurs with nondependent individuals.

ICD-10 Diagnostic Guidelines

A definite diagnosis of dependence should usually be made only if three or more of the following have been present together at some time during the previous year:

- A strong desire or sense of compulsion to take the substance;
- Difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use;
- A physiological withdrawal state when substance use has ceased or have been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses (clear examples of this are found in alcohol- and opiate-dependent individuals who may take daily doses sufficient to incapacitate or kill non-tolerant users);
- Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;
- Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

ICD-10 Diagnostic Criteria for Research

Three or more of the following manifestations should have occurred together for at least 1 month or, if persisting for periods of less than 1 month, should have occurred together repeatedly within a 12-month period:

- A strong desire or sense of compulsion to take the substance;
- Impaired capacity to control substance-taking behaviour in terms of its onset, termination, or levels of use, as evidenced by the substance being often taken in larger amounts or over a longer period than intended, or by a persistent desire or unsuccessful efforts to reduce or control substance use;
- A physiological withdrawal state when substance use is reduced or ceased, as evidenced by the characteristic withdrawal syndrome for the substance, or by use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Evidence of tolerance to the effects of the substance, such that there is a need for significantly increased amounts of the substance to achieve intoxication or the desired effect, or a markedly diminished effect with continued use of the same amount of the substance;
- Preoccupation with substance use, as manifested by important alternative pleasures or interests being given up or reduced because of substance use; or a great deal of time being spent in activities necessary to obtain, take or recover from the effects of the substance;
- Persistent substance use despite clear evidence of harmful consequences as evidenced by continued use when the individual is actually aware, or may be expected to be aware, of the nature and extent of harm.

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's name:		Date:	
Buprenorphine induction:			
Times (enter scores at time zero, 30min after first dose, 2 h after first dose, etc.)	 		
Resting Pulse Rate (beats/minute): Measured after patient is sitting or lying for one minute o pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120			
Sweating (over past ½ hour not accounted for by room temperature or patient activity) o no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face; 4 sweat streaming off face			
Restlessness (observation during assessment) o able to sit still reports difficulty sitting still, but is able to do so grequent shifting or extraneous movements of legs/arms unable to sit still for more than a few seconds	 		
Pupil Size o pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible			
Bone or Joint Aches (if patient was having pain previously, only the additional component attributed to opiates withdrawal is scored) o not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort			

Addendum D 51

Runny Nose or Tearing (not accounted for by cold symptoms or allergies) o not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks		
GI Upset (over last ½ hour) o no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting		
Tremor (observation of outstretched hands) o no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching		
Yawning (observation during assessment) o no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute	 	
Anxiety or Irritability o none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult		
Gooseflesh Skin o skin is smooth g piloerrection of skin can be felt or hairs standing up on arms prominent piloerrection		
Total Scores (with observer's initials) 5–12 = mild 13–24 = moderate 25–36 = moderately severe more than 36 = severe withdrawal	 	

 $\underline{http://www.csam\text{-}asam.org/sites/default/files/pdf/misc/COWS_induction_flow_sheet.doc}$

52 Addendum D

Bibliography: AATOD

American Association for the Treatment of Opioid Dependence Opioid Maintenance Pharmacotherapy – A Course for Clinicians 2013

Referenced Bibliography

Epidemiology

- Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm
- Results from the 2008 National Survey on Drug Use and Health: National Findings, http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf
- 3. A Day in the Life of American Adolescents: Substance Use Facts Update, The OAS Report, SAMHSA, Office of Applied Studies, April 29, 2010
- 4. Trends in Emergency Department Visits Involving Nonmedical Use Narcotic Pain Relievers, The DAWN Report, http://DAWNInfo.samhsa.gov
- 5. Mary Jeanne Kreek, K. Steven LaForge & Eduardo Butelman, Pharmacotherapy of addictions, *Nature Reviews Drug Discovery* **1**, 710-726 (September 2002)

Methadone-Associated Deaths

- Methadone Mortality A 2010 Reassessment. http://dpt.samhsa.gov/pdf/Methadone Briefing Paper.pdf
- 2. GAO-09-341, Methadone-Associated Overdose Deaths, Report to Congressional Requesters, March 2009
- 3. Sheilds, LB, et. al, Methadone Toxicity Fatalities: A Review of Medical Examiner Cases In A Large Metropolitan Area, J. Forensic Sci, November 2007, Vol. 52, No. 6
- 4. Modesto-Lowe V, Brooks D, Petry N, Methadone deaths: risk factors in pain and addicted populations., J Gen Intern Med. 2010 Apr;25(4):305-9. Epub 2010 Jan 20.
- 5. Letsky MC, Zumwalt RE, Seifert SA, Benson BE, Cause of Death Conundrum With Methadone Use: A Case Report. Am J Forensic Med Pathol. 2010 Feb 25.
- Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. <u>Addiction.</u> 2009 Sep;104(9):1541-8.
- 7. Graham NA, Merlo LJ, Goldberger BA, Gold MS. Methadone- and heroin-related deaths in Florida. <u>Am J Drug Alcohol Abuse</u>. 2008;34(3):347-53.

Opioid Pharmacology

- 1. Eap, CB, et al. Interindividual Variability of the Pharmacokinetics of Methadone. Implications for the treatment of Opioid Dependence. Clin Pharmacokinet 2002 41 (14) 1153-1193.
- 2. Smith, HD, Opioid Metabolism, Mayo Clin Proc, July 2009, 84(7):613-624.



Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 53

- 3. Li Y, Kantelip JP, Gerritsen-van Schieveen P, Davani S. Interindividual variability of methadone response: impact of genetic polymorphism. <u>Mol Diagn Ther.</u> 2008;12(2):109-24.
- 4. Fredheim OM, Moksnes K, Borchgrevink PC, Kaasa S, Dale O., Clinical pharmacologyof methadone for pain. Acta Anaesthesiol Scand. 2008 Aug;52(7):879-89. Epub 2008 Mar 7.
- 5. Rostami-Hodjegan, A., et. al, Population pharmacokinetics of methadone in opiate users:characterization of time dependent changes, Br J Clin Pharmacol 1999, 48:43-52
- 6. Wolfe, K., et. al, The Pharmacokinetics of methadone in health subjects and opiate users, Br J Clin Pharmacol 1997, 44:325-334.

Neurobiology

- 1. Stimmel B, Kreek MJ. Neurobiology of addictive behaviors and its relationship to methadone maintenance. Oct/Nov 2000, Mt Sinai Journal of Medicine, Vol 67 Nos. 5&6.
- 2. Bechara, A, Decision making, impulse control, and loss of will power to resist drugs: a neurocognitive perspective. November 2005, Nature Neuroscience Vol. 8 No.11.
- 3. Nasir H, et. al, The hidden island of addiction: the insula, Trends in Neurosciences, 2008, Vol xxx, No.x

Treatment Options

- 1 Neufeld K, Kidorf M, King V, Stoller K, Clark M, Peirce J, Brooner RK. <u>Using enhanced and integrated services to improve response to standard methadone treatment: changing the clinical infrastructure of treatment networks</u>. J Subst Abuse Treat. 2010 Mar;38(2):170-7
- 2 Kinlock TW, Gordon MS, Schwartz RP, Fitzgerald TT, O'Grady KE. A randomized clinical trial of methadone maintenance for prisoners: results at 12 months post release. <u>J Subst Abuse Treat.</u> 2009 Oct;37(3):277-85. Epub 2009 Mar 31.
- 3 Oviedo-Joekes E, Brissette S, Marsh DC, Lauzon P, Guh D, Anis A, Schechter MT. Diacetylmorphine versus methadone for the treatment of opioid addiction. N Engl J Med. 2009 Aug 20;361(8):777-86.
- 4 Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in pharmacotherapy. Expert Opin Pharmacother. 2009 Aug;10(11):1727-40. Review
- 5 Sorensen JL, Andrews S, Delucchi KL, Greenberg B, Guydish J, Masson CL, Shopshire M. Methadone patients in the therapeutic community: a test of equivalency. Drug Alcohol Depend. 2009 Feb 1;100(1-2):100-6
- 6 Kleber HD, Methadone maintenance 4 decades later: Thousands of Lives Saved But Still Controversial. JAMA 2008;300(19):2303-2305.
- 7 Joseph H, Stancliff S, Langrod J. Methadone maintenance treatment (MMT): a review of historical and clinical issues. Mt Sinai J Med. 2000 Oct-Nov;67(5-6):347-64.
- 8 Paul G. Barnett, Ph.D., and Sally S. Hui, B.A, The Cost-Effectiveness of Methadone Maintenance, Oct/Nov 2000, Mt Sinai Journal of Medicine, Vol 67 Nos. 5&6.
- 9 Merrill JO, Jackson TR, Schulman BA, Saxon AJ, Awan A, Kapitan S, Carney M, Brumback LC, Donovan D. <u>Methadone medical maintenance in primary care. An implementation evaluation.</u> J Gen Intern Med. 2005 Apr;20(4):344-9.

Methadone Induction / Stabilization



Opioid Maintenance Pharmacotherapy: A Course for

54 Addendum E

- 1. Trafton, JA, Determining Effective Methadone Doses for Individual Opioid-Dependent Patients, PLOS Medicine March 2006, Vol 3 Issue 3.
- 2. Leavitt, SB, Methadone Dosing and Safety In the Treatment of Opioid Addiction, AT Forum, www.atforum.com
- 3. Srivastava A, Kahan M. Methadone induction doses: are our current practices safe? <u>J Addict Dis.</u> 2006;25(3):5-13.
- 4. <u>Greenwald MK</u>, Early impact of methadone induction for heroin dependence: differential effects of two dose sequences in a randomized controlled study. <u>Exp Clin Psychopharmacol</u>. 2006 Feb;14(1):52-67.

Drug-Drug Interactions

- 1. Gruber VA, McCance-Katz EF, Methadone, buprenorphine, and street drug interactions with antiretroviral medications, Curr HIV/AIDS Rep. 2010 Aug;7(3):152-60.
- 2. Keller GA, Ponte ML, Di Girolamo G, Other drugs acting on nervous system associated with QT-interval prolongation. Curr Drug Saf. 2010 Jan;5(1):105-11. Review
- 3. McCance-Katz EF, Sullivan LE, Nallani S. <u>Drug interactions of clinical importance among the opioids</u>, <u>methadone and buprenorphine</u>, <u>and other frequently prescribed medications: a review</u>. Am J Addict. 2010 Jan-Feb;19(1):4-16
- 4. McCance-Katz EF, Mandell TW, <u>Drug interactions of clinical importance with methadone and buprenorphine.</u> Am J Addict. 2010 Jan-Feb;19(1):2-3
- 5. Batkis MF, Treisman GJ, Angelino AF, <u>Integrated opioid use disorder and HIV treatment: rationale, clinical guidelines for addiction treatment, and review of interactions of antiretroviral agents and opioid agonist therapies.</u>
- 6. Izzo AA, Ernst E. <u>Interactions between herbal medicines and prescribed drugs: an updated systematic</u> review. Drugs. 2009;69(13):1777-98

Cardiac Considerations

- Anchersen K, Hansteen V, Gossop M, Clausen T, Waal H, <u>Opioid maintenance patients with QTc prolongation: Congenital long QT syndrome mutation may be a contributing risk factor.</u> Drug Alcohol Depend. 2010 Aug 9
- 2. Fareed A, Vayalapalli S, Byrd-Sellers J, Casarella J, Drexler K, Amar R, Smith-Cox J, Lutchman TS. Onsite QTc interval screening for patients in methadone maintenance treatment. J Addict Dis. 2010 Jan;29(1):15-22.
- 3. Fonseca F, Marti-Almor J, Pastor A, Cladellas M, Farré M, de la Torre R, Torrens M. Prevalence of long QTc interval in methadone maintenance patients. Drug Alcohol Depend. 2009 Jan 1;99(1-3):327-32
- 4. Wallner C, Stöllberger C, Hlavin A, Finsterer J, Hager I, Hermann P. <u>Electrocardiographic abnormalities</u> in opiate addicts. Addiction. 2008 Dec;103(12):1987-93.
- 5. Peles E, Bodner G, Kreek MJ, Rados V, Adelson M. <u>Corrected-QT intervals as related to methadone dose and serum level in methadone maintenance treatment (MMT) patients: a cross-sectional study.</u> Addiction. 2007 Feb;102(2):289-300.



Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 55

- 6. Latowsky M, Methadone, Death, Dosage and Torsade de Pointes: Risk-Benefit Policy Implications. *Journal of Psychoactive Drugs;* Dec 2006; 38, 4; 513-519
- 7. Krantz MJ, Lowery CM, Martell BA, Gourevitch MN, Arnsten JH. <u>Effects of methadone on QT-interval dispersion</u>. Pharmacotherapy. 2005 Nov;25(11):1523-9
- 8. Pearson EC, Woosley RL. <u>QT prolongation and torsades de pointes among methadone users: reports to the FDA spontaneous reporting system.</u> Pharmacoepidemiol Drug Saf. 2005 Nov;14(11):747-53
- 9. Cruciani RA, Sekine R, Homel P, Lussier D, Yap Y, Suzuki Y, Schweitzer P, Yancovitz SR, Lapin JA, Shaiova L, Sheu RG, Portenoy RK. <u>Measurement of QTc in patients receiving chronic methadone therapy</u>. J Pain Symptom Manage. 2005 Apr;29(4):385-91
- 10. Krantz MJ, Rowan SB, Mehler PS. <u>Cocaine-related torsade de pointes in a methadone maintenance patient</u>. J Addict Dis. 2005;24(1):53-60
- 11. Maremmani I, Pacini M, Cesaroni C, Lovrecic M, Perugi G, Tagliamonte A. <u>QTc interval prolongation in patients on long-term methadone maintenance therapy</u>. Eur Addict Res. 2005;11(1):44-9
- 12. Krantz MJ, Kutinsky IB, Robertson AD, Mehler PS. <u>Dose-related effects of methadone on QT prolongation in a series of patients with torsade de pointes.</u> Pharmacotherapy. 2003 Jun;23(6):802-5

Medical Comorbidity

- 1. Walley AY, Farrar D, Cheng DM, Alford DP, Samet JH. <u>Are opioid dependence and methadone</u> <u>maintenance treatment (MMT) documented in the medical record? A patient safety issue.</u> J Gen Intern Med. 2009 Sep;24(9):1007-11
- 2. Mancino M, Curran G, Han X, Allee E, Humphreys K, Booth BM. <u>Predictors of attrition from a national sample of methadone maintenance patients</u>. Am J Drug Alcohol Abuse. 2010 May;36(3):155-60.
- 3. Rajaratnam R, Sivesind D, Todman M, Roane D, Seewald R. <u>The aging methadone maintenance patient: treatment adjustment, long-term success, and quality of life.</u> J Opioid Manag. 2009 Jan-Feb;5(1):27-37
- 4. Litwin AH, Harris KA Jr, Nahvi S, Zamor PJ, Soloway IJ, Tenore PL, Kaswan D, Gourevitch MN, Arnsten JH. <u>Successful treatment of chronic hepatitis C with pegylated interferon in combination with ribavirin in a methadone maintenance treatment program.</u> J Subst Abuse Treat. 2009 Jul;37(1):32-40. Epub 2008 Nov 28
- 5. <u>Kreek MJ</u>, <u>Talal AH</u>, <u>Piccolo P</u> Treating chronic hepatitis C in recovering opiate addicts: yes, we can. <u>Dig Liver Dis.</u> 2009 Apr;41(4):308-10. Epub 2009 Feb 23.
- 6. Liver Transplantation in the United States, 1999-2008 http://www.ustransplant.org/annual_reports/current/Chapter_IV_AR_CD.htm#4
- 7. Thomas F. Kresina1, Diana Sylvestre2, Leonard Seeff3, Alain H. Litwin4, Kenneth Hoffman1, Robert Lubran1 and H. Westley Clark, Hepatitis Infection in the Treatment of Opioid Dependence and Abuse, Substance Abuse: Research and Treatment 2008:1
- 8. M. S. Sulkowski1 and Y. Benhamou, Therapeutic issues in HIV/HCV-coinfected patients. Journal of Viral Hepatitis, 2007, 14, 371–386
- 9. Bekker LG, Wood R. <u>The changing natural history of tuberculosis and HIV coinfection in an urban area</u> of hyperendemicity. Clin Infect Dis. 2010 May 15;50 Suppl 3:S208-14. Review.



Opioid Maintenance Pharmacotherapy: A Course for

56 Addendum E

- Gourevitch MN, Chatterji P, Deb N, Schoenbaum EE, Turner BJ. On-site medical care in methadone maintenance: associations with health care use and expenditures. J Subst Abuse Treat. 2007 Mar;32(2):143-51.
- 11. Herman M, Gourevitch MN. <u>Integrating primary care and methadone maintenance treatment:</u> implementation issues. J Addict Dis. 1997;16(1):91-102
- 12. Richter KP, Choi WS, McCool RM, Harris KJ, Ahluwalia JS. <u>Smoking cessation services in U.S. methadone maintenance facilities.</u> Psychiatr Serv. 2004 Nov;55(11):1258-64
- 13. Winklbaur B, Kopf N, Ebner N, Jung E, Thau K, Fischer G. <u>Treating pregnant women dependent on opioids is not the same as treating pregnancy and opioid dependence: a knowledge synthesis for better treatment for women and neonates.</u> Addiction. 2008 Sep;103(9):1429-40. Review.PMID
- 14. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
- 15. HIV Counseling with Rapid Tests. http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt counseling.htm 16.

Pain Management

- Peles E, Schreiber S, Hetzroni T, Adelson M, Defrin R. <u>The Differential Effect of Methadone Dose and of Chronic Pain on Pain Perception of Former Heroin Addicts Receiving Methadone Maintenance Treatment.</u> J Pain. 2010 Jun 18.
- 2. Barry DT, Beitel M, Cutter CJ, Joshi D, Falcioni J, Schottenfeld RS. <u>Conventional and non-conventional pain treatment utilization among opioid dependent individuals with pain seeking methadone maintenance treatment: A needs assessment study.</u> J Addict Med. 2009 Sep;18(5):379-385
- 3. Barry DT, Beitel M, Garnet B, Joshi D, Rosenblum A, Schottenfeld RS. Relations among psychopathology, substance use, and physical pain experiences in methadone-maintained patients. J Clin Psychiatry. 2009 Sep;70(9):1213-8.
- 4. Barry DT, Beitel M, Cutter CJ, Garnet B, Joshi D, Schottenfeld RS, Rounsaville BJ. <u>Allopathic, complementary, and alternative medical treatment utilization for pain among methadone-maintained patients</u>. Am J Addict. 2009 Sep-Oct;18(5):379-85
- 5. Blinderman CD, Sekine R, Zhang B, Nillson M, Shaiova L. <u>Methadone as an analgesic for patients with chronic pain in methadone maintenance treatment programs (MMTPs).</u> J Opioid Manag. 2009 Mar-Apr;5(2):107-14.
- 6. Barry DT, Beitel M, Joshi D, Schottenfeld RS. <u>Pain and substance-related pain-reduction behaviors among opioid dependent individuals seeking methadone maintenance treatment.</u> Am J Addict. 2009 Mar-Apr;18(2):117-21.
- 7. Berg KM, Arnsten JH, Sacajiu G, Karasz A. <u>Providers' experiences treating chronic pain among opioid-dependent drug users.</u> J Gen Intern Med. 2009 Apr;24(4):482-8
- 8. Hines S, Theodorou S, Williamson A, Fong D, Curry K. <u>Management of acute pain in methadone maintenance therapy in-patients</u>. Drug Alcohol Rev. 2008 Sep;27(5):519-23.
- 9. Cruciani RA, Esteban S, Seewald RM, Altilio T, Bookbinder M, Sheu R, Portenoy RK. <u>MMTP patients with chronic pain switching to pain management clinics. A problem or an acceptable practice?</u> Pain Med. 2008 Apr;9(3):359-64



Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 57

10. Seddon R. Savage, M.D., M.S. Kenneth L. Kirsh, Ph.D. Steven D. Passik, Ph.D. Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders. Addictions Science & Clinical Practice June 2008. http://www.nida.nih.gov/PDF/ascp/vol4no2/Challenges.pdf

Psychiatric Comorbidity

- Wedekind D, Jacobs S, Karg I, Luedecke C, Schneider U, Cimander K, Baumann P, Ruether E, Poser W, Havemann-Reinecke U. <u>Psychiatric comorbidity and additional abuse of drugs in maintenance treatment with L- and D,L-methadone</u>. World J Biol Psychiatry. 2010 Mar;11(2 Pt 2):390-9
- 2. Norman SB, Wilkins KC, Tapert SF, Lang AJ, Najavits LM. A pilot study of seeking safety therapy with OEF/OIF veterans. J Psychoactive Drugs. 2010 Mar;42(1):83-7
- 3. Zlotnick C, Johnson J, Najavits LM. Randomized controlled pilot study of cognitive-behavioral therapy in a sample of incarcerated women with substance use disorder and PTSD. <u>Behav Ther.</u> 2009 Dec;40(4):325-36. Epub 2008 Oct 31.
- 4. Carpentier PJ, Krabbe PF, van Gogh MT, Knapen LJ, Buitelaar JK, de Jong CA. <u>Psychiatric comorbidity reduces quality of life in chronic methadone maintained patients.</u> Am J Addict. 2009 Nov-Dec;18(6):470-80
- 5. Tenore PL. Psychotherapeutic benefits of opioid agonist therapy. J Addict Dis. 2008;27(3):49-65. Review.
- 6. Maremmani I, Pacini M, Lubrano S, Perugi G, Tagliamonte A, Pani PP, Gerra G, Shinderman M. <u>Longterm outcomes of treatment-resistant heroin addicts with and without DSM-IV axis I psychiatric comorbidity (dual diagnosis).</u> Eur Addict Res. 2008;14(3):134-42.
- 7. Peles E, Schreiber S, Naumovsky Y, Adelson M. <u>Depression in methadone maintenance treatment patients: rate and risk factors.</u> J Affect Disord. 2007 Apr;99(1-3):213-20
- 8. Shaul Schreiber, Einat Peles, Miriam Adelson, Association between improvement in depression, reduced benzodiazepine (BDZ) abuse, and increased psychotropic medication use in methadone maintenance treatment (MMT) patients. Drug and Alcohol Dependence 92 (2008) 79–85
- 9. Brooks DJ, Vosburg SK, Evans SM, Levin FR. <u>Assessment of cognitive functioning of methadone-maintenance patients: impact of adult ADHD and current cocaine dependence.</u> J Addict Dis. 2006;25(4):15-25.
- 10. Gelkopf M, Weizman T, Melamed Y, Adelson M, Bleich A. <u>Does psychiatric comorbidity affect drug</u> <u>abuse treatment outcome? A prospective assessment of drug abuse, treatment tenure and infectious diseases in an Israeli methadone maintenance clinic. Isr J Psychiatry Relat Sci. 2006;43(2):126-36</u>
- 11. Dean AJ, Bell J, Mascord DJ, Parker G, Christie MJ. <u>A randomised, controlled trial of fluoxetine in</u> <u>methadone maintenance patients with depressive symptoms.</u> J Affect Disord. 2002 Oct;72(1):85-90
- 12. Cacciola JS, Alterman AI, Rutherford MJ, McKay JR, Mulvaney FD. <u>The relationship of psychiatric comorbidity to treatment outcomes in methadone maintained patients.</u> Drug Alcohol Depend. 2001 Feb 1;61(3):271-80

Polysubstance Dependence



Opioid Maintenance Pharmacotherapy: A Course for

58 Addendum E

- 1. Nyamathi A, Compton P, Cohen A, Marfisee M, Shoptaw S, Greengold B, de Castro V, Reaves M, Hasson A, George D, Leake B. <u>Correlates of hospitalization for alcohol-using methadone-maintained persons with physical health problems.</u> West J Nurs Res. 2009 Jun;31(4):525-43.
- Nyamathi A, Cohen A, Marfisee M, Shoptaw S, Greengold B, de Castro V, George D, Leake B. <u>Correlates of alcohol use among methadone-maintained adults.</u> Drug Alcohol Depend. 2009 Apr 1;101(1-2):124-7
- 3. Wurst FM, Dürsteler-MacFarland KM, Auwaerter V, Ergovic S, Thon N, Yegles M, Halter C, Weinmann W, Wiesbeck GA. Assessment of alcohol use among methadone maintenance patients by direct ethanol metabolites and self-reports. Alcohol Clin Exp Res. 2008 Sep;32(9):1552-7.
- 4. Srivastava A, Kahan M, Ross S. The effect of methadone maintenance treatment on alcohol consumption: a systematic review. J Subst Abuse Treat. 2008 Mar;34(2):215-23.
- 5. Nava F, Manzato E, Leonardi C, Lucchini A. <u>Opioid maintenance therapy suppresses alcohol intake in heroin addicts with alcohol dependence: preliminary results of an open randomized study.</u> Prog Neuropsychopharmacol Biol Psychiatry. 2008 Dec 12;32(8):1867-72
- 6. Stenbacka M, Beck O, Leifman A, Romelsjö A, Helander A. <u>Problem drinking in relation to treatment outcome among opiate addicts in methadone maintenance treatment.</u> Drug Alcohol Rev. 2007 Jan;26(1):55-63.
- 7. Stenbacka M, Beck O, Leifman A, Romelsjö A, Helander A. <u>Problem drinking in relation to treatment outcome among opiate addicts in methadone maintenance treatment.</u> Drug Alcohol Rev. 2007 Jan;26(1):55-63.
- 8. Hillebrand J, Marsden J, Finch E, Strang J, <u>Excessive alcohol consumption and drinking expectations among clients in methadone maintenance.</u> J Subst Abuse Treat. 2001 Oct;21(3):155-60.
- 9. Schreiber S, Peles E, Adelson M, <u>Association between improvement in depression, reduced benzodiazepine (BDZ) abuse, and increased psychotropic medication use in methadone maintenance treatment (MMT) patients.</u> Drug Alcohol Depend. 2008 Jan 1;92(1-3):79-85.
- 10. Brands B, Blake J, Marsh DC, Sproule B, Jeyapalan R, Li S. <u>The impact of benzodiazepine use on</u> methadone maintenance treatment outcomes. J Addict Dis. 2008;27(3):37-48
- 11. Mol, AJ, et. al. The Role of Craving on Relapse After Discontinuation of Long-Term Benzodiazepine Use, J. Clin Psychiatry 68:12, December 2007
- 12. Bramness JG, Kornør H. <u>Benzodiazepine prescription for patients in opioid maintenance treatment in Norway.</u> Drug Alcohol Depend. 2007 Oct 8;90(2-3):203-9
- 13. Peles E. et. al, Melatonin for perceived sleep disturbances associated with benzodiazepine withdrawal among patients in methadone maintenance treatment: a double-blind randomized clinical trial. Addiction. 2007 Dec; 102(12):1947-53
- 14. Soares B, Lima Reisser AA, Farrell M, Silva de Lima M. <u>WITHDRAWN: Dopamine agonists for cocaine dependence.</u> Cochrane Database Syst Rev. 2010 Feb 17;2:CD003352. Review
- 15. Silva de Lima M, Farrell M, Lima Reisser AA, Soares B. WITHDRAWN: Antidepressants for cocaine dependence. Cochrane Database Syst Rev. 2010 Feb 17;2:CD002950. Review.
- 16. Stitzer ML, Petry NM, Peirce J. Motivational incentives research in the National Drug Abuse Treatment Clinical Trials Network. J Subst Abuse Treat. 2010 Jun;38 Suppl 1:S61-9.
- 17. Castells X, Kosten TR, Capellà D, Vidal X, Colom J, Casas M. Efficacy of opiate maintenance therapy and adjunctive interventions for opioid dependence with comorbid cocaine use disorders: A systematic review and meta-analysis of controlled clinical trials. Am J Drug Alcohol Abuse. 2009;35(5):339-49.



Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 59

- 18. Tzilos GK, Rhodes GL, Ledgerwood DM, Greenwald MK. <u>Predicting cocaine group treatment outcome in cocaine-abusing methadone patients.</u> Exp Clin Psychopharmacol. 2009 Oct;17(5):320-5
- 19. DeFulio A, Donlin WD, Wong CJ, Silverman K. <u>Employment-based abstinence reinforcement as a maintenance intervention for the treatment of cocaine dependence: a randomized controlled trial.</u> Addiction. 2009 Sep;104(9):1530-8.
- 20. Peles E, Kreek MJ, Kellogg S, Adelson M, High methadone dose significantly reduces cocaine use in methadone maintenance treatment (MMT) patients. J Addict Dis. 2006;25(1):43-50.
- 21. Ghitza UE, Epstein DH, Preston KL. <u>Nonreporting of cannabis use: Predictors and relationship to treatment outcome in methadone maintained patients.</u> Addict Behav. 2007 May;32(5):938-49.
- 22. Epstein DH, Preston KL. <u>Does cannabis use predict poor outcome for heroin-dependent patients on maintenance treatment? Past findings and more evidence against.</u> Addiction. 2003 Mar;98(3):269-79. Review
- 23. Okoli CT, Khara M, Procyshyn RM, Johnson JL, Barr AM, Greaves L. <u>Smoking cessation interventions among individuals in methadone maintenance: a brief review.</u> J Subst Abuse Treat. 2010 Mar;38(2):191-9
- 24. Nyamathi AM, Sinha K, Marfisee M, Cohen A, Greengold B, Leake B. <u>Correlates of heavy smoking among alcohol-using methadone maintenance clients.</u> West J Nurs Res. 2009 Oct;31(6):787-98
- 25. Elkader AK, Brands B, Selby P, Sproule BA, Methadone-nicotine interactions in methadone maintenance treatment patients. J Clin Psychopharmacol. 2009 Jun;29(3):231-8.
- 26. Richter KP, Hamilton AK, Hall S, Catley D, Cox LS, Grobe J. <u>Patterns of smoking and methadone dose in drug treatment patients.</u> Exp Clin Psychopharmacol. 2007 Apr;15(2):144-53
- 27. Stein MD, Anderson BJ, Niaura R <u>Smoking cessation patterns in methadone-maintained smokers.</u> Nicotine Tob Res. 2007 Mar;9(3):421-8

Evidenced-based Psychotherapeutic Interventions / Treatment Outcome

- Veilleux JC, Colvin PJ, Anderson J, York C, Heinz AJ, <u>A review of opioid dependence treatment:</u> <u>pharmacological and psychosocial interventions to treat opioid addiction.</u> Clin Psychol Rev. 2010 Mar;30(2):155-66
- 2. Bell J, Trinh L, Butler B, Randall D, Rubin G <u>Comparing retention in treatment and mortality in people after initial entry to methadone and buprenorphine treatment.</u> Addiction. 2009 Jul;104(7):1193-200.
- 3. King VL, Burke C, Stoller KB, Neufeld KJ, Peirce J, Kolodner K, Kidorf M, Brooner RK. Implementing methadone medical maintenance in community-based clinics: disseminating evidence-based treatment.
 J Subst Abuse Treat. 2008 Oct;35(3):312-21
- 4. Jones HE, Martin PR, Heil SH, Kaltenbach K, Selby P, Coyle MG, Stine SM, O'Grady KE, Arria AM, Fischer G. <u>Treatment of opioid-dependent pregnant women: clinical and research issues.</u> J Subst Abuse Treat. 2008 Oct;35(3):245-59



Opioid Maintenance Pharmacotherapy: A Course for

60 Addendum E

- 4. Ducharme LJ, Roman PM. Opioid treatment programs in the Clinical Trials Network: representativeness and buprenorphine adoption. J Subst Abuse Treat. 2009 Jul;37(1):90-4.
- 5. Minozzi S, Amato L, Davoli M, Maintenance treatments for opiate dependent adolescent. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD007210. Review
- 6. Orman JS, Keating GM. <u>Spotlight on buprenorphine/naloxone in the treatment of opioid dependence.</u> CNS Drugs. 2009 Oct 1;23(10):899-902.
- 7. Ling W. Buprenorphine for opioid dependence. Expert Rev Neurother. 2009 May;9(5):609-16.
- 8. Schwartz RP, Kelly SM, O'Grady KE, Mitchell SG, Peterson JA, Reisinger HS, Agar MH, Brown BS Attitudes toward buprenorphine and methadone among opioid-dependent individuals. Am J Addict. 2008 Sep-Oct;17(5):396-401.

Dole / Nyswander / Kreek and others

- 1. Dole VP. What have we learned from three decades of methadone maintenance treatment? Drug Alcohol Rev. 1994;13(1):3-4
- 2. Dole VP. Methadone maintenance: optimizing dosage by estimating plasma level. J Addict Dis. 1994;13(1):1-4
- 3. Dole VP. <u>Hazards of process regulations</u>. The example of methadone maintenance. JAMA. 1992 Apr 22-29;267(16):2234-5
- 4. Dole VP. <u>Implications of methadone maintenance for theories of narcotic addiction.</u> JAMA. 1988 Nov 25;260(20):3025-9. Review
- 5. Dole VP, Nyswander ME, DesJarlais D, Joseph H. <u>Sounding Board. Performance-based rating of</u> methadone maintenance programs. N Engl J Med. 1982 Jan 21;306(3):169-71
- 6. Dole VP, Nyswander ME. Methadone maintenance: a theoretical perspective. NIDA Res Monogr. 1980 Mar;30:256-61
- 7. Dole VP, Joseph H. Long-term outcome of patients treated with methadone maintenance. Ann N Y Acad Sci. 1978;311:181-9.
- 8. Dole VP, Nyswander ME Methadone maintenance treatment. A ten-year perspective. JAMA. 1976 May 10;235(19):2117-9.
- 9. Dole VP, Wolkstein EC. <u>Vocational rehabilitation of patients on the Beth Israel methadone maintenance program</u>. Mt Sinai J Med. 1974 Mar-Apr;41(2):267-71
- 10. Dole VP, Kreek MJ. Methadone plasma level: sustained by a reservoir of drug in tissue. Proc Natl Acad Sci U S A. 1973 Jan;70(1):10.
- 11. Dole VP. Methadone maintenance treatment for 25,000 heroin addicts. JAMA. 1971 Feb 15;215(7):1131-4
- 12. Dole VP. Research on methadone maintenance treatment. Int J Addict. 1970 Sep;5(3):359-73
- 13. Dole VP, Nyswander ME. Methadone maintenance and its implication for theories of narcotic addiction. Res Publ Assoc Res Nerv Ment Dis. 1968;46:359-66
- 14. Dole VP, Nyswander ME Heroin Addiction A Metabolic Disease. Arch Intern Med July 1967 Vol 120
- 15. Dole VP, Warner A, Evaluation of Narcotic Treatment Programs, AJPH, November 1967 Vol 57 No 11
- 16. Dole VP, Nyswander ME, A Medical Treatment for Diacetylmorphine (Heroin) Addiction: A Clinical Trial with Methadone Hydrochloride. JAMA Aug 23, 1965 Vol 193 No 8



Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 61

- 5. Gunderson EW, Fiellin DA. Office-based maintenance treatment of opioid dependence: how does it compare with traditional approaches. CNS Drugs. 2008;22(2):99-111. Review
- 6. King VL, Burke C, Stoller KB, Neufeld KJ, Peirce J, Kolodner K, Kidorf M, Brooner RK. Implementing methadone medical maintenance in community-based clinics: disseminating evidence-based treatment. J Subst Abuse Treat. 2008 Oct;35(3):312-21
- 7. Sindelar JL, Olmstead TA, Peirce JM., <u>Cost-effectiveness of prize-based contingency management in methadone maintenance treatment programs.</u> Addiction. 2007 Sep;102(9):1463-71.
- 8. Ducharme LJ, Knudsen HK, Roman PM. <u>Evidence-based treatment for opiate-dependent clients:</u> availability, variation, and organizational correlates. Am J Drug Alcohol Abuse. 2006;32(4):569-76
- 9. Van den Brink W, Haasen C. Evidenced-based treatment of opioid-dependent patients, <u>Can J Psychiatry</u>. 2006 Sep;51(10):635-46.
- Simoens S, Ludbrook A, Matheson C, Bond C. <u>Pharmaco-economics of community maintenance for opiate dependence: a review of evidence and methodology.</u> Drug Alcohol Depend. 2006 Sep 1;84(1):28-39
- 11. Stitzer M, Petry, N CONTINGENCYMANAGEMENT FOR TREATMENT OF SUBSTANCE ABUSE. Annu. Rev. Clin. Psychol. 2006. 2:411–34
- 12. STEPHAN MAGURA, PH.D., AND ANDREW ROSENBLUM, PH.D. Leaving Methadone Treatment: Lessons Learned, Lessons Forgotten, Lessons Ignored, THE MOUNT SINAI JOURNAL OF MEDICINE Vol. 68 No. 1 January 2001

Drug Testing

- 1. Varenbut M, Plater-Zyberk CJ, Worster A, Daiter J. <u>Does low urine creatinine level indicate the presence of urine alcohol in methadone maintenance treatment patients?</u> Am J Drug Alcohol Abuse. 2010 Jul;36(4):199-201
- 2. Gray TR, Dams R, Choo RE, Jones HE, Huestis MA, Methadone disposition in oral fluid during pharmacotherapy for opioid-dependence. Forensic Sci Int. 2010 Jul 26
- 3. Shakleya DM, Dams R, Choo RE, Jones H, Huestis MA. Simultaneous liquid chromatography-mass spectrometry quantification of urinary opiates, cocaine, and metabolites in opiate-dependent pregnant women in methadone-maintenance treatment. J Anal Toxicol. 2010 Jan-Feb:34(1):17-25
- 4. Drummer, O, Review Article: Drug Testing in Oral Fluid. Clin Biochem Rev, Vol 27 August 2006, pp. 147-159

Buprenorphine

- 1. Kinlock TW, Gordon MS, Schwartz RP, Fitzgerald TT. <u>Developing and Implementing a New Prison-Based Buprenorphine Treatment Program.</u> J Offender Rehabil. 2010 Feb;49(2):91-109
- 2. Wesson DR, Smith DE. <u>Buprenorphine in the treatment of opiate dependence.</u> J Psychoactive Drugs. 2010 Jun;42(2):161-75
- 3. Orman JS, Keating GM. <u>Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence.</u> Drugs. 2009;69(5):577-607



Opioid Maintenance Pharmacotherapy: A Course for

62 Addendum E

- 17. Dole VP, Nyswander ME, Kreek MJ Narcotic Blockade. Arch Intern Med Vol 118 Oct 1966
- 18. Dole VP. Thoughts on Narcotic Addiction, Bull N. Y. Acad. Med. February 1965 Vol 41 No 2
- 19. Kreek MJ. Overview and historical perspective of four papers presented on research related to the endogenous opioid system. Drug Alcohol Depend. 2010 May 1;108(3):195-9.
- 20. Kreek MJ, Borg L, Ducat E, Ray B Pharmacotherapy in the treatment of addiction: methadone. J Addict Dis. 2010 Apr;29(2):200-16.
- 21. Kreek MJ. Methadone-related opioid agonist pharmacotherapy for heroin addiction. History, recent molecular and neurochemical research and future in mainstream medicine Ann N Y Acad Sci. 2000;909:186-216. Review.
- 22. <u>Kreek MJ</u>, <u>Zhou Y</u>, <u>Butelman ER</u>, <u>Levran O</u>. Opiate and cocaine addiction: from bench to clinic and back to the bench. <u>Curr Opin Pharmacol.</u> 2009 Feb;9(1):74-80. Epub 2009 Jan 18.
- 23. Kreek MJ, Vocci FJ. <u>History and current status of opioid maintenance treatments: blending conference session.</u> J Subst Abuse Treat. 2002 Sep;23(2):93-105. Review
- 24. Kreek MJ. Opioid receptors: some perspectives from early studies of their role in normal physiology, stress responsivity, and in specific addictive diseases. Neurochem Res. 1996 Nov;21(11):1469-88. Review
- 25. Courtwright DT. <u>The prepared mind: Marie Nyswander, methadone maintenance, and the metabolic theory of addiction.</u> Addiction. 1997 Mar;92(3):257-65
- 26. Goldstein A. Heroin addiction: neurobiology, pharmacology, and policy. J Psychoactive Drugs. 1991 Apr-Jun;23(2):123-33. Review
- 27. Warner A, Dole VP. <u>The operation of the data system in the methadone maintenance treatment program for heroin addiction.</u> Am J Public Health. 1971 Oct;61(10):2106-14.
- 28. Novick DM, Pascarelli EF, Joseph H, Salsitz EA, Richman BL, Des Jarlais DC, Anderson M, Dole VP, Nyswander ME Methadone maintenance patients in general medical practice. A preliminary report. JAMA. 1988 Jun 10;259(22):3299-302.
- 29. Des Jarlais DC, Joseph H, Dole VP, Nyswander ME. Medical maintenance feasibility study. NIDA Res Monogr. 1985;58:101-10
- 30. Des Jarlais DC, Joseph H, Dole VP. Long-term outcomes after termination from methadone maintenance treatment. Ann N Y Acad Sci. 1981;362:231-8.
- 31. Sapira JD, The Narcotic Addict as a Medical Patient. Am J Med October 1968 Vol 45



11

Opioid Maintenance Pharmacotherapy: A Course for

Addendum E 63

Patient/Family Information

What Every Individual Needs To Know About Methadone Maintenance Treatment: Introduction to Methadone

The following information is extracted ver batim from the SAMHSA brochure What Every Individual Needs to Know About Methadone Maintenance: Introduction to Methadone.

What Is Methadone?

Methadone is a long-acting opioid medication that is used as a pain reliever and, together with counseling and other psychosocial services, is used to treat individuals addicted to heroin and certain prescription drugs.

What Is Methadone Maintenance Treatment (MMT)?

MMT helps normalize your body's neurological and hormonal functions that have been impaired by the use of heroin or misuse of other short-acting opioids. Opioids are a group of drugs that act on the central nervous system. They include opiates such as codeine, morphine, and heroin as well as synthetic drugs such as oxycodone, oxycontin, hydrocodone, and methadone.

Appropriate MMT provides several benefits:

- · Reduces or eliminates craving for opioid drugs
- · Prevents the onset of withdrawal for 24 hours or more
- Blocks the effects of other opioids
- Promotes increased physical and emotional health
- · Raises the overall quality of life of the patient.

Is Methadone Maintenance Treatment Right for You?

Have you been through detoxification and found you couldn't feel normal? MMT can allow you to regain a sense of normalcy. Have you been using opioids such as heroin, codeine, or oxycodone but can't seem to stop? MMT can help you quit using those drugs and focus your life. Are you pregnant and using heroin? Seek MMT right away to prevent miscarriage and protect your baby from life-threatening withdrawal. Have you tested positive for HIV or Hepatitis C? If you have tested positive, MMT can allow you to regain your quality of life and begin essential treatment of your viral infection. If you have not tested positive, MMT can help you stop using needles, which is the primary route of infection for drug users. Beginning MMT can help stabilize and improve your health and can move you toward getting the care you need.

Starting Methadone Maintenance Treatment

Depending on where you live, you may have a choice of methadone providers, or you may live in an area where methadone treatment is not available. If you have not already made contact with a doctor or clinic that treats opioid addiction, find out whether treatment is available nearby.

- Talk with your family doctor. Generally, your doctor is not authorized to prescribe methadone for addiction treatment or withdrawal management purposes. Ask to be referred to an authorized doctor or a methadone clinic, or ask whether other treatment options such as buprenorphine are available.
- Contact a referral service. To find the treatment provider closest to you, call SAMHSA's National Helpline at 1-800-662-HELP at any time of the day or night, or search online for a treatment facility at www.findtreatment.samhsa.gov.

Assessment

Assessment includes determining your history with drug use as well as a physical examination by a doctor. You should be asked about medical problems that are commonly associated with opioid addictions, and you may be asked to consent to a blood test to check for HIV, Hepatitis, and other infectious or sexually transmitted diseases.

Expect questions. You may be asked about your drug use, your physical and mental health, your home and family, and your employment.

Ask questions. What are you being tested for? What other services are available? Remember, knowledge is power. You may be assessed again during treatment to review your progress.

64 Addendum F

Dosing

For safety, your first dose of methadone will be low or moderate. New patients usually start at a dose not to exceed 30 to 40 mgs. A larger dose of 60 to 120 mgs a day may be required for long-term maintenance. You and your physician should determine what dose works best for you.

Your dose is right when withdrawal symptoms, drug cravings, drowsiness, and side effects fade. With a correct dose, you should feel more energetic, clearheaded, and able to do the things that matter in your life. Until you have adjusted, make sure not to drive a car or operate heavy machinery.

You should discuss a dose adjustment with your doctor if you still are experiencing drug cravings. The majority of properly dosed patients have no physical desire to use other drugs.

Drug Testing

Routine tests of urine or oral fluids will show whether you have been using other illicit or inappropriate drugs and whether you have been taking your methadone. You may have to give supervised samples to ensure they are yours. With continual negative results, you'll be asked to take drug tests less often.

If you test positive for other drugs, it may hold up your schedule for taking home doses, and your provider may ask that you take drug tests more often. Some providers expect zero drug use while others are more tolerant.* If you test positive for a drug when you know you haven't used, you can request to be retested.

Confidentiality

Drug treatment patients are protected by special Federal confidentiality regulations. No one will be told you are in treatment or what you talk about in treatment, except for certain situations:

- Information about a client often is shared within a treatment team in the clinic.
- You may consent in writing that your information be shared under certain specified conditions—for example, to forward your records to another doctor or clinic.
- If your doctor or counselor has reason to think you might hurt yourself or others, he or she must inform others.
- If you are facing trial, the court may subpoen a your treatment records.
- If you test positive for HIV and other communicable diseases, these facts will be shared with public health officials. In certain States, your intimate partners at risk for these diseases may be told that they have been exposed.

Living With Methadone Take Home Doses

At the start of treatment, you will have to go to the clinic daily to take your dose under observation. This daily contact confirms to the staff that you are taking the dose ordered by the physician. It also helps the staff to see if your dose is enough or too much and whether you are experiencing side effects, in which case an adjustment may be necessary. After a few months, your provider may let you take home or "carry" doses for unsupervised use. Ask to find out when and under what conditions you will be given carry doses.

It is likely that you will be asked to sign an agreement claiming responsibility for using and storing the doses safely. Your provider may take away your take-home privileges if you do not comply with the agreement or if your drug tests are positive for drug use.

Safety and Storage

Your maintenance dose of methadone could seriously harm or kill someone who has no tolerance for the drug. Take precautions:

- Never transfer your medication to a container that might make it easier to mistake what's inside.
- Keep your doses in a locked box, such as one sold for fishing tackle or cash.

Hospital Stays

If you are admitted to the hospital, let the staff there know that you are a methadone patient. This is vital so that you can receive your dose and because other drugs can be dangerous if combined with methadone. Urge the hospital staff to talk with your MMT doctor about your medication and care.

Dealing With Side Effects

Methadone maintenance carries some side effects:

- Constipation. Eat foods that are high in fiber and drink plenty of water. You also should avoid foods that are high in fat; they are harder to digest and tend to make your system sluggish.
- Excessive sweating. Adjusting the dose may stop the sweating, and there are other medications available to help control this.
- Changes in sex drive. Some people on methadone have little sex drive and are unable to have an orgasm. You may be taking a medication that affects your sex drive. Talk with your doctor about possible treatments that will improve this side effect.

Addendum F 65

Methadone Facts

When methadone is taken as directed:

- MMT can improve your health.
- Methadone will not cause euphoria.
- Methadone will not make you sick.
- Methadone will not affect your immune system.
- Methadone does not damage your teeth and bones.
- Methadone does not make you gain weight.

Tips on Taking Methadone

- Methadone usually works best when it's taken once a day at the same time every day.
- You drink your dose of methadone, usually in a mixture with orange juice.
- It takes a few days to feel the full effects of a dose adjustment.
- Taking other drugs may interfere with the adjustment of your dose.
- Taking more opioids won't get you high, but you could overdose.
- Hang in there—give it 2 to 6 weeks to find the right dose.

Methadone and Employment

Once you're on a stable dose of methadone, it shouldn't affect the work you do or how well you do your job. For most jobs, there's no need to mention that you take methadone. Your employer has no right to know.

HIV, Hepatitis, and Methadone

Methadone can be a great benefit if you are HIV/AIDS or Hepatitis B (HBV) or C (HCV) positive. Methadone allows you to lead a "normal" life so it's easier to take care of yourself, to eat better, and to take your medication at the right times. However, prescription drugs for your HIV/AIDS or HBV/HCV may interfere with methadone, and your dose may need to be changed. Talk with the program doctor about other drugs you have been prescribed.

Patient Rights and Responsibilities

If you are unhappy with your treatment—for example, you feel your dose has not been adjusted correctly— talk it over with your doctor or counselor. If a treatment problem hasn't been fixed to your satisfaction by talking with your doctor or counselor, you may consider changing your provider.

You also can anonymously report problems with your treatment provider to his/her accrediting agency. To learn more about grievance procedures, you can visit the Patient Support and Community Education Project online at www.dpt.samhsa.gov/patient/index.htm.

As a patient in treatment, you are protected by a set of Medication-Assisted Treatment Patient Rights and Responsibilities. You can see the SAMHSA Guidelines for the Accreditation of Opioid Treatment Programs online at www.dpt.samhsa.gov/guidelines.pdf.

Methadone and Pain Relief

Methadone can provide effective pain relief. Yet, once you are on a stable dose of methadone, you may be tolerant to its pain-relieving effects and may require additional pain medication. Some MMT patients need more pain medication than patients who are not a part of MMT.

66 Addendum F

Supporting Recovery from Opioid Addiction: Best Practice Guidelines for Buprenorphine and Suboxone®

Community Care published Supporting Recovery from Opioid Addiction: Best Practice Guidelines for Buprenorphine and Suboxone® in January 2013. This document, which can be accessed at http://www.ccbh.com/providers/phealth-choices/bestpractice/index.php, introduced the Guiding Principles for Medication-Assisted Treatment (MAT) for Opioid Addiction and addressed the domains of:

- · Screening and Assessment to Determine Candidacy
- Selection of Candidates for Buprenorphine Treatment
- Treatment Agreement with Person in Recovery (PIR)
- · Appropriate Dosing—Induction, Stabilization, Maintenance, and Tapering Off
- Concurrent Psychosocial Treatment and Recovery Supports
- Co-occurring Mental Health Treatment

Addendum G 67