

# Effective Risk Management Strategies in Outpatient Methadone Treatment

## TRAINER'S MANUAL



Northeast  
**ATTC**

Addiction Technology Transfer Center Network  
Funded by Substance Abuse and Mental Health Services Administration



Substance Abuse and Mental Health Services Administration

[www.samhsa.gov](http://www.samhsa.gov) • 1-877-SAMHSA-7 (1-877-726-4727)

Prepared 2012 by:  
Northeast Addiction Technology Transfer Center  
Institute for Research Education and Training in Addictions (IRETA)  
425 Sixth Avenue, Suite 1710  
Pittsburgh, PA 15219  
T: 412-258-8565  
F: 412-391-2528  
northeast@ATTCnetwork.org

The Northeast ATTC prepared this training, *Effective Risk Management Strategies in Outpatient Methadone Treatment*, under a special supplement from the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (T1013404-10).

At the time of writing, Peter F. Luongo, PhD, served as the Principle Investigator of the Northeast ATTC, Holly Hagle, PhD, served as the Director of the Northeast ATTC and Donna Doolin, LCSW, served as the CSAT Project Officer to the ATTC Network.

The opinions expressed herein are the views of the authors and do not reflect the official position of the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment. No official support or endorsement of the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment for the opinions described in this document is intended or should be inferred.



**Behavioral Health is Essential to Health. Prevention Works. Treatment is Effective. People Recover.**

## ACKNOWLEDGEMENTS

The Northeast ATTC and IRETA would like to acknowledge the following individuals support and contribution to the topic of risk management for opioid treatment providers. Many of the individuals listed below either contributed as content experts, trainers, curriculum writers, editors or designers.

One of the many contributors to this curriculum was Lisa Mojer-Torres. Sadly, Lisa passed away on April 5, 2011 after a prolonged struggle with ovarian cancer. We salute her tireless, passionate, committed advocacy for recovery. She was a civil rights attorney and the Consumer and Recovery Advocate for the State of New Jersey. Lisa was also the leading national representative/advocate for people in medication-assisted recovery, teaching that medications are an underused tool with which to combat active addiction. She also served as the Consumer and Recovery Advocate for the New Jersey Division of Addiction Services. Lisa was a leading figure in the new addiction recovery advocacy movement. She served as a founding member and first chairperson of Faces and Voices of Recovery and was a board member of the National Alliance of Methadone Advocates. Her bravery in sharing her story opened hearts and minds, changing attitudes and inspiring hope. We are grateful for the work she helped begin, and for serving as a role model for recovery advocacy.

Specific writing acknowledgement to Trusandra Taylor, MD (lead content expert and writer ); Lisa Mojer-Torres, JD (lead content expert and writer); Edna Talboy, PhD (curriculum writer); Monica Mahin MFT, MBA (curriculum writer), William White (special consultant writer Module 7); Holly Hagle, PhD (curriculum developer and writer); Lisa Howard, BSW (editor) and Martha Wasik (layout and formatting).

## CONTRIBUTORS

**H. Westley Clark, MD, JD, MPH, CAS, FASAM**

Director, Center for Substance Abuse Treatment DHHS/SAMHSA-CSAT

**Anthony Campbell, RPH, DO, CDR, USPHS**

Medical Officer, Substance Abuse and Mental Health Services Center for Substance Abuse Treatment, Division of Pharmacological Therapies

**Eric Ennis, LCSW, CACIII**

American Association for the Treatment of Opioid Dependence, Risk Management Committee Chair

**Michael T. Flaherty, PhD**

Former Executive Director, IRETA

**Carl-Henry J. Fortune, MPH**

Project Director Prescription Drug Misuse and Abuse Activities Health and Clinical Services Division, DB Consulting Group, Inc.

**Todd Mandell, MD**

Clinical content expert

**J. Thomas Payte, MD**

Clinical content expert and curriculum reviewer

**David Szerlip, David Szerlip & Associates, Inc.**

Insurance industry expert

**Sabato Stile, MD**

Clinical content expert and curriculum reviewer; IRETA consultant

**Alan Wartenberg, MD**

Clinical content expert

**Richard Willetts, CPCU, ARM**

Program Director, M\NSM Insurance Group – Insurance industry expert

# EFFECTIVE RISK MANAGEMENT STRATEGIES IN OUTPATIENT METHADONE TREATMENT

## BACKGROUND

The Northeast ATTC developed this curriculum because of the extensive work that this ATTC has done educating opioid treatment providers both regionally and nationally. The Northeast ATTC has conducted five trainings which directly addressed the issues around patient safety and risk management: beginning in May 2008 with a statewide conference held in Harrisburg, Pennsylvania, followed by three SAMHSA/CSAT sponsored risk-management and patient safety national webinars conducted throughout 2009, and a full day training in October 2009 in Chicago, Illinois and a full day training in September 2012 in Albuquerque, New Mexico (see: [www.ireta.org](http://www.ireta.org)).

## GOAL OF THIS TRAINING

The goal of this one-day training is to increase opioid treatment providers' (both clinical and administrative staff) knowledge and skills on the most effective ways to conduct risk management strategies for opioid treatment centers. Given the increased demand for the assessment, treatment and proper management of opioid use and dependence, the Northeast Addiction Technology Transfer Center designed a training curriculum for use by SAMHSA/CSAT, Addiction Technology Transfer Centers (ATTCs) and their trainers, and OTPs and their staff so that all may have access to the best science and evidence-based practices related to risk management and patient safety connected to opioid dependence.

For nearly 30 years, research has consistently supported the perspective that opioid addiction is a medical disorder that can be treated effectively with medications when administered under conditions consistent with their pharmacological efficacy and best practice for patient safety – and when treatment includes necessary supportive services such as psychosocial counseling, treatment for co-occurring disorders, medical services and vocational rehabilitation. Medication-assisted treatment (MAT) for opioid addiction has been effective in facilitating recovery from opioid addiction for many patients<sup>1</sup>. However, since 1995, there has been an enormous upsurge in the non-medical use of prescription opioids and sedatives with measures now counting over 1 million opioid dependent individuals in the U.S. and some 260,000 of them enrolled in Opioid Treatment Programs (OTPs)<sup>2</sup> – and growing! OTPs, and methadone providers in particular, are clearly the single largest treatment intervention for this population. Since 2002, office-based maintenance treatment using sublingual buprenorphine has also become available in the United States and has been reported as both expanding the access to opioid care and, for some, the growth of further need for OTPs and methadone<sup>3</sup>. Lastly, an increasing amount of addiction patients are appearing for opioid treatment related to chronic pain. Between 1997 and 2002 there is a reported 642% increase in patients reporting prescription opioid abuse while also receiving pain management services<sup>4</sup>. All of these converging factors have led to the development of this curriculum.

1. 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.

2. Ries, R.K. (2009). *Principles of addiction medicine*. (4th ed). Philadelphia, PA: Lippincott Williams & Wilkins.

3. Ibid.

4. Ibid.

## ABOUT THE TRAINING MATERIALS

The Risk Management materials, Modules 1-6, provide information and content for a stand-alone training of approximately 7 hours – not including breaks and lunch. The time allotted for each module will vary depending on the size of the group. The training can be conducted in small-to-large groups. Smaller sized groups will allow more time for discussion and interactive exercises. Larger size groups may necessitate a more didactic teaching style interspersed with brief question and answer periods.

Modules 7, 8 & 9 are supportive content to the topic of Risk Management and can be delivered in approximately three additional hours. The sponsoring organization may choose to deliver the entire curriculum, Modules 1-9, by offering the training over the course of one and one-half days (10-12 hours including breaks and lunch). Trainers are encouraged to adapt these materials to meet the needs of the specific audience. The Trainer Notes contain information that can be presented with each corresponding PowerPoint slide including literature and publication references.

The manual was created as a guide to facilitate your successful delivery of *Effective Risk Management Strategies in Outpatient Methadone Treatment*. The suggested scripts and activities in each module will guide you through the entire training process. It is important that you become familiar with the content of each module so that you can facilitate the discussion of each topic.

The content written in italics and preceded by “Note” is intended to provide direction and not a step-by-step approach to facilitation. Adaptations such as integrating professional experiences and using the trainer’s style of expression are expected.

### OBJECTIVES

- Describe and heighten awareness for best practices and the need for increased vigilance of patient safety with methadone treatment.
- Improve ability to identify and access and manage risks.
- Employ an in-depth understanding of the clinical issues for safe induction, dosing, assessment of impairment and cardiac factors, etc. that can strengthen patient safety and improve care.
- Assess and expand the knowledge of current trends in opioid treatment.
- Define strategies for improving use of methadone in opioid treatment.

## **AUDIENCE**

This training is designed for both clinical staff and administrators working to manage a licensed methadone treatment clinic. To assure a quality experience, it is recommended that the training audience be limited to no more than 25 to 30 persons.

## **MATERIALS**

You will need equipment to run the PowerPoint. If you have access to an Internet connection you may review the Risk Management resources on the IRETA Risk Management page – ([www.ireta.org](http://www.ireta.org)). A flip-chart paper easel/whiteboard and markers are recommended to write down relevant comments or conduct activities. It is suggested to provide participants with print copies of the PowerPoint slides, and the following:

- Module 4: slide #23, “Community Substance Abuse Center Impairment Assessment Tool”
- Module 4: slide #31, “Clinical Sobriety Checklist” and the “Standardized Field Sobriety Test”
- Module 5: slide #4, “Exception Request and Record of Justification” Form SMA-168
- Module 5: slide #4, CSAT “Dear Colleague” letter (2008) (take-home medication)
- Module 6: slide #19, CSAT “Dear Colleague” letter (2007) (dosing and standing orders)
- Module 8: slide #26, “Opioid Risk Tool”

The trainer(s) will need a print copy of the trainer manual with notes.

## RESOURCES

### Module 1: What's Going On Out There?

(Introduction, Methadone-Associated Mortality, Professional Liability)

WHO Access to Controlled Medications Programme:

[http://www.who.int/medicines/areas/quality\\_safety/ACMP\\_BrNoteGenrl\\_EN\\_Feb09.pdf](http://www.who.int/medicines/areas/quality_safety/ACMP_BrNoteGenrl_EN_Feb09.pdf)

Epidemic Responding to America's Prescription Drug Abuse Crisis:

[http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx\\_abuse\\_plan.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf)

Prescription painkiller overdoses at epidemic levels:

[http://www.cdc.gov/media/releases/2011/p1101\\_flu\\_pain\\_killer\\_overdose.html](http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html)

SAMHSA:

<http://www.samhsa.gov/newsroom/advisories/1112074117.aspx>

Methadone Mortality: A 2010 Reassessment:

[http://www.dpt.samhsa.gov/pdf/Methadone\\_Mortality\\_Data\\_2010.pdf](http://www.dpt.samhsa.gov/pdf/Methadone_Mortality_Data_2010.pdf)

GAO Methadone Mortality Associated Overdose Deaths March 2009:

<http://www.gao.gov/products/GAO-09-341>

Dear Colleague letter OTP Mortality Form11-20-2008:

[http://www.dpt.samhsa.gov/pdf/dearColleague/OTPMortalityForm\\_Letter.pdf](http://www.dpt.samhsa.gov/pdf/dearColleague/OTPMortalityForm_Letter.pdf)

Insurance Information Institute (Basic risk-management information and professional liability):

<http://www.iii.org/>

### Module 2: Managing Risk

Progressive Steps in the Risk Management Process: Burlando, A.J. (1990) The 1990s: The decade of risk management. *Risk Management* 37(3):50-56.

Risk Management in Health Care Institutions: A Strategic Approach, Kavalier, F, Speigel AD, Jones and Bartlett. 1997.

### Module 3: Risk Management and OTP Practice

Dear Colleague letter encouraging use of Prescription Monitoring Programs 2011:

[http://www.dpt.samhsa.gov/pdf/pmp\\_otp\\_2011\\_letter.pdf](http://www.dpt.samhsa.gov/pdf/pmp_otp_2011_letter.pdf)

Dear Colleague letter on dosing 9-4-2007:

<http://www.dpt.samhsa.gov/pdf/dearColleague/09-04-07%20DearColleagueLetter%20on%20Dosing.pdf>

## **Module 4: Impairment**

AMA Impaired Drivers and Their Physicians:

[http://www.ama-assn.org/resources/doc/ethics/ceja\\_1i99.pdf](http://www.ama-assn.org/resources/doc/ethics/ceja_1i99.pdf)

Mental Status Examination (MSE): Basic primer:

<http://www.psychpage.com/learning/library/assess/mse.htm>

## **Module 5: Take-Home Medication**

CSAT Accreditation Guidelines 2007:

[www.dpt.samhsa.gov/pdf/OTPAccredGuidelines-2007.pdf](http://www.dpt.samhsa.gov/pdf/OTPAccredGuidelines-2007.pdf)

Dear Colleague letter May 14, 2008, take-home bottle labeling:

[http://www.dpt.samhsa.gov/pdf/dearColleague/DearColleague\\_BottleLabels\\_051408.pdf](http://www.dpt.samhsa.gov/pdf/dearColleague/DearColleague_BottleLabels_051408.pdf)

## **Module 6: Three Case Studies**

Admission / Induction, Take-home Medication, Cardiac Issues:

[http://www.fda.gov/downloads/Drugs/  
DrugSafetyPostmarketDrugSafetyInformationforPatientsandProviders/UCM142839.pdf](http://www.fda.gov/downloads/Drugs/DrugSafetyPostmarketDrugSafetyInformationforPatientsandProviders/UCM142839.pdf)

## **Module 7: Recovery-Oriented Methadone Maintenance (ROMM)**

Provider Approaches to Recovery-Oriented Systems of Care: Four Case Studies:

[pfr.samhsa.gov/docs/Provider\\_Approaches.pdf](http://pfr.samhsa.gov/docs/Provider_Approaches.pdf)

Recovery: National Perspective and Future Directions:

[casat.unr.edu/docs/National\\_Perspective\\_Future\\_Directions.ppt](http://casat.unr.edu/docs/National_Perspective_Future_Directions.ppt)

Pathways to Recovery: Embrace Innovation:

<http://ireta.org/resource/links/2010Winter.pdf>

## **Module 8: Pain Management Therapy**

PainEDU.org-Improving Pain Treatment Through Education (An excellent educational website):

[http://pain-topics.org/opioid\\_rx/methadone.php](http://pain-topics.org/opioid_rx/methadone.php)

Dear Colleague letter: December 2006:

<http://www.dpt.samhsa.gov/pdf/DearColleague-Methadone-lbl.pdf>

FDA Health Advisory (FDA Black Box Warning):

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm124346.htm>

Carisoprodol misuse:

[http://oas.samhsa.gov/2k11/DAWN071/WEB\\_DAWN\\_071\\_HTML.pdf](http://oas.samhsa.gov/2k11/DAWN071/WEB_DAWN_071_HTML.pdf)

<http://www.samhsa.gov/newsroom/advisories/1111025907.aspx>

## Module 9: Special Populations

### PREGNANCY

1. Higher maternal doses of methadone does not increase neonatal abstinence syndrome. Pizarro D, Habli M, Grier M, Bombrys A, Sibai B, Livingston J, *J Subst Abuse Treat*. 2011 Apr;40(3):295-8. Epub 2011 Jan 20.
2. Duration of Methadone Maintenance Treatment During Pregnancy and Pregnancy Outcome Parameters in Women With Opiate Addiction. Peles E, Schreiber S, Bloch M, Dollberg S, Adelson M. *J Addict Med*. 2011 Aug 3.
3. Buprenorphine versus methadone in pregnant opioid-dependent women: a prospective multicenter study. Lacroix I, Berrebi A, Garipuy D, Schmitt L, Hammou Y, Chaumerliac C, Lapeyre-Mestre M, Montastruc JL, Damase-Michel C, *Eur J Clin Pharmacol*. 2011 Oct;67(10):1053-9. Epub 2011 May 3.

### CO-OCCURRING PSYCHIATRIC DISORDERS

1. Psychiatric comorbidity reduces quality of life in chronic methadone maintained patients. Carpentier PJ, Krabbe PF, van Gogh MT, Knapen LJ, Buitelaar JK, de Jong CA, *Am J Addict*. 2009 Nov-Dec;18(6):470-80.
2. Patterns in admission delays to outpatient methadone treatment in the United States, Gryczynski J, Schwartz RP, Salkever DS, Mitchell SG, Jaffe JH. *J Subst Abuse Treat*. 2011 Dec;41(4):431-9. Epub 2011 Aug 6.
3. Drug interactions of clinical importance among the opioids, methadone and buprenorphine, and other frequently prescribed medications: a review. McCance-Katz EF, Sullivan LE, Nallani S. *Am J Addict*. 2010 Jan-Feb;19(1):4-16.

## **TABLE OF CONTENTS**

MODULE 1: What Is Going On Out There?

MODULE 2: Managing Risk

MODULE 3: Relationship Between Risk and Practice in the OTP

MODULE 4: Impairment

MODULE 5: Take-Home Medication

MODULE 6: Case Studies

MODULE 7: Recovery Oriented Methadone Maintenance (ROMM)

MODULE 8: Pain Management Therapy

MODULE 9: Special Populations and Risk

# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 1:**

### **What Is Going On Out There?**

# MODULE 1 – What Is Going On Out There?

TIME: 120 minutes

PURPOSE: Describe and heighten awareness of risk and the need for increased vigilance of patient safety with methadone treatment.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Describe risks and trends with opioid analgesics.
2. Discuss the insurance market and OTPs.
3. Identify risk-management strategies for OTPs.

TOPICS:

- What is going on in the world of opioids?
- National and state statistics
- Generation Rx
- Unique perspective: Insurance carriers & OTPs
- Trends in claims
- Insurance market cycles
- Hard markets/ soft markets
- Challenges for OTPs
- Strategies for risk management
- Risk management culture

## KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

## Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

MODULE 1  
What is going on out there?

### In Memoriam Lisa Mojer-Torres, JD

1956-2011



*Through her words, deeds and example, she showed that medication-assisted therapy was essential for some and no less a pathway to Recovery... I can only hope that her example inspires others to bring their energy, stories and advocacy into the public forum.*

-H. Westley Clark, M.D., JD, MPH, CAS, FASAM

[http://www.facesandvoicesofrecovery.org/pdf/Lisa\\_Mojer-Torres\\_Tribute.pdf](http://www.facesandvoicesofrecovery.org/pdf/Lisa_Mojer-Torres_Tribute.pdf)

## 1. MODULE 1

*NOTE: Welcome participants to the training. Introduce yourself and depending on the size of the group have participants introduce themselves. Alternatively if the group is large, ask participants for a show of hands as you ask polling type questions to establish group composition by license or certification, role (administrator or clinician), length of experience working in the addiction field, OTP etc.*

*It would also be an interesting question to pose if any had ever participated in a training or workshop on risk management. Regardless of individual or collective response, this provides a segue as to why SAMHSA funded the Northeast ATTC to develop this curriculum and to acknowledge those who contributed to its development.*

## 2. TRAINER NOTE:

One of the many contributors to this curriculum was Lisa Mojer-Torres. Sadly, Lisa passed away on April 5, 2011 after a prolonged struggle with ovarian cancer.

We salute her tireless, passionate, committed advocacy for recovery.

She was a civil rights attorney and the Consumer and Recovery Advocate for the State of New Jersey.

Lisa was also the leading national representative / advocate for people in medication-assisted recovery, teaching that medications are an underused tool with which to combat active addiction.

She also served as the Consumer and Recovery Advocate for the New Jersey Division of Addiction Services.

Lisa was a leading figure in the new addiction recovery advocacy movement.

She served as a founding member and first chairperson of Faces and Voices of Recovery and was a board member of the National Alliance of Methadone Advocates.

Her bravery in sharing her story opened hearts and minds, changing attitudes and inspiring hope. We are grateful for the work she helped begin, and for serving as a role model for recovery advocacy.



## Acknowledgement

- **Michael Flaherty, PhD** (Pennsylvania)
- **Todd Mandell, MD** (Vermont)
- **Ilene Robeck, MD** (Florida)
- **Anthony Stile, MD** (Pennsylvania)
- **Trusandra Taylor, MD** (Pennsylvania)
- **Lisa Mojer-Torres, JD** (New Jersey)
- **Alan Wartenberg, MD** (Rhode Island)
- **Richard J. Willetts, PCU, ARM** (Pennsylvania)

## The “Big Picture”



## Primary Indication for Use of Opioid Medications

- **Pain management**
  - Moderate to severe pain
  - Acute and chronic pain
  - Malignant (cancer) and (non-malignant) pain
- **Opioid dependence**
  - Illicit drugs and prescription medications

### 3. TRAINER NOTE:

In addition to Lisa, the people listed on this slide made significant contributions to the development of this curriculum and we gratefully acknowledge their work and talents shared.



### 4. TRAINER NOTE:

What do we mean by this?

What is the significance of this?



### 5. TRAINER NOTE:

What are the primary indicators for the use of opioid medications?

Depending on how you want to characterize it, opioids are used for:

- Pain management
- Moderate to severe pain
- Acute and chronic pain
- Malignant (cancer) and (non-malignant) pain
- Opioid dependence
- Illicit drugs and prescription medications



## OpioiD Analgesics (Morphine)



- **Global consumption** has increased substantially over the past two decades.
- **80% of the world's population** is inadequately treated for moderate to severe pain

## Inadequate Treatment of Pain in Developing Countries

- 1 million end-stage HIV/AIDS patients
- 5.5 million terminal cancer patients
- 0.8 million patients suffering injuries due to accidents and violence
- **Patients:**
  - With chronic illnesses
  - Recovering from surgery
  - In labor (110 million births each year)
  - Pediatric

## OpioiD Consumption

The United States is responsible for \_\_\_\_% of world-wide opioiD consumption.



## 6. TRAINER NOTE:

Let's look at the broad class of opioiD analgesics. Morphine is included because it is the prototype drug and many of the statistics and studies will use morphine as an indicator.

Global consumption of opioiD analgesics, including morphine, has increased substantially over the past two decades.

However, in many developing countries pain management is poorly addressed. It is estimated that over 80% of the world's population is inadequately treated for moderate to severe pain, although we have the capacity and the medical science to do it.



## 7. TRAINER NOTE:

When we look at developing countries, we recognize there is inadequate treatment of pain for:

- 1 million end-stage HIV/AIDS patients
- 5.5 million terminal cancer patients
- 0.8 million patients suffering injuries caused by accidents and violence
- Patients with chronic illnesses
- Patients recovering from surgery
- Women in labor (110 million births each year)
- Pediatric patients

It is a serious problem world wide and there are many reasons for this disturbing health inequity.



## 8. TRAINER NOTE:

To engage the audience ask participants, "How much of the world's opioids does the United States use?" Ask for a show of hands if you think 30%, then 60%, and finish with 80%.

*NOTE: Click to the next slide to show the answer.*



## Opioid Consumption in the US

- The United States, with **4.6%** of the world's population, uses **80%** of the world's opioids.

Control

Patricia Good, DEA's Drug Diversion



Pain Physician, 2006

## 9. TRAINER NOTE:

At the American Society of Interventional Pain Physicians (ASIPP) 2004 annual meeting in Washington, Patricia Good of the DEA's Drug Diversion Control stated that the United States, with 4.6% of the world's population, uses 80% of the global opioid supply.



## So Where does this “Big Picture” Lead Us?

- Prescription drug abuse **epidemic** in the United States
- Comprehensive plan of action at a Federal level:
  - ONDCP (Office of National Drug Control Policy)
  - HHS/SAMHSA/CSAT (Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment)
  - NIDA (National Institute on Drug Abuse)
  - FDA (Food and Drug Administration)
  - DEA (Drug Enforcement Administration)
- Celebrity deaths and addiction
- Media involvement

## 10. TRAINER NOTE:

So where does this “Big Picture” lead us in the United States?

Prescription drug abuse is epidemic in the United States. Commonly abused prescription drugs:

- OPR (Opioid Pain Relievers)
- CNS (Central Nervous System) depressants (benzodiazapines, sedative-hypnotic medication)
- Stimulants

This has led the government to consider a comprehensive plan of action to address the prescription drug abuse epidemic. In regards to Federal Requirements, there is a concerted effort to come together to educate the medical community about prescribing practices and related issues. The offices involved include:

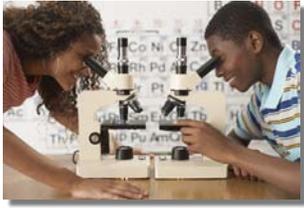
- ONDCP (Office of National Drug Control Policy)
- HHS/SAMHSA/CSAT (Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment)
- NIDA (National Institute on Drug Abuse)
- FDA (Food and Drug Administration)
- DEA (Drug Enforcement Administration)

**Celebrity deaths and addiction:** The lives of many celebrities have tragically ended after struggling with substance abuse. This segment of the epidemic is in the news all too often.

**Significant media involvement:** There is a spotlight on the issue of prescription drug abuse on a very regular basis in all types of media outlets.



## “Getting Down to the Details”



### 11. TRAINER NOTE:

Now that we have a sense of the “Big Picture” both globally and here in the United States, we are going to turn our discussion to the details specifically related to risk management and prevention.



## How does this relate to OTPs?

Methadone–Associated Mortality



### 12. TRAINER NOTE:

How does this relate to Opioid Treatment Programs (OTPs)?

Methadone conundrum or challenge?

Methadone has received a lot of attention (as one of the medications in the class of opioids) due to methadone-associated mortality.



## Methadone–Associated Deaths

- Increasing reports of methadone–related deaths in 2002
- SAMHSA/CSAT convenes first Methadone Mortality Working Group in 2003
  - Published report demonstrates OTPs were **not primarily responsible for deaths**
    - Use of methadone to treat pain increased markedly through distribution of pharmacy channels
    - Not OTPs, but pain-management practices responsible

### 13. TRAINER NOTE:

One of the reasons this is true is because of increasing published reports of methadone-associated deaths in 2002.

To address this alarming and growing concern, SAMHSA/CSAT convened the first Methadone Mortality Work Group in 2003.

This workgroup published an important report demonstrating that OTPs were not primarily responsible for methadone-associated mortality.

This comprehensive report indicated that the use of methadone to treat pain had increased markedly through the distribution of pharmacy channels in the United States.

The analysis determined that it was not the OTPs that were involved, but rather the practices involved with pain management.



## Methadone-Associated Deaths



- 2007 SAMHSA/CSAT report concurs with 2003 findings
- Additional reports establish similar findings:
  - Department of Justice, National Drug Intelligence Center: (2007) "Methadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rate"
  - General Accountability Office (GAO): (2009) "Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them"

## Methadone-Associated Deaths

- DEA was partner in development of the Methadone Mortality Reports
  - Worked to restrict the 40 mg methadone dispersible tablet sales to authorized hospitals and programs, effective 2008
- SAMHSA/CSAT convened multi-agency symposium **Methadone Mortality-A 2010 Reassessment**

## The Mortality Reports

- SAMHSA's **voluntary** initiative for collection of mortality data- the *Mortality Report*
- Analysis of 2009 data on 406 patients who died while in an OTP:
  - 27% of OD deaths occurred within **first two weeks of treatment**
  - 32% of overdose deaths had **benzodiazepines** mentioned in the report

## 14. TRAINER NOTE:

SAMHSA/CSAT subsequently convened two national meetings and produced a second report in 2007 and findings were similar to the original 2003 report in that methadone-associated deaths were related to pain management.

Two additional reports established similar findings:

- Department of Justice National Drug Intelligence Center: (2007) "Methadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rate"
- General Accountability Office (GAO): (2009), "Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them"



## 15. TRAINER NOTE:

The DEA has also been a federal agency partner in the development of the Methadone Mortality Reports. They worked with U.S. pharmaceutical companies to restrict the 40 mg methadone dispersible tablet sales to hospitals and Opioid Treatment Programs authorized to treat opioid addiction, effective January 2008. Through their analysis it was discovered that it was being diverted for misuse and restricted sale of this drug to hospitals and OTPs with authorization to change the channels of distribution.

SAMHSA/CSAT convened a symposium, Methadone Mortality-A 2010 Reassessment, July 2010. Involved agencies include: SAMHSA, DEA, FDA, NIDA and HHS.

A written report will be published shortly. However, some of their discussions will be included in the next few slides.



## 16. TRAINER NOTE:

Since late 2008, SAMHSA has had a voluntary initiative for collection of mortality data, the Mortality Report is now online (originally it had to be sent or faxed to SAMHSA). All OTPs should be participating in this voluntary effort to track mortalities that are actually happening in OTPs.

Analysis was done on the data submitted. This analysis indicated of the 406 patients reported in 2009, who died while in an Opioid Treatment Program:

- 27% of OD deaths occurred within the first two weeks of treatment
- 32% of overdose deaths had benzodiazepines mentioned in the report



## The Mortality Reports

### Demographics:

- 67% male
- Average age: 49.8 years (18–88)
- Average length of stay: 4.5 years (0–38.6)
- Average number of take homes: 5 (range:0–29)
- Average dose: 91.8 mg (range: 10–270 mg)

## The Mortality Reports

- 61% mental disorder
  - 14% Major Depression
  - 9% Anxiety Disorder
- Psychotropic medication
  - 22% Benzodiazepine prescription
  - 15% anti-depressants
  - 12% SSRIs
- Other diseases
  - 28% liver disease
  - 19% hepatitis C
  - 17% chronic obstructive pulmonary disease (COPD)
  - 10% metabolic diagnosis
  - 9% musculoskeletal disorder
  - 9% hypertension
  - 8% circulatory
  - 6% diabetes mellitus
  - 4% kidney disease
  - 4% trauma
  - 3% asthma

## 17. TRAINER NOTE:

The information in this slide reports the demographics of this population of patients:

- 67% male
- Average age: 49.8 years (18–88)
- Average length of stay: 4.5 years (0–38.6)
- Average number of Take Homes: 5 (range:0–29)
- Average dose: 91.8 mg (range: 10–270 mg)

*NOTE: Point out the range in the parenthesis.*

## 18. TRAINER NOTE:

The data gathered specific to “other diseases”— the distribution was as follows:

- There was a significant number that had a mental disorder or co-occurring disorder-61%

Specifically indicated were:

- 14% Major Depression Disorder
- 9% Anxiety Disorder

Psychotropic medication was prescribed:

- 22% Benzodiazepine prescription
- 15% anti-depressants
- 12% SSRIs

Other diseases (possible mortality contributors):

- 28% liver disease
- 19% hepatitis C
- 17% chronic obstructive pulmonary disease (COPD)
- 10% metabolic diagnosis
- 9% musculoskeletal disorder
- 9% hypertension
- 8% circulatory
- 6% diabetes mellitus
- 4% kidney disease
- 4% trauma
- 3% asthma



## The Mortality Reports

Two categories of deaths:

1. **Older patients** with long treatment durations dying of illnesses of liver disease, CVD and or COPD
2. **Younger patients** who died of trauma, overdose, motor vehicle accidents, homicide and suicide

## The Mortality Reports

Recommendations:

- Monitor potential toxicities of **methadone and benzodiazepines**
- Need better data to understand **suicide and overdose deaths**
- **Educate families** on overdose symptoms

## The “Big Picture”



## 19. TRAINER NOTE:

Keep in mind that although 406 reported deaths are too many, for purposes of statistical analysis, it is a small number. Hopefully, as more programs participate in the reporting of deaths, the data will yield more information. The summary of the analysis indicated two categories of deaths:

- Older patients with long treatment durations dying of illnesses of liver disease, Cardiovascular Disease (CVD) and or Chronic Obstructive Pulmonary Disease (COPD)
- Younger patients who died of trauma, overdose, motor vehicle accidents (MVA), homicide and suicide

## 20. TRAINER NOTE:

Recommendations included:

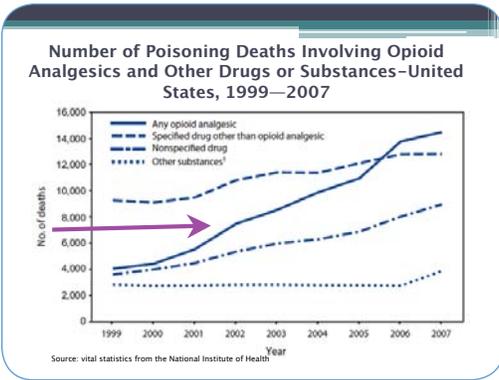
- Monitor potential toxicities of methadone and benzodiazepines
- Need for better data to understand suicide and overdose deaths of OTP patients

Educate families better on overdose symptoms. It is not uncommon for a patient in an OTP who appears to be over-medicated, or who may have the potential for overdose, to be told to go home and sleep it off. That should not take place as it is a harbinger for overdose or potential overdose. The patient is displaying symptoms of sedation and the patient may die from respiratory depression. WE need to educate families in symptoms of overdose. The analysis indicated that warning signs were present but appropriate action did not take place.

## 21. TRAINER NOTE:

Going back to the big picture we want to focus on some additional details.





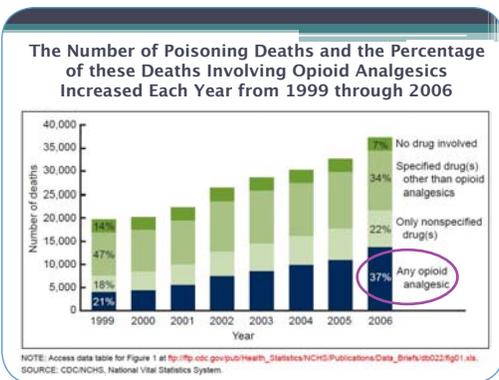
## 22. TRAINER NOTE:

Let's look at some of the data we have from the vital statistics from the National Institute of Health.

Number of Poisoning Deaths Involving Opioid Analgesics and Other Drugs or Substances — United States, 1999-2007

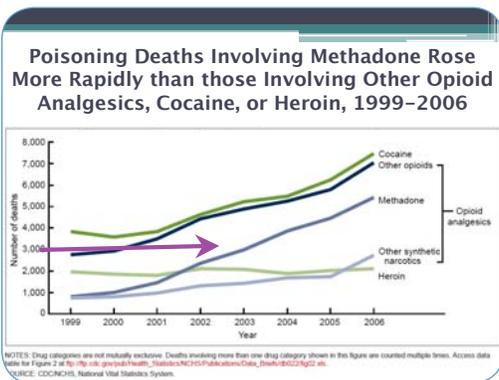
If you look at the category of “Any opioid analgesic,” which is a broad category, the line has a dramatic increase. They all indicate an increase, but opioids is the most dramatic.

This is ongoing and further information is being collected.



## 23. TRAINER NOTE:

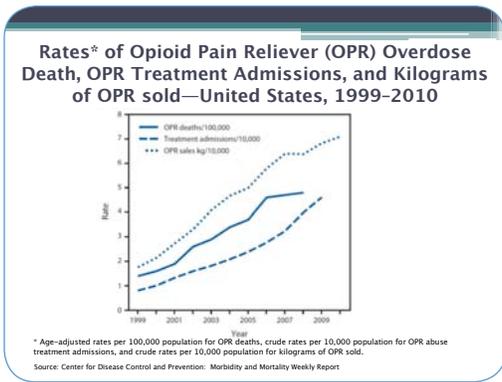
This graph provides a look at the data (1999-2006) and shows this increase, the most significant being opioids.



## 24. TRAINER NOTE:

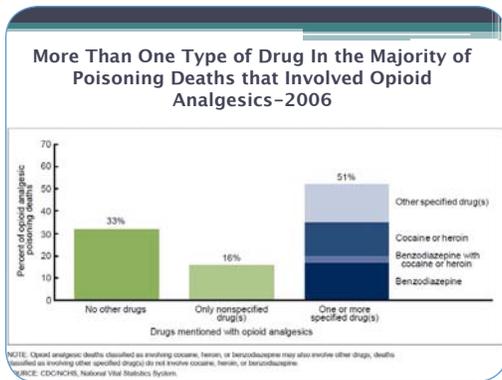
The information depicted in this graph (1999-2006) indicates, once again, the slope is steep for methadone.





## 25. TRAINER NOTE:

If you look at the rates of overdose death with treatment admissions and drugs sold, you are able to see the phenomenon that both of these trends increase with the rate of death.

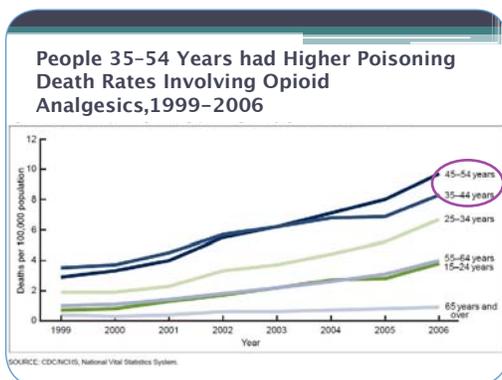


## 26. TRAINER NOTE:

According to the CDC, knowing whether other drugs are involved with opioid analgesics in poisoning deaths helps in developing prevention strategies. The data suggest that multiple drugs were involved in at least half of the opioid analgesic-related deaths. The involvement of benzodiazepines (sedatives used to treat anxiety, insomnia, and seizures) is very concerning because studies have shown that people who were prescribed both methadone and benzodiazepines are at greater risk of overdose than those prescribed only one of these drugs.

The involvement of other drugs in the majority of opioid analgesic deaths should also be noted.

- About one-third of opioid analgesic-related poisoning deaths involved no other drugs
- About one-half of opioid analgesic-related deaths involved at least one other drug that was specified on the death certificate
  - benzodiazepines in 17% of the deaths
  - cocaine or heroin in 15%
  - benzodiazepines with cocaine or heroin in 3%



## 27. TRAINER NOTE:

During this same time period, the data in this graph indicates that people in their “prime” or the most productive years of their life (35–55, the 2 upper lines) had the highest poisoning death rates.

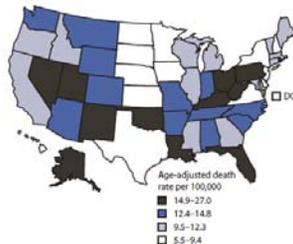
## Drug Overdose Deaths

**36,450** people died of drug overdoses in 2008— a national rate of nearly **12 per 100,000 people**.

### Top States – National Average of 11.9 Rate of Drug Overdose Deaths

- New Mexico 27.0
- West Virginia 25.8
- Nevada 19.6
- Utah 18.4
- Alaska 18.1
- Kentucky 17.9
- Rhode Island 17.2
- Florida 16.5
- Oklahoma 15.8
- Ohio 15.1
- Louisiana 15.0
- Pennsylvania 15.1
- Tennessee 14.8
- Washington 14.7
- Colorado 14.6
- Delaware 14.5
- Wyoming 14.4
- Montana 14.1
- Indiana 13.2
- Alabama 13.1
- Arizona 13.1
- Arkansas 13.1
- Missouri 13.1
- North Carolina 12.9
- South Carolina 12.6
- Maine 12.3
- Michigan 12.2

### Drug Overdose Death Rate – 2008 Age-adjusted Death Rate Per 100,000



Source: Center for Disease Control and Prevention. Morbidity and Mortality Weekly Report

## 28. TRAINER NOTE:

Looking at one isolated year, deaths from drug overdoses, particularly prescription painkillers, increased significantly over a decade, the Centers for Disease Control and Prevention reported. In 2008, 36,450 people died of drug overdoses — a national rate of nearly 12 per 100,000 people and this was again a significant rise from previous years in the 1990s.



## 29. TRAINER NOTE:

The information presented here is from 2008 data as reported by the Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*: There were 27 states that had a higher rate of drug overdose deaths than the national average of 11.9 per cent per 100,000 people.

Where does your state rank?



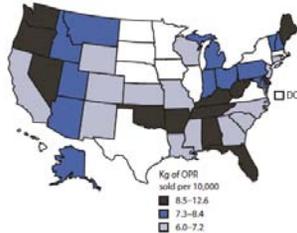
## 30. TRAINER NOTE:

This is a pictorial representation of the same data that was presented in the previous slide. You are able to see the different colors in the geographic areas.

Point out that states (in darker colors) have the higher incidence of overdose death, but are not the most densely populated areas.



### Rate of Kilograms Of Opioid Pain Relievers Sold 2010- Kg Of OPR Sold Per 10,000



Source: Center for Disease Control and Prevention: Morbidity and Mortality Weekly Report

## 31. TRAINER NOTE:

The 2010 data this graphic illustrates indicates where the drugs were sold— which states rank at the top for sales of opioids? Focus your attention on the brown and blue states.



### Lets Take A Closer Look at Two of The States With The Highest Rates



## 32.

## 33. TRAINER NOTE:

Let's take a closer look at the statistics for West Virginia. During 1999-2004, West Virginia experienced a 550% increase in the rate of unintentional drug overdose deaths which was the highest in the nation.

Because of this high rate and the centralization of West Virginia's data, the CDC conducted a study to determine some of the risk characteristics. This was intended to help practitioners and public health officials in prevention efforts.

As we look at this data try to remember the data presented by the DEA in 2010 with the analysis of the Mortality Report (slides 16-17).



### West Virginia

#### Patterns of Abuse Among Unintentional Overdose Fatalities West Virginia - 2006

- 67.1 % were men
- 91.9 % were 18-54 years
- 63.1 % associated with diversion
- 21.4 % associated with doctor shopping
- 79.3% used multiple substances contributing to their fatal overdoses



Source: JAMA, December 2008

CONTINUED 

### 33. CONTINUED

Results showed the following Patterns of Abuse Among Unintentional Overdose Fatalities West Virginia - 2006

- 67.1 % were men – twice that of women
- 91.9 % were 18-54 years – prime years
- 63.1 % associated with diversion – greatest among 18-24 years old (see note below)
- 21.4 % associated with doctor shopping – women were more likely to doctor shop (see note below)
- 79.3 used multiple substances contributing to their fatal overdoses

NOTE: In this CDC study:

- Diversion refers to a prescription drug used without documented prescription records (non-medical use).
- Doctor shopping refers to having received prescriptions for controlled substances from five or more clinicians during the year prior to the death.

#### New Mexico

- **Characteristics of drug-induced deaths**
  - Hispanic or White male
  - 43 years of age
  - Living in Rio Arriba, Guadalupe or Torrance counties
- **Risk factors for drug overdose deaths**
  - History of substance abuse
  - Using alone
  - Previous drug overdose
  - Injection drug users
  - Mixing drugs (illicit and prescription drugs together)
  - Male
  - Chronic pain patients treated with prescription opioids



### 34. TRAINER NOTE:

Let's look at New Mexico which is ranked among the top three U.S. states for drug induced deaths.

Characteristics of drug-induced deaths:

- Hispanic or White male
- 43 years of age
- Living in Rio Arriba, Guadalupe or Torrance counties

Risk factors for drug overdose deaths

- History of substance abuse
- Pattern of using alone
- Previous drug overdose
- Majority were injection drug users
- Mixing drugs (including the use of illicit and prescription drugs together)
- Male
- Chronic pain patients treated with prescription opioids



## Generation Rx

"... today's teens are more likely to have abused a prescription painkiller to get high than they are to have experimented with a variety of illicit drugs – including Ecstasy, cocaine, crack and LSD... 'Generation Rx' has arrived."

– Roy

Bostock, Partnership for a Drug Free America, 2004

- One in five teens (4.3 million) have abused Vicodin
- One in 10 teens (2.3 million) have abused OxyContin
- One in 10 teens (2.3 million) tried Ritalin and/or Adderall without Rx
- One in 11 teens (2.2 million) abused OTC cough medications to get high

Source: PATS Teen Report, 2004

## 35. TRAINER NOTE:

In addition to the national and state statistics, current statistics point to an emerging culture in our upcoming generations regarding prescription drug use. They are more knowledgeable, more sophisticated, and more importantly they are normalizing prescription drug use. These are just a few of the components that make for a perfect storm and continued risk.

"... today's teens are more likely to have abused a prescription painkiller to get high than they are to have experimented with a variety of illicit drugs – including Ecstasy, cocaine, crack and LSD... 'Generation Rx' has arrived (Partnership Attitude Tracking Study (PATS) 2004)."

- One in five teens (4.3 million) have abused Vicodin
- One in 10 teens (2.3 million) have abused OxyContin
- One in 10 teens (2.3 million) tried Ritalin and/or Adderall without Rx
- One in 11 teens (2.2 million) abused OTC cough medications to get high

Teens reported "ease of access" as a major factor in prescription medication abuse. The majority of teens cited medicine cabinets of parents and friends as major access points. They are right in the medicine cabinet, they don't have to go out onto the street to "pop" or "score." This accessibility contributes to the epidemic.

According to the PATS Teen Report (2004), "teens demonstrate a remarkable sophistication when it comes to Rx and OTC medications, and all other drugs. Teens are familiar with brand names of a wide variety of medications and accurately describe their effects." This indicates an awareness and normalization of substance abuse.

## 36. TRAINER NOTE:

Consumption of opioid analgesics has increased along with reports of methadone-related deaths.

There is a comprehensive plan of action at the Federal level to respond to this epidemic.

Reports demonstrate OTPs were not primarily responsible for deaths, but rather pain management practices.

Recommendations:

- Monitor potential toxicities of methadone and benzodiazepines
- Need better data to understand suicide and overdose deaths
- Educate families on overdose symptoms

*NOTE: depending on how long Part 1 of this module took to deliver, you may want to give participants a short break before launching into Part 2.*



## In Summary

- **Consumption** of opioid analgesics has increased along with reports of **methadone-related deaths**
- Plan of action at a Federal level to respond to this epidemic
- Recommendations:
  1. Monitor potential toxicities of **methadone and benzodiazepines**
  2. Need better data to understand **suicide and overdose deaths**
  3. **Educate families** on overdose symptoms





Part 2:  
**Insurance Carriers & Opioid Treatment Programs (OTP)**

**Insurers Are Growing More Concerned With Adverse Drug Claims In OTPs**

- Two general aspects of the industry are bringing increased scrutiny to OTPs:
  - **Significant increases** in the overall number of methadone-related deaths (including pain clinics)
  - Public information and news articles about methadone are **increasingly negative**

**What Are Some of the Overriding Trends in OTP Claims Involving Adverse Drug Events?**

1. Increased **FREQUENCY** of reported incidents and claims made.
2. Increased **SEVERITY** of outcomes and settlements.

**37. TRAINER NOTE:**

Part 2 of this first module looks at what is going on out there from an unique perspective: Insurance Carriers & Opioid Treatment Programs (OTP).

OTPs have liability insurance for their program and their staff. Depending on their structure, a physician may be part of that or may have their own malpractice insurance. Insurance policies are a part of the Big Picture.



**38. TRAINER NOTE:**

Let's look at the big picture from yet another perspective, as it relates to OTPs and insurance carriers, as adverse drug events are a growing concern for insurers.

Two general aspects of the industry are bringing increased scrutiny to OTPs:

- Significant increases in the overall number of methadone-related deaths (including pain clinics)
- Public information and news articles about methadone are increasingly negative about OTPs and the safety of the medication



**39. TRAINER NOTE:**

Pose the question: What are some of the overriding trends in OTP claims involving adverse drug events?

1. Increased **FREQUENCY** of reported incidents and claims made.
2. Increased **SEVERITY** of outcomes and settlements.

*NOTE: the next two slides will describe each of these in more detail.*



## Increased Frequency Trend

- Reduced stigma
- Greater availability of information
- More attorney involvement
- New causes of action

## Increased Severity Trend

- More attorney involvement
- Greater availability of information
- Patient demographic shift

### 40. TRAINER NOTE:

We will focus on the first overriding trend: An increased FREQUENCY of reported incidents and claims made.

#### What we think are driving these:

Reduced stigma:

- There is a down side to reduced stigma. Plaintiffs and the families are more willing to proceed with claims related to an adverse event or wrongful death involving methadone. These claims often lead to litigation.

Greater availability of information:

- Methadone is in the news and seen in a negative fashion. There has been a proliferation of bad news about methadone on the Internet. Additionally, there are more organizations sounding the alarm about methadone safety. All of this information is readily available to the public.

Increased involvement of attorneys in litigation:

- There was a time in the past when attorneys were hesitant to take cases involving deceased heroin addicts. There are more attorneys now that need work and are willing to take these cases.

New causes of action:

- Claims and allegations that we didn't see 5-10 years ago—such as impaired drivers, and cardiac related issues.

### 41. TRAINER NOTE:

The second overriding trend that we see is: An increased SEVERITY of outcomes and settlements.

#### What we think are driving these:

More attorney involvement:

- Naturally this drives up the cost.

Greater availability of information: (Internet)

- This has increased an attorney's ability to file claims and to sue.

Patient demographic shift:

- The number of patients taking prescription opioids who become addicted has increased from 5% to 30%, over the last 5 years. This has an economic impact in regards to “valuing the life” of the decedent. Insurance agencies have a mechanism with which they determine the “value” of the loss of the person's life. With the demographic shift, the life value of someone in their 30s or 40s (in their prime) compared to an older person is greater. This makes the claims much more expensive.



## Insurance Companies

- Insurance pricing and availability has **cyclical** swings primarily based on the **level of capital** or surplus in the market to pay claims.
  - Surplus can be **depleted**:
    - Slowly by an **increase in overall claims and loss costs** versus premiums collected
    - Rapidly by a **catastrophic event(s)**

## 42. TRAINER NOTE:

Keep in mind the two trends we just discussed (frequency and severity) as we take a closer look at what drives the insurance markets.

The insurance market works very much like the credit market. It is cyclical. Essentially insurance companies work from a large pool of capital from which they pay claims (450 billion dollars nationally). The pool gets depleted:

- Slowly by an increase in overall claims and losses versus premiums collected
- Rapidly by a catastrophic event(s)

This has a large impact on the hard and soft markets.



## Insurance Market Cycle

### “Hard Market”

- Decreased competition among carriers
- Higher rates
- More stringent (worse) coverage terms and conditions

### “Soft Market”

- Increased competition among carriers
- Lower rates
- Broader (better) coverage terms and conditions

## 43. TRAINER NOTE:

As mentioned, the insurance market is cyclical. It cycles from a hard market to a soft market and back again.

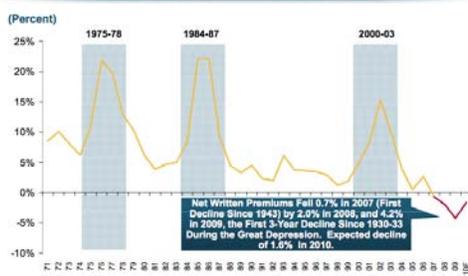
A “Hard Market” is characterized by: decreased competition among insurance carriers, higher rates, and more stringent (worse) coverage terms and conditions.

A “Soft Market” is characterized by: increased competition among insurance carriers, lower rates, and broader (better) coverage terms and conditions.

We have been in a soft market since 2002. The last hard market 2000-2002 spiked after the World Trade Center catastrophe.



### Strength of Recent Hard Markets by NWP Growth



## 44. TRAINER NOTE:

Point out to participants that this graph highlights the last 3 “hard market” cycles, and shows that we have been in a soft market since 2002.

When we experience a soft market it may give us a false sense of security. Decreased premiums are easier to get, and there are a lot of insurance carriers willing to provide a quote—there is more competition. However, it is not a matter of if, but a matter of when this market cycle will turn.

Insurance companies made a nice profit in 2006. That all changed in 2007 when their investments went down and losses and claims grew. Insurance companies will only lose money for so long, then you will see:

- decreased competition
- fewer carriers willing to quote you insurance
- increased rates/higher deductibles
- harsher terms and conditions



## OTPs “Subprime”?

OTPs are considered “subprime” risks by insurance carriers primarily due to the increased frequency and severity trends which cannot be offset by higher rates during a soft market.



## What Contributes to the Labeling of OTPs as “Subprime”?

1. Ambiguity around the Accepted Standards of Care
2. Defense challenges
3. Deterioration of the public’s image of methadone

## Insurance Claims Trends in OTPs

- Malpractice Claims and Lawsuits are almost always settled out of court.
- Very few methadone-related suits have been tried in the U.S. —outcomes have not been favorable for OTPs.

## 45. TRAINER NOTE:

To continue with the credit market analogy, there are other factors to consider.

OTPs are considered “subprime” risks by insurance carriers primarily due to the increased frequency and severity trends, which cannot be offset by higher rates during a soft market.

OTPs are “subprime” because of the markets frequency and severity claims trend as we mentioned earlier. There is nothing worse for an insurance carrier than frequency and severity. For example, think about Florida and the hurricanes in the summers of 2004 and 2005. Not only were there a lot of claims (frequency), but there were also a lot of large settlements (severity) during that time. Frequency and severity makes a risk difficult to insure.

*NOTE: “Subprime” is a term used in the credit market and refers to loans offered to high-risk individuals with less than perfect credit.*

## 46. TRAINER NOTE:

Other factors contributing to labeling OTPs “subprime” status are:

1. Ambiguity around the Accepted Standards of Care.

There is ambiguity in the practice of the standards of care, such as the issue related to medication management or whether it is regional or by state.

2. Defense challenges.

Methadone is often referred to as the “smoking gun” because it lingers in the body for so long. Medical examiners’ reports often list methadone poisoning as the cause of death, even if there are multiple substances of abuse in the body. But the spotlight is on methadone as the cause of death.

3. General deterioration of the public’s image of methadone.

## 47. TRAINER NOTE:

Additionally, the current trends in the courts make OTPs less attractive to insurance carriers.

Malpractice Claims and Lawsuits are almost always settled out of court.

Very few methadone-related lawsuits have been tried in the U.S. —outcomes have not been favorable for OTPs. Because few have gone to trial, there is a limited track record. This makes it more likely insurance carriers will settle out of court because they are reluctant to face the uncertainty of a jury trial and an unfavorable verdict.



## What is an OTP to do?

### Implement sound risk management (RM) strategies

- What OTPs can control:
  - Your own loss
  - Your own RM program
- You can and should deploy RM strategies to:
  - Secure **better pricing and terms** in a soft market.
  - Make you **more attractive** to insurance carriers when the market hardens.
  - Improve track record of loss, which will help you withstand the inevitable hard market.

## 48. TRAINER NOTE:

Right now times are good, next year or the year after things may not be so good. The best thing you can do is take care of your own “credit report,” clean up your own house. How do you do that? Implement a sound risk management (RM) strategy from top to bottom.

You as an individual OTP have no control over the insurance market cycle. What you can control is your own loss and your own RM program.

You can, and should, deploy RM strategies which we will be discussing in greater detail in the upcoming modules. RM strategies can:

- secure better pricing and terms in the remainder of the soft market.
- make you more attractive to insurance carriers when the market hardens.
- improve track record of loss, which will put you in a better position in the market to withstand the inevitable hard market.

Agents and carriers will support and encourage risk management programs. CARF and other accrediting bodies will also support risk management.



## Risk Management is NOT Complicated

Risk management is essentially a 3 step process:



## 49. TRAINER NOTE:

Risk management is used everyday in our lives—when we buckle our seatbelts, or look both ways before crossing. These are good risk management strategies to avoid an accident. You can take that same concept and apply it to patient care. Good business practice and risk management is essentially a 3 step process:

1. Identify the risks
2. Develop strategies to mitigate those risks
3. Monitor that strategy for its effectiveness

You cannot just identify risks and develop strategies, you need to monitor those strategies to minimize risk.



## Risk Management in Healthcare

- From an insurance standpoint, **PROVIDING QUALITY CLINICAL CARE** is the most effective way to manage your liability exposure
- Follow the Basic Tenets of Risk Management (the four “C”s)

## 50. TRAINER NOTE:

Risk Management in Healthcare

From an insurance standpoint, **PROVIDING QUALITY CLINICAL CARE** is the most effective way to manage your liability exposure. Is the care your clinic provides based on best practice? Is it quality care?

Follow the Basic Tenets of Risk Management (the four “C”s).

These risk management strategies will be covered over the next few slides and are specific to patient care and adverse drug events.



### The Basic Tenets of Risk Management– the Four “C”s

1. Stay **CURRENT** with scientific and clinical information about methadone and best practices in OTPs.

### 51. TRAINER NOTE:

1. Stay **CURRENT** with scientific and clinical information about methadone and best practices in OTPs. It is important that the appropriate staff members are current and up-to-date.



### The Basic Tenets of Risk Management– the Four “C”s

2. Thoroughly **COLLECT** patient information **before** and **during** treatment.

### 52. TRAINER NOTE:

2. Thoroughly **COLLECT** patient information before and during treatment. Assessment is continuous. It is not limited to admission. It is a continuous and thorough process throughout the treatment episode.



### The Basic Tenets of Risk Management– the Four “C”s

3. **COMMUNICATE** with patients (e.g. informed consent), family members, and other healthcare providers.

### 53. TRAINER NOTE:

3. **COMMUNICATE** with patients (e.g. informed consent), family members, and especially other healthcare providers. One of the goals of electronic medical records is to provide better communication of information among healthcare providers. It can also help the provider to better communicate with the patient and ensure they have needed information. It is a two way exchange.



## The Basic Tenets of Risk Management– the Four “C”s

- 4. **CAREFULLY** document patients' records.

## Create a Risk Management Culture

- Risk management culture starts at the top
- Put a key employee in charge of risk management
- Training and reinforcement of the rules and guidelines for all clinical staff

## You Can't Avoid Risk Completely, BUT You Can Manage It.

- Strive to provide top quality clinical care.
- Pay close attention to the basic risk management tenets outlined.

## 54. TRAINER NOTE:

4. CAREFULLY document patients' records. Document what you did and what you did not do. If it is not documented, it did not occur. Serious problems can result from something as simple as forgetting to fill out a form. Complacency is simply not acceptable.

The fourth “C” cannot be stressed enough. It has been shown that the best documentation often wins in court and negotiations. Unfortunately, documentation is often inadequate. Document what occurs prior to and after an adverse event.

These are real basic tenets of patient care. In almost every adverse event that is reviewed, breakdowns in these risk management practices has occurred.

Risk management strategies need constant reinforcement. Your entire clinical staff is essential to the risk management culture in your agency.

## 55. TRAINER NOTE:

*NOTE: To engage participants in this discussion, you may want to begin by asking how many of them would describe their agency as having a culture of risk management embedded in their respective programs. If participants are willing to share, you may wish to facilitate a brief discussion of the process by which that culture grew before you go on to outline the strategies to create a risk management culture at their agency.*

Good Risk Management Culture starts at the top and permeates an organization from top to bottom. It should start with the parent organization, your executives, and right down to your front line staff (security, receptionist).

Consider putting a key employee in charge of risk management for your OTP. Provide top level support for this person. You need to have a structure to your program and have designated staff involved.

Continuous training and reinforcement of the rules and guidelines of your organization are critical for all your clinical staff. Risk management is not a do-it-once and check-it-off-the-list effort. Risk management needs continual reinforcement and training.

## 56. TRAINER NOTE:

In closing, what we have discovered is that you can't avoid risk completely, but you can manage it.

Strive to provide top quality clinical care and pay close attention to the basic risk management tenets outlined. Make this a source of pride in your agency.



# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 2: Managing Risk**

## MODULE 2 – Managing Risk

TIME: 45 minutes

PURPOSE: Describe and define basic terms in risk management.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Explain the terms and definitions used with risk management.
2. Describe the risk management cycle.

TOPICS:

- What is risk management?
- Risk management cycle
- Risk assessment
- Risk treatment options

### KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

# Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

MODULE 2  
Managing Risk



## WHAT IS RISK MANAGEMENT (RM)?

## 1. MODULE 2

*NOTE: Before launching into Module 2, (particularly if there was a break taken between Module 1 and 2) check-in with participants to determine if they have any questions regarding the material discussed in Module 1. Respond as appropriate and then introduce the topic of this module.*



## 2. TRAINER NOTE:

As we begin to delve deeper into RM throughout this course, I would like to announce some disclaimers:

This module is:

- Not a lecture on law or practice guidelines. We will use actual situations to identify trends and highlight options for an OTP's response to risk.
- Not giving legal advice specific to your OTP.
- Not implying that application of these strategies or even adoption of best clinical practices will insulate OTPs from being the subject of legal actions.



## 3. TRAINER NOTE:

Risk Management (RM) is not a new concept, although we have been hearing more about it. As mentioned in Module 1, risk management is something we practice everyday unconsciously.

What is Risk Management?

- Ideally, it is a fluid process through which you address risk in your OTP (i.e. How are you going to deal with risks? What are your financial limits?).
- The heart of RM is risk assessment/identification, analysis and evaluation of risks, and risk treatment options.
- After the analysis, you will be looking for what change, strategy, and/or non-action is going to give you the biggest bang for your buck when developing your Plan of Action.
- Once your plan is developed and approved, successful implementation will require thorough communication regarding your plan throughout your OTP.
- The risk management cycle (described in the next slide) ties all of these concepts together in an easy to understand visual.





#### 4. TRAINER NOTE:

*NOTE: Refer to these as “steps or stages” in the cycle as you discuss these concepts.*

There are several stages in RM. Unfortunately, many people limit RM to the second stage: risk assessment. But as this visual shows, this is merely a stage.

There are four stages within the RM cycle:

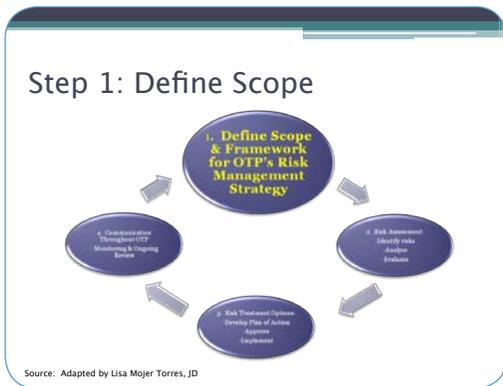
1. Define the scope & framework for OTP’s RM strategy.
  - Where does RM fit into your agencies priorities?
  - Who needs to be involved?
  - What resources do you have or need for your RM?
2. Do a comprehensive Risk Assessment which includes:
  - Identify the risks
  - Analyze the risks
  - Evaluate the risks

We will discuss how to assess on the next slide.

3. Develop a plan of action (a treatment plan for RM) with the risk treatment options that are the right fit for your OTP. Critical components are:
  - Develop and approve a plan of action
  - Get buy-in from everyone at your OTP to implement your plan of action. This would also include patients’ buy-in, as they have the biggest investment in safe practice.
4. Provide ongoing communication and monitoring throughout your OTP.
5. Continue to cycle back through all the stages all over again.

Next we will take a closer look at the stages that are at the heart of RM.

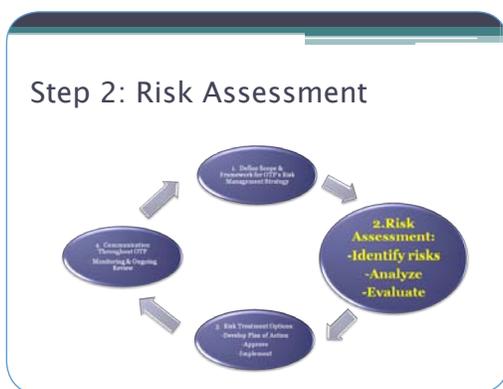




## 5. TRAINER NOTE:

Step 1: Define scope and framework for OTP's RM strategy. You may ask yourself the following:

1. Is Risk Management a priority for the OTP?
2. Who within the OTP has involvement with Risk Management? AND who needs to be involved with Risk Management?
3. What resources are available to the OTP for Risk Management? Your RM strategies will be influenced by what resources you have available.



## 6. TRAINER NOTE:

*NOTE: Ask participants, "How can you identify risks (loss exposure) within your OTP?" As participants offer ideas, record their responses on flip-chart paper in the front of the room. If the group does not come up with the strategies listed below, write those missed on the flip-chart paper and discuss.*

Step 2: Risk Assessment. As we mentioned earlier, most people think the assessment process is risk management. It isn't. It is merely a stage where risks are identified.

There are different ways to identify risk:

- You can do a thorough assessment from the front door to back door, reviewing policy and procedures—this is a very big undertaking.
- You can assign different people to different areas and look at risks in each of those areas.
- Or you may do an assessment as risks occur.

Regardless of how you do it, you need to use multiple sources of information for your assessment.

"Red flags" (something that is occurring that does not seem right and warrants further investigation) are a good source for you RM assessment. Ask the group if they can suggest some examples?

If they don't mention the following ideas, suggest the following sources:

- Patient complaints
- Adverse events



CONTINUED

## 6. CONTINUED

- News from the field, including controversial issues (e.g. torsades de pointes-cardiac issue), letters from Dr. Westley Clark and SAMHSA (e.g. clinic openings, standing orders). These are all situations that affect the standards by which you would ultimately be judged.

Analysis of risks looks at the frequency, likelihood & severity (probable size of loss within a certain time). You will want to analyze the impact of the risk by looking at the frequencies and severity (Module 1).

- What is the probable size of the losses within a certain time or phase?
- What are the chances of loss?
- If loss occurs, what is the worst that could happen?

Evaluate options in light of the maximum possible losses and the maximum probable loss. You will need to ask, “What is cost-effective for my OTP?” There will be treatment strategies that your agency just cannot afford. Courts have been more receptive to these kinds of defenses, especially in light of the recession.



## 7. TRAINER NOTE:

### Step 3: Risk Treatment Options

RM options should not be viewed as a single formal process because there are varied and overlapping elements

There should be collaboration between your RM and your Safety Management and Quality Assurance activities.

Ask participants to identify areas for potential liability problems:

- Bodily injury—wrongful death
- Liability losses
- Property loss
- Consequential losses

We will examine some of your risk treatment options in the next few slides.



What are your RM options?



## 8. TRAINER NOTE:

As you think about risk in your OTP, consider these four risk treatment options:

You can:

- Accept all or some of the risk
- Avoid risk
- Mitigate risk
- Transfer risk



What are your RM options?



## 9. TRAINER NOTE:

Let's look at the first option.

You can decide that the best thing to do to address a risk or contain a risk — accept or assume all or some of the risk.

For example: The risk of QTc/torsades happening to your patient population is so miniscule compared to the cost of giving all new and regular patients ECGs (electrocardiogram), you are willing to assume the risk of it happening. Or you may assume some of that risk by screening your patients to evaluate who is at high or higher risk (by asking questions and doing a thorough medical history and exam) and just do ECGs with those patients.



What are your RM options?



## 10. TRAINER NOTE:

You can treat risk by avoiding it through abandonment or elimination of the source.

For example: A patient requests the dosing nurse to hold and dispense prescription blood pressure medication because he was having a hard time storing it and taking it everyday. This is costing him in terms of full efficacy of the medication. The nurse really wants to do it, as it would not take a great deal of time or effort. However, in terms of risk, it is too costly to permit this practice and assume the risk of this medical condition and medication. Additionally, there are other resources that can assist him (this is a counseling issue).



What are your RM options?



## 11. TRAINER NOTE:

You can mitigate the risk to reduce the likelihood, severity and/or impact.

For example: To deal with the risks related to violent patients, you could:

- Mandate anger management
- Investigate how the OTP may be contributing to setting patients off. Are the lines too long? Are certain patients coming at certain times from two different groups that don't get along?
- Brainstorm strategies to reduce patients' stress (shorter lines, TV while waiting to be dosed, etc).
- Adopt and promote policies about violence and threats. You can have patients consent to abide by them as a condition of admission. Here is an example: we do not tolerate violence of any sorts—one strike and you are out. Devise policies that are consistent with your agency's values and objectives.



What are your RM options?



## 12. TRAINER NOTE:

You can transfer the risk to a capable third party.

For example: Refer patients with co-occurring mental health issues to psychiatric providers.

You can transfer some of the risk to patients themselves through the informed consent process. This allows patients to take more responsibility for their actions, they know what they are doing, they are advised of the risks. Informed consent is an underutilized resource. There will be more on using patient consent/agreement to transfer risk in the next module.

Once you have decided what your response will be, develop and/or incorporate it into your "Risk Treatment Plan." The "Risk Treatment Plan" is an actual plan that has approval and buy-in, and will be implemented by the entire OTP (including patients, etc.).

Ongoing monitoring of your risk is critical to manage untreated risks and new loss exposure.





### 13. TRAINER NOTE:

The last step in the Risk Management Cycle is Communication. Ongoing monitoring and review is critical, as there may be risk that is left over or caused by your treatment. Or you may have initially decided to do nothing and now it is time to do something or act differently. Some ways to do this is to have:

Active involvement of all staff within the OTP at some level:

- Staff development / training
- Assignment of functions / duties
- Adopting policies and procedures
- Formal structure
- Committee or task force
- Regular meetings that are documented / recorded
- Collected data / information is appropriately acted upon

### Other "Risk" Terms You Should Know

- **Residual Risk**
- **Contingency Plans**

### 14. TRAINER NOTE:

As we continue through the rest of the modules, there are two terms you need to be familiar with:

**Residual Risk:** risk that is left over or caused by your treatment, after you have accepted or assumed some or all of the risk. You may have implemented a strategy that did not eliminate all of the risk as desired. Or your strategy may have eliminated the initial risk, but created new risks.

For example: You may have used a risk treatment strategy to eliminate "standing orders" in an effort to increase documentation of individualized treatment (by physicians). There is a residual risk of patients' dose adjustment requests becoming backlogged because the doctors are spending time documenting individualized care. This residual risk would need to be addressed and also the issues and risks associated with limited physicians' time and priority.

**Contingency Plans:** Steps to reduce the impact should the risk materialize.

For example: You have a patient death and the family calls. Confidentiality laws can be very frustrating to family members and significant others. You want to provide a caring response, but are unsure what can be said. Some resources for this situation are:

CONTINUED

## 14. CONTINUED

“Sorry Works!” is an advocacy organization that offer tools to help with adverse medical events. They can provide you with a plan that guarantees you won’t be conceding liability yet allow you to convey a human and caring response and provide information in accordance with your jurisdiction and applicable state and reporting apology laws.

(Their website is [www.sorryworks.net](http://www.sorryworks.net). The link is also provided in the Toolbox at [www.ireta.org](http://www.ireta.org).)

Another way to handle this situation is to have advanced waivers or ongoing waivers. Waivers allow patients to waive their confidentiality rights under certain circumstances. This would make it possible for an OTP to contact family members or specified individuals if an adverse event was specified by the waiver. Waivers are referred to as “liability shields” by many lawyers.

The next module will take a closer look at the relationship between Risk and Practice in the OTP.



### In Summary

#### Risk Management Cycle:

1. Define the scope & framework for OTP’s RM strategy
2. Do a comprehensive Risk Assessment
3. Develop a plan of action (a treatment plan for RM).  
Risk treatment options include:
  - Accept all or some of the risk
  - Avoid risk
  - Mitigate risk
  - Transfer risk
4. Provide ongoing communication and monitoring throughout your OTP

## 15. SUMMARY

# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 3: Relationship Between Risk and Practice in the OTP**

## MODULE 3 – Relationship Between Risk and Practice in the OTP

TIME: 45 minutes

PURPOSE: Describe core liability risks and strategies to manage those risks.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Describe a variety of risks faced by OTPs.
2. Identify a menu of risk management strategies.

TOPICS:

- Ideal standard of care
- Core liability risks
- RM strategies:
  - o Informed consent
  - o Induction
  - o Impairment

### KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

# Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

MODULE 3  
The Relationship between  
Risk and Practice in the OTP

## OTP Ideal Standard of Care

From admission, each patient receives:

- Individualized clinical care
  - Ongoing
  - Documented
- Competent staff
- Good clinical judgment
  - OTP clinical practice standards
  - Incorporating best evidence-based practices

\* Adapted from CSAT Workshop on Risk Management - 2005

## 1. MODULE 3

### 2. TRAINER NOTE:

Let's begin by considering the ideal standard of care as described by CSAT to set the stage to look at the relationship between risk and practice.

From admission, each patient receives ongoing, documented, individualized clinical care by competent staff acting within their appropriate scope of practice, using good clinical judgment in accordance with OTP clinical practice standards and incorporating best- and evidence-based practices.

This means that assessment and treatment are ongoing and well documented.

Individualized clinical care is provided by competent staff acting within their appropriate scope of practice. Competence implies someone who has both knowledge and experience in an area. If you have staff that does not have any prior experience in the specialized area of opioid addiction treatment, one could question competence. This includes the medical staff and counseling staff. They need to be competent and knowledgeable about the specifics of opioid addiction treatment, particularly methadone. If they do not have this expertise, it needs to be addressed, and staff need to have education and training required for competence.

You need to use and practice good clinical judgment in accordance with OTP clinical practice standards which are published and available.

You also need to incorporate best- and evidence-based practices into your overall approach to treatment.

This is why RM is very important within this standard. RM is a win-win for everyone. However, RM is not a one size fits all. It must be individualized and is dependent on your resources and objectives. You cannot trump best practice with RM, and RM should not come at the expense of best practice.





**OTP Core Liability RISKS**

**Failure to:**

- Document
- Communicate risks
- Review and correct
- Consider what's "reasonable" and "foreseeable"
- Assess for impairment
- Attend to RED flags

\* Borrowed from CSAT Workshop on Risk Management-2005

### 3. TRAINER NOTE:

When you understand your risks and you understand your strategies, you can have a more effective risk management plan. The two go hand in hand.

As we go through this module we will explore some of the core liabilities for OTPs and offer some strategies to address risk. For each OTP, RM will look different. You will need to assess and know what your risks are, AND do the same for when identifying your options and strategies.

Risk is not something you can manage by looking the other way and hope nothing happens. Instead, having a clear understanding of your risks and strategies will have an impact on the resulting risk.



### 4. TRAINER NOTE:

Let's explore some of the core liability risks for OTPs. We will be looking into these in more depth throughout this module. OTP core liability risks include:

**Failure to document** patient's receipt of "individualized care." Documentation is an issue that will come up time and time again as a critical RM tool. It's important to document, as completely as possible, your involvement with the patient, patient care, and all related activities. Many claims are won because documentation was not complete, the information was simply not there.

**Failure to communicate** to patients the risks and importance of true and full disclosure regarding their use of other substances including prescribed medications, medical histories, other medical providers, conditions, etc.

**Failure to review** OTP policies, procedures and practices to determine whether they are effective in protecting patients' safety and protecting against foreseeable harm to others OR failure to correct policies, procedures and practices that are ineffective. Just having OTP policies, procedures and practices in place is not enough.

**Failing to consider** what's "reasonable" and "foreseeable." You would want to consider:

- What is reasonable?
- What's logical?
- What would a reasonable reaction be?
- What is foreseeable, what could possibly happen?
- How would a "reasonable" physician/nurse/counselor/OTP usually respond (actions, or in omission/failures to act)?



CONTINUED

## 4. CONTINUED

### RM Strategy: Informed Consent

Consent must be  “informed”  
“voluntary”

Patient’s signature  Informed Consent  
PROCESS

**Failure to investigate** and assess for impairment. This is an important area and we will go into details regarding impairment later in this training.

**Ignoring “red flags”** – incidents that are outside the realm of “usual and customary.” If it sounds unusual and is a “red flag,” attend to those indicators.

You can minimize your risk by addressing the items on this list. Failure to do so increases your liability.

## 5. TRAINER NOTE:

To follow our discussion of some of the core liabilities, let’s consider one RM strategy that can address some of these — it may be less complex than you thought. A tremendous RM tool that you have already in place is your patient informed consent.

As we look at the critical components of the patient informed consent process, you will be able to recognize its value in addressing risk involving documentation and informing the patient of risks. However, there are many things an OTP needs to consider to make sure their process results in true “informed” consent.

Let’s review the key components of the informed consent process:

- It is the OTP physician’s responsibility under the federal regulation 42 CFR Section 8.12(e)(i) to obtain a patient’s written informed consent to [voluntary] treatment.

For consent to be “informed,” communication must include all material risks that could potentially affect the patient’s decision. You should provide enough information for the patient to be able to appreciate the risks of harm versus treatment [including options]. OTPs generally can presume the patient is competent and capable of making intelligent decisions (except when using or in early withdrawal) if appropriate information is provided. A patient’s consent represents competency to understand and appreciate:

- What methadone is
- What it’s supposed to do and how it does it
- Side effects of methadone

Alternatives for treatment: During the admission process patients need to be made aware of other treatment options (e.g. buprenorphine). This should be included in your informed consent.

Consent must be “voluntary” and cannot be given while under pressure/threat of coercion/duress. OTPs need to take into consideration an opioid patient’s state during the early days of withdrawal and induction.



CONTINUED 

## 5. CONTINUED

Consider the duress of being in opioid withdrawal and the “coercive” nature of having to sign a consent form prior to being “dosed,” etc. Keep in mind that patients want relief and the only thing standing in the way of their relief is a piece of paper. They will sign it to get relief, and really they are signing under duress. Consent should be followed up when the patient is not under duress, not necessarily in early treatment (when the patient can be unstable), but rather when stable. Reinforce the patient about risks and information needed to stay in treatment.

A patient’s signature on an informed consent form is evidence that informed consent was obtained, however, it is not a substitute for the informed consent process. Recall our previous discussion about obtaining consent when the patient is under duress. Informed consent is a process that needs to be followed up as treatment progresses.

Patient consent should be ongoing: would a reasonable person wish to alter treatment decisions based upon more or different information? It is the OTPs responsibility to provide this information and revisit the consent throughout treatment.

### Informed Consent for OTPs

#### Patients should understand:

- Basic science of addiction
- Methadone treatment
  - Benefits
  - Risks
  - Alternatives

## 6. TRAINER NOTE:

As you think about your OTP’s consent process, here are some elements that should be included:

It is important to educate patients about addiction as a primary chronic disease of the brain (basic science of addiction). To appreciate the benefits methadone treatment offers those with opioid addiction (compared to other modalities), patients need to understand the disease of addiction. We are not talking about a full course in addiction medicine, but rather educating them in terms they can understand that addiction is a brain disease.

Education on methadone treatment. As we already mentioned, for consent to be “informed,” communication must include all material risks that could potentially affect the patient’s decision. OTPs should provide information regarding:

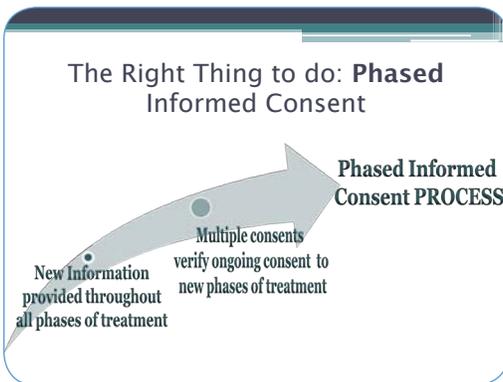
- Benefits of treatment with methadone and what it is intended to do.
- How methadone works in the body (pharmacology).
- Importance of staying in treatment for an adequate length of time (therapeutic trial). Let them know this is not a quick fix, but a long-term strategy.
- Risks and side effects of methadone.
- Danger of impairment during induction.
- Dangers of mixing other substances with methadone.



CONTINUED



## 6. CONTINUED



### Consents: A Valuable RM Tool

- Providing information via consents may increase and motivate patient involvement in treatment
- Phased informed consent
  - Helps share or “transfer” risk
  - Provides patient buy-in
  - Identify understanding and comprehension related to treatment

- Importance of communicating with other providers (family physicians, psychiatrist, emergency room physician).
- Alternatives to methadone, (safer, with less side effects; etc., i.e., Suboxone, Naltrexone etc.) including the option of no medication/treatment.

The education we provide our patients should be ongoing; it needs to be done over time throughout the patient’s treatment and recovery.

## 7. TRAINER NOTE:

Providing phased informed consent is a great RM tool, and ethically speaking, it is the right thing to do! It will help manage your liability when done correctly.

What is Phased Informed Consent?

- New information needs to be communicated as the patient progresses through new phases of treatment.
- Multiple consent forms are staggered throughout treatment and recovery to verify continuous, ongoing consent as new phases progress.
- New consent forms are signed.

It is continuous and not a one-time event done at the beginning of treatment and never to be revisited again.

## 8. TRAINER NOTE:

Let’s look at the value of consent for OTPs and your patients.

An often overlooked benefit is that the patient’s involvement can be changed as new information is shared and learned. As health literacy grows, patients are becoming more motivated to be actively involved in their treatment and recovery. This is supported by multiple recommendations that systems of care for substance abuse be transformed from professionally-driven acute-care episodes to a partnership in managing a chronic disease.

### Value of Phased Informed Consent

Helps “transfer” risk onto the person most in control of his/her behavior, the patient. Responsibility for consequences of risky behavior (causing a car crash and injuring others while driving impaired) is transferred from OTP to the patient.

For patients who are stable in their methadone treatment and not using other substances, it is OK to presume that they are capable of making decisions and can be accountable for their behavior. This is true if you are providing patients all the information they need to know. By treating patients with dignity you are demonstrating good clinical/ethical practice.



CONTINUED

## 8. CONTINUED

Patients will buy-in to the fact that they are consenting. This gives meaning to treatment as patients become aware there are risks involved—if they assume the risks, there could be consequences. It is a process that will improve rapport with patients.

The phased informed consent process provides an opportunity to observe and identify the patient's level of understanding and comprehension related to treatment. Patients are often anxious to get into treatment and will sign anything to get started on their dose. They may not fully understand, and you need to take time to make sure they really do understand.

It also brings to your attention the patients that are not competent (i.e., co-occurring mental disorders). If they are not capable of assessing risk to benefits, then they are not able to consent to treatment. This process will help you identify and refer incompetent patients to appropriate psychiatric services.



## 9. TRAINER NOTE:

Another critical area that must be considered where risk is greater is at admission/induction.

When a patient presents for treatment there are many unknowns for the OTP:

- OTP staff does not know the patient, and the information the patient provides may be unreliable.
- Does not know what other substances may be in the patient's system.
- Not certain of patient's tolerance level.

*NOTE: To involve participants in the discussion ask the training participants to brainstorm factors that impact a patient's response to methadone. The following are some of the responses you can anticipate. Feel free to fill in specific areas that may not be elicited during the brainstorm.*

Patients' responses to methadone vary considerably given:

|                       |                        |
|-----------------------|------------------------|
| Metabolism            | Rates of absorption    |
| Digestion & excretion | Substance use          |
| Diet                  | Co-occurring disorders |
| Medical diseases      | Genetic factors        |

Another important consideration that you are all likely well familiar is that patients may not adhere to treatment recommendations. They may not come daily and skip days. They may take other medications without letting you know.





## 10. TRAINER NOTE:

Integration of the patient’s family is an important strategy. OTP staff are only with the patient for a limited amount of time, but family/significant others are around much more to see warning signs. However, it can be very challenging as many of our patients are stigmatized and cast out from their families.

This RM strategy can be done in the following ways:

**Invite participation** of family/significant others/ roommates or other allies in the patient’s methadone treatment beginning with education. This can be done through “family night” where attendance is voluntary and generic information is provided without violating confidentiality.

Have patients **sign consent to Release Confidential Information** to family/significant others. This will allow you to openly communicate without breaching confidentiality.

**Provide critical information about warning signs** of a potential overdose, particularly during induction. This is a significant area that needs to be addressed in terms of preventing wrongful death claims because the family wasn’t aware of the potential risks, warning signs of over-medication, and/or medication interactions in order to respond and prevent the patient’s death. Make sure family members know to call OTP or ER with any/all questions. One of the biggest errors is that family members will see patients nodding off and tell them to go sleep it off, which is the last thing they should do. You are much more likely to reduce the risk of overdose if families:

- Understand the process of metabolizing methadone and tissue storage
- Receive instructions and support as to what to do if they are concerned or suspect overdose

## 11. TRAINER NOTE:

The last area of risk we are going to cover is impairment. The impaired patient presents a severe risk exposure and there can be many consequences.

Impairment is among the most severe interactions— trends show it as an increasingly likely factor in filed claims against OTPs.

### RM Strategy: Integrate Patient’s Family



How can we get a patient’s family and significant others involved in their treatment? Maybe we could.....

- Invite participation of family in patient’s treatment?
- Have patients sign Release of Confidential Information
- Educate family members about warning signs of potential overdose.

### Impairment-A Severe RISK Exposure

- Trends show impairment as an increasingly likely factor in more claims filed against OTPs



## High Risk for Impairment

- During the **induction process**
- **Drug-Drug interactions** with methadone
  - Benzodiazepines
  - Alcohol
  - Cocaine
  - Other sedative-hypnotic medications
  - Muscle relaxants

## RM Strategy: Do Not Bury your Head in the Sand

- Duty to take **action**
- Duty to **warn**



## 12. TRAINER NOTE:

What are the sources of impairment risk?

A newly induced patient who has not matched/built up tolerance and whose optimal dose has not been established can be impaired by methadone.

Certain substances and medication taken in combination with methadone can also cause a patient to become impaired. Prescription and illicit drugs can cause impairment:

- Benzodiazepines in combination with methadone almost always causes impairment in the patient
- Alcohol
- Cocaine
- Other sedative-hypnotic medications
- Muscle relaxants (Soma)

OTPs need to familiarize themselves with state of the art sources and be able to access this valuable information on a regular basis.

## 13. TRAINER NOTE:

You CANNOT bury your head in the sand. You have a duty to respond. When dealing with impairment the core liability of failing to consider what is “reasonable” and “foreseeable” becomes clear.

In the context of negligence:

There is a duty to take reasonable action when it is foreseeable that third parties could be injured by your patient’s actions and you have the ability to intervene (e.g. driving while impaired). To review what we have previously discussed, you should be asking:

- What is reasonable?
- What’s logical?
- What would a reasonable reaction be?
- What is foreseeable, what could possibly happen?
- How would a “reasonable” physician/ nurse/ counselor/ OTP usually respond (actions, or in omission/ failure to act)?

There is a duty to warn. Patients should be warned of the consequences of taking methadone and driving/ operating heavy machinery. The patient consent should cover this. Make it crystal clear to patients and get it in writing. You do not want a patient harming someone because they did not know the risks and consequences of methadone treatment.

This module has provided an overview of impairment; we will be exploring this topic in-depth in the next module.



## In Summary

- DON'T IGNORE
- Duty to warn
- Duty to make reasonable inquiry and assess
- Obtain Phased Informed Consent
- **Document, document, document**

## 14. TRAINER NOTE:

In summary, let's take a quick look at what we discussed in this module.

**DON'T IGNORE.** You need to take reasonable action to inquire further. Err on the side of caution—if in doubt, don't medicate.

It is a good idea to have a no tolerance policy that patients agree to as a condition of treatment. If impairment is suspected they will need to wait to be medicated.

Make reasonable inquiry and assess patients that are likely to be impaired or are impaired.

At a minimum, patients need to be informed that there are serious drug-drug interactions when taken together and that they absolutely should not drive.

Obtain phased informed consent. Patients need to be fully informed about the risks, including driving automobiles during induction or at least until tolerance is met. Obtain patient consent that they were fully informed about the risks of mixing methadone with other substances. And should other medication need to be taken, it is necessary to consult their physician to find out the precise known risks, side effects etc. Provide this information on an ongoing basis to ensure that your program's consent process is truly "informed" and "voluntary."

Develop a protocol to ensure complete documentation of reasonable inquiries and actions taken to prevent harm. It is the actual documentation of your reasonable action that will save you in terms of liability.



# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 4: Impairment**

## MODULE 4 – Impairment

TIME: 120 minutes

PURPOSE: Gain insight about impairment from a legal and clinical perspective.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Discuss the legal standard and issues in regard to impairment.
2. Use the Risk Management Cycle to identify strategies to minimize risk with impairment.
3. Describe the OTP's legal duties.
4. Identify and assess impairment.

- TOPICS:
- Definition of impairment
  - Impairment and risk management
  - RM strategies:
    - o “Climate of impairment awareness”
    - o Identifying impairment
    - o Impairment risk treatment options
  - Legal Standard and OTP duties
  - Clinical criteria and symptoms of intoxication
  - RM suggestions
  - Clinical assessment of impairment

## KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

# Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

## MODULE 4 Impairment

### Impairment

- Impairment:
  - Definition and general understanding
  - Legal perspective
  - Medical/Clinical perspective
- Assessment for impairment
- High risk situations in OTPs
- Risk Management strategies

### Part I: Terminology and Definitions

- Impairment
- Intoxication
- Competence
- Informed consent
- Disability

## 1. MODULE 4

### 2. TRAINER NOTE:

*NOTE: It is important as a trainer to really know and understand the information to support the discussion relative to the content described in the following bullets.*

In this module we are first going to establish a definition and general understanding of impairment and then we will spend some time looking at impairment from a couple of perspectives including:

- Legal
- Medical/clinical

We will also discuss:

- Assessment for impairment
- High risk situations in OTPs
- Risk management strategies

### 3. TRAINER NOTE:

As we begin, it is important to clarify and define the terminology associated with impairment. Often times these terms are used interchangeably in everyday language; however, medically and legally there is a clear distinction between them. We will consider each of them individually.

- Impairment
- Intoxication
- Competence
- Informed consent
- Disability



## Legal Definition of Impairment



- A person's faculties are reduced so that his/her ability to see, hear, walk, talk and judge distances is below the normal level.
- Generally caused by drug or alcohol use.

## 4. TRAINER NOTE:

From the legal perspective impairment is:

A person's faculties are reduced so that his or her ability to see, hear, walk, talk and judge distances is below the normal level as defined by the state.

Impairment is generally caused by drug or alcohol use, but can also be caused by a medical disease state including mental illness.

Interestingly, even if a person's alcohol level is lower than the legal intoxication level, he can still be convicted if the state can show his abilities were impaired.



## Medical Definition of Impairment



Any abnormality of (partial or complete loss of), or loss of the function of a body part, organ, or system.

## 5. TRAINER NOTE:

A global definition of impairment from the medical perspective is as follows: Any abnormality of (partial or complete loss of), or loss of the function of a body part, organ, or system.



## Intoxication

### Medical Definition

- A pathologic state induced by an exogenous or, less commonly, endogenous toxic substance.

### Legal Definition

- A state in which a person's normal capacity to act or reason is inhibited by alcohol or drugs.
- An intoxicated person is incapable of acting as an ordinary, prudent and cautious person would act under similar conditions.

## 6. TRAINER NOTE:

Let's look at intoxication from both perspectives.

### MEDICAL DEFINITION:

- A pathologic state induced by an exogenous or, less commonly, endogenous toxic substance.

### LEGAL DEFINITION:

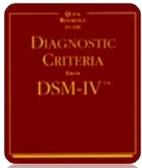
- A state in which a person's normal capacity to act or reason is inhibited (typically) by alcohol or drugs.
- An intoxicated person is incapable of acting as an ordinary, prudent and cautious person would act under similar conditions.

The law may allow intoxication to be used as a defense to certain crimes (i.e., "they were intoxicated so their judgment was impaired").

The underlying rationale is that the intoxicated individual cannot possess the requisite mental state necessary to establish the offense.



## Diagnostic Criteria Review



*Alcohol  
Sedative, Hypnotic,  
Anxiolytic  
Opioids  
Stimulants  
Hallucinogens*

## DSM-IV Criteria for Intoxication Alcohol

- A. Recent use of alcohol.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after alcohol use.
- C. One or more of the following:
  1. Slurred speech
  2. Incoordination
  3. Unsteady gait
  4. Nystagmus (eye movement)
  5. Impairment in attention or memory
  6. Stupor or coma
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

## 7. TRAINER NOTE:

Before we continue defining terms, we are going to review the common intoxicants with substance use disorders and their diagnostic criteria, as per the DSM-IV:

- Alcohol
- Sedative-hypnotic
- Anxiolytic: anti-anxiety, sleep aids
- Opioids: natural and synthetic prescription drugs
- Stimulants: cocaine, amphetamines
- Hallucinogens: phencyclidine, marijuana at high doses is included here

Muscle relaxants is a category not typically associated with substance use disorders; however, it is a medication that can be considered in terms of intoxication. In particular, Carisoprodol, commonly known as Soma, has recently been in the press due to a dramatic increase in emergency room presentations for adverse reactions and overdose.

There have been reports of intoxication due to a combinations of drugs, such as:

- Opioids-methadone
- Benzodiazapines

## 8. TRAINER NOTE:

Now we are going to take a closer look: DSM-IV Criteria for Intoxication: Alcohol

- A. Recent use of alcohol. There should be documented use of alcohol.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after alcohol use.
- C. One or more of the following:
  - (1) Slurred speech
  - (2) Incoordination
  - (3) Unsteady gait
  - (4) Nystagmus (eye movement which is discussed later)
  - (5) Impairment in attention or memory
  - (6) Stupor or coma
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.



### DSM-IV Criteria for Intoxication- Sedative, Hypnotic, Anxiolytic

- A. Recent use of a sedative, hypnotic or anxiolytic.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after sedative, hypnotic or anxiolytic use.
- C. One or more of the following:
  - 1. Slurred speech
  - 2. Incoordination
  - 3. Unsteady gait
  - 4. Nystagmus (discussed later)
  - 5. Impairment in attention or memory
  - 6. Stupor or coma
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

### DSM-IV Criteria for Intoxication Opioid

- A. Recent use of and opioid.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after opioid use.
- C. Pupillary constriction or pupillary dilation due to anoxia from severe overdose and one (or more) of the following signs, developing during, or shortly after opioid use:
  - 1. Drowsiness or coma
  - 2. Slurred speech
  - 3. Impairment in attention or memory
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

## 9. TRAINER NOTE:

DSM-IV Criteria for Intoxication: Sedative, Hypnotic, or Anxiolytic (drugs used for sedation, anti-anxiety, assist with sleep i.e., benzodiazapines)

- A. Recent use of a sedative, hypnotic or anxiolytic.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after sedative, hypnotic or anxiolytic use.
- C. One or more of the following: (You can notice there is overlap in the symptoms, they can look the same as alcohol).
  - (1) Slurred speech
  - (2) Incoordination
  - (3) Unsteady gait
  - (4) Nystagmus (discussed later)
  - (5) Impairment in attention or memory
  - (6) Stupor or coma
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.



## 10. TRAINER NOTE:

DSM-IV Criteria for Intoxication: Opioid

- A. Recent use of an opioid.
- B. Clinically significant maladaptive behavioral or psychological changes that developed during, or shortly after opioid use.
- C. Pupillary constriction (narrow pupils, “pinpoint”) or pupillary dilation due to anoxia (without oxygen-not breathing) from severe overdose and one (or more) of the following signs, developing during, or shortly after opioid use:
  - Drowsiness or coma
  - Slurred speech
  - Impairment in attention or memory
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.



## Opioid Intoxication

- Suspected when the clinical triad of CNS is present:
  - Depression (*lethargy, sedation, coma*)
  - Respiratory depression (*vital signs important*)
  - Pupillary miosis (*constriction*)
- Drowsiness
- Conjunctival injection (redness of the eye)
- Euphoria

## DSM-IV Criteria for Intoxication Stimulant

- A. Recent use of a stimulant.
- B. Clinically significant maladaptive behavioral or psychological changes (e.g., euphoria or affective blunting; changes in sociability; hypervigilance; interpersonal sensitivity; anxiety, tension or anger; stereotyped behaviors; impaired judgment; or impaired social or occupational functioning; that developed shortly after stimulant use.
- C. Two or more of the following, developing during, or shortly after stimulant use:

|                                       |  |
|---------------------------------------|--|
| 1. Tachycardia or bradycardia         | 6. Evidence of weight loss   |
| 2. Pupillary dilation                 | 7. Psychomotor retardation or agitation  |
| 3. Elevated or lowered blood pressure | 8. Muscular weakness, respiratory depression, chest pain, or cardiac arrhythmias |
| 4. Perspiration or chills             | 9. Confusion, seizures, dyskinesias, dystonias or coma                           |
| 5. Nausea or vomiting                 |  |
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

## 11. TRAINER NOTE:

Some of the symptoms that are characteristic with opioid intoxication:

- Intoxication is suspected when the clinical triad of CNS is present:
  - Depression (lethargy, sedation, coma), depressed level of consciousness
  - Respiratory depression (vital signs important)
  - Pupillary miosis (constriction)
- Drowsiness
- Conjunctival injection (redness of the eye)
- Euphoria

## 12. TRAINER NOTE:

DSM-IV Criteria for Intoxication: Stimulant

What would you see or observe and document with intoxication of a stimulant (cocaine, amphetamine)?

- A. Recent use of a stimulant.
- B. Clinically significant maladaptive behavioral or psychological changes note the difference (e.g., euphoria or affective blunting; changes in sociability; hypervigilance; interpersonal sensitivity; anxiety, tension or anger; stereotyped behaviors; impaired judgment; or impaired social or occupational functioning; that developed shortly after stimulant use.
- C. Two or more of the following, developing during, or shortly after stimulant use:
  1. Tachycardia or bradycardia
  2. Pupillary dilation
  3. Elevated or lowered blood pressure
  4. Perspiration or chills
  5. Nausea or vomiting
  6. Evidence of weight loss
  7. Psychomotor retardation or agitation
  8. Muscular weakness, respiratory depression chest pain, or cardiac arrhythmias
  9. Confusion, seizures, dyskinesias, dystonias or coma
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.



## Acute Stimulant Intoxication

### Adrenergic:

- Dilated pupils
- Diaphoresis (profuse sweating)
- Hypertension (elevated blood pressure)
- Tachycardia (increased heartbeat), with or without arrhythmia and chest pain
- Hyperthermia (elevated temperature)
- Bruxism (teeth grinding)
- Tremors
- Seizures

## DSM-IV Criteria for Intoxication Hallucinogens

- Recent use of hallucinogen.
- Clinically significant maladaptive behavioral or psychological changes (e.g., marked anxiety or depression, ideas of reference, fear of losing one's mind, paranoid ideation, impaired judgment or impaired social or occupational functioning) that developed during or shortly after hallucinogen use.
- Two or more of the following:
  - Pupillary dilation
  - Tachycardia
  - Sweating
  - Palpitations
  - Blurring of vision
  - Tremors
  - Incoordination
- The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

## 13. TRAINER NOTE:

Stimulant intoxication involves the adrenergic or sympathetic nervous system. You will see:

### Adrenergic:

- Dilated pupils
- Diaphoresis (profuse sweating)
- Hypertension (elevated blood pressure)
- Tachycardia (increased heartbeat), with or without arrhythmia and chest pain
- Hyperthermia (elevated temperature)
- Bruxism (teeth grinding)
- Tremors
- Seizures

## 14. TRAINER NOTE:

The last category we will look at is hallucinogens (phencyclidine, marijuana).

- Recent use of hallucinogen.
- Clinically significant maladaptive behavioral or psychological changes (e.g., marked anxiety or depression, ideas of reference, fear of losing one's mind, paranoid ideation, impaired judgment or impaired social or occupational functioning) that developed during or shortly after hallucinogen use.
- Two or more of the following:
  - Pupillary dilation
  - Tachycardia
  - Sweating
  - Palpitations
  - Blurring of vision
  - Tremors
  - Incoordination
- The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

*NOTE: Ask participants if there are any questions about the DSM-IV criteria just presented before moving on to the next topic area: competence.*



### Competence – Forensic Perspective

- Legal recognition of an individual's ability to perform a task.
- Directed at a specific category of demands, such as:
  - *competence* to assist counsel in preparing a defense
  - *competence* to manage financial affairs
  - *competence* to give informed consent in legal or medical matters

### Informed Consent – Forensic Perspective

- Authorization given by a person:
  - *free from coercion* or undue influence
  - has been *given adequate information* on the decision to be made
  - has the *capacity to understand* the information disclosed.
- An *incompetent patient* is *unable* to authorize informed consent.

### Disability

#### Forensic Perspective

- A physical or mental impairment that *substantially limits* one or more of the major life activities
- A *record* of such an impairment; or
- Being regarded as *having* such an impairment

#### Medical Perspective

- “Disability” is commonly used when an entity providing benefits ( e.g. insurer, Social Security) to those unable to work requires the treating professional to certify that the patient is disabled

## 15. TRAINER NOTE:

Let’s continue our discussion of terminology. We need to understand what is meant by competence from the forensic perspective (legal or related to the courts).

The legal recognition of an individual’s ability to perform a task: The concept is not applied globally, but it is the general consensus. Rather, it is directed at a specific category of demands, such as:

- Competence to assist counsel in preparing a defense.
- Competence to manage financial affairs.
- Competence to give informed consent in legal or medical matters.

A patient has to be competent in order to give consent.

## 16. TRAINER NOTE:

From a forensic perspective informed consent is:

Authorization given by a person who is free from coercion or undue influence, who has been given adequate information on the decision to be made, and who has the capacity to understand the information disclosed.

An incompetent patient is unable to authorize informed consent to admission when in distress. They are not able to give informed consent if they are not able to understand the treatment and the risks of treatment.

Think about the patients who come to your program. How does this concept apply? What examples can you give that demonstrate this concept?

## 17.

On this slide, we see a side-by-side comparison as to how “disability” is defined from two different perspectives.

From the forensic perspective disability is:

- A specific physical or mental impairment that substantially limits one or more of the major life activities.
- A record of such an impairment.
- Being regarded as having such an impairment.

In medical practice, “disability” is commonly used when an entity providing benefits ( e.g. insurer, Social Security) to those unable to work requires the treating professional to certify that the patient is disabled.



## Part II: Assessing Impairment: Medical/Clinical Perspective

### Common Triggers for Assessment

- History of recent prior episodes
- Induction period
- Smell of alcohol, +BAC, +UDS
- Reports from other patients
- Staff observation
- Aberrant behavior

### 18. TRAINER NOTE:

*NOTE: Before moving to this next topic, ask participants if they have any questions about the previous material covered. When the group is ready to move on, transition with a summary statement.*

We now have an understanding of the legal and medical perspectives of impairment, intoxication, competence, and disability. Next, we are now going to discuss how to assess impairment.



### 19. TRAINER NOTE:

There are a number of common triggers for assessment.

**History of recent prior episodes:** You may not have such history on a new patient, we will discuss this more in-depth later on in the module.

**Induction period:** The period of time when the patient is starting methadone. During the induction period, patients should be evaluated to assure they are not impaired. The induction period generally takes about two weeks (but can be as long as 4 weeks) for the patient's body to adjust. At that point you are able to witness tolerance to the medication.

**Smell of alcohol, +BAC (blood alcohol content), +UDS (urine drug screen):** Patients often use other substances, such as alcohol. Detection of alcohol (on their breath or through a urine screen) is a good indicator for assessment. Many programs use a breathalyzer to get a blood alcohol reading on the spot.

**Reports from other patients:** Patients will report other patients, and often you need to take it with a grain of salt, but that is a trigger.

**Staff observation:** This includes all staff not just the medical and clinical staff. Often times, support staff (receptionist, security) will note behaviors that should be followed up on and can be a trigger for assessment.

**Aberrant behavior:** Unusual behavior is a trigger for assessment.



## Other Etiologies for Impairment

- Medical condition or illness
- Drug–drug interactions involving medications
- Illicit substances use

## Adequate and Effective Assessment for Impairment

### Impairment Assessment

- Observation
- Respectful conversation, reason for evaluation
- Privacy and confidentiality
- Simple diagnostic testing: BAC, UDS
- Specific testing, MSE, MoCA, neurological exam
- Handwriting, signature
- Treatment plan review

## 20. TRAINER NOTE:

It is important to consider that the impairment may be due to other factors. For example, you need to rule out the possibility of a medical cause, even if you think it is due to intoxication or drug withdrawal.

Drug-drug interactions:

There are a number of drugs that when combined with methadone cause a reaction. There are two ways a drug-drug interaction impacts methadone:

- Drugs can speed up the patient’s metabolism affecting methadone and cause withdrawal. There are a number of drugs, both over the counter and prescription, that can do this such as stadol and buprenorphine.
- Drugs can act synergistically with methadone and cause sedation or cause increases in methadone levels (i.e., Luvox, even drinking a lot of grapefruit juice can impact the metabolism of methadone and increase levels).

Illicit substances are commonly the cause of intoxication or withdrawal, but make sure to rule out other causes, such as disease or injury.

*NOTE: Before leaving this topic area, address any lingering questions.*

## 21. TRAINER NOTE:

Our next topic is a logical next step: how to adequately and effectively assess for impairment.

## 22. TRAINER NOTE:

The information on this slide provides an overview of some considerations you will want to keep in mind when doing an assessment/examination.

Your assessment/examination begins with observation. Do you smell alcohol on the patient’s breath? Is his/her speech slurred? You will get an impression and then will make a decision on how you want to proceed. Observation is your index of suspicion.

Engage in respectful conversation to gain information and further promote the examination. Advise the patient why you are concerned and why the assessment needs to be done.



CONTINUED



Explain to the patient the reasons for assessment in a private and confidential manner. The patient should be taken aside and not confronted in front of other staff or patients. Always maintain privacy and confidentiality.

Staff will need to be trained on how to respond to impairment. You may choose to develop a script for staff to assure that the right thing is said at the right time and in a consistent manner throughout the agency. Train your nurses and physicians who will be doing the examination. Make sure you document when the training occurred and schedule recurrences of the training to assure that new staff is educated in a timely manner.

Make a decision as to whether you will perform additional diagnostic tests. This decision needs to be based on clinical report/data, not just staff or patient report. Simple diagnostic testing can be used:

- blood alcohol level
- breathalyzer
- instant kit for drug testing for a quick assessment (cannot be used for documentation upon assessment, but can be used in circumstances when you want a rapid assessment for recent use)

Use specific testing/instruments. The Montreal Cognitive Assessment (MoCA) has about 30 questions and is a tool in the public domain that can be used without permission. The mini mental status exam requires training and permission to use. You can use Blood Alcohol Concentration (BAC), Urine Drug Screen (UDS), and/or neurological exams.

A very easy assessment is to look at the patient's handwriting and/or signature. In some programs patients are required to sign-in for their day of service, and you can compare their signatures to previous service logs. You can ask a patient to write down their name and address when you are observing them privately. This can be very telling when a patient is really impaired.

The treatment plan should be reviewed. Maybe the patient is not getting the right level of service, or needs an increase or change in the level of care. The results of your examination should be reflected in the treatment plan.

For example: the documentation of take-homes (THs) is very important. If a patient's impairment is from withdrawal you will medicate and not alter their THs. If the impairment is suspected from illicit drug use their THs would be altered. The non-action and/or action should be documented in the treatment plan.

## What Areas Need to be Assessed?

### 23. TRAINER NOTE:

Ask participants, “when you do an assessment of impairment, what areas will you need to look at?” Add any of the following areas if participants fail to include it their recommendations.

- memory
- orientation
- judgment
- intellection capacity
- affect expression

Why do we assess these areas? These are the five areas affected by organic changes.

As we move through the next several slides, we will discuss these five areas to be included in the clinical exam.

(To help document each of these areas, the “Community Substance Abuse Center Impairment Assessment Tool” is available at <http://ireta.org/riskmanagement>.)



## Indicators of Intoxication / Impairment

- Central Nervous System functioning
- Autonomic Nervous System functioning



### 24. TRAINER NOTE:

Indicators of Intoxication / Impairment generally involve:

- Central Nervous System which is responsible for the body’s overall functioning.
- Autonomic Nervous System functioning (acts as a control system functioning largely below the level of consciousness.)

You are evaluating both of these systems.



## Mental Status Examination

- Appearance
- Attitude toward the examiner
- Mood
- Affect
- Speech
- Thought process
- Thought content
- Insight
- Judgment
- Impulsivity
- Reliability

### 25. TRAINER NOTE:

The major areas of a Mental Status Examination are:  
Appearance (their manner of dress and overall appearance)

Attitude toward the examiner: is the patient hostile?

Mood

Affect

Speech

Thought process

Thought content

Insight

Judgment

Impulsivity

Reliability

There are many sources and versions of forms that have mental status exams.



### Assess: Appearance and Attitude



- Physical and mental
- Overt and obvious
- Subtle

## 26. TRAINER NOTE:

Assess: Appearance and Attitude

- Physical and mental
- Many times it is overt and obvious
- However, often times it can be subtle

The more you get to know your patient, the more attuned you will be to seeing the subtle signs indicating an issue.



### Assess: Mood and Affect

- Euthymic-Dysthymic-Manic
- Angry-Irritable-Hostile
- Calm-Anxious-Panic
- Elated



## 27. TRAINER NOTE:

When addressing mood and affect, you are assessing how the patient is relating to you. Is he/she....?

- Euthymic-Dysthymic-Manic
- Angry-Irritable-Hostile
- Calm-Anxious-Panic

Many of our patients will do what we ask of them. They will follow the program and discontinue all medications, often abruptly. They are going to discontinue their opioid and we are going to replace that with methadone. Some of them may discontinue heavy use of alcohol, barbiturates, and benzodiazepines. Two or three days later, this may result in panic attacks, hyper-anxiety, and/or irritability which can be associated with withdrawal from sedatives. Mood and affect and the patient's expression of mood and affect are important in determining their organic state.

- Elated

Are they elated? Is this a bipolar patient who is off his/her medication because he/she was told to stop all meds? The patient has quit using lithium/depakote/seroquel and now is hyper-elated because he or she is having a manic swing.

It is important to evaluate the emotional expression of the patient.



### Assess: Speech



- Spontaneous
- Slow-Deliberate
- Slurring
- Rapid
- Illogical

## 28. TRAINER NOTE:

Assessing speech can be very helpful in determining the patient's organic state. If the patient is intoxicated from a sedative, his/her speech may be slow, deliberate, and/or slurring. If high on speed, methamphetamine, or amphetamine, the patient may speak rapidly. If the patient has been on a binge, he or she may be speaking illogically. You will look to see if the patient's speech is:

- Spontaneous
- Slow-Deliberate
- Slurring
- Rapid
- Illogical

The longer you have worked with a patient, the better you will be able to pick up on subtle differences or changes in his/her speech.



### Assess: Eyes

- Nystagmus

| Nystagmus             | Appearance   | May Indicate   |
|-----------------------|--|--|
| Horizontal Gaze (HGN) | Uneven movement of the eye in the horizontal direction in <b>both</b> directions | Sedative, hypnotic, anxiolytics (alcohol, barbiturates, benzodiazepines) |
| Vertical Gaze (VGN)   | Uneven movement of the eye in the vertical direction                             | phencyclidine (PCP), ketamine or even high dose morphine.                |
|                       | Uneven movement in <b>only one</b> direction and not the other                   | Inner ear issue  |

- Pupils constricted-Dilated-Uneven-Reactive

## 29. TRAINER NOTE:

There are some neurological tests that you will want to consider and put in your assessment document. You will document and track what is being evaluated and how the patient is doing. The following are some neurological tests that you may use. This is something you should have knowledge of even if you are not performing the assessment.

Nystagmus is rapid, involuntary movement of the eyes.

However, you do not just want to look for nystagmus, but you want to look for horizontal (lateral) gaze nystagmus. The horizontal gaze Nystagmus (HGN) is extremely important. Sedative, hypnotic, anxiolytics (alcohol, barbiturates, benzodiazepines) typically affect the eyes in such a way as to cause a nystagmus (uneven movement of the eyes in the horizontal direction in both directions). If it is in both directions equally-looking left and right- it is more likely to be a sedative, hypnotic, anxiolytic. So if you see this type of nystagmus, you need to assess for sedative, hypnotic, anxiolytic impairment.

When you have vertical gaze nystagmus (having the patient look up or down and you see nystagmus) you generally are dealing with phencyclidine (PCP), ketamine or even high dose morphine.

If you see nystagmus in only one direction, and not in the other, it could indicate an issue with the inner ear.



CONTINUED 

With alcohol there are several types of nystagmus. For example, when someone drinking very heavily tries to lay down, they begin to have vertigo (“the spins”). Their eyes will move back and forth-that is called positional alcoholic nystagmus. There is positional alcoholic nystagmus first phase, positional alcoholic nystagmus second phase, and rotary nystagmus. (IRETA offers the “Standardized Field Sobriety Test” which outlines how to administer the horizontal gaze nystagmus.)

Pupils constricted, dilated, uneven or reactive:

- Are the pupils constricted like they are supposed to be for someone on methadone?
- Are they dilated? Eyes should not be dilated if on methadone.
- Are they uneven? If they are uneven that generally is a neurological sign that is not good.
- Do they react when you shine a light in them?
- Are they slow to get smaller or non-reactive?

### Assess: Psychomotor Status

#### Sedated

- Unconscious
- Stuporous
- Conscious but drowsy
- Some psychomotor retardation

#### Alert

- Hyper alert
- Hyperactivity
- Cooperative
- Combative

### 30. TRAINER NOTE:

As you look at the psychomotor status of the patient, you want to keep in mind that impairment is not just on the sedative side.

Sedated: Is it retarded, slow?

- Unconscious
- Stuporous
- Conscious but drowsy
- Some psychomotor retardation: moves slow and speech is slow

Impairment can also be on the alert side:

- Hyper alert
- Hyperactivity
- Cooperative
- Combative



### Assess: Gait

- Walk-and-turn
- One-leg stand
- Romberg
- Finger to nose
- Heel to toe walking in a straight line (Sobriety Test)



## 31. TRAINER NOTE:

Gait is a very practical means of testing to evaluate impairment.

The WALK-AND-TURN is a coordination test. You have the patient walk heel to toe in a straight line, then tell him/her to turn around and walk back. You assess his/her level of coordination in following directions and maintaining balance.

The ONE-LEG STAND assesses the patient's ability to stand on one leg and maintain his/her balance.

The ROMBERG TEST is a coordination test. It tests the patient's ability to stand (without swaying back and forth) with feet together, hands at side with their eyes open. Then you have the patient close their eyes and maintain that posture without swaying or stepping to the side losing their balance. The Romberg is a good test to show motor impairment.

FINGER TO NOSE also tests the patient's coordination. You have a person stand with arms out, and have them close their eyes and bring their finger towards their nose.

HEEL TO TOE walking in a straight line, (Sobriety Test) is simple to do in a private setting. Ask the patient to start at the back of the room and walk heel to toe in a straight line to the front of the room. You will see that a patient who is impaired will not be able to do this test. This is a practical test that does not require a physician to administer.

Our discussion of how to administer these tests is brief. For more thorough descriptions of how to administer these tests using the "Clinical Sobriety Checklist" and the "Standardized Field Sobriety Test" visit the IRETA website at <http://ireta.org/riskmanagement>.



### Assess: Orientation



- Time
- Place
- Person
- Situation
- Space

## 32. TRAINER NOTE:

There are five levels of orientation. You will want to move from the micro to macro (micro-time, micro-place, micro-person to macro-time, macro-place, macro-person). Let's review what we mean by this:

|        |   |
|--------|---|
| Time   | What is today?<br>What month?<br>What year is it?             |
| Place  | Where are you?<br>What city is it in?<br>What state is it in? |
| Person | Who are you?<br>Who am I?<br>Who is that person?              |



CONTINUED 

**Assess: Memory**

- Immediate
- Remote
- Recent



**Assess: Vital Signs**



- Temperature
- Pulse
- Respirations
- Systolic BP
- Diastolic BP

Situation: the patient’s ability to orient themselves to the situation.

Why are you here?

What is going on?

Space is the patient’s ability to do a figure, such as the bender gestalt figure, MoCA, (Montreal Cognitive Assessment) or the mini mental status exam. The patient’s ability to write his/her name in a fluid manner is an important tool. It is good to have a sample of the patient’s non-impaired signature for comparison. The MoCA and the mini mental status requires patients to write a sentence, you could compare it with those.

**33. TRAINER NOTE:**

Memory is important to assess because with many of the drugs of abuse (alcohol, benzodiazepines, and barbiturates) a patient may have the ability to show immediate memory (i.e. you say “repeat 3,4,5” and the patient repeats back “3,4,5”).

The patient’s remote memory may be intact (i.e. they know how to get to the OTP; they know who you are).

However, the recent memory disturbance is a concern with those using alcohol, benzodiazepines, and barbiturates. You can ask the patient to repeat the numbers they repeated to you 5 minutes earlier, and the patient is unable to do so and may not remember you asking them.

Remember that certain substances will impair certain parts of the memory.



**34. TRAINER NOTE:**

Vital signs can be helpful, but are not “diagnostic.” When assessing vital signs during an impairment assessment you will look at:

**TEMPERATURE:** on methadone maintenance, body temperature will go down a little bit. There may be an increase in temperature if using stimulants.

**PULSE:** should go down if on the appropriate dose of methadone. If the pulse is rapid, it could indicate withdrawal or stimulants causing that impairment.

**RESPIRATIONS:** on methadone, the rate should be slower than the normal 12-16 respirations per minute. When dealing with opioids, if the respirations are markedly depressed (less than 12) it could be indicative of a potential overdose.



CONTINUED 

## 34. CONTINUED

**SYSTOLIC BLOOD PRESSURE:** should be within the normal range of 120 or less, unless the person has hypertension issues.

**DIASTOLIC BLOOD PRESSURE:** essentially should be under 80, higher may indicate anxiety, hypertension issues or stimulant abuse.

*NOTE: this marks the end of the discussion on assessment, before moving to the next topic, Impairment and Risk Management, ask participants if there are any questions before moving on.*



### Part III: Impairment and Risk Management

## 35.

### Impairment and RM

- Impaired patients **present potential danger** to themselves and others.
- Impaired patients are **prohibited** from:
  - Operating heavy equipment, machinery
  - Driving motor vehicles, automobiles, motorcycles, motorbikes, boats
- Suspicion of impairment should trigger a set of preemptive actions.

## 36. TRAINER NOTE:

We need to recognize an impaired patient presents potential danger to themselves and others if they do not restrict activities to those which can be done safely, and without significant risk of harm.

Regardless of source of impairment and the degree of impairment, impaired individuals are prohibited from operating heavy machinery. This includes automobiles and motorcycles (operating anything with a motor). The policy of no tolerance for impairment is strongly recommended.

Recent trends in insurance claims are showing an increase in wrongful deaths of patients in OTP/methadone treatment who were driving.

Suspicion of patient impairment can and should trigger a set of preemptive actions aimed at avoiding and minimizing the risk of potential harm to the patient and others. We will discuss some strategies as we move through this module.



## Impairment: High Risk Situations

- During the **induction process**
- **Drug-Drug interactions** with methadone involving illicit drugs and or prescribed medications:
  - Heroin, opioid pain relievers
  - Benzodiazepines
  - Alcohol
  - Cocaine
  - Other sedative-hypnotic medications
  - Muscle relaxants



## 37. TRAINER NOTE:

Although we have stated this several times, it cannot be stressed enough, impairment is a high risk situation.

From a RM perspective, impairment is more likely during the induction stage. Statistically, during the first two weeks of induction, patients have the highest risk of overdose and death. Some of the challenges faced during the induction period are:

Getting to know the patient. It can be a tremendous challenge medicating a new patient to relieve withdrawal without over medicating and subjecting the patient to overdose. Medicating is an art and necessitates experienced medical personnel to dispense.

Getting an accurate history. A challenge you as a provider face is that even though a new patient provides information at intake, you do not know that patient and you often are unable to verify their information.

A patient's attendance may be irregular and he/she may miss a dose(s). This makes it more difficult to titrate the patient's dose safely and get them to the point where the medication is effective.

Some common sources of impairment at induction:

- Not receiving enough medication and the patient is in withdrawal. The state of withdrawal can bring on impairment.
- Not receiving enough medication and patient self-medicates with illicit substances to relieve withdrawal.
- Overmedication due to a patient exaggerating their history of drug use.

Certain substances and medications taken in combination with methadone can also cause a patient to become impaired (drug-drug interactions).

- Heroin, opioid pain relievers
- Benzodiazepines
- Alcohol
- Cocaine
- Other sedative-hypnotic medications

Muscle relaxants: Point out to participants that there is a recent SAMHSA publication noting the problems related to Carisoprodol (Soma). "The Dawn Report" is available on the SAMHSA website. [http://www.samhsa.gov/data/2k11/WEB\\_DAWN\\_071/ED\\_Visit\\_Carisoprodol.pdf](http://www.samhsa.gov/data/2k11/WEB_DAWN_071/ED_Visit_Carisoprodol.pdf)



CONTINUED

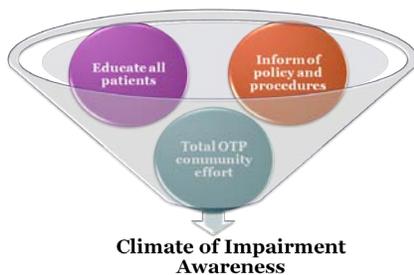
## 37. CONTINUED

### Prescribed Medications



- The impairment must be dealt with first
- Then the treatment plan can be amended to deal with the longer term issues

### Risk Management Strategy for Impairment



Stress to your patients the importance of informing:

- Medical providers about their methadone treatment
- The OTP staff about other medication being taken

Alcohol and benzodiazepines are among the most common substances taken with methadone that warrant heightened scrutiny for impairment. There is a greater likelihood of generalized anxiety disorders among methadone treatment patients than the general population. These anxiety disorders continue to exist during methadone treatment and may warrant a prescription of a benzodiazepine. However, an OTP needs to remember that there is a heightened risk of impairment when benzodiazepines and/or alcohol are combined with methadone.

## 38. TRAINER NOTE:

A patient may have a prescription for medication from an physician outside of the OTP. If there is evidence that there is impairment due to the medication interacting with the methadone:

- The impairment must be dealt with first in terms of medicating the patient.
- Then the treatment plan can be amended to deal with the longer term issues. The patient's prescribing physician needs to be contacted, and the patient needs to give consent to allow that process to take place.

## 39. TRAINER NOTE:

An universal risk management recommendation is to establish an environment, climate, or tone of impairment awareness in your agency/program.

In order to establish this environment, everyone at an OTP needs to be involved. So, how do you begin to go about doing this?

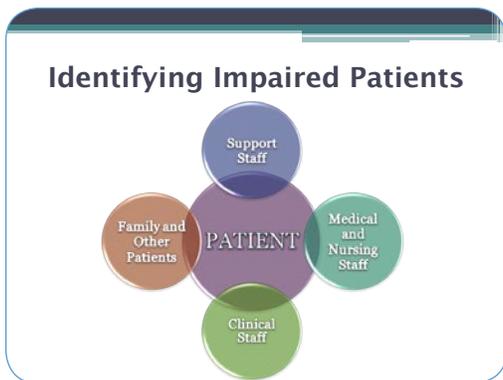
- Educate all patients regarding various sources and potential consequences of impairment. Many patients may not know the drug-drug interactions.
- Give patients resources so they can educate themselves.
- Invite them to ask questions about impairment.

OTPs and patients should familiarize themselves with reliable, updated resources regarding methadone interactions with other drugs. (See Addiction Treatment Forum's website [www.ATForum.com](http://www.ATForum.com)).



CONTINUED





Inform patients of the OTP’s impairment policies and procedures. These may include no tolerance for impairment and/or protocols for responding to suspicion of impairment such as deferring or denying methadone dosing. Patients need to know what to expect if they are impaired or if there is suspicion of impairment. Include patients when creating, revising, and drafting impairment policies and procedures; this will increase their buy-in.

It is a total OTP community effort to observe and report signs, symptoms and information regarding impairment in order to determine the safest, most appropriate course of action. Utilize all your resources, including patients.

#### 40. TRAINER NOTE:

As we said, it is a total OTP community effort to address and identify patient impairment and there are several opportunities within your OTP to do so.

Include members of the team who may not have responsibilities of direct client care. Utilize direct observation by your support staff who observe and interact with patients prior to dosing (e.g., fee collection, UAs, appt. scheduling, etc). These members have the opportunity to observe and report concerns of impairment.

Dosing nurses are the most important resource in identifying patient impairment. They have the opportunity to look for specific symptoms via interaction and observation before dosing (heightened observation during induction). Nurses are trained to identify symptoms and have the advantage of observing the patient closely. They are in close proximity of the patients and have conversations or smell alcohol on their breath.

Counselors and clinical staff are critical in identifying impairment. They have the benefit of knowing a patient’s current and past substance use history (i.e., UAs, etc).

Family and other patients are the most underused resource to help identify impairment. Educate families on the signs of impairment. Get other patients involved by:

- Removing disincentives and punitive consequences for identifying patient impairment, including patient’s own.
- Creating incentives for patients to share true information about patient impairment. Involve your patients to get their perspective when creating incentives.

Again, it cannot be over emphasized, identifying impairment requires a community effort, including patients in developing policies and procedures regarding impairment in the OTP is an important strategy not to be overlooked.



## Identifying Impairment: Reasonable Inquiries



- Conduct **regular inquiries** directly with **all** patients
- For **new patients** and **alcohol/substance abuser** verbal inquiries may not be enough

## 41. TRAINER NOTE:

The information in this slide points out some general legal standards in generic terms, not specific to any state. The generic advice for OTPs is to meet the “reasonable action” standard. Is this the reasonable thing to do? If you act unreasonably, you are more likely to be held responsible for the consequences. The following is recommended:

- Conduct regular inquiries directly with all patients as to what other substances and medications they are currently or have recently taken (e.g., in counseling and at dosing window, etc.). This practice needs to become the norm and explored routinely, not just done once at intake. You should not rely exclusively on UA because patients can manipulate the UA’s results.
- For new patients and patients struggling with alcohol/substance abuse (especially those with positive drug screens), verbal inquiry may not be sufficient to identify impairment or to meet the legal “reasonable action” standard. It is recommended that you validate with additional actions, such as an impairment assessment tool or other resources at your disposal.



## What are your RM options for Impairment during induction?



## 42. TRAINER NOTE:

In Module 2, we discussed risk management options, now we are going to look at those same options to specifically address impairment.

From a practical standpoint, risk treatment options that you adopt are going to be driven by the OTP’s resources. Many RM decisions are guided by what resources you have at your disposal to adopt a risk treatment plan. It is not expected that you would spend large amounts of resources on risks that are relatively minor. In the following slides, we outline some of the risk treatment options during induction. Please note that there can be many variations of these options.





### Impairment: Risk Treatment Options (Induction)

#### 1. Accept or assume all/some of the risk.

- Accept risk that new patients will experience impairment.
- Limit risk during induction by making patients remain at the OTP for the full first day, then reducing time.
- Impose a call-in process.



### 43. TRAINER NOTE:

Accept or assume all/some of the risk.

You are going to have new patients and there is some risk that they may experience impairment (either withdrawal symptoms or somnolent, lethargic) until tolerance is matched. However, you are willing to assume that risk because of your confidence in your medical staff and the individual treatment provided. This decision to assume risk is something that needs to be done consciously.

You may opt to assume the risk, but also to limit the risk. This could be done by making patients remain at the OTP for the full first day, then reducing their hours to half a day. This would allow the doctor to observe and assess the patients during their peak levels.

Or you may impose a call-in process to check patients over the first few days of induction.



### Impairment: Risk Treatment Options (Induction)

#### 2. Avoid risk- by abandoning or eliminating source of risk.

- Insist inductions be done inpatient
- Only accept stable patients



### 44. TRAINER NOTE:

You may choose to avoid risk by abandoning or eliminating the source of risk.

Insist all inductions be done in an inpatient treatment setting.

Only accept patients who are stabilized and are tolerant to their methadone dose.



### Impairment: Risk Treatment Options (Induction)

#### 3. Mitigation (Control Loss)

- reduce frequency, likelihood, severity and/or impact loss:

- Policy & Procedures
- Utilize patients as resources
- Delay dispensing medication
- Take reasonable action to assure the patient is transported safely



### 45. TRAINER NOTE:

Most of the risk treatment strategies deployed come from this option.

Mitigation (Control Loss): reduce frequency, likelihood, severity and/or impact of impairment related loss.

#### Policy and Procedures

When addressing risk during induction, often the risk treatment action comes from policy/procedures.

Implement an OTP wide policy of no tolerance for impairment in patients. It is critical that staff members and patients are aware of the no tolerance policy.

CONTINUED



## 45. CONTINUED

With input from patients, establish a policy and procedure for responding to suspicions of impairment. Patients need to know what to expect and what the consequences will be for impairment. As previously discussed, some impairment is not intentional or due to illicit substance use. Impairment may come from disease (epilepsy) or other sources that are not associated with patient malfeasance (wrong doing).

### **Utilize patients as resources to identify impairment**

Remove disincentives and punitive consequences for identifying impairment in others and self.

Create incentives for patients who share information about patient impairment. Ask your patients what would incentivize them to share impairment information.

### **Dispensing Medication**

Defer dispensing of a patient's medication until the OTP is confident the patient is not impaired or at risk of harm. Have impaired patients wait at the OTP and reassess using an assessment tool 4 hours later. If the patient's impairment risk still remains, refer to your OTP's policy/procedures. Often patients will leave instead of waiting around, and you would need to assess whether the patient is safe or at risk of harm (driving) and take appropriate action.

### **Patient Transportation**

At the OTP's closing time, take reasonable action to assure the patient is transported safely home. OTPs need to know their legal obligation to report to law enforcement if an impaired patient is intending to drive against medical advice (unmedicated but potentially impaired). OTPs need to know their state laws regarding reporting and confidentiality, and which law trumps the other. OTPs may want to utilize legal counsel to clarify their legal responsibility in these situations.

Impairment: Risk Treatment Options (Induction)

**3. Transfer Risk to a capable third party:**

- Informed Consent
- Refer to other facility



## 46. TRAINER NOTE:

### 3. Transfer Risk to a capable third party:

As we discussed in Module 2, you can transfer some of the risk to patients themselves through the informed consent process. Educate the patient about the risks associated with methadone induction and the pharmacology of methadone (this will be discussed in a later module). You also need to make sure your patient is competent to make true informed consent.

Refer patients to inpatient facilities for inductions.



## RM Decisions: Addressing Impairment

- Medicate
- Medicate and monitor
- Do not medicate and further monitor
- Do not medicate, arrange for transport home

## Cases Where OTPs Knew or Should Have Known...

- “Red flag” patient would drive while impaired
- Medicating knowing patient would drive impaired
- Evidenced ignored
- Benzodiazepine use (licit or illicit)

## 47. TRAINER NOTE:

To review, we have mentioned earlier you have RM treatment options to:

- Medicate
- Medicate and monitor: Have the patient wait 2-3 hours so that you can continue to observe and monitor.
- Not medicate and further monitor-have the patient wait and you can monitor to see if you want to medicate.
- Not medicate and arrange for transport home. It is helpful to get consent prior to impairment (intake), so you can contact someone to pick up the patient.

## 48. TRAINER NOTE:

*NOTE: The curriculum provides some actual cases where the OTP was held liable. (After you review a few of the following examples, perhaps you can solicit participants for additional examples, as time permits.)*

As we mentioned in Module 1, case law is extending liability to OTPs for harm caused by a patient’s impaired driving when there were plenty of “red flags” from which to reasonably conclude a patient would drive while impaired.

OTPs held liable:

- For medicating despite knowledge (actual or inferred) that a patient would drive while impaired.
- Failing to take action to prevent an impaired patient from driving.

OTPs have been charged with having knowledge and held liable when evidence of impairment was ignored (i.e. urine screens, reports of patient stumbling or unable to keep eyes open while in medication line). Always resort to the “reasonable action” standard by asking yourself, “What would be the reasonable action under the circumstances?”

Patients who use benzodiazepines with methadone are in the high risk category. If you have these types of patients in your program, you should:

- Have a policy whereby the patient signs a waiver allowing the OTP to talk to the prescribing physician. It should also include absolute prohibition against driving under the influence of benzodiazepines and methadone.
- Inform the patient of serious drug-drug interactions when taken with methadone and advise that they absolutely should not drive.

Obtain the patient’s consent that they were fully informed about the risk of operating heavy machinery.



CONTINUED 

## 48. CONTINUED

### OTPs' Duties: Addressing Impairment

**Duty to:**

- Inform (consent process)
- Warn
- Observe
- Assess/monitor
- Investigate polydrug issues
- Delay, defer or refuse dispensing methadone
- Assess and act if patient poses a foreseeable risk
- Report potentially dangerous situations



### Summary: Legal Standard

- OTPs must take all precautions and “reasonable action” to :
  - Assure a patient is **not impaired** prior to dosing
  - **Inform** the patient of the side effects
  - **Prevent** the impaired patient from driving
- OTPs have a **legal duty to take action** once impairment is identified

It is a state-by-state decision whether to allow third parties to sue an OTP. The legal system will look at “What are the facts.” If you have evidence of impairment, it cannot be ignored.

Even if impairment is only suspected, you need to take reasonable action and err on the side of caution. Do not medicate.

You have a duty to make a reasonable inquiry if you suspect impairment (falling asleep at the window, tripping over themselves).

You should have a policy of no tolerance for impairment in place. Patients must be aware that if impairment is suspected they will have to wait to be medicated. And they must agree to this policy.

## 49. TRAINER NOTE:

*NOTE: Use this slide to guide a summary of an OTP’s duties as discussed in this Module.*

- Inform (consent process).
- Warn if there is evidence of impairment that jeopardizes the safety of the public or others.
- Observe whether patient is impaired.
- Assess/monitor newly admitted patients and those known to abuse substances.
- Take reasonable investigatory steps to determine whether a patient has/had a poly-drug problem.
- Delay, defer or refuse dispensing methadone. If the patient is truly impaired, the patient should not receive their medication for the day. It needs to be a medical and clinical decision as to how to dose the patient.
- Assess whether a patient poses a foreseeable risk of danger to self and to third parties and to act reasonably to prevent the same.
- Report potentially dangerous situations (AMA) involving impaired driver/driving (to police and/or Department of Motor Vehicles (DMV)).



## 50. TRAINER NOTE:

OTPs must take proper /all precautions and use “reasonable action” to:

- Assure that a patient is not impaired prior to administration of methadone.
- Inform the patient of the side effects of medications prescribed or dispensed (a function of patient consent). Let them know that they need to establish time and tolerance and allow their body to adjust to methadone.



CONTINUED 

- Prevent the impaired patient from driving which may include reporting to local police/highway safety patrol &/or Department of Motor Vehicles. Check on your state regulations as they vary, but most states require that if you feel a patient is impaired, you should report that patient and prevent them from driving.

OTPs have a legal duty to take action once impairment is identified.

OTPs cannot bury their head in the sand and expect legal protection due to lack of knowledge. OTPs have been charged for ignoring evidence of impairment in “plain sight” or observed by others. Because the OTP should have known, it should have taken reasonable actions to intervene.

Liability of the OTP does not extend to patients who become intoxicated after leaving the OTP without providing the OTP any indication or reason to suspect impairment.

### Summary: Addressing Impairment

- Adopt a “No Tolerance” clinic policy for impairment with communication to patients
- Phased informed consents, release of information
- Discuss concerns privately, maintain confidentiality
- Diagnostic instruments / tools for assessment
- Staff training
- Document

### **51.** TRAINER NOTE:

In summary, this slide reviews some RM suggestions that we have discussed in this Module.

Have a clinic policy for no toleration of impairment AND communicate this policy to the patients regularly.

Use preparatory consents/release of information to involve the family should an impairment issue arise. It is important to have the consent before you have an issue with impairment. The patient will then know how the OTP will respond if impairment is suspected. Have a release of information to a prescribing physicians in case there are issues.

Privately discuss with the patient your concerns about impairment. The patient’s privacy and confidentiality always need to be maintained.

You need to have an understanding of diagnostic instruments and tools for assessing impairment.

Provide staff training and education that will help improve their competence regarding impairment.

Documentation is key. Document whenever there is an index of suspicion, even if the patient ends up not being impaired. Documentation should start from the moment when impairment is suspected. Reflect what action or non-action was taken in the treatment plan.



# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 5: Take-Home Medications**

## MODULE 5 – Take-Home Medications

TIME: 30 minutes

PURPOSE: Gain insight into the law regarding take-home medications.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Describe the eight point criteria for take-home medication.
2. Discuss restrictions and exceptions related to take-home medication.
3. Identify risk management strategies to address risks associated with take-home medications.

TOPICS:

- Federal criteria for take-homes
- Restrictions and exceptions
- Monitoring
- Risk management strategies
  - o Policies
  - o Toolkit

### KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

# Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

## MODULE 5 Take-Home Medication

### Take-Home Medication

- Medical Director responsibility
- Federal Regulation (42 CFR, Part 8 § 12(i)):
  1. Absence of recent drug and alcohol abuse
  2. Regular OTP attendance
  3. Absence of behavioral problems at the OTP
  4. Absence of recent criminal activity
  5. Stable home environment and social relationships
  6. Acceptable length of time in treatment
  7. Assurance of safe storage
  8. Rehabilitative benefits outweigh potential diversion risk

Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

## 1. MODULE 5

### 2. TRAINER NOTE:

In this module, we will discuss the issue of take-home medication. Take-home (TH) refers to unsupervised doses of medication being sent home with the patient. There are Federal and state regulations regarding THs. Additionally, specific guidelines and recommendations for OTPs are provided by SAMHSA. This module will explore the issues, criteria and recommendations for THs.

It is the medical director who has the ultimate responsibility in determining a patient's eligibility for THs. Regardless of how your program is structured, your medical director is accountable if there are any problems or issues related to THs.

This decision needs to be in accordance with the eight point criteria as specified in Federal Regulations (42 CFR, Part 8 § 12(i)). The patient must meet all of the eight criteria:

- Absence of recent drug and alcohol abuse.
- Regular OTP attendance including their dosing and clinical activities.
- Absence of behavioral problems at the OTP.
- Absence of recent criminal activity.
- Stable home environment and social relationships.
- Acceptable length of time in comprehensive maintenance treatment (we will review the criteria).
- Assurance of safe storage of take-home medication (there are guidelines).
- Determination that rehabilitative benefits of decreased OTP attendance outweigh the potential risk of diversion.



### Federal Guideline Take-Home Medication: Restrictions

| Length of Time                 | Months | Dose   |
|--------------------------------|--------|--|
| First 90 days                  | 1-3    | 1 dose per week                                  |
| Second 90 days                 | 4-6    | 2 doses per week                                 |
| Third 90 days                  | 7-9    | 3 doses per week                                 |
| Fourth 90 days                 | 10-12  | 6 days' supply per week                          |
| 1 year (continuous treatment)  | 13-24  | 2 weeks' supply                                  |
| 2 years (continuous treatment) | 25-36  | 1 months' supply, but monthly OTP visit required |

Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

### 3. TRAINER NOTE:

Once these clinical criteria are met, maximum TH doses must be further restricted based on length of time in treatment. The Federal Guidelines are outlined in this chart.

- First 90 days (months 1 through 3): one TH dose per week.
- Second 90 days (months 4 through 6): two TH doses per week.
- Third 90 days (months 7 through 9): three TH doses per week.
- Fourth 90 days (months 10 through 12): 6 days' supply of TH doses per week.
- After 1 year of continuous treatment: 2 weeks' supply of TH medication.
- After 2 years of continuous treatment: 1 month's supply of TH medication, but monthly OTP visits are still required.

The caveat here is these are the Federal Guidelines. States have sovereignty, so depending on what state your program is in there may be additional restrictions imposed. For example, in Pennsylvania the maximum supply that a patient can have is a 13 day supply, they must be in treatment a minimum of 3 years, AND there has to be a specific reason why.



### Take-Home Medication: Exceptions



- OTP closed and holidays
- Medical conditions
- Rehabilitative potential
- Emergency circumstances
- State & Federal requirements
  - State approval/coordination
  - SAMHSA SMA-168 form
- SAMHSA
  - "Dear Colleague" letters
  - Guidelines for Accreditation

Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

### 4. TRAINER NOTE:

There are other clinical considerations when deciding whether THs are appropriate for the patient. Despite the stringent requirements, there are some special situations when exceptions may be appropriate. SAMHSA's TIP 43 provides information regarding exceptions for TH medication.

According to a Federal provision, any OTP patient may receive a single TH dose for a day when the OTP is closed for business, including Sundays and State and Federal holidays. However, the patient still must meet the criteria.

When a patient is being evaluated for the criteria, the assessment does allow for clinical judgment to be used. This means that even though a patient may meet the eight point criteria, the physician can deny eligibility based on their clinical judgment. The physician may decide that the patient is not responsible enough or the benefit of the THs do not outweigh the potential risk. In these situations an OTP may utilize other options, such as having another medical facility or OTP administer the medication to ensure the patient is dosed under medical supervision.



CONTINUED

You may have patients with concurrent medical conditions or disease which may keep them from attending treatment at the OTP. Or their medical condition may cause complications and/or a potential medication interaction. In these situations the OTP should consider applying for medical exceptions for patients who would not otherwise be permitted to receive THs.

The OTP would need to make this request using the Substance Abuse and Mental Health Services Administration (SAMHSA) form SMA-168, Exception Request and Record of Justification. Form SMA-168 is available at <http://ireta.org/riskmanagement>.

Another clinical consideration is when a patient starts a new medication treatment that is known to interact with opioid treatment. The patient's TH dose may need to be adjusted. THs should be avoided until the patient is stable on the new medication and the risk for interaction is no longer there.

It is important to have frequent monitoring of patients with concurrent medical conditions.

THs are a consideration when it is likely to help rehabilitate a patient. For example, THs may enable patients to engage in employment, education, child-care, or other important endeavors.

Unscheduled THs may arise during emergency situations or unforeseen circumstances such as:

- Personal or family crises
- Bereavement
- Medical, family, or employment

The OTP's policies should explain who can request exceptions, and how it is done. Courtesy dosing at a distant OTP can generally be arranged for unstabilized patients who are traveling. An OTP can facilitate emergency or hardship access to medication for a patient by submitting SAMHSA form SMA-168.

OTPs need to comply with State and Federal requirements and procedures. As we have already mentioned, to request an exception there are forms that need to be utilized which are available through SAMHSA. There is an online form (SMA-168 form: Exception Request and Record of Justification) making it very easy to put in the request for exception. In many cases, the state and Federal approval is coordinated at the same time. SAMHSA also provides guidance with procedures regarding THs.

SAMHSA issued a "Dear Colleague" letter January 24, 2008 specifically addressing TH medication. This letter reiterated the importance of using clinical judgment in determining eligibility for THs. The Federal Guideline states a patient MAY receive a single TH when the OTP is closed for business.



CONTINUED 

## 4. CONTINUED

### Take-Home Medication: Monitoring

- Review the rationale
- Drug Testing
- PDMP review
- Review of all prescriptions
- Attendance for counseling



Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

However, this letter stresses that OTPs should not interpret this provision extends to all patients. The patient still needs to meet the criteria and the medical director's clinical judgment for eligibility.

The letter is available on the IRETA website at <http://ireta.org/riskmanagement>.

Additionally, SAMHSA's Guidelines for the Accreditation of Opioid Treatment Programs (<http://www.dpt.samhsa.gov/pdf/OTPAccredGuidelines-2007.pdf>) provides elaboration on this issue, under Chapter 2, section V, titled "Unsupervised Approved Use" (Take-Home Medication).

## 5. TRAINER NOTE:

Patients often have THs as a goal in their treatment. Patients should not automatically get THs, even if they have been in the program a certain length of time and their drug screens are negative.

Often times the rationale is not clearly documented. The rationale for providing take-home medication should be reviewed regularly and documented to determine whether initial justifications continue to apply. For example:

- A patient may have received an exception for the purpose of an employment opportunity; the patient's continued employment should be routinely verified.
- A medical disorder was the basis for an exception; a medical reassessment to determine whether the status of the disorder continues to warrant reduced OTP attendance.

The monitoring process also should include an assessment of whether medical, psychological, or social reasons exist to rescind these privileges.

A physician should periodically review the status of every patient provided with take-home medication.

Monitoring should ensure that patients with TH medication privileges are not using illicit drugs and are consuming their medication as directed. This can be done through drug testing and it should be comprehensive. It should test for common drugs of abuse such as benzodiazepines, marijuana, and alcohol. It is the consensus of experts that THs are inadvisable for the patient who uses illicit drugs or misuses prescription medication. A patient's eligibility for THs should be reviewed when testing or assessment indicates illicit substances or misuse of his/her methadone medication.

CONTINUED 



## 5. CONTINUED

Something that is new which you may not be aware of comes from a recent SAMHSA “Dear Colleague” letter regarding OTPs and prescription drug monitoring programs (PDMP). In this communication, it is advised that physicians and nurse practitioners use these programs. There are some states that have excellent PDMP, whereby you can access patient information regarding what prescriptions they have and who is prescribing.

This information can be very helpful in detecting “doctor shopping” or polydrug prescribing. Sometimes doctors are not aware that the patient is on methadone and prescribes an opioid or benzodiazepine. PDMPs are very helpful in providing this information. If you do not have this kind of program in your area, sometimes the patient’s managed care program can provide you with information related to pharmacy records as they are paying for the patient’s medications. You can coordinate and check this information to help inform your clinical decisions.

There should be a review of all prescription medication. It is good to have a policy that requires the patients to bring their medications in to the physician and the clinical staff to review and DOCUMENT in the patient’s record. Further, there should be a patient consent to the prescribing physician for collaboration.

Patients are required to maintain full attendance for their counseling services. They need to have full adherence to counseling even if it is an outpatient group that meets once a month.

### Take-Home Medication: Legal



Federal regulation permits THs for patients; however, it **does not** absolve the OTP of their legal responsibility.

## 6. TRAINER NOTE:

Federal Regulations permit OTPs to circumvent usual take-home criteria for all patients on Sundays and holidays when the OTP is closed. However, this regulation does not absolve OTPs of their legal responsibility and duties to patients and foreseeable third parties.

The OTP still has the duty to make sure all patients handle medication responsibly and meet criteria. Just because it states “all” patients does not mean all patients automatically get TH privileges.



## Take-Home Medication: Policies

- The TIP 43 recommends the following diversion control policies:
  - Return empty bottles
  - Procedure for those who fail to return bottles
  - Stay open 7 days a week



Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

## 7. TRAINER NOTE:

The TIP 43 recommends the following diversion control policies for take-home medication:

- Require patients to return all empty dose bottles on their next OTP visit after TH dosing. Staff who accept these bottles should inspect them to verify that they are from the indicated patient during the appropriate period of time.
- Institute procedures for responding to patients who frequently fail to return or have unverified reasons for failing to return empty take-home bottles. TH privileges should be reconsidered for these patients.
- Stay open 7 days a week for dispensing medication. This allows the OTP to provide TH doses for stable patients who have a record of adherence to treatment, and the ability to monitor those who do not meet criteria and are otherwise ineligible for THs.



## Take-Home Medication: TOOLKIT



- Conduct “call-backs”
  - Monitor take-home medication
- Home safety inspections
  - Case management staff
- Locked containers
  - Not a total guarantee for safety

Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

## 8. TRAINER NOTE:

It is good to have a policy to monitor patients’ take-home medication by imposing a “bottle recall or call back” procedure where patients are randomly asked to come in with their medication for review and documentation. With a pill count or callback procedure, the patient who has THs receives an unannounced phone call and must show up at the OTP within a reasonable period (e.g., 24 to 36 hours) with all medications. The number of pills remaining must correspond to the number expected based on prescribed ingestion. Some programs send the bottles off for quantitative review to make sure the patient has not tampered or substituted a liquid that would appear to be their take-home medication.

In some cases it may be helpful to conduct random home safety inspections to ensure TH medication is stored properly. There can be an issue with privacy, but many programs have case management staff go to the patient’s home. They are able to see how the patient stores the medication, if there are children in the home, and they can document if there are any issues.

It is strongly advised that patients use a locked container or storage boxes when they pick up and transport THs. It is suggested that the OTP randomly check to make sure the lock box functions.

It is not a guarantee for safety. There was a case where a grandmother stored her lock box under the bed. The OTP had it documented that they dispensed all of her medication in a locked container. However, she forgot to lock it one day. One of her grandchildren found the medication, consumed it and had an overdose.



## Take-Home Medication: TOOLKIT

- Screen for patients who:
  - Have children
  - Are using/abusing substances
- Policies to address treatment interruptions:
  - Travel
  - Illnesses or disabilities
  - Bereavement / funerals
  - Emergencies
  - Hospitalizations



Clinical Pharmacology, Chapter 5, (TIP) Treatment Improvement Protocol #43.  
<http://www.ncbi.nlm.nih.gov/books/NBK25944/>

## 9. TRAINER NOTE:

Screen patients who:

- Have children in their home. OTPs need to have increased diligence about protecting them from harm and assuring safe use of medication. Encourage patients to keep medications in a locked cabinet away from the reach of children. Educate them on how to take medication safely. Advise them not to drink medicine in front of children since they tend to mimic the adults around them.
- Screen for patients who are using/abusing substances. Not only do these patients present risk for drug interaction, but they are more vulnerable /higher risk to sell their medication. There have been cases where patients were charged criminally for selling medication.

Have policies to address treatment interruptions, such as:

- Travel
- Illnesses or disabilities
- Funeral
- Emergencies
- Hospitalizations

## 10. TRAINER NOTE:

To summarize our discussion of the material in this module:

- You need to evaluate patients carefully for THs. A patient being evaluated for TH privileges will need to meet the eight point criteria and the physician's clinical judgment for eligibility. It also needs to be in coordination with your state requirements, as they can be more restrictive than the Federal Guidelines.
- Just because there is Federal provision for exceptions, that does not mean all patients qualify for THs. The patient must meet the criteria. This is a clinical decision as to whether the patient will benefit AND that benefit outweighs the risks of misuse/diversion.

The medical director has ultimate responsibility and accountability for any actions related to take-home medication.

The rationale for providing take-home medication should be reviewed regularly and documented to determine whether initial justifications continue to apply. Is the patient still benefiting from the "lack of supervision?" Monitoring should ensure that patients with TH medication privileges are not using illicit drugs and are consuming their medication as directed. As always, there needs to be good documentation.



## In Summary

- Criteria for eligibility
  - State and federal criteria
  - Clinical judgment
- Medical Director responsibility and accountability
- Monitor, reassess and document



# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 6: Case Studies**

## MODULE 6 – CASE STUDIES

TIME: 60 minutes

PURPOSE: Explore three case studies highlighting cardiac, take-home and induction concerns.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Discuss how risk may present in their OTP.
2. Identify situations and red flags for risk.
3. Describe the “road map” of methadone and steady state.

TOPICS:

- Torsades de Pointe
- Take-home medication
- Induction
  - o Steady state
  - o Methadone dose equivalent effect

## KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

# Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

## MODULE 6 Case Studies

### Case Studies Overview

- Case Study 1 – Admission / Induction
- Case Study 2 – Take-Home Medication
- Case Study 3 – Cardiac Arrhythmia

### Case I: Admission / Induction

## 1. MODULE 6

### 2. TRAINER NOTE:

This module provides us an opportunity to apply all the information that we have discussed thus far. The three cases that we are going to be working with are actually real cases.

Case Study 1 – Admission / Induction

Case Study 2 – Take-Home Medication

Case Study 3 – Cardiac Arrhythmia



### 3.

## Mary: Presenting Information

Mary is 28 years old



"I need to get clean. I'm tired and run down and I don't want to be a drug addict for the rest of my life because I know it's going to kill me."

## 4. TRAINER NOTE:

*NOTE: Before presenting these cases, have the participants break into small groups. Use your discretion as to the size and mix of groups.*

*The following information will be provided in a handout to the participants. Have them refer to this handout as you review the presenting information.*

Let's look at Mary's presenting information.

### PATIENT SUMMARY:

Mary is a 28 year old female who presented to an opioid treatment program.

### CHIEF COMPLAINT:

"I need to get clean. I'm tired and run down and I don't want to be a drug addict for the rest of my life because I know it's going to kill me."



## History of Present Illness

- Onset of drug abuse as a teenager
- Intravenous "opiates" during past 5 yrs
- Oxycodone, "drug of choice", heroin substitute
- Denied use of "opioid" drugs for the past week and admitted withdrawal symptoms.
- Symptoms had resolved and denies any for past three days.

## 5. TRAINER NOTE:

### HISTORY OF PRESENT ILLNESS:

Mary admitted using opioids intravenously for the past five years. Her substance of choice is OxyContin, but when she can't access OxyContin, she uses heroin. She began drug use as a teenager and has used other drugs including alcohol, marijuana, cocaine, benzodiazepines, ecstasy and LSD. She admitted smoking cigarettes, 1 pack per day (PPD) for 15 years.

Upon intake she denied using any opioids for the past week. She admitted withdrawal symptoms of sweats, chills, restlessness, sleep disturbance, daytime fatigue, and loose stools. However these symptoms had resolved and she denied withdrawal symptoms for the past three days.



## Past History of Treatment

- Several admissions for inpatient and outpatient
- Unable to sustain abstinence longer than 2-3 months
- History of treatment for “depression”
- “Self medicating” by increasing her drug use

## Mary: Presenting Information

- Mary’s physical exam revealed:
  - Vital signs within normal limits
  - Scattered scarring on her arms and hands
  - No fresh puncture wounds visible
- Mary’s UDS was negative for:
  - Amphetamines
  - Barbiturates
  - Benzodiazepines
  - Cocaine
  - Opioids
  - Methadone and methadone metabolites



## 6. TRAINER NOTE:

**PAST TREATMENT HISTORY:** Mary admitted to several admissions for inpatient and outpatient detoxification. Despite participation in 12-Step Meetings, she was unable to sustain abstinence for longer than two or three months. Mary admitted a six month period of sobriety several years ago after she relocated to another state to live with her aunt and uncle.

**PSYCH HISTORY:** She admitted a history of treatment for “depression” and was evaluated by two psychiatrists within the past three years; she admitted previous prescription for Prozac, Celexa and Wellbutrin but they were ineffective and she had discontinued the medications. She admitted to “self medicating” her symptoms by increasing her drug use.

**REVIEW OF SYSTEMS (ROS):** Except for her previously noted resolved withdrawal symptoms, her ROS was only remarkable otherwise for weight loss of ~ 5lbs within the past 6 months regarding physical complaints.

**MENTAL STATUS EXAMINATION:** Remarkable for feelings of sadness and depression, described as moments of “darkness” when she “didn’t believe there was a point to her suffering” and while she had considered overdosing, she had not found the “strength” to act upon it. Mary stated she found some comfort in her religion, and the Catholic church.

## 7. TRAINER NOTE:

**PHYSICAL EXAMINATION:**

Mary was examined by the nurse practitioner. Her physical examination revealed:

- Vital signs within the normal limits
- Skin was smooth, warm and moist
- Arms and hands revealed scattered scarring consistent with injection marks
- No fresh puncture wounds or abscess formation was visible
- Her sclera were mildly injected (red) and pupils slightly dilated
- Nasal mucosa appeared mildly erythematous (red and inflamed)
- Remainder of her focused physical examination was unremarkable

**LABORATORY RESULTS:**

Urine toxicology screen at intake was negative for amphetamines, barbiturates, benzodiazepines, cocaine, opioids, methadone and methadone metabolites. This was the drug screen sent to the lab. They also did a dipstick test which was positive for benzodiazepines.



## Mary: Treatment Plan

### Preliminary Treatment Plan:

- The physician's statement for documentation of current physiological dependence upon opioids was completed and signed.
- Mary was recommended for admission to opioid maintenance treatment.

Are There Any Red Flags With the Presenting Information?

## "Red Flags"

- Diagnosis of Opioid Dependence
- Documentation of current physiological dependence upon opioids
- UDS results
- Examination findings



## 8. TRAINER NOTE:

### PRELIMINARY TREATMENT PLAN:

The physician's statement for documentation of current physiological dependence upon opioids was completed and signed. This is a requirement, there must be a physician statement documented and signed stating "current physiological dependence upon opioids." It is documented in different ways—a form, in the history and physical, or at the end, but nonetheless it needs to be documented and signed prior to admission to an opioid treatment program.

The patient was recommended for admission to opioid maintenance treatment because her lack of minimal family and community support which places her at high risk for relapse.

## 9. TRAINER NOTE:

*NOTE: At this point, give the groups a couple of minutes to discuss this question. It is suggested that you have one group respond and have the other groups add in any additional concerns they identified that the previous group had not mentioned.*

The slide that follows lists several "red flags."

- Are there any red flags with the presenting information?

Other possible discussion points:

- What do you think about this preliminary treatment plan? Was there really enough information for an appropriate diagnosis for treatment?
- Based on the presenting information, should Mary be admitted?

## 10. TRAINER NOTE:

Diagnosis of Opioid Dependence: It is a **requirement** to have opioid dependence; use diagnostic criteria to determine.

Documentation of current physiological dependence upon opioids: You should be knowledgeable regarding the signs and symptoms of opioid withdrawal. These symptoms indicate that the patient is currently physiologically dependent. Mary did not report significant withdrawal symptoms.

Urine Drug Screen results to support the use: Mary's UA did not come up positive for opioids. This should warrant further investigation and cause for concern.

Examine findings to support the dependence.



| Clinical Opiate Withdrawal Scale  |   | Leave one (0) blank; Type Date, Time   |
|---|---|--|
| <b>Respiratory Pulse Rate:</b><br>Measured after patient is sitting or lying for one minute<br>0 pulse rate 80 or below<br>1 pulse rate 81-100<br>2 pulse rate 101-120<br>3 pulse rate greater than 120   | <b>Diarrhea:</b><br>0 No GI symptoms<br>1 Stomach cramps<br>2 Nausea or loose stool<br>3 Vomiting or diarrhea<br>4 Multiple episodes of diarrhea or vomiting  | <b>Score:</b><br>5-12 = mild<br>13-24 = moderately severe<br>25-36 = moderately severe<br>more than 36 = severe withdrawal |
| <b>Temperature:</b> over past 15 hour not accounted for by room temperature or patient activity<br>0 no report of chills or flushing<br>1 subjective report of chills or flushing<br>2 flushed or observable redness on face<br>3 beads of sweat on brow or face<br>4 visible sweating off face   | <b>Tremor:</b> observation of outstretched fingers<br>0 No tremor<br>1 tremor can be felt, but not observed<br>2 slight tremor observable<br>4 gross tremor or muscle twitching   |  |
| <b>Restlessness:</b> Observation during assessment<br>0 able to sit still<br>1 reports difficulty sitting still, but is able to do so<br>3 frequent shifting or substantial movements of legs/arms<br>5 Unable to sit still for more than a few seconds   | <b>Yawning:</b> Observation during assessment<br>0 no yawning<br>1 yawning once or twice during assessment<br>2 yawning three or more times during assessment<br>4 yawning several times/minute                                       |  |
| <b>Pupil size:</b><br>0 Pupils normal or normal size for room light<br>1 pupils possibly larger than normal for room light<br>2 pupils moderately dilated<br>5 pupils so dilated that only the rim of the iris is visible   | <b>Anxiety or irritability:</b><br>0 none<br>1 patient reports increasing irritability or anxiousness<br>2 patient obviously irritable/anxious<br>4 patient so irritable or anxious that participation in the assessment is difficult |  |
| <b>Shivers or joint aches:</b> if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored<br>0 not present<br>1 mild diffuse discomfort<br>2 patient reports severe diffuse aching of joints/muscles<br>4 patient is rubbing joints or muscles and is unable to sit still because of discomfort | <b>Sweatiness skin:</b><br>0 skin is smooth<br>3 pilorection of skin can be felt or hairs standing up on arms<br>5 prominent pilorection  |  |
| <b>Runny nose or tearing:</b> Not accounted for by cold germs or allergies<br>0 not present<br>1 nasal discharge or unusually moist eyes<br>2 nose running or tearing<br>4 nose constantly running or tears streaming down cheeks   | <b>Total Score:</b> _____<br>The total score is the sum of all 11 items completing Assessment: _____  |  |

## 11. Trainer Note:

Many programs use the Clinical Opiate Withdrawal Scale (COWS) to determine opioid withdrawal. It is a convenient method to document what was observed and get a diagnostic number which puts it in a range of severity.

For example: if you had a patient with severe withdrawal they would have:

- Beads of sweat on their forehead
- Very restless, fidgeting, unable to sit still, restless leg syndrome
- Pupils would be very dilated
- Complaints of joint pain
- Runny nose
- Severe stomach cramps or vomiting—they may have to excuse themselves during the process
- Yawning more than 1 or 2 times
- Very anxious
- Goosebumps when you palpate the backs of their arms

*NOTE: Ask the small groups to look over the scale and score where they think Mary would be based on the presenting information provided.*

Based on the information from her intake, Mary would be at the low end of this scale, around a 5 which is a mild form. Mary had already gone through the worse part of withdrawal.

Is methadone treatment Mary's best option? As we discussed previously, providing patient education about treatment options is very important.

There are going to be patients that your OTP should not take. Methadone treatment is not the only option for treatment. If you do good informed consent, there will be patients that do not opt for methadone treatment.



Upon admission, Mary was started on methadone.

## 12. TRAINER NOTE:

Let's continue with Mary's case. Upon admission, Mary was started on methadone.



### Mary's Induction Schedule

Mary's dosing schedule per standing orders:

|       |          |                     |
|-------|----------|---------------------|
| Day 1 | Thurs.   | Methadone dose 30mg |
| Day 2 | Fri.     | Methadone dose 40mg |
| Day 3 | Sat.     | Methadone dose 50mg |
| Day 4 | Sun.(TH) | Methadone dose 60mg |
| Day 5 | Mon.     | Methadone dose 65mg |

### Mary: Induction

#### Day 1

- Mary was started on a dose of 30 mg methadone with a standing order to increase 5 to 10 mgs daily.

#### Day 2

- Mary received a dose of 40mg of methadone

#### Day 3

- Mary reported withdrawal symptoms
- Mary received an increased dose of 50 mg
- Mary given TH 60 mg for **Day 4**, Sunday

## 13. TRAINER NOTE:

At this particular program they had standing orders.

Mary was admitted towards the end of the week. The standing orders for her methadone dosing were as follows:

|       |           |  |
|-------|-----------|--|
| Day 1 | Thurs.    | Methadone dose 30mg  |
| Day 2 | Fri.      | Increased methadone dose 40mg  |
| Day 3 | Sat.      | Increased methadone dose 50mg  |
| Day 4 | Sun. (TH) | All patients receive TH. Mary's dose was increased to 60mg (The clinic is closed on Sunday.) |
| Day 5 | Mon.      | Increased methadone dose 65mg  |

## 14. TRAINER NOTE:

Day 1

- Mary was started on a dose of 30 mg methadone with a standing order to increase 5 to 10 mgs daily up to a maximum dose of 80 mg.
- There were no symptom indications to guide the dose increases.

Day 2

- Mary received a dose of 40mg of methadone.

Day 3

- Mary reported withdrawal symptoms.
- Mary received an increased dose of 50 mg.
- Mary was given her TH 60 mg.

Review of Systems (ROS):

Except for her previously noted resolved withdrawal symptoms, her ROS was only remarkable otherwise for weight loss of ~ 5lbs within the past 6 months regarding physical complaints.

Mental Status Examination:

Remarkable for feelings of sadness and depression, described as moments of "darkness" when she "didn't believe there was a point to her suffering" and while she had considered overdosing, she had not found the "strength" to act upon it. Mary stated she found some comfort in her religion, and the Catholic church.



## Mary: Complications

### Day 4

- TH dose 60 mg

### Day 5

- Mary reported no withdrawal symptoms and did not want an increase
- Mary was noted to be slightly unsteady on her feet
- Mary given 65 mg of methadone as per standing orders

### Day 6

- Mary was a no show
- Counselor made outreach call and was informed Mary passed away the day before.

## Mary: Autopsy

An autopsy was performed 48 hrs after Mary's death. The report stated:

- The Circumstantial Cause of Death, due to pulmonary edema secondary to methadone intoxication
- The forensic toxicology report indicated high levels of methadone and methadone metabolites

## 15. TRAINER NOTE:

Day 4.

- The clinic was closed on Sundays and as per regulations, the clinic customarily gave all patients Sunday take-home medication.

Day 5

- Mary reported that she was no longer experiencing withdrawal symptoms, and that she did not want an increase because she did not want to be like those “other patients on high doses.”
- Mary was noted to be slightly unsteady on her feet at the dispensing window.
- The dispensing nurse recommended to Mary to adhere to the standing order protocol and not to worry. She told her she needed to be on an adequate dose to stabilize and stop using. She encouraged her to take her dose as ordered and further increased Mary's dose of methadone to 65 mg.

Day 6

- Mary was a no-show.
- The counselor made an outreach call and was informed that Mary had passed away the day before.

## 16. TRAINER NOTE:

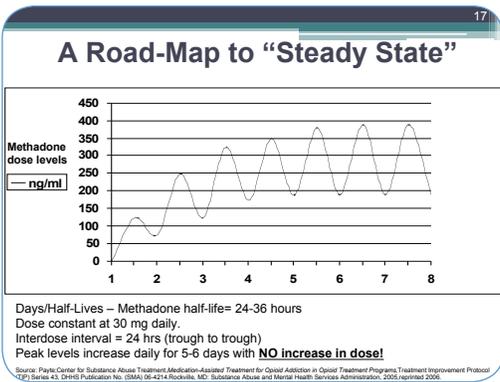
An autopsy was performed 48 hrs after Mary's death. The report stated:

- The Circumstantial Cause of Death due to pulmonary edema (which is classic of opioid intoxication) secondary to methadone intoxication.
- The forensic toxicology report indicated high levels of methadone and methadone metabolites, there were no other drugs present.

If someone had looked at Mary's pupils they would have been narrow which would indicate toxicity versus withdrawal.

There are a number of symptoms that can result from either too much or too little methadone. Too little will cause nausea and the patient will throw up, too much will cause nausea and the patient will throw up. How can you tell the difference? Look for other indicators: in one instance, the pupils will be 1mm; in the other, the pupils will be 7mm. Having qualified medical staff trained in what they need to look for is critical to RM.





## 17. TRAINER NOTE:

To understand induction we must understand the half-life and steady state pharmacology (“build-up”) of methadone. This “road map” can be used with staff and patients to educate about the induction process with methadone. You can see the trough, the peak, the trough, the peak, and there is a steady rise until about day 4 or 5 where it starts to level out. This is with a constant dose and **NO** increases (30 mg on day 1 and 30 mg on day 5). This reflects the accumulative or build-up effect of methadone.

Half-life of a drug is the time needed to eliminate half a dose. Assuming a 24 hour half-life, about half of the recent dose will still be in circulation 24 hours after the dose.

With half the dose still present at 24 hours, the same dose will result in a significantly higher peak level, particularly on days 1-3.

Here you see the daily peaks and troughs with a significant increase in the peaks, with **NO** increase in dose. Most of the increase in serum methadone levels (SMLs) take place during the first 3 days.

The rate of increase decreases as steady-state is approached. This takes about 5 half-lives (5-7 days). The longer the half-life the longer it takes to reach steady state, a rule of thumb is it takes 5 half-lives.

With a half-life of 48 hours it could take 10 days to reach steady state. Methadone half-life can vary from 15 to 55 hours.

Without increasing the dose on a daily basis, the peak level will continue to increase automatically over time.

Methadone is not a typical opioid. It is an outlier as demonstrated by this road map. Other opioids have very different road maps. Unfortunately, many physicians do not know this.

You have to remind patients that how they feel with methadone is not going to feel the same as when they were using their drugs. Many of your patients have high levels of pain and are accustomed to using their drugs (opioid, benzodiazepines) to disassociate with their pain—even to the point of reaching levels of unconsciousness. So although they are feeling sedated from the methadone, they may report they are not on enough and still feel sick. However, if you keep on increasing their dose you can have disastrous consequences.



## Methadone Dose “Equivalent Effect”

- Day 1 Thurs Methadone dose 30mg 30mg
- Day 2 Fri Methadone dose 40mg 55mg
- Day 3 Sat Methadone dose 50mg 77.5mg
- Day 4 Sun (TH)Methadone dose 60mg 98.75mg
- Day 5 Mon Methadone dose 65mg 114.37mg
- Day 6 Tue No Show

Methadone “dose equivalent effect” due to accumulative effect of tissue buildup

## 18. TRAINER NOTE:

Now that we understand the induction process better, let’s look at Mary’s dosing schedule and what the equivalent effect was:

- Day 2 she had an increase of 10 mg (40 mg) resulting in 55 mg “accumulative effect”
- Day 3 she had an increase of 10 mg (50 mg) resulting in 77.5 mg “accumulative effect”
- Day 4 she had an increase of 10 mg (60 mg) resulting in 98.75 mg “accumulative effect”
- Day 5 she had an increase of 5 mg (65 mg) resulting in 114.37 mg “accumulative effect”

As you look at these doses you can see that they are high, especially considering this patient had mild withdrawal symptoms. As we discussed earlier, it is important to have documentation that the patient has current physiological dependence upon opioids and recognize the criteria.

Other non-medicated options might have been a better fit for this patient. She had made it past the worst of her withdrawal. Because of her mild withdrawal and negative urine, alternative dosing would have been appropriate, such as 10-20 mg with close observation.

Go “low and dose slow” is a great practice. The fear with this practice is that the patient will experience more withdrawal symptoms and use substances. However, many patients will report that they had symptoms, but they were able to tolerate the withdrawal and not use.

Let your patients know they will experience some withdrawal symptoms. Show them and explain to them the “road map” we just went over so they will have a better understanding of their treatment. Even if you gave them a high dose on the first day, they are going to feel sick when they get to their trough level. Let the patients know that on the first day they are going to feel better for a couple hours, on the second day they are going to feel better for 4-5 hours.



## Induction: Summary

- Everyone is responsible for best practice and risk management
  - Thorough, comprehensive assessment
  - Establish diagnosis “current physiological dependence upon opioids”
- Avoid standing orders
  - Dear Colleague letter from Dr. Clark in Sept. 4, 2007
- Observe and document carefully
- START LOW and GO SLOW
- Respond to patient complaints and changes in status

## 19. TRAINER NOTE:

Everyone is responsible for best practice and risk management:

- Provide a careful and thorough assessment of the patient.
- Establish a diagnosis of opioid dependence based upon documentation of “current physiological dependence upon opioids.” You should not be in a rush to admit patients unless you are truly confident that they are physiologically dependent based on their physical presentation, their history of use, and you have some way to confirm that. It is required that you have evidence or information that the patient has been physiologically dependent for a year.

Standing orders are not considered best practice. Given what is known about the need for individualized care and patient safety, especially with those first doses, it could almost be considered negligence to use standing orders. In this day and age, using the same dose with all patients will get you into trouble. CSAT provided guidance and caution against standing orders with their *Dear Colleague Letter* (Sept. 4, 2007). This letter stressed the importance of:

- OTP physician responsibility to individualize methadone administration.
- Knowledge of the pharmacology of methadone in particular the pharmacokinetic and pharmacodynamic properties.

*NOTE: Advise participants that if they have not read the letter, it is recommended that they do so. The letter is available on the IRETA website at <http://ireta.org/riskmanagement>.*

Observe your patients and document:

- Observe the patient 4 hours after dose to observe the peak effect
- Use phone monitoring to have the patient check in to explore symptoms
- Use family’s involvement to help observe
- Don’t just document if it is abnormal
- Document when doses are changed
- Document how you can get in touch with a physician should you have concerns and need an assessment

“Start Low and Go Slow” Start at a low dose and go slow. Guidelines state that you can start at 30 mg, but not every patient requires that. You do not start at 30, 40, 50, 60 mg because that ignores the pharmacology of methadone that we just discussed. Doctors need to review the pharmacology of methadone.

CONTINUED 



## 19. CONTINUED

The culture around methadone treatment has been to “dose and go,” we need to change this. We need to educate patients that they may need to wait versus just getting their dose and going.

Work with the patient and develop a partnership:

- Respond to their complaints and issues. – Have policies in place that assure patient complaints and issues are adequately assessed and addressed.
- Explore patient expectations. – Educate your patients about what to expect, such as peak and trough and that they will not be relieved of their withdrawal symptoms immediately.

### Case II: Take Home Medications

## 20. TRAINER NOTE:

Let’s take a look at a case that involves take-home medication.



### Stan: Presenting Information

Stan is a 35 y/o AAM

- Long history of snorting heroin/oxycontin
- Titrated to methadone 120 mg
- Requested THs due to work hardship
  - Given 5 TH doses per week by week 4
  - First 2 UAs negative



## 21. TRAINER NOTE:

Let’s look at the presenting information for this case.

Stan is a 35 y/o African American male with a long history of snorting heroin/oxycontin.

Stan was admitted to the program and titrated to methadone 120 mg over the first 2 weeks and tolerated it well.

After Stan brings a letter from his employer about needing to be at work at 6:00am which was in conflict with the clinic hours, a request was made by FDA/State authority for unscheduled TH medication due to work hardship.

Stan was given five TH doses per week by week four.

First two UAs negative for substances of abuse.



## Stan: Complications

- By month 3:
  - Stan had missed several counseling appointments
  - 1 week later his UA is positive for oxycodone
  - Stan had a party and a 21 year old died after taking Stan's methadone
  - Lawsuit brought against OTP

## 22. TRAINER NOTE:

By month 3:

Stan had missed several counseling appointments. He would reschedule his appointments, then would not be able to make them and reschedule again.

One week later his UA was positive for oxycodone. The clinic did stop his TH at this point.

That same week, Stan was accused of providing methadone at a party which resulted in the death of a 21 year old. He claimed that someone went into his bedroom, found his methadone and took it.

A lawsuit was brought against the OTP for allowing TH doses with evidence of noncompliance.

*NOTE: Before disclosing the actual outcome of the case, ask the groups to discuss and come to a decision as to the outcome based on the limited information provided. Ask a representative of one of the small groups to give a brief summary of their finding. Solicit remaining groups for anything additional that they may have discussed that the first group did not consider. After a brief discussion, report the outcome of the case:*

The OTP clinic was not held liable, however, the court did find Stan to be liable.

What protected the clinic during this lawsuit?

- Excellent policy and procedures in place to prevent “foreseeable action.”
- Good documentation.
- Warnings were given when he missed the counseling appointment.
- THs were discontinued when his UA came up positive for oxycodone, however the event took place around the same time.
- The patient was liable in this case because he did not store his medication out of the reach of others.



### Take-Home Medication: Summary

- Follow policy and procedure
  - Receive all TH bottles at next visit
  - Random callbacks, (quantitative)
  - Urine drug screens on patient with expanded TH (hardship)
- Explore alternatives to lower risk and make the OTP work better for the patient
  - Change hours
  - Open 7 days
- What is the clinic's responsibility to third parties?

### Case III: Cardiac Arrhythmia Torsades de Pointes (TdP)

## 23. TRAINER NOTE:

Based on what we have discussed thus far in the training, let's quickly review a summary of best practices regarding TH medication.

- Follow your OTP's policy and procedures.
- Receive all TH bottles at next visit.
- Make random callbacks and bottle counts.
- Perform urine drug screens on patient with expanded TH (hardship).

Explore alternatives to lower risk and make the OTP work better for the patient.

- Many clinics are changing their hours to accommodate patients who work. Opening at 5:00am allows patients to get their methadone and get to work on time. If this clinic had been opened earlier Stan would not have required TH medication.
- Another alternative is to open the clinic 7 days a week. On these extended days, OTPs do not need to keep normal business hours (it may just be a two hour window). This would allow patients who are not stable to be supervised during their dosing.

What is the clinic's responsibility to third parties? The legal system will look to see:

- Was the risk of harm foreseeable?
- Did the OTP take reasonable action to prevent harm?

Make sure your reasonable action is done consistently and document it. While there may be a patient who wants THs due to employment issues, the risk to the OTP may be too great to approve THs for that patient.

## 24. TRAINER NOTE:

The last case we are going to discuss involves cardiac arrhythmia more specifically called Torsades de Pointes (TdP). For those that are not physicians, this is a life-threatening, abnormal heart rhythm.

*Note: There is no handout for this third case presentation. It is a presentation about the medical facts related to Glenn's case and a brief description of the medical outcome. There is no small group work related to this case. This case study provides the trainer with the opportunity to share information related to the medical condition: Torsades des Pointes.*



## Glenn: Presenting Information

Glenn is a 36 y/o white male

- Methadone dose - 300 mg
- Transferred to a new program
- No cardiac history
- No other medications
- Physical exam:
  - Marfanoid habitus
  - Bronchitis
  - The remainder of exam was normal
- Father with heroin addiction
- Dose increases began at 25-35 mg



## 25. TRAINER NOTE:

Let's look at the presenting information of this case.

- Glenn is a 36 y/o white male who was on methadone 300 mg
- Transfers to new program insisting “meds aren’t holding”
- No cardiac history
- On no other medications

Physical exam

- Marfanoid habitus (features of Marfan’s syndrome such as long limbs and fingers, hyper-flexibility of joints)
- Bronchitis
- Physical exam within normal limits

Family history

- His father had a heroin addiction and required > 500mg of methadone

Glenn’s dose increases began at 25-35 mg



## Glenn: Treatment

- November
  - 435 mg
  - Feeling “10% better”
- February
  - 600 mg
  - Feeling “30% better”
  - Dilated pupils at trough
- March –
  - 660 mg
  - Feeling “50% better”
  - Call from the ER -ventricular tachycardia (TdP)

## 26. TRAINER NOTE:

As Glenn progressed through his treatment, he received slow increases in his doses. His dosing schedule looked as follows:

- November– he was on 435 mg of methadone and his peak/trough = 532/135. Stated he felt 10% better and pushes for an increase.
- February– he was on 600 mg and reported feeling “30% better.” At trough he was examined and the clinical evaluation indicated dilated pupils, and it was felt he was in withdrawal. The physician continued to increase his methadone dose.
- March– he was on 660 mg peak/trough 860/344), feeling “50% better.”

OTP received a call from the ER, Glenn was experiencing ventricular tachycardia (TdP) with grand mal seizure presentation.



## Glenn: Complications

- Glenn continued to have repeated episodes of ventricular tachycardia
- Over the next few days:
  - Methadone reduced over next 4 days to 100 mg every 6 hours
  - Glenn received an Intra Cardiac Defibrillator (ICD) and temporary pacemaker
  - Ongoing withdrawal symptoms
    - Dose increased, but resulted in ongoing firing of ICD

## Glenn: Outcome

- Ultimately Glenn's treatment results in:
  - 420 mg of methadone with complaints of withdrawal symptoms
  - Gradual increase in dose to 600 mg
  - Dose remains at 600 mg with 1-2 episodes monthly of the ICD firing

## Torsades de pointes (TdP): Summary

- Cases of torsades de pointes (TdP) are rare
- Mostly associated with methadone >200 mg
- QTc may be prolonged
  - Some have occurred with normal QTc
  - Majority of prolonged QTc do not result in cardiac problems
- CSAT convened a Cardiac Expert Panel in 2008 to provide recommendations for QTc Interval Screening in Methadone Maintenance Treatment, final published report is pending

## 27. TRAINER NOTE:

Glenn continued to have repeated episodes of ventricular tachycardia. His EKG results were QTc=580 msec (anything above 500 is potentially dangerous). He was admitted to ICU.

Over the next few days:

- Methadone was reduced over next 4 days to 100 mg every 6 hours.
- Glenn received an Intra Cardiac Defibrillator (ICD) and temporary pacemaker along with medical management. His QTc was 520 msec.
- Glenn reported ongoing withdrawal symptoms at the 400 mg. His dose was increased, but resulted in ongoing firing of ICD.

## 28. TRAINER NOTE:

Ultimately Glenn's treatment results in:

- 420 mg with complaints of ongoing withdrawal symptoms. Glenn continued to state "the meds are not holding."
- Very gradual increase in dose (in consultation with the cardiologist) to 600 mg.
- Glenn remains on 600 mg with 1-2 episodes monthly of the ICD firing despite several anti-arrhythmic medications. It was concluded that the methadone caused a molecular variation in his heart.

## 29. TRAINER NOTE:

In summary:

- Cases of Torsades de Pointes (TdP) are rare, and are mostly associated with methadone doses greater than 200 mg.
- QTc interval (specific segment of the EKG) may be prolonged (greater than 440).

But there have been some cases that have occurred with normal QTc (Less than or equal to 440).

- Overwhelming majority of prolonged QTc cases do not result in cardiac problems.
- CSAT issued guidelines for monitoring this issue, but there are enormous controversies. CSAT convened a Cardiac Expert Panel in 2008 to provide recommendations for QTc Interval Screening in Methadone Maintenance Treatment, final published report is pending.



### Torsades de pointes (TdP): Summary

- AATOD recommends a thorough exam including:
  - Patient's history
  - Family's history
  - Physical exam
- Ask your patients if they have:
  - Any heart related symptoms, problems
  - Fainting spells
  - Palpitations
  - Unexplained seizures
  - Family history of any of the above
  - Other drugs that can prolong QTc intervals.
- If risk factors present, order an ECG

## 30. TRAINER NOTE:

The American Association for the Treatment of Opioid Dependence (AATOD) has made some good recommendations. They recommend that you do a thorough exam of the patient's history, family history and a physical exam.

Ask patients if they have:

- Any heart issues
- Fainting spells
- Palpitations
- Unexplained seizures (i.e., ventricular tachycardia)
- Family history of any of the above

Other drugs prescribed can prolong QTc intervals. This list is increasing, including cardiac and psychotropic medication, such as Zyprexa, Seroquel, SSRI in high doses. You may need to look at switching a patient's meds to one that does not cause the increase.

If risk factors are present, order an EKG. It is not cost effective to do EKGs on all of your patients. As we look at this case in particular, Marfan's syndrome was an indicator for an EKG to be done. If you have an indicator to do an EKG and the resulting QTc is less than 300:

- Proceed with moderate changes
- Observe the patient with each dose change

If the levels start getting higher, it becomes an informed consent issue. The patient has the ultimate decision. Inform the patient that even if the QTc gets over 500 an ill effect is extremely rare.

One way to think about the risk of Torsades is if a patient decides to use heroin/oxycontin they are at risk of an overdose or getting arrested. That risk may be a greater risk to them than Torsades.



## **MODULE 6: CASE STUDY II - MARY**

### **PATIENT SUMMARY:**

Mary is a 28 year old female who presented to an opioid treatment program.

### **CHIEF COMPLAINT:**

“I need to get clean. I’m tired and run down and I don’t want to be a drug addict for the rest of my life because I know it’s going to kill me.”

### **HISTORY OF PRESENT ILLNESS:**

Mary admitted using opiates intravenously for the past five years. Her substance of choice is OxyContin, but when she can’t access OxyContin, she uses heroin. She began drug use as a teenager and has used other drugs including alcohol, marijuana, cocaine, benzodiazepines, ecstasy and LSD. She admitted smoking cigarettes, 1PPD times 15 years.

Upon intake she denied using any opiates for the past week. She admitted withdrawal symptoms of sweats, chills, restlessness, sleep disturbance, daytime fatigue, and loose stools. However these symptoms had resolved and she denied withdrawal symptoms for the past three days.

### **PAST TREATMENT HISTORY:**

Mary admitted to several admissions for inpatient and outpatient detoxification. Despite participation in 12-Step Meetings, she was unable to sustain abstinence for longer than two or three months. Mary admitted a six month period of sobriety several years ago after she relocated to another state to live with her aunt and uncle.

### **PSYCH HISTORY:**

She admitted a history of treatment for “depression” and was evaluated by two psychiatrists within the past three years; she admitted previous prescription for Prozac, Celexa and Wellbutrin but they were ineffective and she had discontinued the medications. She admitted to “self medicating” her symptoms by increasing her drug use.

### **REVIEW OF SYSTEMS (ROS):**

Except for her previously noted resolved withdrawal symptoms, her ROS was only remarkable otherwise for weight loss of ~ 5lbs within the past 6 months regarding physical complaints.

### **MENTAL STATUS EXAMINATION:**

Remarkable for feelings of sadness and depression, described as moments of “darkness” when she “didn’t believe there was a point to her suffering” and while she had considered overdosing, she had not found the “strength” to act upon it. Mary stated she found some comfort in her religion, and the Catholic church.

### **PHYSICAL EXAMINATION:**

Mary was examined by the nurse practitioner. Her physical examination revealed:

- Vital signs within the normal limits
- Skin was smooth, warm and moist
- Arms and hands revealed scattered scarring consistent with injection marks

- No fresh puncture wounds or abscess formation was visible
- Her sclera were mildly injected (red) and pupils slightly dilated
- Nasal mucosa appeared mildly erythematous (red and inflamed)
- Remainder of her focused physical examination was unremarkable

#### **LABORATORY RESULTS:**

Urine toxicology screen at intake was negative for amphetamines, barbiturates, benzodiazepines, cocaine, opioids, methadone and methadone metabolites. They also did a dipstick test which was positive for benzodiazepines.

## **MODULE 6: CASE STUDY II - STAN**

#### **PATIENT SUMMARY:**

Stan is 35-year-old African American male with a long history of snorting cocaine and heroin.

Stan was admitted to the program and titrated to methadone 120 mg over the first two weeks and tolerated it well.

#### **COMPLICATION:**

After Stan brings a letter from his employer about needing to be at work at 6:00 am, which was in conflict with the clinic hours, a request was made by FDA/State authority for unscheduled take-home medication (TH) due to work hardship.

By week four, Stan was given five doses of TH medication per week.

#### **LABORATORY RESULTS:**

Stan's first two urine analyses (UAs) were negative for substances of abuse.

#### **TREATMENT COMPLIANCE:**

By month three, Stan had missed several counseling appointments. He would reschedule his appointments, then not be able to make them and reschedule again.

One week later his UA was positive for oxycodone. The clinic did stop his take-home doses at this point.

That same week, Stan was accused of providing methadone at a party, which resulted in the death of a 21 year old. He claimed that someone went into his bedroom, found the methadone, and took it.

A lawsuit was brought against the OTP for allowing TH doses with evidence of noncompliance.

# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 7: Recovery-oriented Methadone Maintenance (ROMM)**

# MODULE 7 – Recovery-oriented Methadone Maintenance (ROMM)

TIME: 60 minutes

PURPOSE: To explore efforts to increase the recovery orientation of medication-assisted treatment.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Define and discuss ROMM.
2. Describe at least four milestones in the history of medication-assisted treatment of opioid addiction.
3. Define “recovery” in the context of ROMM.
4. Identify at least five changes of service practices within ROMM.
5. Discuss three broad strategies for reducing stigma attached to medication-assisted treatment of opioid addiction.

TOPICS:

- Define recovery-oriented methadone maintenance
- Milestones in methadone maintenance treatment
- Medication and recovery
- ROMM and changing service practices
- Stigma as an obstacle to ROMM
- Strategies to address professional and social stigma

## KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

## Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

MODULE 7  
Recovery-oriented Methadone Maintenance

### Learning Objectives

1. Define and discuss ROMM
2. Report at least 4 milestones in the history of medication-assisted treatment of opioid addiction
3. Define “recovery” in the context of ROMM
4. Identify at least 5 changes in service practices within ROMM
5. Discuss 3 broad strategies for reducing stigma attached to medication-assisted treatment of opioid addiction

### Recovery-oriented methadone maintenance

Recovery-oriented methadone maintenance (ROMM) is an approach to the treatment of opioid addiction that combines methadone pharmacotherapy and a sustained menu of professional and peer-based recovery support services to assist patients and families in initiating and maintaining long-term addiction recovery (White & Torres, 2010).

## 1. MODULE 7

In this module we will explore efforts to increase the recovery orientation of medication-assisted treatment. The material presented here is drawn from the monograph *Recovery-oriented Methadone Maintenance* by William White and Lisa Mojer-Torres.

### 2. TRAINER NOTE:

By the time we finish this discussion, you should be able to:

1. Define and discuss ROMM,
2. Report at least four milestones in the history of medication-assisted treatment of opioid addiction,
3. Define “recovery” in the context of ROMM,
4. Identify at least five changes in service practices within ROMM, and
5. Discuss three broad strategies for reducing stigma attached to medication-assisted treatment of opioid addiction.

### 3. TRAINER NOTE:

Recovery-oriented methadone maintenance (ROMM) is an approach to the treatment of opioid addiction that combines methadone pharmacotherapy and a sustained menu of professional and peer-based recovery support services to assist patients and families in initiating and maintaining long-term addiction recovery. This approach flows out of efforts to extend current approaches to addiction treatment toward a model of assertive and sustained recovery management (RM) and to wrap these RM approaches within larger recovery-oriented systems of care (ROSC).

*NOTE: If questions come up on RM & ROSC, you can define them as follows.*



CONTINUED 

Recovery management (RM) is 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. It is an alternative to the ever-briefer acute care models of addiction treatment. 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 treatment agency but a macro level organization of a community, a state or a nation.

*NOTE: Ask participants if they are aware of RM and ROSC initiatives? Are you aware of any of these initiatives that involve medication-assisted treatment and related recovery support services?*

In this module we will explore the historical emergence of calls for ROMM, changes in service practices that accompany ROMM and professional and social stigma as a barrier to ROMM.



#### 4. TRAINER NOTE:

Treatments for opioid addiction prior to the 1960s included institutionalization, exotic and sometimes lethal withdrawal procedures, electro- and chemo-convulsive therapies, and prefrontal lobotomies—all followed by exceptionally high relapse rates that generated impetus for new approaches to treatment. Methadone maintenance (MM) was pioneered in 1964 by Dr. Vincent Dole, Dr. Marie Nyswander, and Dr. Mary Jeanne Kreek at Rockefeller Institute for Medical Research (now Rockefeller University) and Rockefeller Hospital. Following early studies on its safety and effectiveness, MM was integrated into multi-modality treatment systems in New York, Illinois, Connecticut, Massachusetts, Pennsylvania, and Washington D.C. and then more widely disseminated in the 1970s within a growing national network of addiction treatment programs in the United States.

Early practices (later confirmed to be linked to enhanced recovery outcomes) included rapid access, emphasis on therapeutic alliance, individualized doses capable of achieving “blockade” effects (average of 80-120 mg), therapeutic response to continued drug use, no arbitrary limits on duration of treatment, use of recovery peers as staff, and medication within a broader menu of medical, psychiatric and social services. These practices declined through the 1970s and 1980s, criticisms of MM increased, and MM became increasingly focused as a social policy on crime control and management of infectious disease rather than a person-centered medical treatment.



#### Methadone Maintenance Milestones

Ineffectiveness of pre-MM treatment of opioid addiction  
1964: MM introduced by Drs. Dole, Nyswander & Kreek  
\* Early recovery orientation  
MM regulation & diffusion in 1970s and 1980s  
MM Critics & Backlash

## Methadone Maintenance Milestones

MM revitalization since 1990s

- \* Scientific re-validation
- \* Quality improvement within OTPS
- \* Medication alternatives
- \* Continued challenges of stigma

Rise of MAT patient advocacy

Calls for ROMM

## 5. TRAINER NOTE:

Since the early 1990s, there has been a revitalization of MM in the United States that has included:

- 1) The scientific reaffirmation of the effectiveness of MM;
- 2) Increased advocacy efforts by MM patients;
- 3) An expansion of national MM treatment capacity—most notably within the private sector;
- 4) National efforts to professionalize and elevate the quality of Opioid Treatment Programs (OTPs); and
- 5) An expansion of pharmacotherapy choices in the treatment of opioid addiction, e.g., buprenorphine/Suboxone/Subutex.

These developments occurred amidst renewed efforts to publicly and professionally portray opioid addiction as a brain disease that can be medically managed with the aid of methadone and other pharmacotherapies. In spite of such advancements, resistance and hostility toward methadone continue from many quarters. Three trends are reshaping the future of MM in the United States:

- 1) A clearer articulation of addiction as a chronic disorder that is best treated through methods used to manage other chronic disorders;
- 2) The emergence of recovery as an organizing paradigm for the addictions field; and
- 3) Calls to develop models of recovery-oriented methadone (and other medication) maintenance.

## 6. TRAINER NOTE:

Methadone patients continue to be socially marginalized, and their recovery status continues to be debated—even within the professional field of addiction treatment and within communities of recovery. The question of the recovery status of methadone patients cannot be answered without a clear understanding of what constitutes recovery from opioid addiction.

*NOTE: Pose the following questions for discussion by the group.*

1. What are the defining elements of recovery?
2. What are the implications of this definition or these elements for persons addressing their addiction with the aid of maintenance medications?

## Medication and Recovery Status

Growing consensus that:

- Recovery is more than intent to stop drug use
- Recovery is more than absence of drug use
- Recovery is both a process and a status



## Recovery Definition

Multiple consensus efforts have defining three central components to recovery from severe substance use disorders: 1) sobriety/abstinence/remission, 2) progress towards global health, and 3) positive community re-integration.

## Recovery and Methadone and Buprenorphine

*“...formerly opioid-dependent individuals who take naltrexone, buprenorphine, or methadone as prescribed and are abstinent from alcohol and all other nonprescribed drugs would meet this definition of sobriety.” --Betty Ford Institute Consensus Panel*

## Distinction between Physical Dependence and Addiction

“The stabilized methadone maintenance patient—here defined as the patient who does not use alcohol or illicit drugs and takes methadone and other prescribed drugs only as indicated by competent medical practitioners—does not, meet key definitional criteria for addiction (e.g., obsession with using, loss of volitional control over use, self-accelerating patterns of use, compulsive use in spite of escalating consequences)” (White & Torres, 2010)

## 7. TRAINER NOTE:

Recent attempts to define addiction recovery (e.g., Betty Ford Institute Consensus Conference, CSAT Recovery Summit, United Kingdom Drug Policy Commission) have focused on three essential elements:

- a) The resolution of drug-related problems (most often measured in terms of sobriety/abstinence or diagnostic remission),
- b) Improvement in global health, and
- c) Citizenship (positive community re-integration).

## 8. TRAINER NOTE:

There is growing professional consensus that denying “abstinence” or “drug free” status to stabilized MM patients (who do not use alcohol or illicit drugs and who take methadone and other prescribed drugs only as indicated by competent medical practitioners) based solely on their status as methadone patients inhibits rather than supports their long-term recoveries. There is growing professional consensus that for stabilized MM patients, continued methadone maintenance or completed tapering and sustained recovery without medication support represent varieties/styles of recovery experience and matters of personal choice, not the boundary and point of passage from the status of addiction to the status of recovery.

## 9. TRAINER NOTE:

Physical dependence and addiction are not the same: the stabilized methadone maintenance patient—here defined as the patient who does not use alcohol or illicit drugs and takes methadone and other prescribed drugs only as indicated by competent medical practitioners—does not, like many pain patients maintained on opioid medications, meet key definitional criteria for addiction (e.g., obsession with using, loss of volitional control over use, self-accelerating patterns of use, compulsive use in spite of escalating consequences).



CONTINUED 



*DISCUSSION NOTE: What other patterns of medication maintenance may result in physical dependence without producing addiction?*

*Long-term recoveries from opioid addiction with or without the use of methadone (or naltrexone or buprenorphine/Suboxone/Subutex) represent personal styles of recovery and should not be framed in categories of superiority or inferiority, right or wrong, or recovery inclusion or recovery exclusion. Rather than a source of disqualification from recovery status, methadone, provided as a medication under competent medical supervision at proper dosages with appropriate ancillary psychosocial support services, aids long-term recovery from opioid addiction and should be so recognized.*

### Recovery and MM Practices

Achieving this vision of recovery as remission, global health, and citizenship for the mass of MM patients will require expanding and elevating the range and quality of clinical and peer-based recovery support services available to MM patients and their families. It will also require creating the physical, psychological, and cultural space in local communities within which medication-assisted recovery can flourish.



### 10. TRAINER NOTE:

Achieving this vision of recovery as remission, global health, and citizenship for the mass of MM patients will require expanding and elevating the range and quality of clinical and peer-based recovery support services available to MM patients and their families. It will also require creating the physical, psychological, and cultural space in local communities within which medication-assisted recovery can flourish.

### ROMM & Changing Service Practices

8 arenas of service practice will be profoundly transformed in the move toward ROMM

- 1) assessment and service planning
- 2) service team composition
- 3) service relationships
- 4) attraction, access, and early engagement

### 11. TRAINER NOTE:

Eight arenas of service practice will be profoundly transformed in the move toward ROMM:

- 1) Attraction, access, and early engagement;
- 2) Assessment and service planning;
- 3) Service team composition;
- 4) Service relationships;

(continued on slide 12)



### ROMM & Changing Service Practices

- 5) service quality and duration;
- 6) locus of service delivery;
- 7) assertive linkage to recovery community resources; and
- 8) long-term recovery check-ups, stage-appropriate recovery support, and when needed, early re-intervention.

### Sample ROMM practices related to Access, Engagement & Retention

- Expansion of treatment capacity
- Assertive waiting list management
- Assertive outreach
- Personally optimum medication doses
- Mobilization of family/kinship support
- Peer-based Recovery Coaching
- Expanded ancillary services

## 12. TRAINER NOTE:

Eight arenas of service practice will be profoundly transformed in the move toward ROMM (continued):

- 5) Service quality and duration;
- 6) Locus of service delivery;
- 7) Assertive linkage to recovery community resources; and
- 8) Long-term recovery check-ups, stage-appropriate recovery support, and when needed, early re-intervention. It can be seen from this list that ROMM constitutes far more than a mere refinement of existing MM treatment practices.



## 13. TRAINER NOTE:

Methadone maintenance treatment voluntarily attracts more people addicted to heroin and other short-acting opioids than any other addiction treatment modality, but most people in need of treatment for opioid addiction are not currently in treatment, will seek treatment only at late stages of their addictions, will drop out of treatment before optimum therapeutic effects are achieved, and will experience prolonged addiction/treatment careers before recovery stability is achieved. Promising practices include:

- Expanding capacity for medication-assisted treatment to address waiting list issues;
- Assertive outreach;
- Mobilization of family/kinship support;
- Individualized methadone doses that fully suppress withdrawal distress;
- Increased patient choices;
- Telephone and email prompts following missed appointments;
- Patient education related to the safety and benefits of MM;
- Provision of sustained peer-based recovery coaching; and
- Provision of mental health services for co-occurring mental illness.



### Sample ROMM Practices Related to Assessment and Service Planning

- Use of global assessment instruments
- Assessment as a continual vs. intake process
- Family as the unit of service
- Transitioning from treatment plans to recovery plans

### Sample ROMM Practices Related to Composition of the Service Team

- Expanded role for physicians
- Access to family/child therapists
- Greater use of peers in recovery in paid and volunteer support positions
- Greater involvement of indigenous helpers

### Sample ROMM Practices Related to Service Relationships

- Recovery representation
- Respect for patient opinions and preferences
- Changes in administrative discharge policies
- Focus on elevating patient hopes and possibilities
- Use of patient-directed recovery plans
- Emphasis on sustained continuity of contact and support across the stages of long-term recovery.

## 14. TRAINER NOTE:

Practices aimed at increasing the recovery orientation of the assessment and service planning process within MM treatment include:

- Shifting from categorical to global assessment instruments, defining the family (as defined by the patient) rather than the individual as the unit of service;
- Using a strengths-based assessment process to identify personal, family, and community/cultural assets that can be mobilized to support recovery initiation and maintenance;
- Viewing assessment as a continual versus single-point-in-time intake process (based on the understanding that service needs change across the developmental stages of recovery); and
- Transitioning from professionally-directed treatment plans to patient-directed recovery plans.



## 15. TRAINER NOTE:

Implementing ROMM involves greater role of addiction medicine specialists in patient/family/ community education, increased involvement of primary care physicians, greater inclusion of family/ child therapists, increased use of current and former patients in medication-assisted recovery as staff and volunteers, and the use of indigenous healers drawn from diverse cultural communities, e.g., leaders of recovery-focused religious and cultural revitalization movements.



## 16. TRAINER NOTE:

Positive indicators of recovery-oriented service relationships include:

- Increased levels of recovery representation at OTP governance, leadership, and service delivery levels;
- Respect for patient opinions and preferences via a choice philosophy;
- Changes in administrative discharge policies;
- Reduced incidence of administrative discharges and other premature disengagements from service;
- Elevating patients' hopes and possibilities;
- Transitioning patients from professionally-directed treatment plans to patient-directed recovery plans; and
- An emphasis on sustained continuity of contact and support across the stages of long-term recovery.



### Sample ROMM Practices Related to Service Quality and Duration

- 1) Assuring safe induction via dosing policies
- 2) Providing recovery-focused addiction counseling
- 3) Providing ancillary resources for co-occurring problems and needs of the patients' families/children
- 4) Extending the average length of duration of MM treatment (at least 1-2 years to achieve the best long-term recovery outcomes)
- 5) Increasing the percentage of MM patients who either sustain or successfully complete treatment
- 6) Building a strong culture of recovery

### Sample ROMM Practices Related to the Locus of Service Delivery

- Increasing access to medication in non-OTP treatment and recovery support sites
- Expanding office-based treatment and medical maintenance
- Greater use of neighborhood- and home-based recovery support services.

### Sample ROMM Practices Related to Linkage to Recovery Communities

- Liaison with local mutual aid service committees
- Supporting development of groups specifically for persons in medication-assisted recovery
- Assertive linkage of patients to the recovery community resources
- Volunteer or paid peer recovery coaching on how to address medication at recovery support meetings
- Visible participation in local recovery celebration events

## 17. TRAINER NOTE:

ROMM involves assuring six critical areas of service practice:

- 1) Dosing policies that assure safe induction;
- 2) Addiction counseling that is focused on building and sustaining a recovery process;
- 3) Expanding ancillary resources to address co-occurring problems and the needs of the patients' families/children;
- 4) Extending the average length of duration of MM treatment (at least 1-2 years to achieve the best long-term recovery outcomes) and offering increased supports to patients choosing to taper off of medication maintenance;
- 5) Increasing the percentage of MM patients who either sustain or successfully complete treatment; and
- 6) Building a strong culture of recovery within the MM service milieu.

## 18. TRAINER NOTE:

Promising practices related to locus of service delivery include shifting from siloed OTPs toward the integration of MM within comprehensive addiction treatment and recovery support centers, the expansion of office-based treatment and medical maintenance, and greater use of neighborhood- and home-based recovery support services. The focus of ROMM is on firmly nesting recovery within the natural environment of each patient or in helping develop an alternative environment in which long-term recovery can be nurtured.

## 19. TRAINER NOTE:

Promising practices for ROMM related to recovery community linkage include active liaison between OTPs and the service committees of local recovery mutual aid societies, encouraging/supporting the development of groups specifically for persons in medication-assisted recovery, assertive linkage of patients to the resources of local communities of recovery (including medication-friendly recovery support meetings), using volunteer or paid peer recovery coaches to facilitate patient connections to recovery community resources, coaching patients on how to address medication issues at recovery support meetings, hosting onsite peer recovery support meetings at or near OTPs, and visibly participating in local recovery celebration events.



### ROMM Practices Related to Post-Treatment Support

- Post-treatment recovery check-ups regardless of discharge status
- Access to peer-based recovery support
- Stage-appropriate recovery education
- Continued assertive linkage to recovery community resources
- Early re-intervention, if and when needed.

### Stigma as an Obstacle to ROMM Implementation

The social and professional stigma attached to MM leaves the MM patient facing:

- Challenges to their recovery status
- Pressure to end MM as soon as possible
- Family and social isolation
- Discrimination related to housing, employment, and access to health care and other forms of addiction treatment & recovery support services

## 20. TRAINER NOTE:

Assertive approaches to post-treatment monitoring significantly enhance long-term recovery outcomes. ROMM envisions a future in which a system of recovery check-ups, peer-based recovery support, stage-appropriate recovery education, assertive linkage to communities of recovery, and early re-intervention will reduce post-treatment mortality and enhance the long-term recovery outcomes of MM patients.

*NOTE: To generate discussion, ask participants how these eight areas of innovation within ROMM differ, if at all, from MM service practices in their area.*

## 21. TRAINER NOTE:

Methadone maintenance has never achieved full legitimacy as a medical treatment by the public, health care professionals, and the recovery community in spite of the overwhelming body of scientific evidence supporting its effectiveness. The person enrolled in methadone maintenance has never received full status as a “patient,” and the methadone clinic has yet to be viewed as a place of healing on par with hospitals or outpatient medical clinics.

Social and professional stigma leaves the MM patient facing challenges to their recovery status, pressure to terminate MM, family and social isolation and discrimination. Stigma-influenced methadone maintenance treatment practices have historically included arbitrary dose restrictions, restrictions on the duration of MM, lowering methadone dose as a punishment for rule infractions, disciplinary discharge for drug use, and shaming rituals (e.g., public queues to receive methadone, supervised consumption, separate bathrooms for staff and patients, observed urine drops for drug testing, discouragement of peer fraternization).



### Stigma-related Assumptions about MM unsupported by Science and Clinical Experience

- 1) Addiction is a choice.
- 2) Methadone simply replaces one drug/addiction for another.
- 3) Methadone Maintenance prolongs rather than shortens addiction careers.
- 4) Low doses and short periods of methadone maintenance result in better rates of long-term recovery.
- 5) Methadone maintenance patients should be encouraged to end methadone treatment as soon as possible.

### Strategies to Address Professional and Social Stigma

- 1) personal or mass protest (advocacy)
- 2) public and professional education
- 3) strategies that increase interpersonal contact between stigmatized and non-stigmatized groups.

ROMM emphasizes the need for sustained campaigns of public and professional education led by persons in medication-assisted recovery.

## 22. TRAINER NOTE:

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 the following:

- 1) Excessive drug use is a choice;
- 2) Methadone is a “crutch;”
- 3) Methadone simply replaces one drug/addiction for another;
- 4) Methadone prolongs rather than shortens addiction careers;
- 5) Low doses and short periods of methadone maintenance result in better rates of long-term recovery; and
- 6) 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.

## 23. TRAINER NOTE:

Three broad social strategies have been used to address stigma related to behavioral health disorders:

- 1) Personal or mass protest (advocacy);
- 2) Public and professional education; and
- 3) Strategies that increase interpersonal contact between stigmatized and non-stigmatized groups.

An anti-stigma campaign recently developed for the city of Philadelphia seeks to:

- 1) Enhance public and professional perceptions of the value of medication-assisted treatment;
- 2) Enhance the perceived value of medication-assisted treatment within the heroin-using community;
- 3) Put a face and voice on medication-assisted recovery and portray the contributions of people in medication-assisted recovery to their communities; and
- 4) Increase the participation of medication-assisted treatment providers within local community activities.



## Resources

White, W. & Torres, L. (2010). *Recovery-oriented methadone maintenance*.

White, W. (2011). *Narcotics Anonymous and the pharmacotherapeutic treatment of opioid addiction*.

Available for free download at [www.williamwhitepapers.com](http://www.williamwhitepapers.com)

## 24. TRAINER NOTE:

This presentation is drawn from two monographs sponsored by the Center for Substance Abuse Treatment's Addiction Technology Transfer Centers and the Philadelphia Department of Behavioral Health and Intellectual disAbility Services. The monographs contain more than 850 citations of scientific studies and are available for free download at [www.williamwhitepapers.com](http://www.williamwhitepapers.com).

If there is sufficient time, you can also present the following summary.

**SUMMARY:** Put simply, ROMM seeks to:

- Attract people at an earlier stage of problem development via programs of assertive community education, screening, and outreach;
- Assure rapid service access for individuals and families seeking help;
- Resolve obstacles to initial and continued treatment participation;
- Achieve safe, individualized, optimum dose stabilization;
- Engage and retain individuals and families in a sustained recovery-focused service and support process;
- Assess patient/family needs using assessment protocols that are global, family-centered, strengths-based, and continual;
- Transition each patient from a professionally-directed treatment plan to a patient-directed recovery plan;
- Expand the service team to include primary care physicians, psychologists, social workers, peer recovery support specialists, and indigenous healers;
- Shift the service relationship from a professional/expert model to a long-term recovery partnership/consultation model marked by mutual respect, hope, and emotional authenticity;
- Assure minimum (at least one year) and optimum (patient choice) duration of treatment via focused retention strategies and assertive responses to early signs of disengagement;
- Shift the treatment focus from an episode of care to the management of long-term addiction/treatment/recovery careers;
- Expand the service menu to include ancillary medical/psychiatric/social services and non-clinical, peer-based recovery support services;



CONTINUED 

## 24. CONTINUED

- Extend the locus of service delivery beyond the OTP to non-stigmatized service sites and neighborhood-based, church-based, work-based, home-based, and technology-based (phone/Internet) recovery support services;
- Assertively link patients/families to recovery community support resources;
- Engage the community through anti-stigma campaigns and recovery community development activities;
- Provide post-treatment monitoring and support, stage-appropriate education, support, and (if and when needed), early re-intervention for all patients regardless of discharge status; and
- Evaluate MM treatment using proximal and distal indicators of long-term personal and family recovery.

# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 8: Pain Management Therapy**

## MODULE 8 – Pain Management Therapy

TIME: 60 minutes

PURPOSE: Examine issues related to pain management therapy.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Describe the efficacy of opioid treatment.
2. Recognize the adverse effects of opioid treatment.
3. Identify both pharmacologic and non-pharmacologic therapy options.
4. Identify, address and monitor aberrant behavior.

- TOPICS:
- Opioid efficacy
  - Adverse effects
    - o Hyperalgesia
    - o Withdrawal
    - o Tolerance
  - Pharmacologic and non-pharmacologic therapy options
  - Universal Precautions in Pain Medicine
  - Managing risk with opioid therapy
    - o Yellow flag behaviors
    - o Red flag behaviors
    - o Differential diagnosis
  - Addressing aberrant behavior

### KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

## Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

Module 8  
Pain Management Therapy

### Primary Indication for Use of Opioid Medications

- Moderate to severe pain
  - Acute pain
  - Chronic pain
- Opioid dependence



### Pain Prevalence Study

#### Study of (2) populations<sup>1</sup>

- (390) pts in MMT
- (531) pts in short term residential
- Prevalence of chronic severe pain
- Brief Pain Inventory (BPI)

1. Rosenblum A, et al Prevalence and characteristics of chronic pain among chemically dependent patients in methadone maintenance and residential treatment facilities; JAMA May 14, 2003 Vol 289: 2370-2375.

## 1. MODULE 8

In this module we will discuss the unique issues related to pain management therapy involving patients receiving opioid maintenance treatment.

We will also discuss risk management (RM) strategies to minimize core liability risks involving the care of patients in opioid maintenance treatment who are also receiving pain management therapy.



## 2. TRAINER NOTE:

As we mentioned in an earlier module, the primary indication for use of opioid medications is to treat:

- Moderate to severe pain
- Acute pain
- Chronic pain
- Opioid dependence



## 3. TRAINER NOTE:

Let's look at a study that looked at the prevalence of pain in two populations of patients with addiction problems.

- 390 patients in methadone maintenance treatment (MMT) were contrasted with 531 patients in short term residential treatment for addiction problems
- Prevalence of chronic severe pain, defined as pain that persisted > 6 months and was moderate to severe intensity or that significantly interfered with daily activities
- Brief Pain Inventory (BPI) was used for assessment





## Pain Prevalence Study

- **Higher prevalence** of chronic pain in MMT population
  - 37% vs. 24% compared with residential
  - Higher than general population
  - Prevalence of pain compared with surveys of cancer patients
- **Great variability** in experience of pain
  - Relatively high scores on items of BPI, 55% to 73% for pts in MMT
- In MMT, chronic pain was associated with both **physical** and **psychiatric** illness
- Less evidence of an association between substance use and chronic pain among inpatients vs. MMT patients

1. Rosenblum A, et al Prevalence and characteristics of chronic pain among chemically dependent patients in methadone maintenance and residential treatment facilities; JAMA May 14, 2003 Vol 289: 2370-2375.

## 4. TRAINER NOTE:

This study showed a higher prevalence of chronic pain in MMT population:

- 37% versus 24%, compared with residential group in study.
- Higher than general population.
- Higher prevalence of pain compared with surveys of patients with cancer related pain.

It also showed a great variability in experience of pain.

- Relatively high scores on items of BPI pain interference scale, 55% to 73% for patients in MMT.

In MMT patients, chronic pain was associated with both physical and psychiatric illness.

Less evidence of an association between substance use and chronic pain among inpatients than among MMTP patients.

What you can see is there is a significant prevalence of pain among patients in opioid maintenance treatment.

## 5.

## Pain Prevalence Study

- Patient Characteristics (MMT)
  - Mean age 43
  - 38% female
  - 25% white
  - 35% black
  - 33% Hispanic

1. Rosenblum A, et al Prevalence and characteristics of chronic pain among chemically dependent patients in methadone maintenance and residential treatment facilities; JAMA May 14, 2003 Vol 289: 2370-2375.

## Under Treatment of Pain

- **Under treatment of pain** is a significant concern in populations with substance use disorders
- **Barriers for inadequate pain management:**
  - Institutional practices
  - Inadequate training and skills of clinicians
  - Lack of access to health care, pain management care
  - Reluctance of physicians to prescribe opioids
  - Reluctance of patients to seek medical care:
    - Stigma
    - Fear of relapse

1. Rosenblum A, et al Prevalence and characteristics of chronic pain among chemically dependent patients in methadone maintenance and residential treatment facilities. JAMA May 14, 2003 Vol 289: 2370-2375.

## Pain Prevalence

MMTP patients have been shown to have **lower pain thresholds** compared with matched controls<sup>1, 2</sup>

1. Compton M, Cold-pressor pain tolerance in opioid and cocaine abusers: correlates of drug type and use status. J Pain Symptom Manage. 1994;9:462-473. 2. Compton P, et al. Pain intolerance in opioid-maintained former opiate addicts. Drug Alcohol Depend. 2001; 63:139-146.

## 6. TRAINER NOTE:

Under treatment of pain is a significant concern in populations with substance use disorders. Often patients do not get adequate treatment for pain.

There are significant barriers as potential reasons for inadequate pain management:

- Institutional practices – It is not uncommon for a patient to present at a hospital with significant pain and once they disclose they are on methadone the hospital will respond differently. They are often told they don't need pain management because they are already on methadone.
- Inadequate training and skills of clinicians.
- Lack of access to health care, pain management care. It is difficult to get patients into good quality pain management for collaborative care.
- Reluctance of physicians to prescribe opioids to treat pain when appropriate.
- Reluctance of patients to seek medical care due to stigma and fear of relapse even when it is appropriate to have an opioid for a certain condition.



## 7. TRAINER NOTE:

Studies do show that MMTP patients have been shown to have lower pain thresholds compared with matched controls which can account for many of our patients taking opioid pain medications for conditions where other pain management is generally used.



## Relationship: Pain & Addiction



Reference: Savage, S, Koob, G, Frank, S. Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders. *Addiction Science & Clinical Practice*. June 2018

## 8. TRAINER NOTE:

There is a synergistic relationship with pain and addiction. This diagram shows the back and forth issues. This makes it a complex issue.

*NOTE: This diagram is available from NIDA at <http://archives.drugabuse.gov/pdf/ascp/vol4no2/Challenges.pdf>*



## Terminology Distinction

- Opioid Dependence
- Tolerance
- Physical Dependence
- Opioid Addiction



## 9. TRAINER NOTE:

As we move on, it is important to know the distinction between the following terminology:

- Opioid Dependence
- Tolerance
- Physical Dependence
- Opioid Addiction



## Dependence

- A state in which an organism functions only in the presence of a drug
- Manifested as a physical disturbance when the drug is removed (withdrawal)

## 10.

## Tolerance

- A state in which an organism no longer responds to a drug
- A higher dose is required to achieve the same effect

## Opioid Addiction

- Opioid tolerance
- Physical dependence
- Organism engages in **compulsive behavior**
  - The behavior is reinforcing (rewarding or pleasurable)
- **Loss of Control** Indices:
  - Continued use despite adverse consequences
  - Illicit or inappropriate drug-seeking behavior
    - In response to craving or drug hunger

## Spectrum of Pain Disorders

- Nocioceptive Pain
- Neuropathic Pain
- Mixed Pain Mechanisms
- Acute Pain
- Chronic Pain
  - Non-cancer related /non-malignant pain
  - Malignant pain



Reference: Savage, S, Krish, K, Passik, S., Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders, Addiction Science & Clinical Practice, June 2008

## 11.

### 12. TRAINER NOTE:

Opioid addiction is identified by:

- Opioid tolerance
- Physical dependence, AND
- A state in which an organism engages in compulsive behavior
- The behavior is reinforcing (rewarding or pleasurable)

Loss of control indices:

- Continued use despite adverse consequences
- Illicit or inappropriate drug seeking behavior
  - In response to craving or drug hunger

The distinction is the compulsive behavior and the loss of control.

### 13. TRAINER NOTE:

This slide provides an overview of pain disorders which we will discuss:

- Nocioceptive Pain
- Neuropathic Pain
- Mixed Pain Mechanisms
- Acute Pain
- Chronic Pain
  - Non-cancer related / non-malignant pain
  - Malignant pain

We are going to focus on acute and chronic pain as these are the issues most faced in OTPs.



## Acute Pain

- Usually associated with an acute physical condition- etiology identifiable
- Generally **self-limited**
- Often primarily nociceptive
- Sympathetic responses, increased BP, P, diaphoresis
- Failure to treat acute pain properly **may lead to chronic pain<sup>1</sup>**

<sup>1</sup> Dahl JB, Moiriche S (2004). "Pre-emptive analgesia". *Br Med Bull* 71: 13-27. PMID: 15088866  
Savage, S, Kirish, K, Passik, S., Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders, *Addiction Science & Clinical Practice*, June 2008

## Chronic Pain

- No longer serves **survival** or beneficial purpose
- Lingered past limits normally associated with **tissue healing**
- May persist because of chronic **ongoing tissue pathology**
  - Degenerative Joint Disease
  - Chronic pancreatitis
  - Progressive cancer

Reference: Savage, S, Kirish, K, Passik, S., Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders, *Addiction Science & Clinical Practice*, June 2008

## Chronic Pain

- Engenders secondary problems
  - Sleep disturbance; anxiety; depressive symptoms; loss of normal functioning; increased stress associated with losses
- Physiological basis may be difficult to determine
- Objective physiological signs often absent, skepticism, mistrust
- Acute exacerbations associated with chronic pain
- Multidimensional approach to treatment

Reference: Savage, S, Kirish, K, Passik, S., Challenges in Using Opioids to Treat Pain in Persons With Substance Use Disorders, *Addiction Science & Clinical Practice*, June 2008

## 14. TRAINER NOTE:

As we consider acute pain:

- Usually associated with an acute physical condition – etiology usually (though not always) known or identifiable.
- Generally self-limited, resolves as underlying etiology resolves.
- Often primarily nociceptive (nerve tissue and nerve injury), may have a neuropathic (chronic nerve injury) component if nerves affected.
- Sympathetic responses, increased blood pressure (BP), pulse (P), diaphoresis. It is an autonomic sympathetic nervous system response.
- Failure to treat acute pain properly may lead to chronic pain.

## 15. TRAINER NOTE:

Chronic pain:

- Differs from acute, no longer serves survival or beneficial purpose.
- Lingered past limits normally associated with tissue healing.
- May persist because of chronic ongoing tissue pathology.
  - Degenerative Joint Disease
  - Chronic pancreatitis
  - Progressive cancer

In our setting patients may report they have chronic pain from an accident that occurred ten years ago. Acute pain generally happens in a relative period of time versus chronic pain happening after tissue healing.

## 16. TRAINER NOTE:

Engenders secondary problems:

- Sleep disturbance; anxiety; depressive symptoms; loss of normal functioning at work, social situations, and recreation; increased stress associated with losses.

Physiological basis may be difficult to determine, associated with many layers of associated problems and distress because of this difficulty.

Objective physiological signs often absent, skepticism, mistrust.

Acute exacerbations associated with chronic pain.

Requires a multidimensional approach to treatment.



## Chronic Pain Disorders & Opioids

- Improvement, stable functioning
- Opioid Tolerance /Opioid Physical Dependence
- Adherent with treatment plan, scheduled visits
- Absence of illicit drug use and aberrant drug seeking behavior
  - No drug hunger in absence of pain
  - No loss of control
  - No "doctor shopping"
  - Little tendency to escalate doses over time

## Pseudo-Addiction

Chronic Pain Patient who is labeled an addict

- **Inadequate** treatment of their pain
- "Apparent" drug seeking behavior
  - Effort to achieve adequate analgesia
  - Early refill, doctor shopping, etc.
  - Manipulation seen as "addictive behavior"
  - Viewed as non-compliant
- "Cured" by adequate treatment of pain

Weissman, D.E.and Haddock, J.D. Opioid pseudo-addiction – An iatrogenic syndrome. Pain, 35 (3):363-366, 1989

## 17. TRAINER NOTE:

Let's look at issues with chronic pain and treatment with opioids.

- When it is appropriate and effective there is improvement and stable functioning.
- There can be opioid tolerance / opioid physical dependence. Meaning when the medication is withdrawn there are withdrawal symptoms.
- Adherent with treatment plan, scheduled visits.
- Absence of illicit drug use and aberrant drug seeking behavior:
  - No drug hunger in absence of pain
  - No loss of control
  - No "doctor shopping"
  - Takes medication as prescribed and there is little tendency to escalate doses over time.



## 18. TRAINER NOTE:

Contrast this with pseudo-addiction: For the chronic pain patient who has been labeled an "addict" often times the real issue is that there has been inadequate treatment of their pain.

"Apparent" drug seeking behavior is identified by:

- An effort to achieve adequate analgesia by increasing dose
- Early refill, doctor shopping, etc.
- Manipulation seen as "addictive behavior"
- Viewed as non-compliant

If you do a history, you would see that the patient doesn't have addiction behavior, rather inadequate treatment of their pain. Once the patient is adequately treated for pain, they are essentially "cured," making them inappropriate for opioid treatment.



## Opioid Efficacy in Chronic Pain

Expectations should be modest considering:

- Studies are surveys & uncontrolled case series
- Randomized Clinical Trials (RCTs) short, small N
- Pharmaceutical sponsored
- Pain relief modest
- Limited or no functional improvement

Baladyne JC, Miao J. NEJM 2003  
Martel SA et al. Ann Intern Med 2007; Eisenberg E et al. JAMA. 2005

## 19. TRAINER NOTE:

What is the efficacy of long-term opioids in treating chronic pain?

Our expectations should be modest considering:

- Most literature looking at opioids in chronic pain are surveys and uncontrolled case studies.
- Those that are randomized clinical trials are short in duration (less than 4 months) and with small sample sizes (less than 300 patients).
- Most studies are pharmaceutical sponsored.
- Overall pain relief was modest in these studies. In one meta-analysis, the decrease of pain was 14 points on a 100 point scale. (Eisenberg E et al. JAMA. 2005). So if your patient is expecting their pain relief to go from ten to zero with opioids, it's very unlikely to happen. It is important to educate patients about the efficacy of opioids and what is realistic in terms of pain relief goals.
- Also, these studies show limited functional improvement, which is an important goal in pain management.

The management of chronic pain is beyond the scope of this training, but it is important to realize that opioids ARE NOT a magic bullet, and to understand the limitations of this therapy.



## Eriksen et al (Pain - 2006)

- Opioid users reported significantly :
  - More moderate to severe pain
  - Poorer self rated health
  - Lower quality of life scores
  - Low levels of physical activity and employment
  - High levels of healthcare utilization

Eriksen et al. Critical Issues on Opioids in Chronic non-cancer Pain: An Epidemiological Study. Pain 125(2006) 172-179

## 20. TRAINER NOTE:

The first population-wide epidemiologic study to assess outcomes of opioid therapy for chronic pain was done in 2006. This study compared a cohort of patients with chronic pain receiving opioids and those not receiving opioids, results indicated:

Opioid users reported significantly:

- More moderate to severe pain
- Poorer self rated health
- Lower quality of life (QOL) scores than non-users
- Positive association between opioid use and low levels of physical activity and employment
- High levels of healthcare utilization

Source: Eriksen et al. Critical Issues on Opioids in Chronic non-cancer Pain: An Epidemiological Study. Pain 125(2006) 172-179.

*NOTE: before advancing to the next slide which is a new topic area (Pain Management Therapies and Risk Management Strategies), ask participants if there are any unanswered questions related to the material covered thus far in module.*



## Pain Management Therapy and Risk Management Strategies

### 21. TRAINER NOTE:

Our next topic area is a discussion of pain management therapy and risk management strategies.



### RM Strategies

- Universal Precautions
- Opioid Risk Tool
- Patient Medication Agreement
- Opioid Agreement
- Guidelines for hospitalized patients
- Patient Informed Consent agreements
- FDA Warning guidelines



### 22. TRAINER NOTE:

As we move through the rest of this module, we are going to discuss the following strategies in the upcoming slides:

- Universal Precautions
- Opioid Risk Tool
- Patient Medication Agreement
- Opioid Agreement
- Guidelines for hospitalized patients
- Patient Informed Consent agreements
- FDA Warning guidelines



### Universal Precautions

- Developed by Gourlay D, Heit H, Almahrezi A
  - Biopsychosocial model for risk assessment
  - Appropriate boundary setting and a respectful approach
  - Recommendations for management and referral
- Adopting of this model:
  - Stigma can be reduced
  - Patient care improved
  - Overall risk contained

Gourlay D, Heit H, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. Pain Med. 2005 Mar-Apr;6(2):107-112.

### 23. TRAINER NOTE:

Gourlay, Heit and Almahrezi developed Universal Precautions using the Infectious Disease Model. The cornerstone of their model is:

- Biopsychosocial model for risk assessment.
- Appropriate boundary setting within the clinician-patient relationship and a respectful approach.

They provide recommendations for management and referral, by adopting this model:

- Stigma can be reduced
- Patient care improved
- Overall risk contained



## Universal Precautions

- Diagnosis with appropriate differential
- Psychological assessment
- Informed consent
- Treatment agreement
- Pre/post assessment of pain level and function
- TRIAL of opioid therapy with adjunctive therapy

Pain Medicine: Volume 6 • Number 2 • 2005

## Universal Precautions in Pain Medicine

- Reassesses pain score and level of functioning
- Regularly assesses the "Four As":
  - Analgesia
  - Activity
  - Adverse reactions
  - Aberrant behavior
- Review pain diagnosis and co-morbid conditions
- Documentation



## 24. TRAINER NOTE:

As we think about medicating for pain, there are some universal precautions that need to be considered:

- Diagnosis with appropriate differential
- Psychological assessment including risk of addictive disorders
- Informed consent
- Treatment agreement
- Pre/post interventions assessment of pain level and function
- Appropriate TRIAL of opioid therapy with adjunctive therapy

## 25.



## Opioid Risk Tool

- Designed for initial assessment
- 5-item initial risk assessment
  - Family History
  - Personal History
  - Age
  - Preadolescent sexual abuse
  - Past or current psychological disease
- Stratifies risk - low (6%), moderate (28%) and high (91%)

Webster, Webster. Pain Med. 2005

## 26. TRAINER NOTE:

The Opioid Risk Tool is commonly used in the pain management community. The 5-item tool was designed for use on an initial visit, prior to prescribing opioid therapy, to assess for aberrant medication-taking behavior (AMTB). Aberrant medication-taking behavior is a spectrum of patient behavior that may reflect misuse, including abuse/dependence. The tool was validated among patients in a pain clinic.

5-item initial risk assessment:

- Family history
- Personal history
- Age
- Preadolescent sexual abuse
- Past or current psychological disease

Stratifies risk into low (6%), moderate (28%) and high (91%) looking at the pain management community.

Low risk group: 6% risk - 94% did not exhibit any aberrant medication-taking behavior (AMTB)

Moderate risk group: 28% risk - had at least 1 AMTB

High risk group: 91% risk - had at least 1 AMTB

*NOTE: The Opioid Risk Tool is available on the IRETA website at <http://ireta.org/riskmanagement>.*



## Patient Medication Agreement

- A patient medication agreement establishes clear expectations and specifies:
  - Purpose of opioid therapy
  - Side effects
  - Treatment goals
  - Physician's role in responsible opioid prescribing
  - Patient's role in responsible opioid use



## 27. TRAINER NOTE:

A patient medication agreement is an excellent tool because it establishes clear expectations between physician and patient and specifies:

- Purpose of opioid therapy
- Side effects
- Treatment goals
- Physician's role in responsible opioid prescribing
- Patient's role in responsible opioid use which is to use them in a responsible fashion.



## Opioid Agreement

- Opioid prescriptions are provided by **only one Provider**
- Patients agree not to ask for opioid medications from any other doctor without the knowledge and assent of the provider
- Patients keep all scheduled appointments
- Urine drug screens obtained as indicated

## Opioid Agreement (continued)

- Patients agree to comply fully **with all aspects of the treatment program**
- A prohibition on use with **alcohol, other sedating medications or illegal medications**
- Agreement **not to drive or operate heavy machinery** until medication-related drowsiness is cleared

## Pain Management Therapy: OTP Setting

- **Continue maintenance** without interruption
- Provide short-acting opioid analgesics
- Higher doses may be required
- Mixed agonists/antagonists or partial or weak agonists **must be avoided**
- Monitor prescriptions closely

\*Solmeca, M.M., Treatment of pain in methadone-maintained patients. The Mt. Sinai Journal of Medicine, 67 (5-6)412-422, 2000

## 28. TRAINER NOTE:

Contrast that with the Opioid Agreement which specifies:

- Opioid prescriptions are provided by only one provider.
- Patients agree not to ask for opioid medications from any other doctor without the knowledge and assent of the provider.
- Patients agree to keep all scheduled medical appointments.
- Urine drug screens will be obtained as indicated to verify that the patient is taking the medication.



## 29. TRAINER NOTE:

Patients agree to comply fully with all aspects of the treatment program including:

- Behavioral medicine and physical therapy if recommended.
- A prohibition on use with alcohol, other sedating medications or illegal medications.
- Agreement not to drive or operate heavy machinery until medication-related drowsiness is cleared.



## 30. TRAINER NOTE:

Let's look specifically at pain management therapy during maintenance pharmacotherapy in an OTP setting.

Continue maintenance medication without interruption. It is not uncommon for patients to be in a hospital/medical setting and their methadone dose is either stopped or altered because of fear.

Provide short-acting opioid analgesics as needed. Drugs such as morphine and hydrocodone are shorter acting than the longer acting drugs like methadone.

Higher doses may be required at increased frequency-titrated for relief of pain. MM patients may need higher doses than "typical" due to the phenomenon of tolerance. Many doctors are uncomfortable with dosing higher because they do not recognize that tolerance has developed.

Mixed agonists/antagonists or partial or weak agonists must be avoided, such as buprenorphine.

Monitor prescriptions closely and have appropriate follow up.



### Guidelines for Hospitalized MM Patients

- Discuss methadone treatment **prior** to admission
- There should be a clear understanding regarding:
  - Uninterrupted maintenance treatment
  - Adequate treatment for pain
  - Program physician should be available to hospital staff



### NPO for MM Patients



- 24 hours after last oral dose of methadone:
  - IM methadone, 40-50% of oral dose every 12 hours OR
  - IM morphine sulfate 20-25% of oral methadone dose every 6 hours
- Monitor for over/under medicating
- Methadone for continued maintenance or substituted morphine, **will not provide analgesia!!**

### Methadone: FDA Black Box Warning

- **Indication** – moderate to severe pain, non-responsive to analgesics
- Initiated with consideration of **risk/benefit, QT prolongation**
- **Acute pain**, appropriateness of methadone for stabilized patients
- **Duration** of analgesic action
- Difference in plasma elimination half-life of methadone vs. shorter acting opioids (8-59 hrs vs. 1-5hrs)
- **Peak respiratory effect** occurs later, lasts longer than peak analgesic
- **Steady state plasma** concentrations and full analgesic effects
- Published **equi-analgesic conversion ratios** between methadone and other opioids are imprecise- **caution** when switching opioids

## 31. TRAINER NOTE:

When you have a patient going into the hospital:

- Discuss methadone treatment prior to admission if possible.

There should be a clear understanding regarding:

- Uninterrupted maintenance treatment.
- Adequate treatment for pain.

The recovery room is not the place to negotiate pain management.

The program physician should be available to hospital staff while the patient is in the hospital.



## 32. TRAINER NOTE:

When a MM patient cannot have medication by mouth some options are:

- 24 hours after last oral dose of methadone:
  - Intramuscular (IM) methadone, 40-50% of oral dose every 12 hours OR
  - Intramuscular (IM) morphine sulfate 20-25% of oral methadone dose every 6 hours, it is a short acting medication
- Monitor for over/under medicating.
- Methadone for continued maintenance, or substituted morphine, will not provide analgesia!! There are doctors that will not prescribe pain medication because the patient is on methadone and feels the maintenance methadone should be providing analgesic relief.



## 33. TRAINER NOTE:

The FDA has recently issued a Black Box Warning for using methadone for pain management. Methadone should only be used taking the following into consideration:

It should only be used for severe pain that is not responding to non-narcotic pain medications. Not for simple pain.

Initiated with consideration of risk/benefit, and acknowledge QT prolongation reported with high doses. If you are going to use methadone as pain management look that the benefits and compare to the risks.



CONTINUED 

### 33. CONTINUED

Acute pain, appropriateness of methadone for stabilized patients, understanding of tolerance.

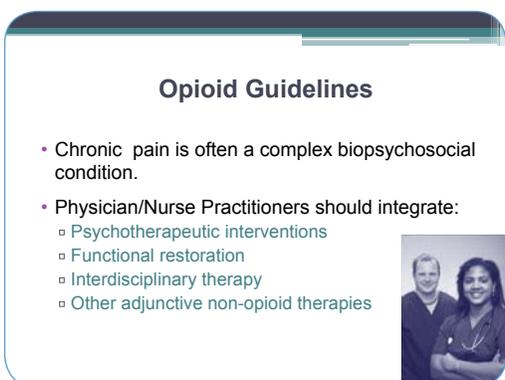
Duration of analgesic action, methadone (4-8 hrs) versus morphine. We are talking about the analgesic effect of methadone, not the effect for withdrawal management. The duration is much shorter and prescribed 3-4 times a day.

Difference in plasma elimination half-life of methadone versus shorter acting opioids in pain management. (8-59 hrs versus 1-5 hrs)

Methadone's peak respiratory effect occurs later, and persists longer than its peak analgesic effect.

Steady-state plasma concentrations and full analgesic effects are usually not attained until 3 – 5 days and as long as 7 days of dosing.

Published equi-analgesic conversion ratios between methadone and other opioids are imprecise, incomplete tolerance, caution when switching opioids. When converting to methadone the tables do not recognize that tolerance can be incomplete and imprecise which can lead to over medication.



### 34. TRAINER NOTE:

Opioids are generally used with pain management, but there are other alternatives.



### 35. TRAINER NOTE:

Here are some opioid guidelines on how to approach chronic pain:

- Chronic non-cancerous pain (CNCP) is often a complex biopsychosocial condition.
- Physician/Nurse Practitioners who prescribe continuous opioid therapy (COT) should routinely integrate:
  - Psychotherapeutic interventions
  - Functional restoration
  - Interdisciplinary therapy
  - Other adjunctive non-opioid therapies



## Pharmacologic Pain Therapy

- Nonopioid Analgesic Agents (NSAIDs)
- Anticonvulsant Agents
- Muscle Relaxants
- Antidepressant Agents
- Alpha Adrenergic Agents
- Topical Agents
- Opioid Analgesics
- Vitamin D deficiency



## Non-pharmacologic therapy

- Heat
- Prosthetic supports
- Physical therapy
- Exercise
- Cognitive-behavioral therapy (CBT)
- Orthopedic Consultation
- Chiropractic Care
- Yoga
- Relaxation Therapy
- Meditation
- Interventional pain therapy
- Sleep Evaluation
- TENS Unit
- Vocational Rehab
- Recreational Therapy



## 36. TRAINER NOTE:

Some of the options for pharmacologic pain control are:

- Non-opioid Analgesic Agents - cornerstone medications
- Anticonvulsant Agents - Neuronton
- Muscle Relaxants - Soma
- Antidepressant Agents - Elavil
- Alpha Adrenergic Agents
- Topical Agents
- Opiates
- Address Vitamin D deficiency



## 37. TRAINER NOTE:

Now let's look at the non-pharmacologic options that should be incorporated into pain management:

- Heat
- Prosthetic supports
- Physical therapy
- Exercise
- Cognitive-behavioral therapy
- Orthopedic consultation for structural problems requiring intervention
- Chiropractic care
- Yoga
- Relaxation therapy
- Meditation
- Interventional pain therapy
- TENS unit (use of electric current produced by a device to stimulate the nerves for therapeutic purposes)
- Vocational rehab



## Summary

- Acute and chronic pain syndromes are prevalent among patients in OTPs
- Knowledge of the multidimensional nature and physiology of pain
- Understanding that pain and addiction have a synergistic relationship
- Best practice recommends a comprehensive approach with interventions using multiple modalities of care

## Summary: General RM Strategies

- Assess and document benefits and harms
- Collaboration and clear communication with PM specialists and or PCP
- Patient education
- Patient agreements
- Careful and frequent monitoring

Christina Nicolaidis, MD, MPH, Oregon Health & Science University, SGIM 2008 precourse

## 38. TRAINER NOTE:

Acute and chronic pain syndromes are prevalent among patients in OTPs.

Having knowledge of the multidimensional nature and physiology of pain is essential to providing treatment for patients in OTPs.

Understanding that pain and addiction have a synergistic relationship is important in the care of patients in OTPs.

Best practice recommendations for pain management for patients in OTPs involve a comprehensive approach with interventions using multiple modalities of care.



## 39. TRAINER NOTE:

Once you have started prescribing opioids, you need to assess and document any benefits and harm to the patient. To continue prescribing opioids:

- There must be some actual functional benefit.
- Benefits must outweigh observed or potential harms.

Remember, you do not have to prove that the person has an addiction or that they are diverting. You only assess the risk-benefit ratio—that they are getting more benefit than risk. If there are addiction or diversion issues, they must be assertively addressed.

Collaboration and clear communication with PM specialists and or PCP is essential for safe and effective pharmacotherapy. OTP staff should be communicating with the prescribing physician if a patient is getting controlled substances for pain management.

Patient education regarding the potential for adverse drug reactions due to combined use of opioid analgesics with methadone is recommended. OTPs need specific strategies and tools to educate patients, and it needs to be done throughout treatment.

Patient agreements are helpful to outline concise understanding and expectations during treatment.

Careful and frequent monitoring for impairment and or adverse drug reactions is important.

*NOTE: Before moving to on to Module 9, entertain remaining questions that participants may have.*



# TRAINER'S MANUAL

## **Effective Risk Management Strategies in Outpatient Methadone Treatment**

### **MODULE 9:**

### **Special Populations and Risk**

## MODULE 9 – Special Populations and Risk

TIME: 60 minutes

PURPOSE: To provide an overview of two special population topics: pregnancy and co-occurring disorders (COD) in relationship to risk.

OBJECTIVES: At the conclusion of this module, participants will be able to:

1. Discuss methadone maintenance as the standard of care for pregnant patients.
2. Recognize issues specific to methadone dose and maintenance for pregnant patients.
3. Identify the potential role of buprenorphine in the treatment of opioid dependent pregnant women.
4. Discuss the importance of early and accurate diagnosis of COD to improve outcomes.
5. Identify broad strategies and treatment considerations for patients who have co-occurring disorders.

TOPICS:

- Pregnancy
  - o Methadone maintenance as the standard of care
  - o Diagnosing opioid addiction in pregnant patients
  - o Detoxification during pregnancy
  - o Methadone dosage and management
  - o Breast feeding and methadone
  - o Use of buprenorphine during pregnancy
  - o Integrated, comprehensive services
- Co-Occurring Disorders
  - o Screening for co-occurring disorders
  - o Making and confirming a psychiatric diagnosis
  - o Treatment considerations for patients with co-occurring disorders

### KEY TO ICONS



The icon above relates to additional instructions for the trainer.



The icon above relates to activities for the group.



The icon above relates to additional reference material provided by the trainer.

## Effective Risk Management Strategies in Outpatient Methadone Treatment: Clinical Guidelines and Liability Prevention Curriculum

Module 9  
Special Population and Risk

### Pregnancy



The Office of Applied Studies indicated that in 1999 of 400,000 women admitted to OTPs 4% were pregnant.

### Methadone Maintenance as the Standard of Care

- Since 1970's, methadone accepted to treat opioid addiction during pregnancy
- Only opioid medication approved by the FDA
- Same effective maintenance treatment benefits
- Methadone reduces fluctuation in maternal serum opioid levels protecting fetus from withdrawal
- Comprehensive MMT must include prenatal care
  - Reduce obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality (Finnegan, 1991)

## 1. MODULE 9

In this module, we will examine two special populations in relationship to RM:

- Pregnancy
- Co-occurring disorders

This module provides an overview of these two topics; it is not comprehensive. Further training and information should be sought to increase competency on these topic areas. Most of the information in this module is taken directly from TIP 43.

## 2. TRAINER NOTE:

Of the 400,000 women admitted to programs in 1999, 4 percent were pregnant when admitted. Opioids were the primary substance of abuse for 19 percent of both pregnant and nonpregnant women who entered these programs (Office of Applied Studies 2002). (TIP 43)

Insurance carriers recommend that you look at pregnancy as a core liability, however, there are a minority of cases involving pregnant women pursuing wrongful death or adverse events.

## 3. TRAINER NOTE:

Methadone has been recognized as the standard of care.

- Since the 1970s, methadone has been accepted to treat opioid addiction during pregnancy.
- Methadone is the only opioid medication approved by the U.S. Food and Drug Administration (FDA) during pregnancy.
- Same effective medial maintenance treatment benefits for pregnant patients as for general patients.
- Methadone reduces the fluctuation in maternal serum opioid levels protecting the fetus from withdrawal (which is what you want to guard against).
- Comprehensive methadone maintenance treatment for pregnant patients includes prenatal care.

Comprehensive MMT with adequate prenatal care can reduce the incidence of obstetrical and fetal complications in utero growth retardation and neonatal morbidity and mortality (Finnegan, 1991). Dr. Loretta Finnegan established the first treatment program for pregnant women, she is recognized as an authority in this area.



## Diagnosing Opioid Addiction in Pregnant Patients

- Establish admission priority for pregnant women
  - Federal waiver –1 year history of opioid addiction
- Establish pregnancy through onsite testing
  - Screening- UDS at admission and monthly
  - Confirmation testing
- Establish protocols to educate patients about the pregnancy risks and neuroendocrine process

## Medical and Obstetrical Concerns and Complications

- Greater-than-normal risk of complication if:
  - Abuse substances
  - Are opioid addicted
  - Lack prenatal care
- Common complications include:
  - Spontaneous abortion
  - Premature labor
  - Low birth weight

## 4. TRAINER NOTE:

- Priority for admission of pregnant women should be established in programs.
- You do not have to establish the one year of opioid addiction. Request the federal waiver for a less than one year history of opioid addiction.
- Establish that the woman is pregnant through onsite pregnancy testing to confirm pregnancy.
- Programs should have the capability to provide a Urine Drug Screen (UDS) upon admission and monthly thereafter.

Establish protocols to continually educate female patients about the risks involved in becoming pregnant while on methadone and the neuroendocrine process which can effect pregnancy. There are many women that report irregular or missing menses. They do not think they can get pregnant, and do not use protection. However, methadone will normalize the neuroendocrine response and regulate their ovulation even though they may not have bleeding. If they continue to not use protection, pregnancy can occur.

Some women who are opioid addicted do not acknowledge pregnancy readily, or they misinterpret early signs of pregnancy, for example, fatigue, headaches, nausea and vomiting, and cramps, as opioid withdrawal symptoms.

## 5. TRAINER NOTE:

Greater-than-normal risk of complication for pregnant women who:

- Abuse substances
- Are opioid addicted
- Lack prenatal care

Common complications include:

- Spontaneous abortion
- Premature labor
- Low birth weight



## Detoxification During Pregnancy

- Rarely appropriate during pregnancy (ASAM 1990)
  - Same recidivism as non-pregnant (Finnegan, 1990)
- Withdrawal during pregnancy (MSW) for patients:
  - Refusing to be placed on MMT.
  - Living where MMT is not available.
  - Stable during treatment and requests withdrawal.
  - So disruptive to the treatment setting that removal from the program is necessary.

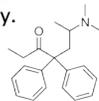
## Methadone Dosage & Management

- Dose of methadone should be individually determined and adequate to control craving and prevent withdrawal syndrome
- As pregnancy progresses, the same dosage produces lower blood methadone levels:
  - Increased fluid volume
  - Larger tissue reservoir for methadone
  - Altered opioid metabolism placenta and fetus (Weaver, 2003).



## Methadone Dosage & Management

- MMT patients who become pregnant should be continued at established dose and titrated as indicated.
- Altered pharmacokinetics during the 3<sup>rd</sup> trimester often requires an increase and a split dose to “flatten the curve” and improve maternal and fetal stability.



## 6. TRAINER NOTE:

Detoxification is rarely appropriate during pregnancy (American Society of Addiction Medicine (ASAM) 1990)

Same recidivism as non-pregnant opioid addicted patient (Finnegan, 1990)

Medically Supervised Withdrawal (MSW) can happen when:

- The patient refuses to be placed on methadone maintenance treatment.
- The patient lives in an area where methadone maintenance is not available.
- The patient has been stable during treatment and requests withdrawal prior to delivery.
- The patient has been so disruptive to the treatment setting that the treatment of other patients is jeopardized, necessitating the removal of the patient from the program. There are protocols on how to safely withdraw a pregnant woman from methadone or deal with withdrawal management from opioids.

## 7. TRAINER NOTE:

The dose of methadone should be individually determined and adequate to control craving and prevent withdrawal syndrome (if the mother is in withdrawal the fetus is in withdrawal), it is essentially the same as for non-pregnant patients.

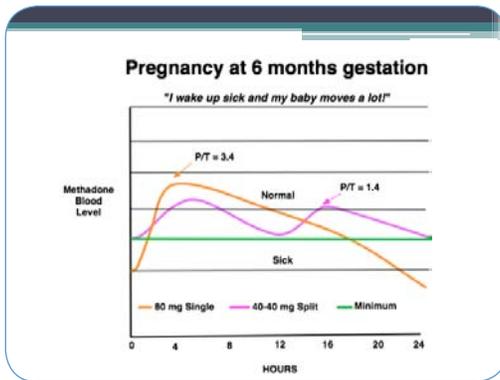
As pregnancy progresses, the same methadone dosage produces lower blood methadone levels owing to increased fluid volume, a larger tissue reservoir for methadone, and altered opioid metabolism in both the placenta and fetus (Weaver 2003).

## 8. TRAINER NOTE:

MMT patients who become pregnant should be continued at an established dose and titrated as indicated.

Altered pharmacokinetics during the third trimester often requires an increase and often a split dose to “flatten the curve” and improve maternal and fetal stability. In the next slide we will see a visual which will clarify how the split dose works.





## 9. TRAINER NOTE:

What this graph represents is a dose response curve over a 24 hour period, and the methadone blood level. The yellow line conveys the typical dose response curve of someone who says, "I wake up sick and my baby moves a lot!" When the mother wakes up sick from withdrawal, the baby is potentially experiencing withdrawal also. As we look at the graph, the patient with the 80 mg of methadone (yellow line) from 0-12 hours looks relatively normal. But somewhere around the 16th hour – till the end of the 24 hour period – the patient falls into the period of being sick (having withdrawal).

Let's look at the pink line. If the patient gets what we call a "split dose" (the same 80 mg dose split into two 40 mg doses) it flattens out the curve. The patient stays in the "normal range" and does not get sick. There is some fluctuation, but it does not get into the area where the patient can potentially get sick.

This is a good demonstration of the effect of a split dose. The patient would take 40 mg at the clinic around 8:00am, and would be given the directions to take the second 40 mg at 6:00pm to flatten out the line.

The numbers above each line show the peak and trough (P/T) ratio. The yellow line shows a P/T ratio of 3.4. This shows that the patient could benefit from a split dose because it is greater than 2. If you look at the P/T of the split dose, it is 1.4 which is less than 2. This puts the patient in the normal range improving her overall response to the dose.



## Methadone Dosage & Management

- No consistent correlation between maternal methadone dose and severity of neonatal withdrawal syndrome (Stimmel et al., 1982)
- Protocols are available for scoring signs of opioid withdrawal to guide use of medications to facilitate withdrawal of the passively addicted neonate (NAS) (Finnegan, 1985).

## 10. TRAINER NOTE:

There is not a consistent correlation between maternal methadone dose (whether it is 40 mg or 200 mg) and the severity of neonatal withdrawal syndrome (Stimmel et al., 1982). Hence the need to provide the patient with adequate doses versus limiting their dose. They should be on the lowest effective dose, but there should not be any discrimination for raising the dose if the patient's dose is not adequate.

Historically, treatment providers have based dosing decisions on the need to avoid or reduce the incidence of neonatal abstinence syndrome (NAS) (Kaltenbach et al. 1998; Kandall et al. 1999) rather than to achieve an effective therapeutic dosage. This low-dose approach, which emerged from several 1970s studies (e.g., Harper et al. 1977; Madden et al. 1977), has been contradicted by more recent studies (e.g., Brown et al. 1998; Kaltenbach and Comfort 1997).

CONTINUED

### Breastfeeding on Methadone

- Mothers can breastfeed
- APA approved breastfeeding at **any dose** in 2003
- Patients should be monitored for the use of both licit and illicit drugs and alcohol (Kalrenback et al. 1998)



### Buprenorphine During Pregnancy

- Buprenorphine may be used in pregnant patients under certain circumstances.
- Buprenorphine recommended only when the physician believes potential benefits justify risks.
  - May continue on buprenorphine with careful monitoring.

The consensus panel knows of no compelling evidence supporting reduced maternal methadone dosages to avoid NAS. On the contrary, higher dosages have been associated with increased weight gain, decreased illegal drug use, and improved compliance with prenatal care by pregnant women in MAT and with increased birth weight and head circumference, prolonged gestation, and improved growth of infants born to women in MAT (De Petrillo and Rice 1995; Hagopian et al. 1996).

Moreover, reduced methadone dosages may result in continued substance use and increase risks to both expectant mothers and their fetuses (Archie 1998; Kaltenbach et al. 1998). The consensus panel recommends that methadone dosages for pregnant women be determined individually to achieve an effective therapeutic level.

Protocols are available for scoring signs of opioid withdrawal to guide the appropriate use of medications to facilitate a safe and comfortable withdrawal of the passively addicted neonate (NAS) (Finnegan, 1985).

## 11. TRAINER NOTE:

Mothers can breastfeed (if not HIV positive) while taking methadone.

American Psychological Association (APA) approved breastfeeding at any dose in 2003 (for 30 years it was limited to doses at 20 mg).

It is essential that patients be monitored for the use of both licit and illicit drugs and alcohol to manage appropriately in the perinatal care of both mothers and infants (Kalrenback et al. 1998).



## 12. TRAINER NOTE:

Buprenorphine may be used in pregnant patients under certain circumstances. The Consensus Panel recommends buprenorphine be used only when the physician believes potential benefits justify risks. Such patients may continue on buprenorphine with careful monitoring.

There are some clinical trials and studies that are showing that babies are experiencing less neonatal withdrawal syndrome, shorter stays in Neonatal Intensive Care Unit (NICU), and the possible benefit of using buprenorphine during pregnancy. It is still being investigated and is not FDA approved. This is something to continue watching; in the future, this may be the best practice since the baby experiences less neonatal withdrawal syndrome.



## Buprenorphine During Pregnancy



- Potential candidates:
  - Opioid addicted but cannot tolerate methadone
  - Program compliance difficult
  - Adamant about avoiding methadone

## Buprenorphine During Pregnancy

- Patient's medical record should clearly document that patient:
  - Refused methadone maintenance treatment or such services are unavailable
  - Has been informed of the risks of using buprenorphine
  - Understands these risks



## Buprenorphine During Pregnancy

- When treating pregnant patients, providers should use buprenorphine monotherapy tablets (Subutex®).
- Patients already maintained on buprenorphine-naloxone combination tablets, who become pregnant, can be transferred directly to buprenorphine monotherapy tablets.

### 13. TRAINER NOTE:

Who are potential candidates for buprenorphine treatment?

- Women who are opioid addicted but cannot tolerate methadone. Some cannot tolerate methadone or have failed on methadone.
- Those for whom program compliance has been difficult.
- Those who are adamant about avoiding methadone.



### 14. TRAINER NOTE:

A patient's medical record should clearly document that the patient:

- Has refused methadone maintenance treatment or such services are unavailable.
- Has been informed of the risks of using buprenorphine, which has not been thoroughly studied in pregnancy.
- Understands these risks.



### 15. TRAINER NOTE:

When treating pregnant patients, providers should use buprenorphine monotherapy tablets (Subutex®). Not the combined tablets.

Patients already maintained on buprenorphine-naloxone combination tablets (Suboxone), who become pregnant, can be transferred directly to buprenorphine monotherapy tablets.



## Integrated, Comprehensive Services

- Establish a relationship between the methadone provider and the OB/GYN, PCP and/or specialist
- Clear communications and linkages among all providers is a must
  - Collaboration for medication management and prenatal evaluation follow up
  - Case management assistance



## Recommendations

- Establish a policy to see pregnant patients more often (especially in the 3<sup>rd</sup> trimester)
- Establish continuous patient education around pregnancy and contraception
- Informed consent procedures
- Adequate dose

## Co-occurring Disorders

### 16. TRAINER NOTE:

Integrated, comprehensive services are a must for OTPs.

Establish a relationship between the methadone provider and the OB/GYN, PCP and/or specialist (e.g., a pregnant woman who has lupus and sees a specialist and an OB/GYN). It is important that this collaboration and communication be documented in the patient's chart.

- Clear communications and linkages among all providers are a must.
- Collaboration for medication management and prenatal evaluation follow up.
- Case management assistance to help manage all aspects of the patient's treatment and care.

### 17. TRAINER NOTE:

Establish a policy to see pregnant patients more often (especially in the third trimester). In many programs, these patients are seen on a weekly basis based on the patient's needs (not the customary minimum of twice yearly follow-up).

Establish continuous patient education around pregnancy and contraception. Educate all female patients, not just pregnant patients.

As we discussed in an earlier module, have Informed Consent Procedures in place (helpful in discussing risks).

Adequate dose: Dose a pregnant patient adequately to make sure she does not experience withdrawal. There is not consistent correlation between maternal methadone dose (whether it be 40mg or 200 mg) and the severity of neonatal withdrawal syndrome.

*NOTE: Before advancing the slide which will take you to the next topic area of patients who have co-occurring disorders, ask participants if there are any lingering questions about opioid treatment and pregnancy.*

### 18. TRAINER NOTE:

Many people who are opioid addicted have co-occurring mental disorders. However, mental health and addiction treatment systems often are separated. This situation may result in patients being treated at one location for addiction and at another for mental disorders.



## Co-Occurring Disorders

- Co-occurring disorder (COD) refers to a mental disorder that co-exists with at least one substance use disorder
- Sometimes COD patients exhibit behaviors or feelings that may interfere with opioid treatment
- The COD should be distinguished by type/category and addressed appropriately

## Co-Occurring Disorder



- Categorized according to Axis I and II disorders, as defined by the *DSM-IV*
  - Axis I-Clinical disorders (include major mental disorders, learning disorders, and substance use disorders)
  - Axis II- Personality disorders and intellectual disabilities

## 19. TRAINER NOTE:

The term co-occurring disorder (COD) refers to a mental disorder that co-exists with at least one substance use disorder in an individual.

Individuals with COD sometimes exhibit behaviors or feelings that may interfere with opioid treatment. They need treatment for both the substance use disorder and the COD. These symptoms may indicate either underlying co-occurring disorders that would be present regardless of substance use (i.e., independent or primary disorders) or co-occurring disorders caused by substance use (i.e., substance-induced or secondary disorders).

OTPs should distinguish COD by type and category in order to address them appropriately. Unless MAT providers distinguish co-occurring disorders accurately by type and address them appropriately, these disorders likely will complicate patients' recovery and reduce their quality of life. Numerous studies have indicated that rapid, accurate identification of patients' co-occurring disorders and immediate interventions with appropriate combinations of psychiatric and substance addiction therapies improve MAT outcomes.

## 20. TRAINER NOTE:

Categorized according to Axis I and II disorders, as defined by the *DSM-IV*

Axis I - Clinical disorders, including major mental disorders, learning disorders, and substance use disorders

Axis II- Personality disorders and intellectual disabilities

Factors found to increase the prevalence of co-occurring disorders among people with substance use disorders include: older age, lower socioeconomic status, and residence in urban areas (Kessler et al. 1994); homelessness (North et al. 2001); and incarceration (Robins et al. 1991).



## Screening for Co-Occurring Disorders

- Admission and ongoing assessment routinely screen for co-occurring disorders
- Establish specific screening procedures for COD and cognitive impairment



## 21. TRAINER NOTE:

OTPs should have protocols in place to screen for COD.

The Consensus Panel believes that admission and ongoing assessment routinely should incorporate screening for co-occurring disorders. This screening should yield a simple positive or negative result, depending on whether signs or symptoms of co-occurring disorders exist. A negative result generally should rule out immediate action, and a positive result should trigger detailed assessment by a trained professional (see Chapter 4, TIP 43).

The list below are specific areas that should be included.

Treatment providers must decide:

- When and how to screen patients.
- How to integrate psychological screening with standard intake assessment.
- Which instruments to use for screening and confirming co-occurring disorders.
- What qualifications are needed by staff who conduct screenings.
- How to classify symptoms and other evidence.
- How to determine the most appropriate treatment methodology and level of care.

Establish specific screening procedures as well as screening for cognitive impairment.

The accuracy of instruments to screen for co-occurring disorders may be compromised if administered to patients with cognitive impairments.

*NOTE: (Optional activity) To involve participants in this discussion, you may wish to ask them to generate the list of issues (above) that the agency must consider and address in order for staff to competently identify patients in MAT who may have co-occurring disorders.*



## Making & Confirming a Psychiatric Diagnosis

- Assure and confirm accurate psychiatric diagnosis.
- Continuous patient education to enhance understanding of their co-occurring disorder is essential.

## Prognosis for Patients with COD

- Early identification and accurate diagnostic evaluation, combined with psychiatric and substance addiction therapies, improve outcomes.
- Unidentified and untreated COD often lead to poor MAT outcomes.

## 22. TRAINER NOTE:

Assure and confirm accurate psychiatric diagnosis. You may have patients that have an established diagnosis upon admission (Bipolar or Major Depression). You may want to seek a second opinion, from either your in-house psychiatrist or an outside psychiatrist to confirm that diagnosis is accurate. When you have patients that are impaired from drugs, it may be difficult to accurately diagnose.

Continuous patient education to enhance understanding of their co-occurring disorder is essential. The goal is for the patient to know and understand that both the substance use disorder and the co-occurring disorder need treatment to get the best outcome.

## 23. TRAINER NOTE:

An early identification and accurate diagnostic evaluation of COD, in combination with psychiatric and substance addiction therapies, improve MAT outcomes.

Unidentified and untreated COD often lead to poor MAT outcomes, and lead to difficulties in:

- Engaging patients in treatment.
- Establishing a therapeutic alliance between patients and treatment providers.
- Maintaining adherence to treatment regimens.
- Eliminating substance abuse and other risky behaviors.
- Preventing premature dropout or early relapse.

Research has suggested that persons with co-occurring disorders are at higher risk of:

- Suicide
- Psychiatric hospitalization
- Legal difficulties and incarceration
- Homelessness
- Life-threatening infectious diseases
- Domestic violence
- Abuse or neglect of their children
- Unemployment
- Other interpersonal problems

(e.g., Dausey and Desai 2003; Room 1998)



## Treatment

- COD patients not excluded from OTP treatment
- TIP 43 lists principles of care for COD
- Establish a protocol for identifying suicide and homicide risk
- Pharmacological treatment for COD when indicated
- Use of psychosocial interventions
- Collaborating with prescribing psychiatric team
- Understanding drug to drug interactions

## 24. TRAINER NOTE:

There are general treatment considerations for patients with co-occurring disorders: Sometimes patients can be stigmatized for their COD. Patients should not be excluded from treatment at OTPs because they have a COD. TIP 43 Consensus Panel lists principles of care for individuals with COD.

**Co-Occurring Disorders and Treatment Planning:** Because patients in MAT exhibit a wide range of co-occurring disorders, the Consensus Panel believes that early treatment planning and resource management should include classifying patients, at least tentatively, into categories based on types and severity of co-occurring disorders, although treatment always should be tailored individually.

**Models of Care:** Although it is not always feasible to provide more specialized services on site, patient adherence to medical treatment was found to drop dramatically when such services were provided through offsite referral (Batki et al. 2002). Even when referrals are to services near an OTP, noncompliance may have significant consequences for personal, social, and public health.

Establish a protocol for identifying and handling suicide and homicide risk. This should be ongoing throughout the patient's treatment, and not just at admission. Must assess for suicidal behaviors being vigilant to manage a crisis, have risk management strategies to assure patients in crisis get support.

All intake workers, certified addiction counselors, and clinicians should be alert to risk factors for suicide and homicide and should question at-risk patients routinely about suicidal or homicidal thoughts or plans. This is important for patients who appear withdrawn, depressed, angry, or agitated or are known to have experienced a recent significant loss or other source of stress—especially if a co-occurring disorder is suspected or diagnosed or if a patient still is intoxicated or withdrawing from a psychoactive substance. Although the Consensus Panel believes such screening is helpful, the research evidence supporting its effectiveness is limited (Kachur and DiGuseppi 1996).

Pharmacological treatment for COD should be used when indicated based on a best practice model.

In many ways, an OTP is an optimal setting to initiate and monitor psychiatric pharmacotherapy for co-occurring disorders because patients attend daily (at least in the early stages of treatment) and onsite physicians and other staff can observe their reactions to psychotropic medications as well as to methadone or other addiction treatment medications.



CONTINUED 

## 24. CONTINUED

Use of psychosocial interventions may improve treatment outcomes.

OTPs should consider a hierarchical approach to treating patients with co-occurring disorders, starting with psychosocial interventions, such as increased counseling or psychotherapy (unless the patient has a disorder clearly needing medication).

Collaborating with prescribing psychiatric team is essential.

Understanding psychiatric drug-drug interactions for medication management is also essential.

OTPs must consider how to manage (i.e. in relation to the use of atypical psychiatric drugs which can cause diabetes) an increase in co-occurring physical disorders and the side effects of these medications, therefore collaborating with the primary care physician care team is critical.

### In Summary

- Consult the TIP 43 for more specific information
- Be proactive in policy and action in assessing clients for special circumstances such as pregnancy and/or COD
- Educate patients

## 25. TRAINER NOTE:

Consult the TIP 43 for more specific information; it is a good resource.

Be proactive in policy and action in assessing OTP clients for special circumstances such as pregnancy and/or COD.

Educate patients on both their COD and their substance use disorder. Inform them of the importance of medication for both.

