

Forum

ADDICTION TREATMENT

A Collaborative Initiative for
Patients and Clinical Professionals

Volume 19, #3
Summer 2009

Methadone Mortality Update – Report Findings, Proposed Legislation, and Planned Education Initiatives

According to the Centers for Disease Control and Prevention (CDC), the number of methadone-associated overdose deaths increased more than fivefold—from 786 to 4,462—between 1999 and 2005.

A key report, “Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them,” prepared by the U.S. Government Accountability Office (GAO), was released in March.

Specifically, the GAO attributed the rise to an increase of nearly eightfold in methadone prescriptions for pain from 1998 through 2006, a lack of practitioner knowledge and patient education about the unique actions of methadone in the body, and a rise in methadone diversion and abuse.

The GAO report noted that data from five states suggest that the specific circumstances of the methadone-associated deaths are variable because of drug combinations, including use of antidepressants and benzodiazepines, and unknown sources of methadone.

Rockefeller Bill Introduced

The GAO report prompted U.S. senators John D. Rockefeller IV (D-W.Va.) and Bob Corker (R-Tenn.) to introduce the Methadone Treatment and Protection Act of 2009. Their bill to reduce opioid-related deaths proposes four solutions. If enacted into law, this legislation will impact opioid treatment programs (OTPs). It will:

Require Provider and Patient Education

– Require the Department of Health and Human Services (HHS) to set up a mandatory, comprehensive practitioner-education program for physicians who prescribe methadone and other opioids for both pain management and

opioid dependence. Practitioners must complete the program as a requirement for registering with the Drug Enforcement Administration (DEA) to prescribe, dispense, and administer controlled substances. Although most deaths involve pain practices, the education requirement will apply to OTP practitioners as well.

– Provide competitive grants to states and to nonprofit community organizations to distribute educational materials about proper methadone use to consumers. Priority will be given to states that have a high incidence of methadone abuse and methadone-related deaths

Senators Introduce the Methadone Treatment and Protection Act of 2009



Improve Federal Oversight

– Create the Controlled Substances Clinical Standards Commission to establish standards for the following areas: patient education, appropriate and safe dosing standards for all forms of methadone, methadone abuse reduction, opioid conversion factors, and methadone initiation for pain management.

(Editorial note: Some pain management specialists warn against using conversion tables, because of unreliable cross-tolerance among opioids and genetic variations among patients; see GAO Report, page 20.)

(continued on page 7)

*Methadone Mortality Update –
Report Findings, Proposed
Legislation, and Planned
Education Initiatives 1*

*From the Publisher
AATOD Convenes National
Conference in New York . . . 2*

Events to Note 3

*Medication-Assisted
Treatment (MAT) During
Pregnancy – Part I 4*

*Adequate, Flexible Dosing
with Methadone Improves
Retention 6*

*New Study Questions the
Need for Routine ECG
Screening 6*

*SAMHSA & FDA Launch
Methadone Safety Campaign . . 7*

*OTP Voluntary Mortality
Report Update 7*

In This Issue

AATOD Convenes National Conference in New York

The American Association for the Treatment of Opioid Dependence, Inc. (AATOD) and hosts—the New York State Office of Alcoholism and Substance Abuse Services (OASAS), and New York State’s Opioid Treatment Coalition (COMPA)—held its 23rd Annual National Conference, “Treatment and Recovery: People and Outcomes,” at the Hilton Hotel in New York City this past April. New York welcomed attendees with unseasonably beautiful weather. Despite tough economic times, attendance exceeded 1,400, including almost 100 attendees from 23 foreign countries.

Plenary Sessions

In the opening plenary, Ira J. Marion, MA, conference chair, and Mark Parrino, MPA, AATOD president, marked the 25th anniversary of AATOD. With great enthusiasm, the keynote speaker, OASAS Commissioner Karen M. Carpenter-Palumbo, presented plans for transforming all opioid treatment programs (OTPs) to become full partners in the prevention, treatment, and recovery system in New York State (see *AT Forum*, *Spring 2009*).

The true value of “Treatment and Recovery: People and Outcomes” can be told only by patients in medication-assisted treatment (MAT) who have the courage to share their stories, and those who welcome them into recovery. At the middle plenary session, those patients were Carolyn Visconte and Anthony Badger, who stood on the conference stage, faced the bright lights and more than a thousand strangers, and spoke of their lives before methadone treatment and their lives in recovery. When Carolyn hesitated a moment during her speech, those seated in the front rows stood as one and applauded, as if reaching across the lights to offer her the acceptance and encouragement to continue.

Center for Substance Abuse Treatment (CSAT) Director H. Westley Clark, MD, JD, MPH, CAS, FASAM, stressed that MAT programs must transition from professionally driven care to a patient-centered approach, actively involving the patient in all decisions. Renowned recovery pioneer William L. White spoke about how the recovery movement has grown and how he has come to embrace MAT as a valid treatment and pathway to recovery.



From left to right: Anthony Badger; Ira J. Marion, MA, conference chair; Carolyn Visconte; H. Westley Clark, MD, JD, MPH, CAS, FASAM; and William L. White, MA.

The true value of “Treatment and Recovery: People and Outcomes” can be told only by patients in MAT who have the courage to share their stories, and those who welcome them into recovery.

AATOD Open Board Meeting

The open board meeting was packed with observers and policy makers, including Health and Human Services (HHS) Senior Public Health Advisor Gregory Goldstein, CSAT staffers, and members of Helping America Reduce Methadone Deaths (HARMD).

Dr. Clark indicated that as costs for substance-abuse treatment in the public sector are rising, states are facing tighter budgets, and a larger percentage of treatment costs are being placed on the private sector. According to the Center on Budget and Policy Priorities, 42 states face midyear budget shortfalls in 2009 totaling \$53 billion. These budgetary constraints prevented some states from sending their State Opioid Treatment Authorities (SOTAs) to the conference.

OTPs Open 7 Days?

CSAT Director H. Westley Clark indicated that the accreditation agencies will review the need for OTP physicians to assess each patient for all take-home decisions, including Sunday and holiday dosing.

Ira Marion pointed out that the New York State take-home procedure has worked well for almost 40 years, even though 90 percent of New York’s OTPs are closed on Sundays, and that implementing the seven-day-opening recommendation would be difficult or impossible for most programs. Dr. Clark said, “Things change,” but offered no suggestions regarding take-homes.

Methadone Mortality and Patient Safety

Dr. Clark updated AATOD board members on methadone mortality, citing the recent report from the Government Accountability Office (GAO) and the voluntary OTP Mortality Report (see page 7). He stressed the need for uniform standards and case definitions in reporting drug-associated deaths, and the urgent need for OTPs to submit methadone mortality reports. He also outlined CSAT initiatives for responding to the GAO Report and to the Rockefeller bill (see *related articles in this issue*).

From the Publisher

Subscribe to the *AT Forum* Newsletter

E-mail: Feedback@ATForum.com

Phone or Fax: 1-847-392-3937

Mail: *AT Forum*

P.O. Box 685 • Mundelein, IL 60060-9953

Include your mailing address with your name, street, apartment number, city, state, and ZIP code.



Key Challenges Facing OTPs

QTc Monitoring

The much anticipated session, "What to do About QT," fueled the continued debate, with attendees lining up to challenge panelists' conclusions. A major concern: Why establish requirements to reduce risks for a few patients, if it means withholding care from many? Earlier in the meeting, Mark Parrino had aptly summed up this philosophy: "By entering treatment, patients are taking a risk. The greater risk is not getting treatment."

Among audience comments on proposed mandatory QTc screening were: Mandatory ECGs would entail additional expenses for patients and programs, and create yet another barrier to treatment; and potential lawsuits from the article already published in *Annals of Internal Medicine* will impact OTP insurance—regardless of final guidelines issued by CSAT. An attendee commented, "It's too late"—because the *Annals* article has already established the new standard of care (see AT Forum, *Spring 2009*).

Risk Management in the OTP

In a preconference session, Alan Wartenberg, MD, FACP, FASAM, discussed the lack of adequate credentialing in methadone for OTP physicians, their limited patient-contact, and the critical need for thoroughly understanding torsade de pointes. He emphasized that MAT patients must be treated by well-trained, experienced OTP charge nurses or other staff members who screen patients about cardiac family history, past seizures, and palpitations, and document results. These staff members

must be taught about interactions of other drugs with methadone, and trained to ask patients about any changes in medication. He suggested adding methadone to patients' home pharmacy records, to help pharmacists avoid potential drug interactions.



"By entering treatment, patients are taking a risk. The greater risk is not getting treatment."



Awards Banquet

Anita Townley, one of the first female patients in methadone maintenance treatment, presented the Nyswander/Dole "Marie" Awards to nine recipients (see below). Ms. Townley was an assistant and a close friend and confidant to Drs. Marie Nyswander and Vincent Dole for more than 20 years.

Other banquet honorees included A. Thomas McLellan, PhD (Friend of the Field Award). President Obama recently nominated Dr. McClellan to be Deputy Director of the Office of National Drug Control Policy (ONDCP). Walter Ginter, CMA, was given the Richard Lane/Robert Holden Patient Advocacy Award for his work on behalf of methadone and recovery.

The next AATOD conference will be held in Chicago, October 23-27, 2010. Plan to attend!

The Association For Addiction Professionals (NAADAC) 2009 Annual Conference

August 18-22, 2009
Salt Lake City, Utah
Contact: www.naadac.org

National Alcohol & Drug Addiction Recovery Month

September 2009
Contact: www.recoverymonth.gov

Cape Cod Symposium on Addictive Disorders

September 10-13, 2009
Hyannis, Massachusetts
Contact: www.ccsad.com

Central East Addiction Technology Transfer Center (ATTC) Keeping it Real 2009 Conference

September 30 - October 2, 2009
Baltimore, Maryland
Contact: www.attcnetwork.org

International Nurses Society on Addictions (IntNSA) National Educational Conference

September 30 - October 3, 2009
Albuquerque, New Mexico
Contact: www.intnsa.org

Events to Note

2009 Nyswander-Dole "Marie" Award Recipients

Recipients were nominated and selected by their peers for extraordinary service in the opioid treatment community.



- Robert K. Brooner, PhD
- Peter Coleman, MS
- Kim Comstock, MEd
- Mercedes Lovrecic, MD
- Judith Martin, MD
- Gloria J. Mouzon, MD
- Raymond M. Pomm, MD
- Deborah Powers, BS
- Alan Wartenberg, MD

- Maryland
- New York
- Texas
- Slovenia
- California
- Illinois
- Florida
- Wisconsin
- Rhode Island



Medication-Assisted Treatment (MAT) During Pregnancy – Part I

This is the first in a series of articles on treating pregnant patients in MAT, clinical considerations related to their care, and outcomes for their babies.

Holly is a 35-year-old tenth-grade dropout who has been addicted to both heroin and cocaine for 15 years. She put her first two children up for adoption because she lacked the financial and emotional resources to care for them. But when Holly learned she was pregnant again, she vowed to change her life and keep her baby. She enrolled in a comprehensive drug-treatment program near her home.

Some women, like Holly, seek treatment in an opioid treatment program (OTP) when they learn they are pregnant. Others, already receiving MAT, are leading active, productive lives, and decide to have babies. These women count on their OTP for support and prenatal care.

Holly delivered her baby, and thanks to counseling, medical care, and methadone treatment, she is keeping her baby.

Addiction Treatment Forum discussed the needs of pregnant women in MAT with two leading experts, Karol A. Kaltenbach, PhD, clinical associate professor of pediatrics and psychiatry and human behavior, Thomas Jefferson Medical College, Philadelphia, PA; and Hendree E. Jones, PhD, associate professor, Department of Psychiatry and Behavioral Sciences, Department of Obstetrics and Gynecology, Johns Hopkins University School of Medicine, Baltimore, MD. Dr. Kaltenbach and Dr. Jones direct comprehensive programs for opioid-dependent pregnant women.

Methadone Recommended as Standard of Care

Methadone has been used in the treatment of opioid-dependent pregnant patients since the 1960s. In 1998, a National Institutes of Health (NIH) consensus panel recommended methadone maintenance as the standard of care for treating pregnant women with opioid dependence. Methadone also is recommended as the standard of care by the Center for Substance Abuse Treatment (CSAT). The CSAT publication TIP 43 states that effective methadone-maintenance treatment and prenatal care improve obstetrical and fetal outcomes.

Buprenorphine as an Alternative to Methadone

CSAT TIP 43 recommends using buprenorphine in treating pregnant patients only when the prescribing physician believes the potential benefits outweigh the risks.

“Buprenorphine is an alternative to methadone for some women,” Dr. Kaltenbach told *AT Forum*, “especially those who are already being maintained successfully, become pregnant, and either refuse transition to methadone, or live in areas without access to an OTP. Physicians

whose patients become pregnant while taking buprenorphine should counsel these patients about the use of buprenorphine during pregnancy. Physicians should also have the patients sign an informed consent if they wish to continue receiving buprenorphine.

Clinical Trial in Progress

Both the NIH and CSAT support methadone as the standard of care for opioid-dependent pregnant women, due to the 40 years of clinical experience and numerous published reports documenting its safety and efficacy. Pregnant women have been allowed to participate in clinical trials examining any medication only since 1993; therefore, methadone, like most other medications, has remained in the U.S. Food and Drug Administration (FDA) Pregnancy Category C (meaning there is a lack of controlled clinical study data in pregnant humans).

An international clinical trial being conducted at eight sites is the first large randomized controlled trial to prospectively evaluate the maternal and neonatal safety and efficacy of buprenorphine versus methadone in opioid-dependent pregnant women. The trial, the Maternal Opioid Treatment Human Experimental Research (MOTHER) project, began in 2005, and includes 175 randomized participants. Dr. Jones is lead principal investigator of the project at the Baltimore site, and Dr. Kaltenbach is the principal investigator at the Jefferson site. Preliminary data are expected by the end of this year. Dr. Jones told *AT Forum*, “Our hope is that we’ll have both medications approved for use in pregnant women, so patients will have a choice.”

Challenges of Diagnosing Pregnancy

The TIP 43 consensus panel acknowledged that some opioid-dependent women may misinterpret early signs of pregnancy—nausea and vomiting, headaches, fatigue—as symptoms of opioid withdrawal. Consequently, they may increase their use of illicit opioids. If an opioid-dependent woman becomes pregnant, early enrollment in an OTP is recommended for the health of the mother and child.

For patients already in treatment, OTP staff members should discuss contraception regularly. Because methadone normalizes endocrine functions, women in the early stages of MAT may become pregnant unintentionally. Dr. Kaltenbach strongly urged that OTPs run periodic pregnancy tests on patients of child-bearing age, because the earlier pregnancy is diagnosed, the earlier medical care for mother and child can begin.

Federal Regulations for Treating Pregnant Patients

Federal regulations require OTPs to:

- Give priority to pregnant women who seek treatment, documenting any reasons for denying admission. For pregnant patients, OTP physicians may waive the usual requirement of a 1-year history of opioid addiction.
- Maintain policies and procedures that reflect the special needs of pregnant patients.

- Provide prenatal care, on site or through linkage agreements, and refer pregnant patients to appropriate health care providers.

Accreditation agencies usually review how OTPs provide care to pregnant patients.

Special Needs of Pregnant Patients in MAT

Pregnant patients in MAT can have complex medical and obstetric issues, as well as co-occurring mental health issues that require careful management.

Stigma affects all opioid-dependent patients to some degree, but prejudice toward those who become pregnant is especially high. Staff must provide patient care in a nonjudgmental way, conveying an understanding of the patient's fears and cultural or ethnic beliefs.

Staff-Patient Relationships. Staff members can build rapport and mutual trust with the patient during the assessment. It's essential to answer the patient's questions openly and thoroughly. A patient should understand that if she follows the OTP staff's recommendations about issues related to her health, the baby's health, and her family or personal situation, she will help to achieve a positive pregnancy outcome.

Stigma affects all opioid-dependent patients to some degree, but prejudice toward those who become pregnant is especially high.

The benefits of methadone maintenance during pregnancy need to be clearly outlined for patients entering treatment, and those already on MAT. Methadone:

- Eliminates risks associated with repeated fluctuations in blood levels of short-acting opioids
- Helps prevent the mother's use of needles and illicit drugs, thus reducing the risk to mother and fetus of bloodborne pathogens
- Improves adherence to medical care
- Reduces the risk of problems during pregnancy and delivery
- Provides better outcomes for the newborn (higher birth weight, lower risk of complications)

Patients need to be aware that some babies born to OTP patients develop withdrawal symptoms, known as neonatal abstinence syndrome (NAS). There is no conclusive evidence that higher methadone doses lead to more severe abstinence. Teamwork between obstetrician, mother, and OTP staff can improve outcomes for mother and child. There are known and effective treatments for NAS. Appropriately treated NAS has not been associated with long-term developmental problems for the child.

Managing Comprehensive Services of Pregnant Patients

Dr. Kaltenbach's and Dr. Jones' programs routinely treat opioid-dependent pregnant patients with methadone. Both programs offer comprehensive services that include obstetrical care, pediatric care, prepara-

tion for child care, psychological therapy, and individual, family, group, and couples counseling. Very few such specialized programs exist. Most OTPs will need to link with outside medical professionals, or community-based agencies, or both.

Coordinating Prenatal Care. "A major challenge for OTPs is to coordinate prenatal care," Dr. Kaltenbach told *AT Forum*. "OTPs need to establish a relationship with an obstetrician willing to work with them, so they can obtain consent and communicate with each other. Then the OTP physician and the obstetrician can exchange clinical information and work cooperatively to achieve the best outcome for mother and child."

Dr. Jones added, "Communication, training, and working with everyone involved throughout the pregnancy is the key. Hospital staff members need to have a clear understanding of OTPs. Ongoing training is necessary, due to high staff turnover, particularly in large public medical centers."

Coordinating Other Services. The list of recommended services is long, but opioid-dependent pregnant women are among the most vulnerable groups in our society. There are special needs of the unborn child as well.

- Patients need services aimed at eliminating substance use, developing personal resources, improving family and interpersonal relationships, and eliminating socially destructive behavior.
- Domestic violence and destructive behavior must be addressed in some families; preventing HIV/AIDS and other communicable diseases are important in others.
- Patients should receive screening for co-occurring psychiatric disorders, including mood disorders (eg, depression), anxiety (eg, post-traumatic stress disorder), and other drug-use disorders (eg, alcohol, nicotine, benzodiazepines, cocaine, marijuana). Patients with positive test results for co-occurring disorders should receive assessment and treatment.
- Patients should have an assessment of their nutritional status, weight, and eating habits, and should receive dietary education when necessary.

Opportunities for OTPs

Some OTPs have very few pregnant patients, and say they haven't any place to send them, and don't have the linkages that lead to effective care. Dr. Kaltenbach told *AT Forum*, "There is a wealth of guidance available to OTPs. TIP 43 has a lot of information on managing opioid dependence during pregnancy. So do many journal articles." (The *AT Forum* website link to this article provides a list of recommended resources.)

A few years ago only three methadone programs in Baltimore actively admitted pregnant patients; now about 25 do. "We have been successful in communicating the message that it's okay to be maintained on methadone during pregnancy," Dr. Jones told *AT Forum*.

OTPs that promote services to attract pregnant patients can gain a competitive edge, while providing a valuable service to pregnant women and their babies.

Sources available online at <http://www.ATForum.com>.



Adequate, Flexible Dosing With Methadone Improves Retention

Patients who stay in medication-assisted treatment (MAT) have much better chances for recovery from opioid dependence than those who drop out. An adequate daily dose of methadone and an individualized dosing schedule adjusted for each patient's needs are key factors in improving retention.

A recent study compiling results from 18 randomized, controlled trials provides solid evidence that retention is higher when daily methadone doses are ≥ 60 mg, and the amount of methadone dosed is adjusted for each patient during treatment. The study data yielded a sample size of 1,797 participants who received either fixed or flexible doses of methadone; follow-up was for one year.

Dose Levels and Retention: In 1998 the National Institutes of Health Consensus Conference recommended a minimum daily dose of methadone of ≥ 60 mg. Some of the studies included in the current paper were published before that date, which may explain why 57 percent of the participants were on daily doses < 60 mg. Follow-up studies show that dose levels ≥ 60 mg per day improved retention significantly for up to a year, with almost 75 percent more participants remaining in treatment than those receiving < 60 mg daily.

Dosing Strategy and Retention: Most participants (65 percent) were on a fixed dosing schedule. Those on flexible dosing were 72 percent more likely to remain in treatment than those on fixed dosing.

Conclusions: The authors commented, "To our knowledge, this analysis is the first to assess the influence of both methadone dose (high/low) and dosage strategy (flexible/fixed) on retention in treatment.

"As expected, retention was lower in studies with longer periods of follow up (6-12 months vs. 3-6 months). However, within each follow-up period, greater retention was associated with greater methadone dose, regardless of flexible or fixed dosing strategy. Greater retention was also associated with flexible dosing strategies, regardless of dose."

The authors acknowledge that the availability of psychosocial services, clinic policies, and maintenance-orientation rather than abstinence-orientation also influence outcomes. But following the recommendations for daily dose levels of methadone of ≥ 60 mg, with a flexible dosing strategy, can greatly improve retention and patient outcomes.

Source: Bao Y, Liu Z, Epstein DH, Du C, Shi J, Lu L. A Meta-analysis of retention in methadone maintenance by dose and dosing strategy. *Am J Drug Alcohol Abuse*. 2009;35:28-33.

New Study Questions the Need for Routine ECG Screening

A recent study from Oslo, Norway, continues to raise questions about the need for routine ECG screening and monitoring of patients in methadone therapy. The study reported two key findings: no increased risk of QTc prolongation or torsade de pointes during the first 30 days of methadone therapy, and a very low mortality rate associated with QTc prolongation during methadone-maintenance treatment. The authors concluded that routine ECGs would not significantly reduce mortality rates during induction. But they did suggest performing ECGs at induction of methadone therapy for patients with medical indications, such as a personal or family history of cardiac problems, and for patients with a daily dose of methadone > 120 mg.

How Common is QTc Prolongation? The investigators used a mobile laboratory to perform 12-lead ECGs on 200 patients (about 20 percent of the treatment population, which averaged 976 patients) after their daily dose. The only cardiologist who read the ECGs did not know details about the patients—dose, age, gender, or duration of treatment. About 86 percent of the patients were treated with methadone (average daily dose, 111 mg), the rest with buprenorphine (average daily dose, 19 mg).

Relation of QTc to Dose. The QTc interval increased as the dose of methadone increased. About 1 in 22 patients had a QTc > 500 milliseconds (ms); no patients on a daily methadone dose < 120 mg had a



QTc > 500 ms. There was no detectable correlation between QTc interval and time in treatment, age, or gender.

Mortality Due to Arrhythmia. The investigators examined the register of all patients receiving medication-assisted treatment (MAT) in Norway (January 1997 - December 2003) and the national death certificate register. The study group comprised 3,850 initiations for 2,382 patients (some patients were initiated repeatedly). Of two deaths that occurred during the first 30 days of methadone treatment, one was from intracranial bleeding and the other was from an unknown cause, so arrhythmia could not be ruled out.

The seven-year observation period totaled 6,450 patient-years in MAT. Ninety deaths occurred in that period. None was known to be due to cardiac arrhythmia. Four deaths were of unknown cause, and therefore could possibly be due to arrhythmia. Based on these data, the investigators placed an upper limit on deaths due to arrhythmia in the study population to be 0.0006 for each patient-year.

Source: Anchersen K, Clausen T, Gossop M, Hansteen V, Waal H. Prevalence and clinical significance of corrected QT interval prolongation during methadone and buprenorphine treatment: a mortality assessment study. *Addiction*. 2009;104(6):993-999.

– Appropriate \$25 million each year for the National All Schedules Prescription Electronic Reporting Act (NASPER), to establish cooperative prescription drug monitoring within each state. NASPER requires data-sharing on Schedule II, III, and IV drugs among states and interoperability to reduce diversion and doctor-shopping across state lines.

Create a Uniform Reporting System for Methadone-Related Deaths

– Create a National Opioid Death Registry to track information about all opioid-related deaths.

– Establish a standard reporting form for medical examiners to send to the National Opioid Death Registry.

A registry might be helpful in establishing standards for cause of death when methadone is found at autopsy. For decades, methadone has been blamed as a “cause of death” whenever it is in blood or tissues of the decedent, regardless of other factors.

Other Provisions

– Require that opioid treatment programs (OTPs) make arrangements to allow patients who are not permitted take-home doses to safely obtain methadone on days when the clinic is closed.

– For two years, no 40-mg diskettes of methadone may be prescribed or distributed, unless done in a way consistent with the policy of the Drug Enforcement Agency (DEA). This means distribution of the diskettes is limited to OTPs and hospitals. Absolutely no 40-mg methadone diskettes can be distributed as a take-home dose.

Educational Initiatives for OTPs

In addition to guidelines being developed on cardiac considerations in OTP patients, the following plans or programs will address methadone

safety in methadone maintenance treatment.

– At the American Association for the Treatment of Opioid Dependence, Inc. (AATOD) conference this past April, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Food and Drug Administration (FDA) held a news conference to introduce an important new methadone safety campaign for consumers (*see below*).

– This year, the Center for Substance Abuse Treatment (CSAT) will conduct up to nine training courses for health care professionals working in OTPs. Priority states include North Carolina, Nevada, Pennsylvania, Kentucky, West Virginia, Texas, and Oklahoma. The course will eventually be converted for Webinar use.

CSAT is also developing a one day risk-management course for OTP clinical and administrative staff, tentatively scheduled for October 22, 2009, in Chicago. The course will address responsibilities and legal liabilities of OTPs and their patients. Priority topics include safety measures during induction, and dangers of using other drugs with methadone. The course will also be offered in other states with high methadone mortality rates. Webinar presentations are planned as well.

Sources and additional information are available at <http://www.ATForum.com>.



SAMHSA and FDA Launch Methadone Safety Campaign

The Substance Abuse and Mental Health Administration (SAMHSA) and the Food and Drug Administration (FDA) launched a collaborative public awareness campaign in April 2009 to inform consumers that methadone, taken as directed, is safe and effective for treating opioid addiction and managing pain.

The campaign, *Follow Directions – How to Use Methadone Safely*, will educate consumers, health care professionals, and clinic staff about how certain other medications, if taken with methadone or not taken as prescribed, can cause life-threatening interactions.

A patient brochure, fact sheet, and poster are available in English and Spanish. A point-of-sale information sheet will be distributed in pharmacies where methadone is dispensed to pain-management patients. To download or order, visit: www.dpt.samhsa.gov/methadonesafety.



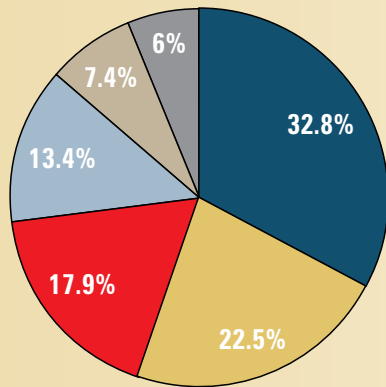
OTP Voluntary Mortality Report Update

Last fall the Substance Abuse and Mental Health Services Administration (SAMHSA) designed a voluntary Mortality Reporting Form to encourage opioid treatment programs (OTPs) to report standardized mortality data on patients who were receiving methadone or buprenorphine at the time of death. The Center for Substance Abuse Treatment (CSAT) hopes to use the form to help reduce deaths among patients in medication-assisted treatment (MAT).

Through March 2009, 53 OTPs in 17 states had returned 73 mortality forms. While it is still early in the reporting process, the forms will not

provide national mortality trends in patients unless OTPs in more states participate. Report findings to date:

- Methadone was the treatment drug in all reports received.
- Almost two-thirds of the deaths occurred in males.
- 85 percent of the deaths were in patients older than age 35.
- 68 deaths occurred in the maintenance phase of MAT, four during induction, and one during medically supervised withdrawal.
- The cause of death, entered in 67 of the 73 reports, was reported as unknown/undetermined in about one-third; followed by liver disease, cancer, and overdose (*see graph on page 8*).



REPORTED CAUSE OF DEATH (TOTAL = 67)

- Unknown/Undetermined
- Liver Disease
- Cancer
- Overdose
- Cardiovascular
- Other

Other category includes diabetes, seizures, suicide, kidney disease, trauma, chronic obstructive pulmonary disease (COPD), and HIV/AIDS.

Induction Mortality Reports of Interest to CSAT

CSAT selected two mortality case reports to present to the AATOD board during the national conference this past April. Both deaths occurred during the induction stage of treatment.

Case #1

A 52-year-old man was admitted to an OTP on February 6, 2009. The patient had been treated for depression, bipolar disease, attention deficit hyperactivity disorder (ADHD), and anxiety. On day four his test results were positive for opiates, amphetamines, methadone, and benzodiazepines.

At his last visit, on day five, he was taking carisoprodol (Soma), alprazolam (Xanax), hydrocodone (Vicodin), a dextroamphetamine sulfate combination (Adderall), bupropion (Wellbutrin), divalproex sodium (Depakote), and clonazepam (Klonopin). On day six he was dosed with 80 mg of methadone. He died the same day.

Case #2

On December 12, 2008, a 31-year-old man with a history of criminal activity and psychiatric illness was admitted to an OTP in a state of withdrawal. He told the clinic staff that he had not used alprazolam (Xanax) or cocaine for three days, and was then dosed with 40 mg of methadone. He continued to show signs of withdrawal the next day, and was given 70 mg of methadone. He died the same day.

Discussion

Both patients entered treatment with co-occurring conditions and had reported taking other drugs that can lead to a complex clinical situation. Alprazolam (Xanax), a benzodiazepine, can lead to unpredictable interactions with methadone, and hydrocodone, an opioid, can potentiate the methadone dose. Both patients were on aggressive methadone doses during induction. A more cautious approach may have been warranted.

The OTP Mortality Report Form and instructions can be accessed at: <http://www.dpt.samhsa.gov/providers/OTPMortalityreport.aspx>

Source: Clark HW. AATOD Open Board Meeting: CSAT Update. Speech presented at: Open Board Meeting of the Annual Meeting of the American Association for the Treatment of Opioid Dependence; April 25, 2009; New York, New York.

CHANGE SERVICE REQUESTED

Forum
ADDICTION TREATMENT
P.O. Box 685
Mundelein, IL 60060

Visit [ATForum.com](http://www.ATForum.com) Today



Is published quarterly
by Clinco Communications, Inc.
PO Box 685 • Mundelein, IL 60060
Phone/Fax: 847-392-3937

Publisher: Sue Emerson
Contributing Writers:
Clyde R. Goodheart, MD, MBA, MS
Barbara Goodheart, BA

- 60+ newsletters
- Monthly news updates
- Addiction resources
- Rx Methadone
- Events
- Related websites
- FAQs...and more
- Register for e-notifications

© 2009 Clinco Communications, Inc.
Addiction Treatment Forum is made possible by an unrestricted educational grant from Covidien Mallinckrodt, a manufacturer of methadone and naltrexone. All facts and opinions are those of the sources cited. The publishers are not responsible for reporting errors, omissions, or comments of those interviewed.

PRSR STD
U.S. POSTAGE
PAID
PALATINE, IL
PERMIT # 7117