



**U.S. DEPARTMENT OF  
HEALTH AND HUMAN SERVICES**  
Substance Abuse and Mental Health  
Services Administration  
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## **Data Summary**

### **METHADONE MORTALITY: A 2010 REASSESSMENT**

Sponsored by the  
Substance Abuse and Mental Health  
Services Administration

Washington, DC  
July 29-30, 2010

## ACKNOWLEDGEMENTS

Jennifer Fan, Pharm.D., J.D., formerly Public Health Advisor in the Division of Pharmacologic Therapies of the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), served as the Government Project Officer for this meeting.

Alina Salvatore, R.Ph., M.S., Public Health Advisor, Division of Pharmacologic Therapies, is the Project Officer for meeting follow-up activities. Onaje Salim, M.A., LPC, Team Leader in the Division of Pharmacologic Therapies, provided valuable guidance, as did other experts within SAMHSA and in other Federal agencies and private sector organizations.

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- Mark W. Parrino, M.P.A., President, American Association for the Treatment of Opioid Dependence (AATOD), New York, NY
- Seddon R. Savage, M.S., M.D., Director, Dartmouth Center on Addiction Recovery and Education (DCARE), and Pain Consultant, Manchester VA Medical Center, and Associate Professor of Anesthesiology, Dartmouth Medical School, Hanover, NH.

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The views, opinions, and content of this document are those of the individual authors and other referenced sources, and do not necessarily reflect the views, opinions, or policies of SAMHSA or any other part of the U.S. Department of Health and Human Services (HHS).

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Dear Colleague:

This report summarizes the presentations and discussions at the July 29-30, 2010 meeting, “Methadone Mortality: A 2010 Reassessment,” which was sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). The meeting brought together more than 90 epidemiologists, clinicians, educators, regulatory and enforcement officials, patient advocates, and policymakers for an in-depth reassessment of the current knowledge base on methadone-associated deaths and a review of progress in addressing the situation.

Methadone has a long, successful history as a potent analgesic and a highly effective medication for reducing the morbidity and mortality associated with opioid addiction. However, diversion, abuse, and deaths associated with many opioid medications, including methadone, have become a significant public health concern.

As the Federal agency tasked with oversight of the Nation’s opioid treatment programs, SAMHSA is concerned about these developments. Accordingly, in May 2003, SAMHSA convened a meeting entitled “National Assessment of Methadone-Associated Mortality.” Participants were tasked with reviewing the available data on methadone-associated deaths; determining whether and to what extent the reported increase in such deaths might be related to the clinical practices of SAMHSA-monitored opioid treatment programs; and formulating recommendations to address the problem. A follow-up meeting on the same topic was held in July 2007.

For the 2010 meeting, SAMHSA convened a group of experts to reassess the situation, review the progress made to date, and provide advice and guidance on needed modifications or additions to the strategies currently being pursued. This document summarizes the information presented and conclusions reached, as well as strategies and action plans endorsed by the participants.

Those of us at SAMHSA found this to be a very valuable session and trust that this summary and the full report (which is posted on the SAMHSA website) capture both the content and the collaborative spirit that marked the session.

Sincerely,

***H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM***

Director  
Center for Substance Abuse Treatment



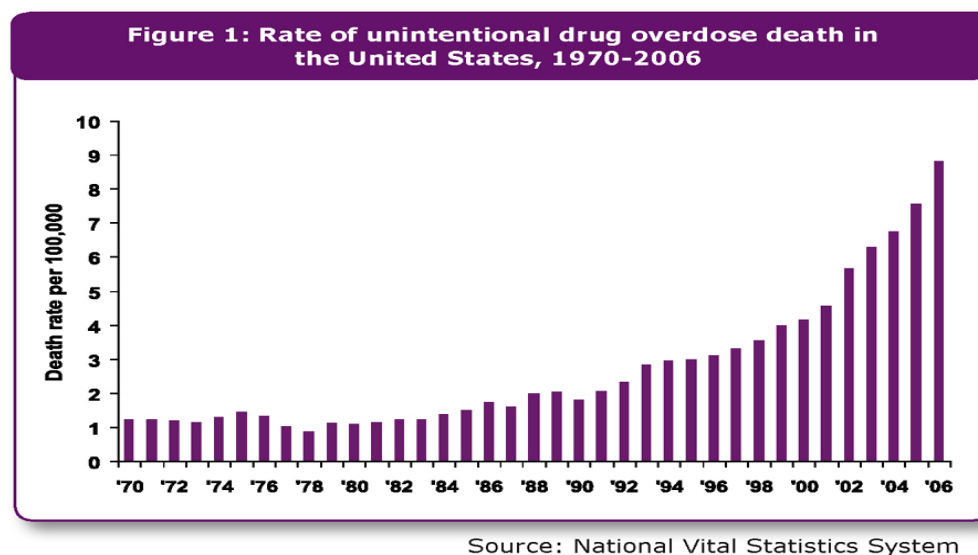
## GOALS OF THE REASSESSMENT

Methadone is an important medication for the treatment of opioid use disorders and chronic pain. It is a well-studied, safe, and powerful medication when prescribed and consumed properly. As a result, methadone has been used for more than 40 years to treat opioid addiction and its use in the treatment of pain has increased in the past 10 years.

### Understanding the Problem

Methadone is life-saving, yet it presents special challenges. Some pharmacologic and pharmacokinetic properties of methadone can lead to harm if the drug is misused or used for nonmedical purposes. Methadone's short duration of analgesic effect, coupled with a significantly longer elimination half-life, increase the risk of toxicity. Methadone can cause fatalities among individuals who have not developed tolerance to opiates; for example, deaths have occurred among children and adults who accidentally ingest methadone. Fatal intoxications also have occurred during the first weeks of medically supervised treatment and at the time of dose adjustments.

Additional difficulties are caused by the absence of a common nomenclature and uniform case definitions for use in distinguishing between deaths caused by methadone and deaths in which methadone is a contributing factor or merely present. These difficulties make it difficult to determine the true number and nature of methadone-involved deaths. However, it is clear that the number of methadone-associated deaths has continued to rise since the first National Assessment meeting in 2003. The increase in methadone-associated deaths has occurred in the context of rising death rates for all prescription opioids, such as oxycodone and hydrocodone.



Despite what we do know, the precise causes of the increase in methadone-associated deaths remain unclear. There is substantial agreement that patients are at elevated risk of

methadone-associated mortality if they: (1) engage in concurrent use of other CNS depressants, such as benzodiazepines, other opioids, and alcohol; (2) have risk factors for adverse cardiac events, such as prolonged QT syndrome and Torsades de Pointes; (3) are given too large induction doses or are not adequately monitored during induction; or (4) engage in deliberate misuse or abuse of methadone.

The increased scrutiny of methadone that has attended the increase in fatalities requires exploration of the benefits of methadone as a medication, the risks associated with its use, and the need to take timely and effective action to reduce harm to individuals who use methadone to treat addiction or pain.

### A Focus on Solutions

SAMHSA's role in monitoring adverse events related to methadone is embedded in both its statutory authority and the agency's commitment to promoting the public health. In 2001, the Secretary of Health and Human Services delegated to SAMHSA the responsibility for regulation and oversight of the Nation's opioid treatment programs (OTPs).

SAMHSA's current actions to address methadone-associated deaths began in 2002, spurred by reports of drug diversion, abuse, and deaths involving many opioid medications, including methadone. SAMHSA already was collaborating with other Federal agencies and with agencies in some of the States most directly affected by rising methadone mortality rates. Their reports, coupled with an increase in requests for consultation and assistance from State authorities and practitioners in the field, created added urgency for SAMHSA to evaluate and address the causes of the increase.

To assist it in developing a comprehensive plan and priorities, SAMHSA acted in July 2010 to convene a multidisciplinary group of more than 90 experts – including representatives of various Federal and State agencies, researchers, epidemiologists, pathologists, toxicologists, medical examiners, coroners, pain management specialists, addiction medicine experts, and others – to re-evaluate and update the findings of the 2003 National Assessment and the 2007 Reassessment. Participants were tasked with:

- Evaluating the best available data on methadone-associated overdoses and deaths.
- Determining whether and to what extent such deaths might be related to the clinical practices of SAMHSA-monitored OTPs as well as to the use of methadone to treat chronic pain.
- Reviewing current activities of SAMHSA and other Federal agencies to address the problem.
- Formulating strategies and action steps to enhance the effectiveness of existing activities and to describe potential new activities and areas of opportunity.

The information presented by the speakers, as well as the discussions and conclusions reached by this distinguished group of experts, are summarized here.



## UNDERSTANDING THE PROBLEM: CURRENT DATA AND TRENDS

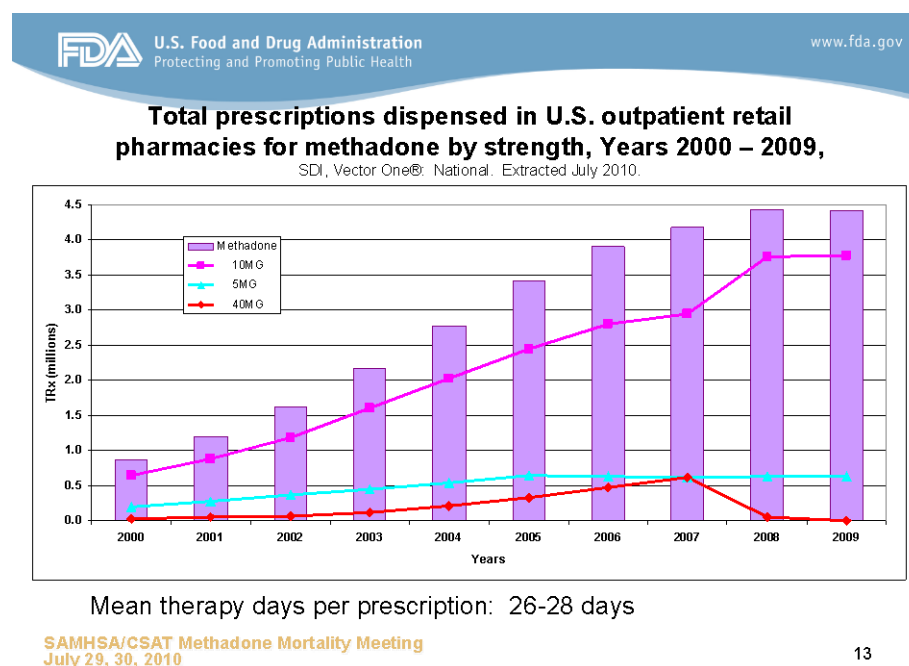
### FDA Data on Methadone

*Laura Governale, Pharm.D., M.B.A., Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration*

The Food and Drug Administration (FDA) purchases access to drug utilization data through a number of commercial drug utilization data vendors. From these data sources, FDA can track the amount of methadone sold by manufacturers.

Drug utilization data show that, in general, the wholesale distribution and outpatient use of methadone have leveled off in recent years. In 2009, methadone constituted approximately 2% of all prescriptions for opioids, at about 4.4 million prescriptions. The 10 mg tablets, which are used to treat pain, have been the most widely dispensed methadone formulation over the past 10 years (Figure 1).

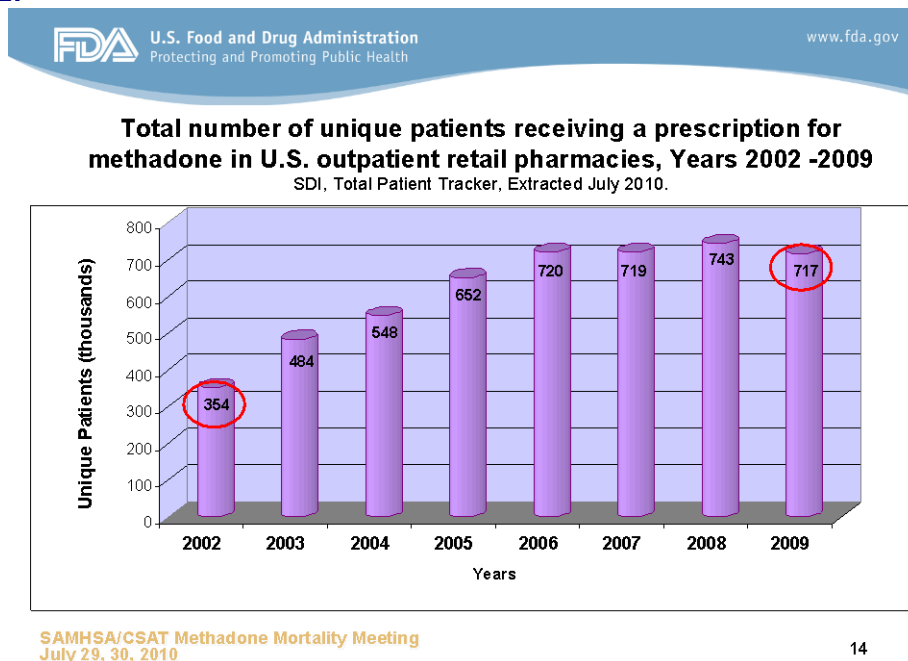
**Figure 1.**



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The number of unique patients receiving a prescription for methadone from 2002 to 2009 increased by 103 percent, from about 354,000 patients in 2002 to about 717,000 patients in 2009 (Figure 2).

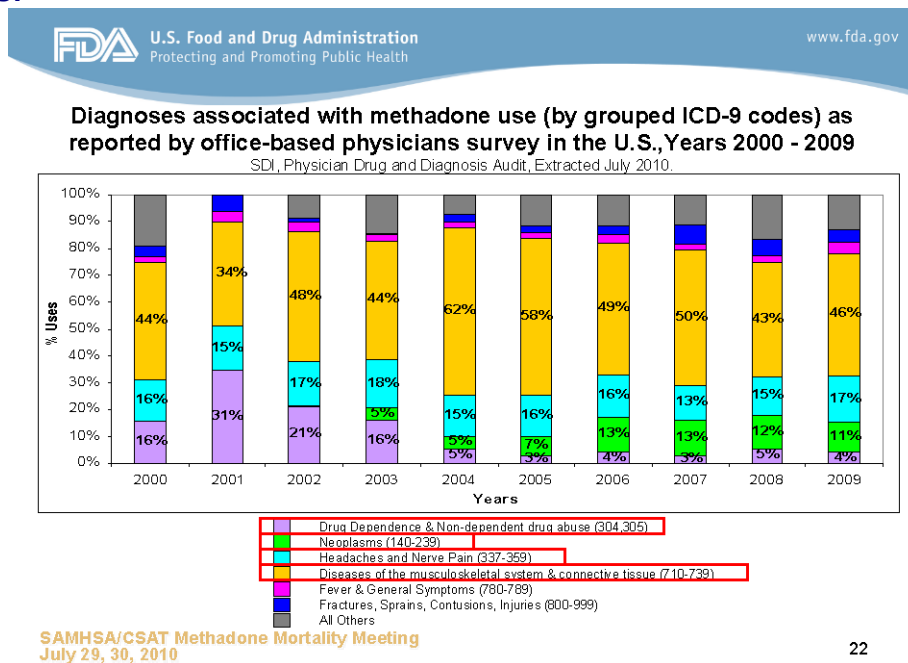
**Figure 2.**



14

In 2009, the majority of prescriptions for methadone were written by primary care physicians and physician extenders. The indications for which methadone was prescribed included pain associated with musculoskeletal disorders (46%), headaches and nerve pain (17%), and cancer-related pain (11%) (Figure 3).

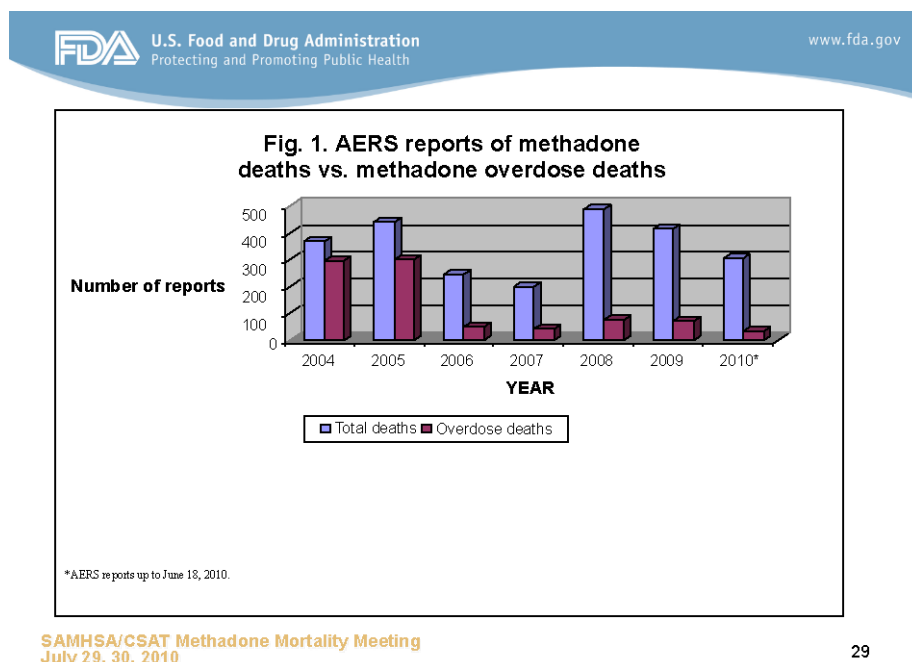
**Figure 3.**



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Between 2004 and June 2010, FDA received 2,500 reports of deaths and 989 reports of overdoses associated with methadone from the Adverse Events Reporting System (AERS; Figure 4).

**Figure 4.**



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## DEA Data on Drug Distribution (ARCOS)

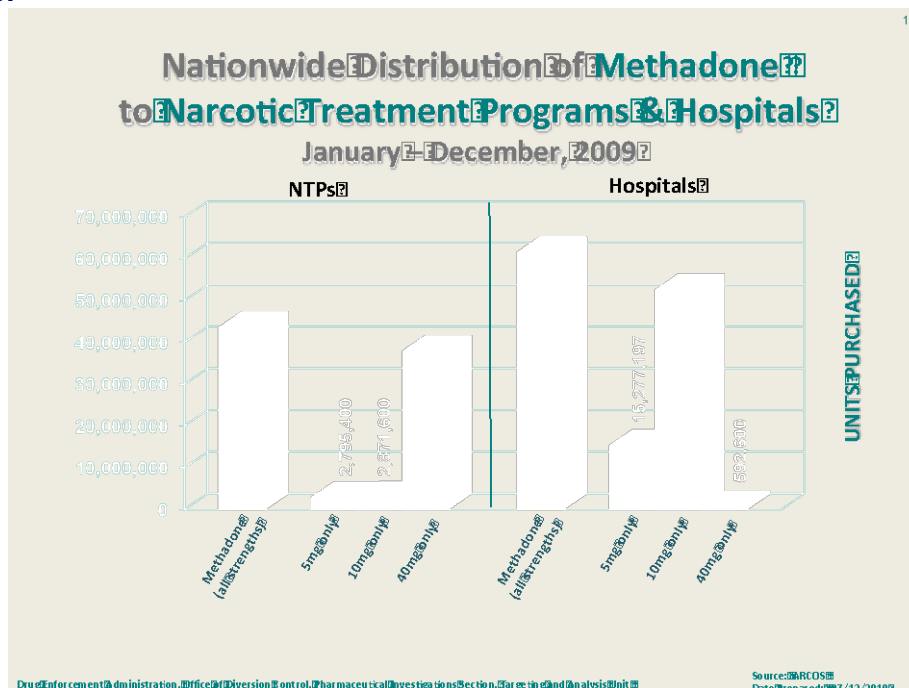
*June E. Howard, Chief, Targeting and Analysis Unit (ODPT), Pharmaceutical Investigations Section, Drug Enforcement Administration*

Every entity that manufactures or distributes prescription drugs is required to report that activity to the Drug Enforcement Administration (DEA). The DEA's Automation of Reports and Consolidated Orders System (ARCOS) captures information on drug inventories, acquisitions, dispositions, and manufacturing activities. Methadone data are included in ARCOS, although the data on distribution are somewhat limited.

ARCOS data for the period January 2006 through June 2010 show that 150 to 200 million dosage units of methadone (at all strengths and in all formulations) were distributed in each quarter, leveling off to 125 million units in the second quarter of 2010.

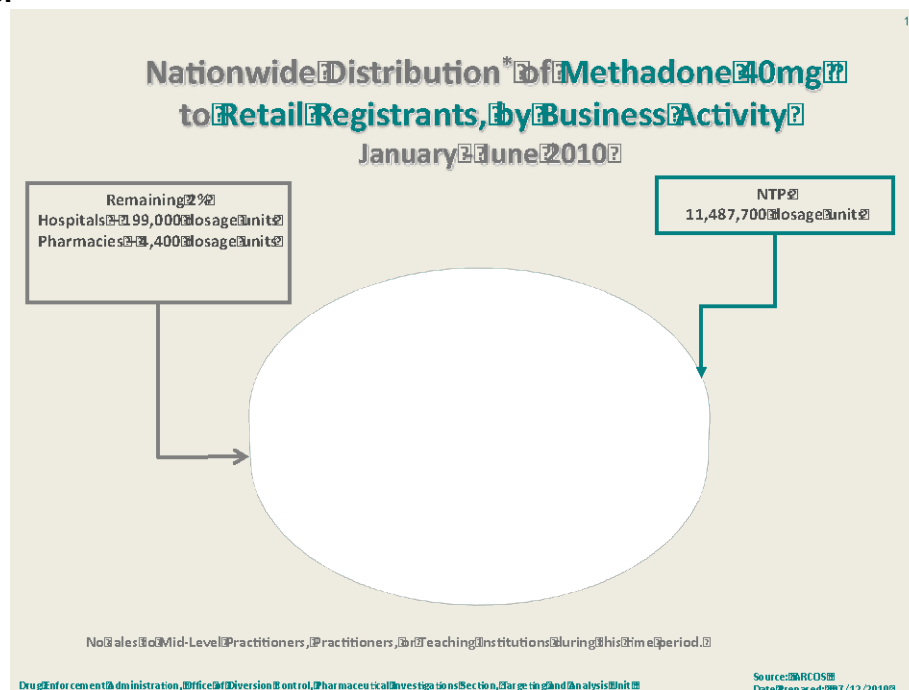
In 2009, 98% of methadone in the 40 mg formulation (about 38 million units) was distributed to OTPs (also known as Narcotic Treatment Programs or NTPs). The remaining 2% was distributed to hospital pharmacies (Figure 5).

Figure 5.



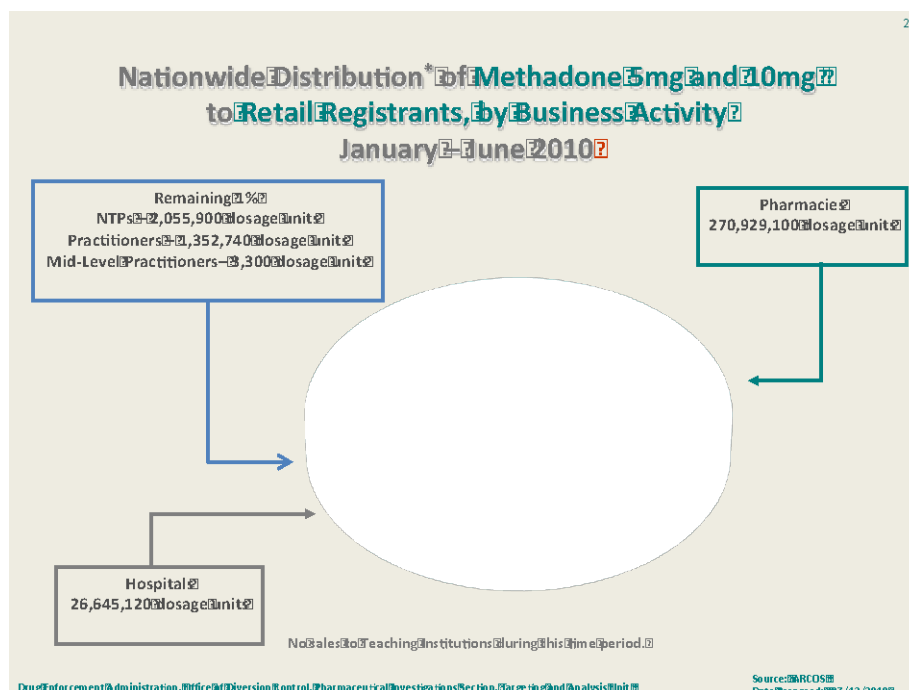
Individual practitioners received approximately 4.5 million dosage units of methadone in 2009 and about 1.3 million units in the first six months of 2010. The patterns of distribution seen in 2009 also were observed in 2010, with the vast majority of the 40 mg formulation going to OTPs/NTPs (Figure 6).

Figure 6.



In contrast, ARCOS data show that a large majority (90%) of the 5 mg and 10 mg formulations of methadone (commonly used for pain treatment) were distributed to retail pharmacies. Of the rest, 9% was distributed to hospitals and 1 percent to OTPs/NTPs (Figure 7).

**Figure 7.**



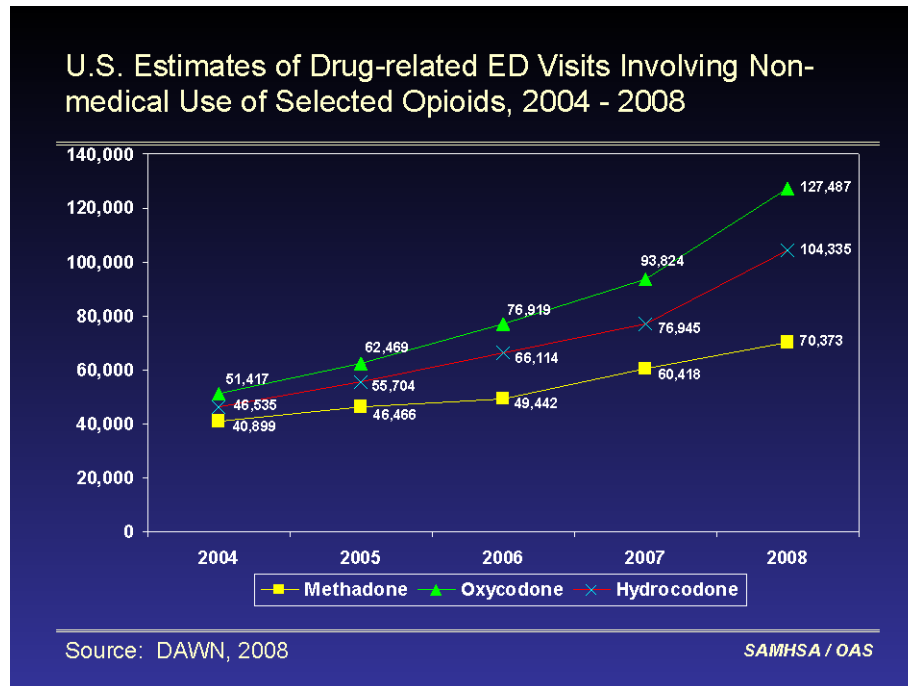
## SAMHSA Data on Emergency Department Visits (DAWN)

*David J. Skellan, B.S., Drug Abuse Warning Network, Center for Behavioral Health Statistics and Quality [formerly Office of Applied Studies], Substance Abuse and Mental Health Services Administration*

The Drug Abuse Warning Network (DAWN) is a public health surveillance system, which collects data from selected emergency departments and medical examiners/coroners. Using DAWN case criteria, reporters in participating institutions classify deaths as drug-related and attempt to determine the motive for drug use. All types of drugs, including illicit, prescription medications, and over-the-counter products--are included in DAWN. Twelve States report data on drug-related deaths.

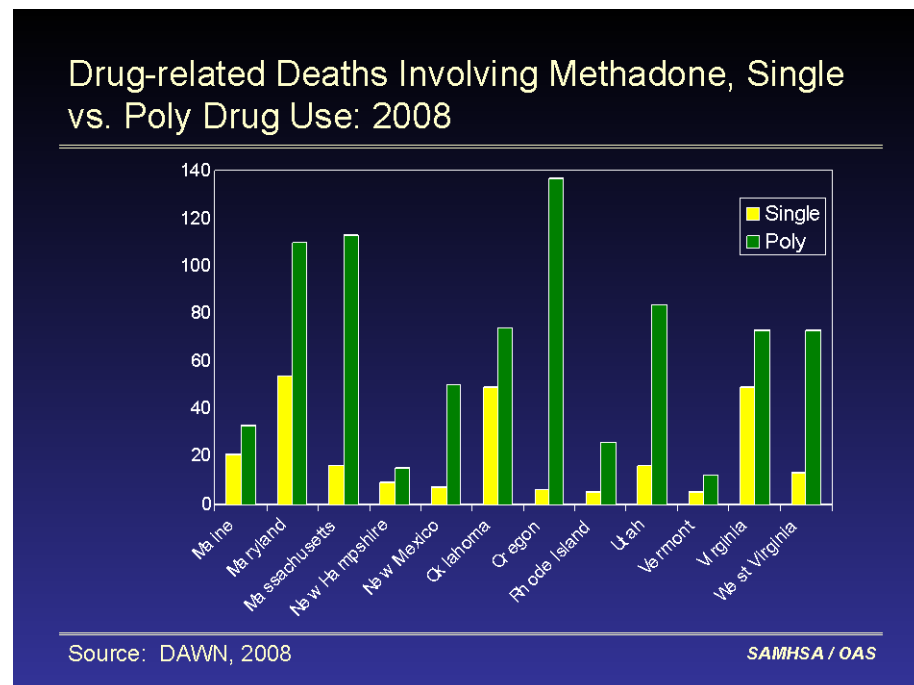
Overall, the number of emergency department (ED) visits resulting from nonmedical use of opioids increased in the period 2004–2008. Visits related to oxycodone and hydrocodone increased by an estimated 36% in 2008 over 2007, while ED visits related to methadone increased by 16% in the same period (Figure 8).

**Figure 8.**



In the States that currently report death data to DAWN, the number of deaths involving methadone in combination with other drugs is approximately three times the rate of deaths associated with use of methadone alone. In 2008, there were 800 polydrug deaths, compared with 250 methadone-only deaths (Figure 9).

**Figure 9.**



## CDC National Data on Drug-Related Deaths

*Margaret Warner, Ph.D., Injury Epidemiologist, National Center for Health Statistics, Centers for Disease Control and Prevention*

The Centers for Disease Control and Prevention (CDC) maintain the National Vital Statistics System (NVSS) to capture data on deaths from numerous causes, based largely on death certificates. Poisonings also are coded by cause.

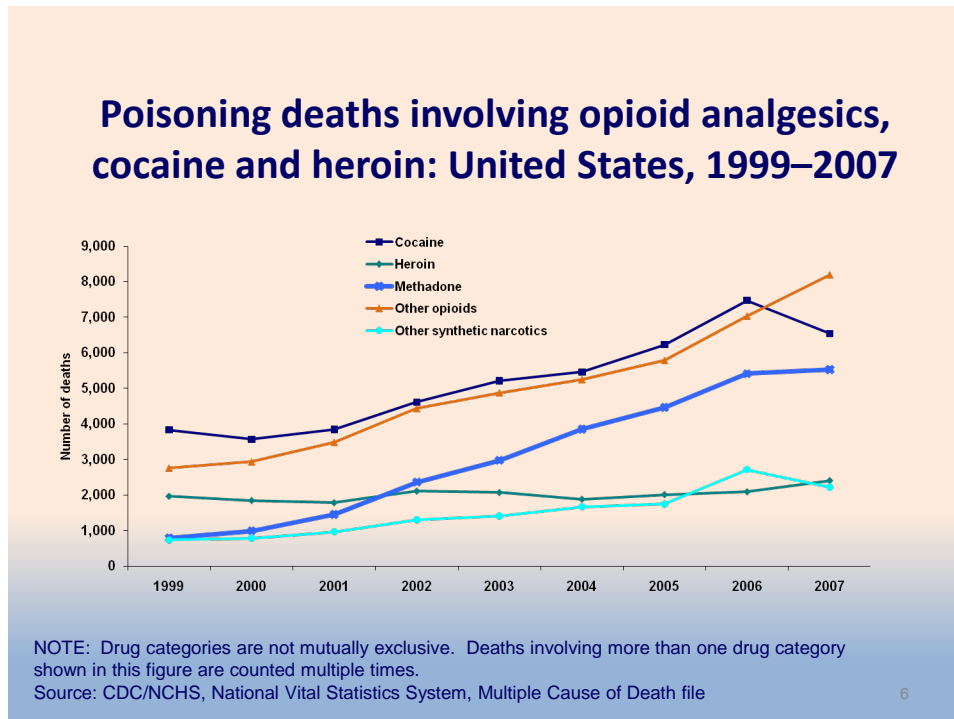
NVSS data show that, in 2007, there were 5,692 deaths in the U.S. involving methadone. This represented an increase over 1999, when 826 deaths were reported (Figure 10). The largest portion of these deaths occurred in persons aged 45 to 54.

**Figure 10.**

<b>Deaths involving methadone: United States, 1999–2007</b>									
	1999	2000	2001	2002	2003	2004	2005	2006	2007
Poisoning unintentional	623	778	1,158	1,911	2,452	3,202	3,701	4,552	4,706
Poisoning undetermined	105	138	186	295	370	441	523	598	591
Poisoning Suicide	56	72	111	149	146	195	232	254	225
Disease	42	62	88	96	125	153	152	187	136
Other Injury	-	-	-	-	-	29	24	30	34
Poisoning homicide	-	-	-	-	-	-	-	-	-
- Less than 20 deaths.									
Source: CDC/NCHS, National Vital Statistics System, Multiple Cause of Death									
10									

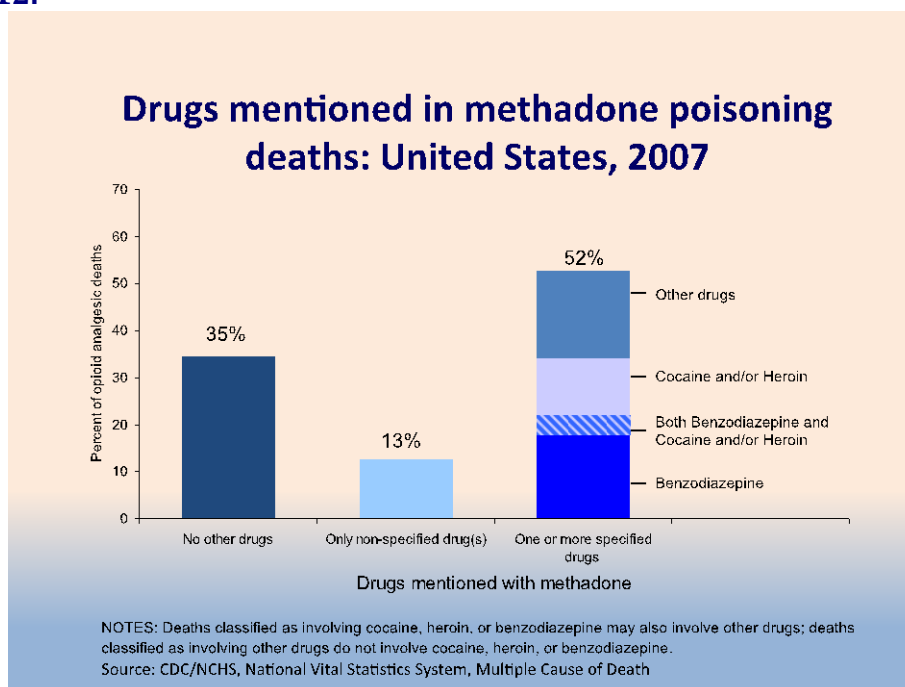
NVSS data show that methadone deaths increased by 2% from 1999 to 2007, while other opiate-related deaths increased by 16% and deaths related to cocaine decreased by 12% (Figure 11).

**Figure 11.**



Of all methadone-associated deaths, 35% involved methadone alone. In 52% of the cases, methadone was used in combination with another known drug. In 13% of the cases, an unspecified drug was involved (Figure 12).

**Figure 12.**





## CDC State-Level Data on Drug-Related Deaths

Leonard J. Paulozzi, M.D., M.P.H., Medical Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention & Control, Centers for Disease Control and Prevention

According to CDC data in the National Vital Statistics System (NVSS), most States reported fewer than 2 methadone-related deaths per 100,000 population in 2007. The most commonly reported death rate was 1 to 2 per 100,000 (Figure 13). However, the data are based on coding on death certificates, and there is a great deal of variability regarding how medical examiners arrive at those codes.

**Figure 13.**

Rates of Poisoning Death Related to Methadone by State, 2007	
Crude Death Rate per 100,000	States in rank order
<1	SD, AK, ND, NE, IL, TX, CA, NJ
1-<2	PA, DC, MS, MN, CO, IA, IN, AZ, WY, SC, MO, NY, MI, ID, HI, KS, CT, OH, VA, AL, MA
2-<3	DE, AR, LA, WI, TN, NM, VT, RI, MT
3-<4	FL, UT, ME, MD, OR, NC, KY
4-<5	WA, NV, NH
5+	OK, WV

Source: National Vital Statistics System, National Center for Health Statistics, CDC

Ten State-level studies conducted between 1987 and 2008 show that, overall, patients in OTPs account for a fairly small percentage of methadone-associated deaths; however, the percentage varies widely from one State to the next, ranging from 4% to 50% (Figure 14). Another 10 State studies suggest that methadone was the leading cause of death in overdoses involving opioids. In some states, methadone has been replaced by oxycodone as the opioid most often involved in overdose deaths. In those states, methadone remains the second most frequently cited opioid.

It should be noted that, in a large number of these deaths, the actual source of the methadone is not reliably known.

**Figure 14.**

Information on Sources of Methadone Among Drug Overdose Deaths				
State/Author	Year of Deaths	Number	Pct in OTP	Pct w Rx
Texas/Barrett	1987-92	54	9%	na
Minnesota/Gagajewski	1992-2002	31	42%	6%
Maryland/Anon	1998-99	8	50%	na
North Carolina/Ballesteros	1997-2001	198	4%	37%
New Mexico/Shah	1998-2002	143	22%	19-26%
Oregon/DOH	2002	103	~25%	33%
Kentucky/Shields	2000-04	95	10%	48%
Maryland/Anon	2004-05	52	15%	2%
West Virginia/Paulozzi	2006	87	12%	32%
North Carolina/Harmon	2007-08	18	na	17%

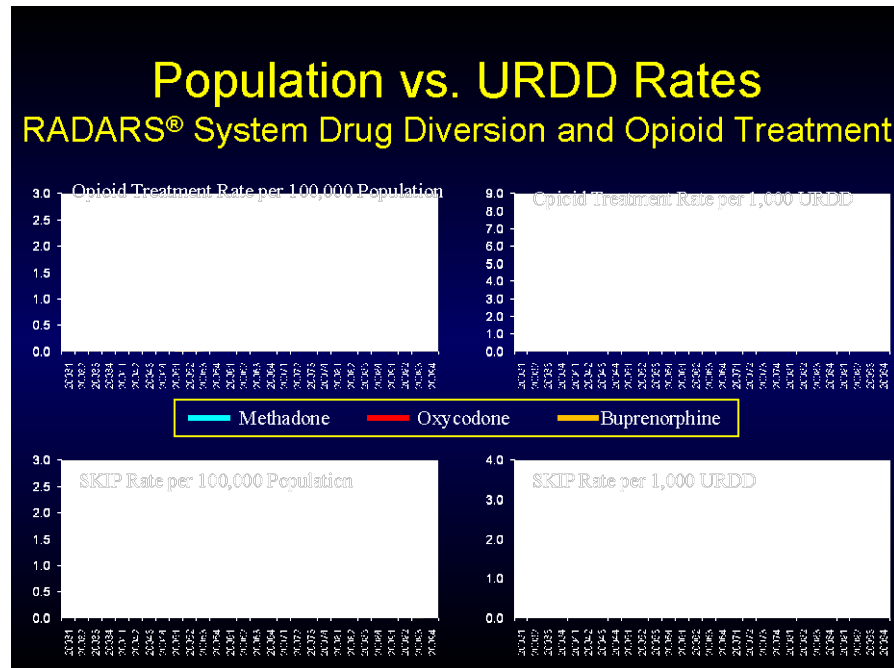
### **RADARS Methadone Study**

*Richard C. Dart, M.D., Ph.D., Director, Rocky Mountain Poison & Drug Center, and Executive Director, RADARS System*

The Researched Abuse, Diversion, and Addiction Related Surveillance (RADARS) System captures data from six sources: drug diversion datasets, surveys of key informants, poison control centers, OTPs, programs that treat impaired health professionals, and college surveys. Each source has its own strengths and weaknesses; together, they identify unique aspects of prescription drug abuse and diversion and the medical consequences thereof.

RADARS data show that deaths associated with oxycodone, buprenorphine, and methadone are increasing substantially. RADARS' poison center research data, which include all intentional exposures among children and adults, show that oxycodone ranks first in terms of deliberate abuse, but that methadone is abused at higher rates given its relatively limited availability (Figure 15).

Figure 15.



Methadone is more likely to be diverted than oxycodone or buprenorphine, even though fewer prescriptions are written for methadone than for oxycodone. While all formulations of methadone are diverted, tablets (which are prescribed for pain) are the most likely to be involved.

Children under the age of 6 were disproportionately involved in unintentional deaths after ingesting methadone, as compared to other prescription opioids. For example, in 2009, 1,105 children under age 6 were exposed to buprenorphine and no child died; 1,655 children under age 6 were exposed to oxycodone and one child died; and 316 children under 6 were exposed to methadone and two children died. This may be because methadone liquid formulations (typically take-home doses) are absorbed quickly, leading to rapid metabolism and death.

### SAMHSA Data on Methadone Deaths in OTPs

*Jane C. Maxwell, Ph.D., Senior Research Scientist, Gulf Coast Addiction Technology Transfer Center (ATTC), University of Texas at Austin*

In late 2008, SAMHSA launched an initiative to collect standardized data on deaths involving patients in OTPs through use of a Mortality Report form. Data submission was voluntary. The data collected were entered into an online database.

A number of problems were encountered in interpreting the data. For example, the report provided within 48 hours of death is subjective, as it uses information collected from family and friends. As a result, the preliminary certificate issued immediately after death

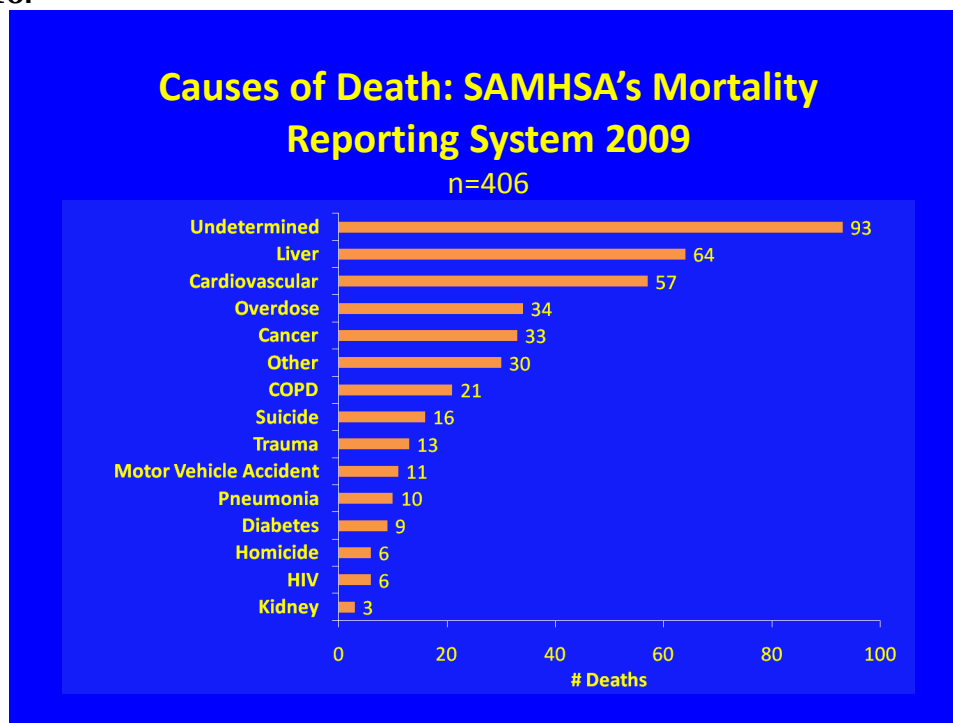
frequently is amended as much as 6 to 8 months later when a coroner or medical examiner issues a final ruling as to cause of death.

In 2009 (the first full year for which data were collected), 406 deaths were reported. Of these, 27% occurred in the first two weeks of treatment. Although the data on cause of death are preliminary, they indicate that persons who died of methadone overdose were more likely to have a history of depression. Also, 32% of the death reports cited the presence of benzodiazepines in addition to the methadone.

According to the data gathered, 67% of methadone decedents were male, with an average age of 49.8 years. The average length of treatment was 4.5 years and the average number of days of “take-home” doses dispensed at the last visit was 5. The average dose was 91.8 mg.

Deceased patients had an average of 1.5 comorbid medical or psychiatric conditions, including mental disorders, depression, or anxiety; liver problems, including hepatitis; cardiopulmonary disorders, including circulatory problems, high blood pressure and COPD; metabolic disorders, particularly diabetes; musculoskeletal disorders; kidney problems; and traumatic injuries. Given the rate of co-occurring disorders, it is not surprising that a large number of deceased patients had been using at least one prescription drug (most frequently a benzodiazepine) in addition to methadone (Figure 16).

**Figure 16.**



SAMHSA's next steps are to ask the expert panel to consider revisions to the current Mortality Report form and to refine the definitions used.

## A FOCUS ON SOLUTIONS: ONGOING AND PLANNED ACTIVITIES

Representatives of the participating Federal agencies described relevant activities that their agencies have undertaken or planned.

### **Substance Abuse and Mental Health Services Administration**

*H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration*

SAMHSA is committed to preventing methadone-associated overdoses and deaths. To do so, we've launched a number of projects and activities. Strategies devised at past reassessment meetings have been the impetus for many of these projects and activities.

A major finding of all the reassessment meetings is that we need a better understanding of the factors involved in methadone-related overdoses and deaths. SAMHSA has been collecting voluntarily submitted OTP mortality data since November 2008 through a Mortality Report Form, which captures information on all causes of death. However, medical examiners and coroners employ reporting standards and case definitions that can vary quite markedly from one jurisdiction to the next. As a result, methadone sometimes is reported as a cause of death when it is only a contributing factor or not a factor at all, while in other cases it actually is the proximate cause of death but is not reported as such.

To address this issue, SAMHSA convened a panel of experts to develop a consensus statement on Uniform Standards and Case Definitions. The statement has been submitted to a peer-reviewed journal for publication, and also will be submitted to a number of professional organizations for their adoption and/or endorsement.

We also are addressing the growing use of methadone to treat pain. This is important because data show us that the greatest growth in distribution of methadone involves the tablet form, which is dispensed only through pharmacies for the treatment of pain and not through OTPs for the treatment of addiction.

Experts attribute the increased use of methadone to treat pain to the drug's long duration of action and relatively low cost, which has led to coverage of methadone by most Medicaid plans. However, not all primary care physicians are sufficiently aware of the unique pharmacologic and pharmacodynamic characteristics of methadone, or the special cautions to be followed during the induction stage of pain treatment.

SAMHSA's programs to address this issue include live and online CME courses and webinars. Our live CME course meets the criteria for Category 1 credits under the Physician Recognition Award™ program of the American Medical Association, as well the accreditation programs of the American Academy of Family Physicians and the American Osteopathic Association. Topics addressed in the course include: (1) evaluating the risks and benefits of methadone use in particular patients; (2) evidence-based strategies for

patient assessment and education; (3) techniques for effective patient monitoring; and (4) determining when to stop use of methadone and treat the patient with an alternative therapy.

Through the end of 2010, live CME courses had been delivered at 36 sites in 19 States (Alaska, Arizona, California, Connecticut, Florida, Illinois, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, New York, North Carolina, Ohio, Vermont, Virginia, Washington State, and West Virginia). In addition, specialized versions of the course have been developed for the VA medical centers and the Indian Health Service. Evaluations of the courses by participants and independent experts have been extremely positive, with an overall average exceeding 6.0 on a scale of 1 to 7, with 7 designated “superlative.”

An online version of the CME course has been developed for posting on SAMHSA’s website and on the sites of medical organizations and State agencies. Case Western Reserve University Medical School provides master accreditation for the online course. The first three modules are undergoing final review before being posted, while the fourth and fifth modules are in production.

In addition, SAMHSA collaborated with the National Association of Community Health Centers (NACHC) to develop a 90-minute webinar based on the live CME courses. The webinar, recorded in February 2010, is available to community health center staff to view on demand through NACHC’s online educational resource center.

Finally, a 30-minute web-based version of the live CME course has been developed in collaboration with MedScape™, the world’s largest medical education website. The MedScape course was completed and posted on MedScape in September 2008. It can be accessed at no charge at <http://www.medscape.com/viewprogram/17268?src=mp>.

MedScape reports that, through the end of calendar year 2010, the course attracted more than 7,000 physicians. Evaluations are exceptionally high: on a scale of 1 (poor) to 5 (excellent), the overall score is 4.42. (This is consistent with the evaluation scores for the live courses.)

Through these multiple educational initiatives, SAMHSA has reached more than 10,000 physicians and other health care professionals with training in current, evidence-based practices and protocols for the safe and effective use of methadone to treat chronic pain.

Health care professionals also need training in the safe use of methadone to treat addiction. While such training should be available to all health professionals, OTP clinical and administrative staff have a special need for up-to-date information on methadone’s unique pharmacology, as well as evidence-based practices for its use and specific indications and cautions to consider when deciding whether to employ methadone in the care of a particular patient. SAMHSA is meeting this challenge through a comprehensive initiative.

For example, a new SAMHSA project directly addresses overdose by creating a comprehensive tool kit that OTP staff and patients can use to identify and respond to opioid

overdoses. Guidance as to the contents and format of the toolkit is provided by an expert panel of stakeholders and agency representatives.

In another project, SAMHSA is working with the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, and the American Academy of Osteopathic Addiction Medicine to support the activities of the Physician Clinical Support System for Methadone (PCSS-M). The essential elements of the PCSS-M are a national network of physician mentors with expertise in treatment and clinical education who can provide individualized support via e-mail, telephone or, in some cases, in person. There is no cost to physicians who use the service.

We've also worked with the Northeast Addiction Technology Transfer Center (ATTC) to develop and deliver risk management workshops for OTP administrative and clinical staff to provide (1) the latest findings on the use of methadone and other therapies for opioid addiction, (2) evidence-based techniques for patient selection, assessment and monitoring, and (3) reliable information about the risks and benefits of methadone use, as well as how to incorporate clinical and administrative practices that reduce risk and enhance patient outcomes.

In a project that focuses on the most risky period of methadone treatment, SAMHSA is supporting work by the American Society of Addiction Medicine (ASAM) to compile evidence-based practices and clinical protocols for the induction stage of methadone treatment. This is significant because multiple studies show that it is during the induction period – roughly the first two weeks of treatment – that the majority of OTP patient deaths occur. The ASAM project has produced a high-quality report, which was submitted to a large number of experts for field review. Final revisions have been made and the finished document submitted to a peer-reviewed journal for publication. SAMHSA will disseminate the published article through its website and through the PCSS-M.

SAMHSA also is addressing health issues specific to methadone. For example, SAMHSA convened an Expert Panel to examine the evidence on adverse cardiac events associated with methadone. The Panel was tasked with providing advice on the use of electrocardiograms and other measures to screen patients for cardiac risk. The resulting statement, which has undergone extensive field review, has been submitted to a peer-reviewed journal for publication. SAMHSA will disseminate the published article on its website and through the PCSS-M.

SAMHSA convened an Expert Panel to evaluate available data on the risk of drug interactions between methadone and other medications, such as those used to treat HIV infection. The panel was tasked with developing strategies for identifying and managing such risk in patients who may be candidates for treatment with methadone, either for pain or addiction. In response, the Panel produced a series of articles on specific risks for drug interactions, which were published in the January-February 2010 issue of the *American Journal on Addictions*. The issue has been widely disseminated by SAMHSA and the journal's publisher, which has made the articles available for download from its website at no charge.

Finally, we're working to build stronger relationships between public health officials, regulators, law enforcement authorities and health care professionals to promote better understanding of the causes of methadone-associated overdoses and deaths, ultimately leading to effective initiatives for prevention and early intervention. For example, SAMHSA hosts biweekly conference calls in which Federal, State and local officials meet with public health experts in the private sector to share information about drug seizures, and drug-related overdoses and deaths. A rapid report is produced and distributed after each call.

SAMHSA also is helping the Federation of State Medical Boards distribute an FSMB-endorsed handbook on the use of methadone and other opioids in the treatment of pain. The books provide clinical guidance and clear explanations of the relevant laws and regulations governing opioid prescribing. With SAMHSA's assistance, books are mailed to primary care physicians by their State Medical Boards, accompanied by a cover letter drawing attention to the need for care in prescribing opioids for pain. The books also are distributed through the SAMHSA prescribing courses.

So we're making progress, but the problem persists. A worrying development is that SAMHSA's Household Survey data show that many individuals who misuse methadone and other prescription opioids are not "on the radar screen" because they're not the patients for whom the prescriptions were written. In fact, more than half of all persons who engage in non-therapeutic use of prescription drugs obtain them from friends or family. Because these individuals are not the patients, government agencies have limited ability to reach them through prescription monitoring programs (PMPs) and other strategies that depend on identifying the patient. So we have a cultural phenomenon to deal with as well as a clinical problem.

Nevertheless, we have many more tools to address the problem today than we did at the time of the initial Assessment of Methadone-Associated Mortality in 2003. We also have a strong partnership among the various Federal agencies, and between those government agencies and their private-sector counterparts, as evidenced by the participation in the 2007 and 2010 Reassessment meetings.

At SAMHSA, we will continue to engage with our partner organizations and agencies, as well as with policymakers and the public, to prevent these needless deaths while continuing to offer patients the highest quality care for their pain or addiction disorders.

### Food and Drug Administration

Bob Rappaport, M.D., Director, Division of Anesthesia, Analgesia, and Addiction Products,  
Center for Drug Evaluation and Research, Food and Drug Administration

Efforts by the Food and Drug Administration (FDA) to address methadone morbidity and mortality include:

- *Public information campaigns:* The FDA is educating prescribers, patients and the public about the risks of methadone and other drugs. We are collaborating with SAMHSA on many of these initiatives, particularly those on methadone.



- *Addressing cardiac concerns:* FDA representatives participated in SAMHSA's Expert Panel on cardiac effects of methadone. Although it is not feasible for the FDA to do the research needed to further evaluate such cardiac risks, FDA personnel continue to analyze literature and to conduct modeling of methadone effects, and to correlate those data with reports of toxicity. The agency needs high-quality data to specify any type of monitoring that should be done, and will continue to cautiously recommend changes in drug labeling as appropriate.
- *Developing and implementing Risk Evaluation and Mitigation Strategies (REMS) for methadone and other extended-release opioid analgesics:* Although FDA was authorized to implement REMS in 2007, it has taken several years to develop REMs because of requirements to demonstrate that (1) there is a safety risk associated with this medication, although the overall benefits exceed the risk; (2) the proposed REMS requirements will not be overly burdensome to health care providers; and (3) the REMS will not restrict access to patients who need the medications. To meet these requirements, FDA has obtained input through public and stakeholder meetings and has received extensive feedback. Debate continues as to whether prescriber education about opioids should be mandated through the FDA, or whether such education can be provided more efficiently through existing programs.
- *Encouraging the development of new drug products:* The ACTION Project is a critical path program that awards to researchers who are developing new -- and potentially less risky -- medications for pain management and addiction treatment.

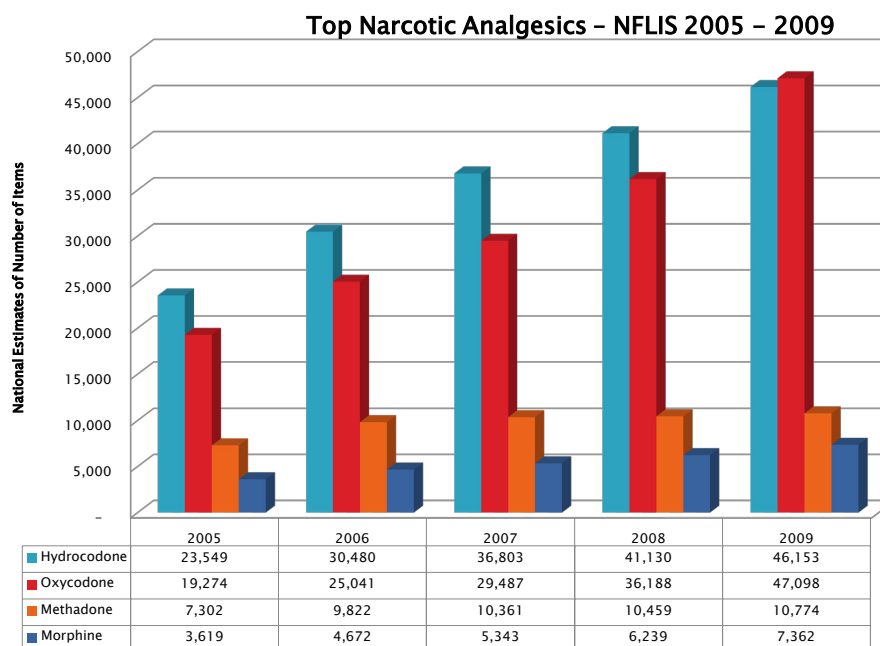
## Drug Enforcement Administration

*Denise Curry, M.A., J.D., Deputy Director, Office of Diversion Control, Drug Enforcement Administration*

The Drug Enforcement Administration (DEA) has extensive data collection and monitoring systems, which help to identify and target emerging drug threats:

- The Automation of Reports and Consolidated Orders System or (ARCOS) is a required DEA database that captures controlled substances activity in schedules I, II, and III narcotic, including methadone from the point of manufacture and/or distribution to the point of sale to the retail level registrant. It allows DEA to track the distribution of these drugs within specific geographic regions.
- The National Forensic Laboratory System (NFLIS) compiles data on drug seizures from hundreds of local and State laboratories that are affiliated with law enforcement agencies. NFLIS allows us to track nationwide trends in nonmedical use of methadone and other drugs (Figure 17)

**Figure 17.**



DEA is beginning to use special targeted enforcement operations through which agency staff can integrate information from multiple datasets (e.g., ARCOS, DAWN, NFLIS, and medical examiner data) to provide leads to DEA agents and other law enforcement officials.

Since the safety warning about the 40 mg dosage form of methadone was released in 2008, DEA has worked with the pharmaceutical industry to restrict distribution of this specific methadone formulation. Manufacturers of methadone voluntarily restrict distribution of 40 mg tablets to OTPs and hospital pharmacies (both settings that allow careful monitoring and rapid intervention for methadone-associated adverse events). ARCOS data show that this "40 mg initiative" has been a success: since January 2009, 99% of sales of 40 mg methadone have been to OTPs, with the remaining 1% to hospital pharmacies.

DEA also is actively supporting drug take-back programs, which encourage the public to participate in coordinated efforts with law enforcement to remove potentially abusable drugs or unneeded medication from homes. The national take-back initiative educates the public about the dangers of keeping unneeded medicines and how to partner with law enforcement to reduce the supply of unused or unneeded medications that are available in homes for misuse or diversion.

DEA's parental awareness and education initiative informs parents about prescription drug abuse and encourages clear communication with young people about the risks of nonmedical drug use. DEA also develops and distributes pamphlets to assist in the identification of methadone and other pharmaceutical controlled substances. Other materials have been developed to educate law enforcement officials about pharmaceutical controlled substances that are subject to diversion and abuse.

Finally, DEA works with SAMHSA, OTPs, and the addiction treatment community to host live training events for State and local law enforcement personnel about the problems associated with diversion and abuse of methadone. The response to these trainings has been enthusiastic; for example, one event in Nashville, Tennessee attracted more than 250 law enforcement personnel.

### National Institute on Drug Abuse

*Wilson Compton, M.D., Director, Division of Epidemiology, Services and Prevention Research, National Institute on Drug Abuse*

The National Institute on Drug Abuse (NIDA) recognizes that the issue of methadone mortality goes beyond the addiction treatment field and challenges the broader public health community. NIDA activities that address methadone deaths include:

- *Epidemiologic Surveillance:* The Community Epidemiology Work Group (CEWG) surveys sentinel areas throughout U.S., Canada and Mexico; analyzes data; and alerts authorities and the public about prescription drug problems. Since 2009, CEWG has identified locations where methadone is frequently cited in medical examiner cases, emergency department admissions (using DAWN data), admissions to addiction treatment programs (using TEDS data), and calls to poison control centers.
- *Extramural research on prescription opioids and pain, as well as prescription drug abuse.* More than 100 peer-reviewed papers on prescription drug abuse or methadone use and abuse have been developed to address epidemiologic trends, clinical practices, interim programs, and appropriate use of medications to treat opioid addiction in correctional populations.
- *NIH Pain Consortium:* A Pain Education Meeting in September 2010 focused on developing a standardized pain education system to address the needs of health practitioners, including nurses and physicians in training.
- *Development of new medications,* including non-addicting pain medications such as resiniferatoxin.
- *Review of existing data* to determine the relationship between opioid prescribing patterns and the risk of significant opioid-related morbidity and mortality (Figure 18).

**Figure 18.**

Opioid Overdose Risk by Average Daily Dose of Prescribed Opioids Received			
Current average daily dose in morphine equivalents (MED) preceding event	All Overdose Events, Persons age 18+ (N=9,940)		Patients, n Overdosed
	Hazard Ratio (95% Confidence Interval)	Rate per 100,000 person years	
1-19 mg MED	1.00	160	22
20-49 mg MED	1.44 (0.57-3.62)	260	6
50-99 mg MED	3.73 (1.47-9.50)	677	6
100+ mg MED	8.87 (3.99-12.48)	1791	11

Hazard ratios adjusted for: Age, sex, index diagnosis, tobacco use, recent depression Dx, recent substance abuse Dx, comorbidity at baseline (RxRISK/Chronic Disease Score & Romano Charlson Score), recent initiation of opioid use, recent sedative-hypnotic prescription.

Future work includes additional efforts to develop more reliable databases, to determine the sources of diverted methadone, and additional education of patients and prescribers about the unique properties of methadone.

### Indian Health Service

*Anthony Dekker, D.O., FAOAAM, FASAM, Acting Director, Office of Health Programs, Phoenix Area Office, Indian Health Service*

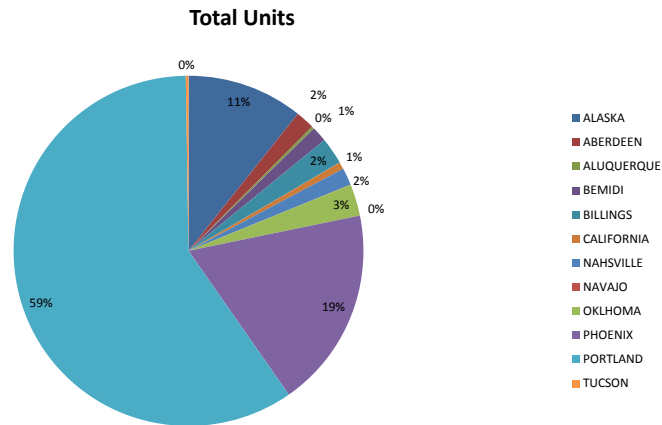
The Indian Health Service (IHS) serves American Indians across the United States. The average age of patients at IHS clinics is 19.

IHS has no OTPs that dispense methadone for opioid addiction treatment, and there are only three tribal OTPs. However, IHS providers frequently prescribe methadone for the treatment of chronic pain.

There are two populations of providers at IHS: (1) providers with more than 15 years' experience and (2) providers with less than 5 years' experience. Provider education is critical for methadone treatment. IHS has worked with SAMHSA to host prescriber education courses and is working on pain treatment policies. All IHS sites now have clinical protocols for chronic pain treatment.

Figure 19.

## 2008 to 2010 Methadone Use



The following efforts are being made within IHS to improve methadone prescribing:

- Hosting educational courses on the use of methadone to treat pain. IHS has hosted two of the SAMHSA opioid prescribing courses--one in Arizona for IHS staff in the in the U.S. Southwest and the other in Alaska. One hundred sixty physicians and 200 nurse practitioners participated in the courses.
- Developing and disseminating evidence-based practices and protocols for the management of chronic pain, focusing on early identification of addiction risk, criteria for patient selection, special populations, and monitoring patients who require opioids for chronic pain management.
- Sponsoring trainings on the use of methadone and buprenorphine for the treatment of opioid dependence.
- Seeking a special DEA waiver for IHS mid-level prescribers (nurse practitioners and physician assistants) to prescribe buprenorphine or methadone, as a part of office-based treatment for people with addictions.
- Requiring policy and procedures for uniform IHS site management of pain and addiction disorders.



## A FOCUS ON SOLUTIONS: PROPOSED STRATEGIES AND ACTION STEPS

After evaluating the data, participants in the 2010 Reassessment met in a series of working groups to develop strategies and action steps to address specific problems.

**Group 1:** Improving the Reporting of Methadone-Associated Deaths

**Group 2:** Improving the Use of Methadone in Addiction Treatment

**Group 3:** Improving the Use of Methadone in Pain Treatment

**Group 4:** Research Needs

**Group 5:** Data and Trend Monitoring

**Group 6:** Legislation, Accreditation and Administrative Actions

Each group reported its findings, strategies and action steps to the larger meeting. A considerable degree of consensus was noted across the six groups, as exemplified by their agreement that highest priority should be assigned to the following strategies:

1. Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.
2. Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.
3. Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).
4. Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.
5. Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.
6. Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.

The reports of the Action Planning Groups, with suggested action steps, are summarized below.

**STRATEGY 1: Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.**

- 1-1. Integrate training about addiction and pain management into the core curriculum for undergraduate and graduate education of all physicians, mid-level providers, and dentists. Focus on specific knowledge and skills, such as those needed to conduct screening and brief intervention.
  - a. Include specific instruction in prescribing controlled drugs as part of the undergraduate and graduate curricula.
  - b. Increase attention to the core competencies of caring for addicted patients, including the risks of drug interactions with methadone and those inherent in the concurrent use of methadone and other sedative drugs such as the benzodiazepines.
  - c. Focus initially on primary care practitioners.
  - d. Employ contextual approaches to training practitioners in specialty care (e.g., emergency physicians, Ob-Gyns, oral surgeons, et al.).
- 1-2. Continue to sponsor continuing education and mentoring programs on the management of pain and addiction for physicians, oral surgeons and dentists, and midlevel professionals.
  - a. Target content to the specific needs of primary care practitioners.
  - b. Develop a cadre of experts at the community level, including peer mentors to provide assistance and peer monitors for physicians with prescribing issues (similar to the system employed by Physician Assistance Programs).
- 1-3. Leverage the success of the SAMHSA opioid prescribing courses to reach even more prescribers and other health care professionals.
  - a. Develop virtual resources such as web modules to expand the number of physicians and other health professionals who can access this valuable resource.
  - b. Find ways to increase awareness of the courses, as by partnering with various State agencies, academic institutions, and private sector organizations.
  - c. Make the courses available to medical schools and residency training programs.
  - d. Continue to develop specialized courses to meet the specific needs of the VA, the Indian Health Service, and other groups serving defined populations.



STRATEGY 2: Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.

2-1. Enhance patient education about the safe use of methadone.

- a. Work with groups such as the National Council on Patient Information and Education to develop educational materials.
- b. Employ peer support to encourage safe methadone use.

2-2. Improve public understanding of the safe use of methadone and other opioid analgesics.

- a. Launch a public awareness campaign about safe use of prescription opioids (including safe disposal of unused medications), in partnership with other Federal agencies and private-sector organizations.
- b. Work with leading medical organizations to develop materials on safe medication use for distribution in medical offices.
- c. Develop public service announcements and other public information vehicles in partnership with other private-sector groups such as the Partnership for a Drug-Free America.

STRATEGY 3: Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).

3-1. Analyze available data and encourage additional studies to develop strategies to prevent, identify and safely manage interactions between methadone and the following:

- a. Benzodiazepines
- b. Antiretroviral medications
- c. HCV medications
- d. Tuberculosis medications
- e. Psychotropics (antidepressants, antipsychotics, and anticonvulsants).

3-2. Encourage and support studies to identify risks that are highly predictive of poor clinical outcomes, including morbidity and mortality, in patients treated with methadone for pain or addiction.

3-3. Conduct a systematic examination of the costs and benefits of implementing the recommendations contained in the report of the SAMHSA Expert Panel on Cardiac Effects of Methadone.

- 3-4. Support a prospective study of patients being treated with methadone for pain or addiction who have QTc prolongation (defined as  $\geq 500$  msec) to determine whether they develop arrhythmias over a specified period of time.
- 3-5. Encourage studies of chronic pain patients to determine the safety of methadone induction in opioid-naïve versus opioid-experienced patients. (This is highly relevant to the common practice of opioid rotation.)

**STRATEGY 4: Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.**

- 4-1. Use available legislative and regulatory frameworks to reduce the toll of methadone induction deaths.
  - a. Employ quality improvement initiatives (such as those conducted by NIATx) to develop program standards and practices that reduce patient risk. Link adoption of the resulting evidence-based standards and practices to accreditation or reimbursement.
  - b. Consider making naloxone available to patients and/or family members during the induction period and whenever take-home doses are prescribed.
- 4-2. Encourage the adoption of evidence-based practices for methadone induction and stabilization, as by making use of approved guidelines part of the standards for OTP accreditation.
- 4-3. Urge the Accreditation Council on Graduate Medical Education to require core competencies related to safe prescribing of opioids as part of all accredited residency training programs. Similarly, agencies that accredit training programs for allied health professionals should require evidence of competency in safe use of opioids where relevant to the scope of practice.
- 4-4. Require every physician to demonstrate competency in the safe prescribing of opioids in order to obtain or renew his or her DEA registration.
- 4-5. Educate health care professionals and policymakers about the value of prescription monitoring programs (PMPs) and take steps to enhance the usefulness of PMPs in preventing and identifying nontherapeutic use of methadone and other controlled drugs.
  - a. Work with the NASPER-funded PMPs and State licensing boards to develop and apply consistent standards as to what constitutes opioid “use” and “misuse.”
  - b. Increase the use of PMPs to identify patients who are using prescribed benzodiazepines concurrently with methadone or other opioids.
  - c. Enhance physician access to the data PMPs contain.

- d. Support legislation that enables pharmaceutical companies to contribute to State pools to fund PMPs in a transparent way. (This was suggested by a pharmaceutical company representative.)
  - e. Expand PMPs to all States, and take steps to assure interoperability across State borders.
  - f. Expand data collection to include controlled drugs in all schedules. Leverage electronic resources to identify knowledge deficits in individual prescribers and provide remediation as needed.
  - g. Provide information and mentoring on the management of challenging patients through the PCSS or a similar network.
- 4-6. Support the development and implementation of Risk Evaluation and Mitigation Strategies (REMS).
- 4-7. Collaborate with organizations that develop health professions curricula, that accredit educational programs, that write questions for specialty board exams, and that support faculty training and development to assure that the knowledge and skills needed to assess and safely manage or refer patients with pain or addiction are included in health professions training.
- 4-8. Develop a system for certifying the competency of OTP clinical staff, similar to the DATA 2000 requirements for physicians who would prescribe buprenorphine for addiction treatment.
- 4-9. Develop pain management competency standards for accreditation programs other than pain medicine (e.g., for ambulatory care, hospitals, and long term care).
- 4-10. Approach professional liability insurers about the possibility of rate adjustments for physicians practicing in States that adopt prescribing guidelines or PMPs, or for individual physicians who complete continuing medical education programs on safe prescribing of opioids and other controlled drugs.

**STRATEGY 5: Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.**

- 5-1. Encourage greater coordination between OTPs and providers of general medical care.
- a. Provide primary care in OTPs, thus making them the patient's "medical home."
  - b. Establish satellite OTPs in Federally Qualified Health Centers (FQHCs).
  - c. Address the expansion of treatment capacity needed to meet the increased demand expected to result from health care reform. For example, expand treatment options by offering medical maintenance with methadone in office-based settings.

- d. Identify a mechanism to observe patients at peak methadone effect in OTPs or at other sites (e.g., pharmacies, FQHCs, primary care settings).
  - e. Find ways to allow communication between OTPs and outside providers, without violating the confidentiality requirements of 42 CFR Part 2.
- 5-2. Work with DEA, pharmacy organizations and State and local officials to encourage the expansion of drug take-back programs and to increase public awareness of their value in limiting unauthorized access to unused opioids and other controlled drugs.
  - 5-3. Reach out to agencies and organizations at the State and Federal levels to identify problems and work with them to craft solutions.

**STRATEGY 6: Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.**

- 6-1. Convene a meeting of epidemiologists, technical experts, and data users to reach agreement on ways to synthesize data from multiple sources to address the need for:
  - a. More complete and accurate data on methadone deaths;
  - b. Access to proprietary data (AAPCC, SDI, IMS);
  - c. Better ethnographic data;
  - d. Adding opioids to arrestee drug testing (ADAM);
  - e. Better support of the existing data infrastructure;
  - f. Expanded State-level capacity for surveillance; and
  - g. An assessment of data needs for prevention activities.
- 6-2. Improve the reporting of deaths among OTP patients (particularly those that involve concurrent use of benzodiazepines).
  - a. Identify barriers to voluntary reporting.
  - b. Develop better methods of collecting data on patient deaths.
  - c. Educate OTP administrative staff about the need for reporting.
  - d. Consider making reporting an accreditation standard.
- 6-3. Improve surveillance of methadone-associated deaths by medical examiners and coroners.
  - a. Work toward greater standardization of case definitions by medical examiners and coroners.
  - b. Provide medical examiners and coroners with reports and other feedback on the uses and consequences of the data they provide.
- 6-4. Develop more detailed and focused analyses of data from all sources.

- 6-5. Study the characteristics of all deaths of patients receiving opioids for the treatment of pain or addiction.
- 6-6. Examine the incidence, prevalence and patterns of concurrent opioid and benzodiazepine use and abuse in opioid-maintained addiction treatment populations and chronic pain populations.
- 6-7. Encourage and facilitate the linkage of data from PMPs with medical examiner/coroner data and OTP death records.
- 6-9. Encourage comparative effectiveness studies, such as those that establish an evidence base for the use of longitudinal opioids in the treatment of pain or addiction.
- 6-10. Pursue a special issue of a peer-reviewed journal on data related to methadone or opioid morbidity and mortality.
- 6-11. Work with DEA and stakeholder groups to enhance the dissemination of geographically targeted data.



## CLOSING REMARKS BY DR. H. WESTLEY CLARK

Since the initial 2003 National Assessment meeting in response to the increasing number of methadone-associated deaths, data show that these deaths, as well as all opioid-related deaths, continue to rise. By reconvening experts and representatives of Federal and State agencies, practitioners, patient advocates, and pharmaceutical industry representatives knowledgeable about the issues surrounding methadone mortality, we have reaffirmed our commitment to understand and address these critical issues. The data, clinical challenges, and stakeholder perspectives examined during the 2010 Reassessment meeting were assessed through the prism of the work groups to ensure that our next steps are informed by current research findings, clinical experience, and patient and family viewpoints.

SAMHSA will continue to work collaboratively with our Federal partners, as well as with the States, with medical societies and organizations, with patient advocacy groups, and with other interested parties to develop and implement practical strategies and action steps that will reduce the toll of methadone-associated deaths. Meeting participants have offered many suggestions for consideration by SAMHSA and others. Some of these suggestions reinforce or expand on those made by meeting participants in 2003, while others reflect our expanded knowledge and take us in new directions.

SAMHSA is particularly interested in taking a balanced approach to reducing methadone-associated deaths and values the input provided by the full spectrum of stakeholder groups. Through this approach, we intend to focus on key issues and avoid unintended consequences from the policies and actions we pursue. We are now better equipped than in 2003 to recognize the complexity represented by methadone-associated deaths and to understand the need to engage patients, medical professionals, health professions organizations, and Federal and State agencies in a mutual effort to achieve our goals.

Multiple initiatives are already under way, but there is much more to be done to gain an accurate understanding of the circumstances that lead to these unfortunate deaths and that will enable us to limit the human losses they represent.

This reassessment effort has provided critical information and guidance to SAMHSA as we work to find the best solutions for patients, their families, and the public, and to meet our regulatory and public health responsibilities.





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