Methadone for Pain Management: The Clinician's Role in Reducing the Risk for Overdose

Clinician Outreach and
Communication Activity (COCA)
Conference Call
August 1, 2012



Objectives

At the conclusion of this session, the participant will be able to accomplish the following:

- Discuss the role of methadone in fatal drug overdoses in the United States
- Compare and contrast methadone prescribing to other opioid analgesics
- State circumstances under which use of methadone might be appropriate

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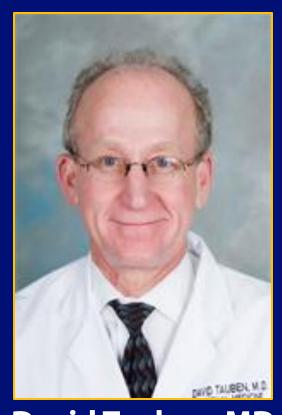
TODAY'S PRESENTER



Len Paulozzi, MD, MPH

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National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

TODAY'S PRESENTER



David Tauben, MD

Clinical Associate Professor

University of Washington

Medical Director University of Washington Center for Pain Relief



Morbidity and Mortality Weekly Report

July 10, 2012

Vital Signs: Risk for Overdose from Methadone Used for Pain Relief — United States, 1999–2010

Methadone for Pain Management: The Clinician's Role in Reducing the Risk for Overdose

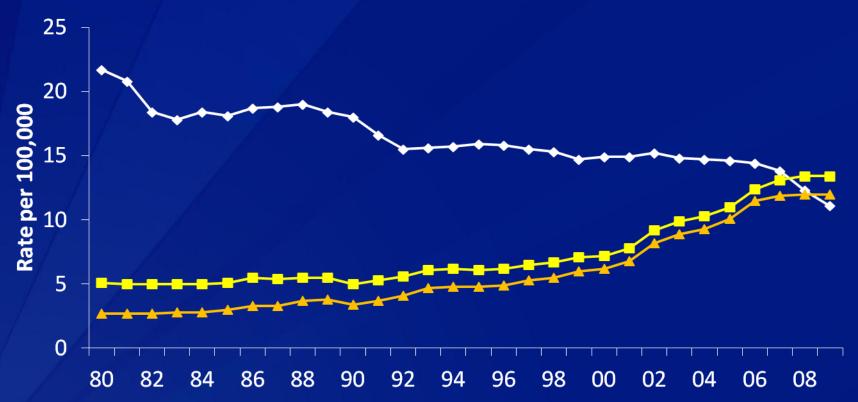
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August 1,2012

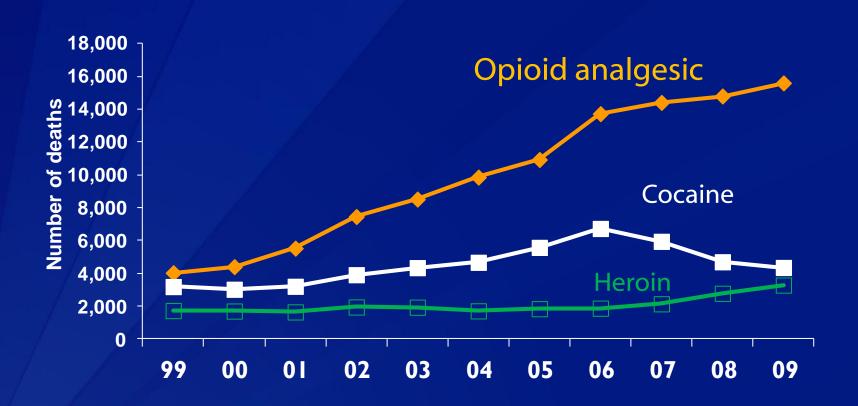


Motor vehicle traffic, poisoning, and drug poisoning death rates of all intents, U.S., 1980-2009



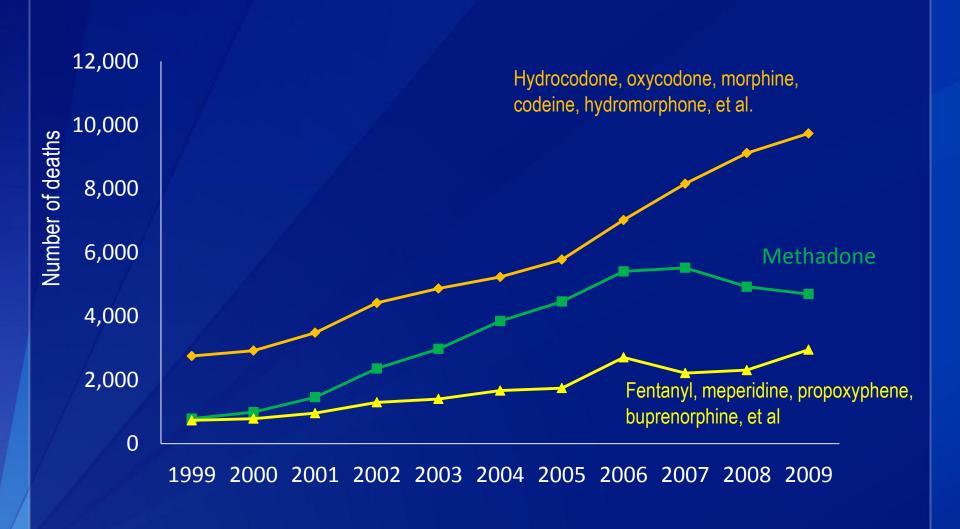
Source: NCHS Data Brief, December, 2011, updated with 2009 mortality data.

Drug overdose deaths of all intents by major drug type, U.S., 1999-2009



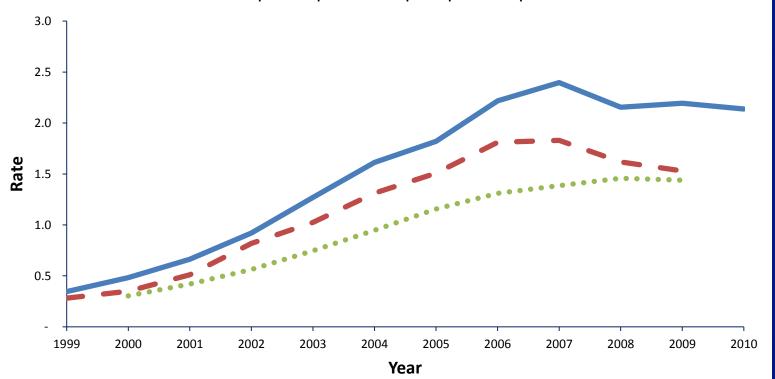
Source: National Vital Statistics System..

Drug overdose deaths of all intents by type of opioid involved, US, 1999-2009



Rising rates of methadone use for pain, methadonerelated overdose deaths, and methadone prescriptions for pain, United States

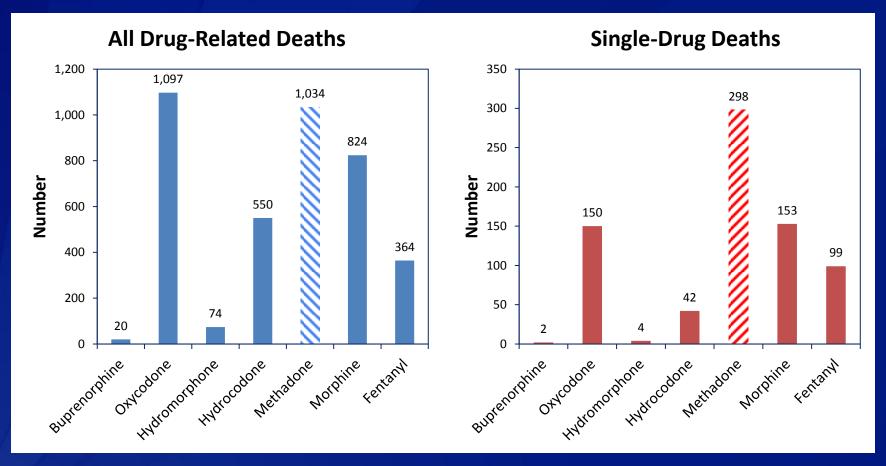
- Methadone use for pain (kg/100,000 persons)
- Methadone-related overdose deaths per 100,000 persons
- • • Methadone prescriptions for pain per 100 persons



State studies of medical examiner data on methadone overdoses

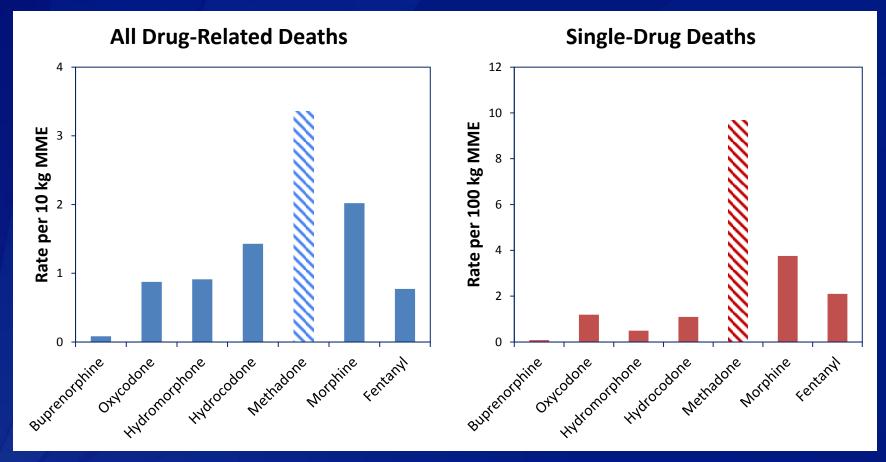
State/Author	Year of Deaths	Number of Deaths	Pct in OTP	Pct with Rx
Utah/Sundwall	1999-2003	114	unknown	42%
Oregon/DOH	2002	103	~25%	33%
Kentucky/Shields	2000-04	95	10%	48%
Maryland/Anon	2004-05	52	15%	2%
West Virginia/Paulozzi	2006	87	12%	32%
North Carolina Medicaid/Whitmire	2007	98	8%	15%

Number of drug-related deaths involving opioids, by type of opioid— Drug Abuse Warning Network Medical Examiner System, 13 states*, 2009



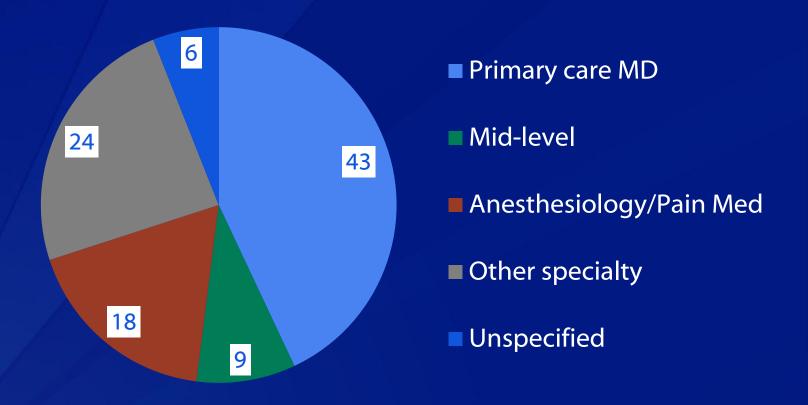
*DE, MA, MD, ME, NH, NM, OK, OR, RI, UT, VA, VT, and WV MME = morphine milligram equivalent

Rates of drug-related deaths involving opioids, by type of opioid— Drug Abuse Warning Network Medical Examiner System, 13 states*, 2009



*DE, MA, MD, ME, NH, NM, OK, OR, RI, UT, VA, VT, and WV MME = morphine milligram equivalent

Distribution of methadone prescriptions by prescriber specialty, US, 2009



Source: SDI, Vector One: National. Extracted July 2010 Analysis by Laura Governale of FDA presented at the SAMHSA Methadone Mortality Meeting, July 29, 2010

Percent distribution of diagnoses associated with methadone use, office-based physician survey, US, 2009

All others, 13

Cancer, 11

Headache, 17

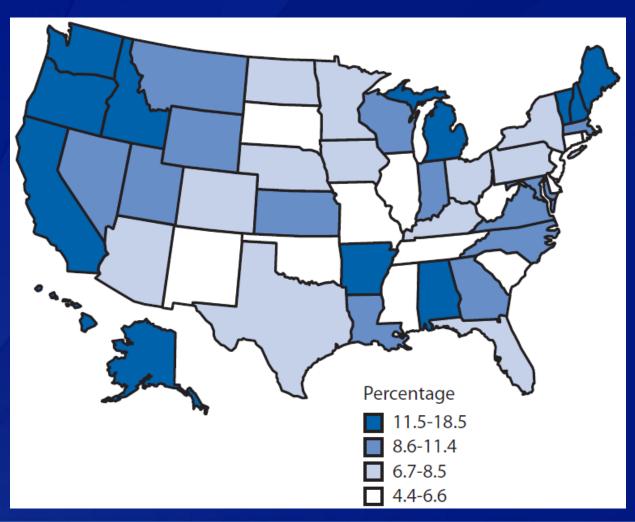
Musculoskeleta I disease, 46 Drug abuse/dependence 4%General symptoms 4%Trauma 5%

Source: SDI, Physician Drug and Diagnosis audit. Extracted July 2010

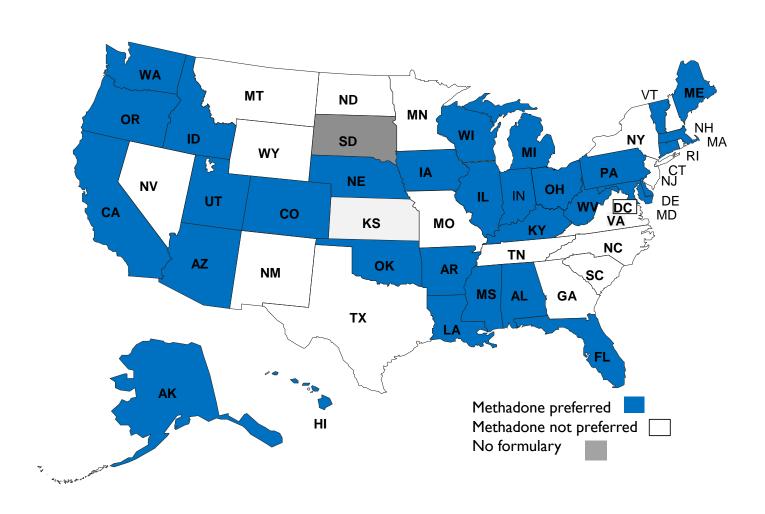
Analysis by Laura Governale of FDA presented at the SAMHSA Methadone Mortality Meeting, July 29, 2010

Percentage of opioid distribution accounted for by methadone prescribed for pain by state

United States, 2010



Methadone as a preferred long-acting opioid analgesic on the Medicaid formulary, US, 2012



Role of states in prevention

- Develop and promote the use of safe prescribing guidelines for methadone.
- Use prescription drug monitoring programs to identify patients who are using methadone or other prescription painkillers for nonmedical purposes.
- Continue to support the use of methadone as a treatment for opioid dependence in opioid treatment programs.

Role of health insurers in prevention

- Evaluate methadone's place on preferred drug lists.
- Consider strategies to ensure that pain treatment with any dose higher than 30 mg of methadone a day (the recommended maximum daily starting dose) is appropriate.

Role of health care providers in prevention

- Follow guidelines for prescribing methadone and other prescription painkillers correctly.
- Educate patients on how to safely use, store, and dispose of methadone.

Thank You

www.cdc.gov/homeandrecreationalsafety/poisoning

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



Methadone for Pain

A Guide for Prescribers

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Disclosures

No conflicts of interest

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- Co-Investigator: R42 CA141875: Doorenbos, AZ (PI) 05/13/10-04/30/13 NCI/NIH PATINA: Pain training in Native American communities
- Center for Medicare and Medicaid Innovation: U of New Mexico*, NIH R01, STTR, HRSA. TelePain access for remote interspecialty management of complex disease
- Unrestricted educational grant Endo
 Pharmaceuticals. University of Washington
 Pain Champions: Look Over the Expert's
 Shoulder/Pain Champions.



Objectives

- Understand indications for use of methadone
- Be knowledgeable about risks of methadone
- Follow safe methadone dosing practice
- Know why and how to apply guidelines for opioid monitoring



Methadone Basic Clinical Pharmacology

- Potent Mu-agonist
- Absorption variability
 - Oral 36-100%
 - Peak plasma 3-4 hrs(up to 1-8 hrs)
- 30-fold inter-patient variability
 - In steady-state concentrations
 - In peak concentrations

- Expect age and illness related increased toxicities
- Frequent drug-to-drug interactions
- Hepatic CYP metabolism
- No active hepatic metabolites



Methadone Special Features

- NMDA antagonist
 - May reduce opioid tolerance
 - Potential non-opioid analgesic effects
- Weak 5-HT/NE Reuptake Inhibitor
 - May also add benefit for neuropathic pain disorders

- Significant accumulation with repeat dosing
 - Initial T½ 13-47 hrs → 48 72 hrs
 - Lipophilic & Protein-bound
 - Inhibits its own CYP metabolism

<20 mg =
$$3-4 \times MS$$

 $30-40 \text{ mg} = 8 \times MS$
 $40-60 \text{ mg} = 10 \times MS$
 $>60 \text{ mg} = 12 \times MS$



Indications for Methadone Use

√ For Pain Treatment

- Effective analgesic
- Chronic Opioid Therapy
- Long acting
- Inexpensive

√ For Addiction Treatment

- Requires special DEA licensing and treatment support
- Once daily liquid dosing eases administration
- Reduces mortality among heroin users



Clinically Important Comparison: Methadone vs. other Opioids

Differences:

- Marked inter-patient pharmacologic variability
- Significant accumulative dosing potency
- Higher OD incidence and mortality
- Indications:
 - When committed to Chronic Opioid Treatment
 - So-called 'last resort'

Similarities:

- Monitoring approach
- Side-effects
 - Sedation
 - Respiratory suppression
 - Anticholinergic
 - Cardiac
- Addiction and diversion risks



Methadone M & M

- Adverse events typically occur early in Rx initiation
 - For Pain treatment and for MMT
- Co-prescription with sedatives adds significant risk
 - Benzodiazepines
 - Carisoprodol
 - Alcohol
- Co-occurring respiratory disorder increases risk
 - Obstructive and Restrictive Lung disease
 - Sleep apnea
- QTc prolongation and arrhythmia risk at higher doses and when used with other drugs that prolong QTc



Methadone & Cardiac Arrthymias 2006 FDA Advisory

"Prescribing methodone is complex. Methodone should only be prescribed for patients with moderate to severe pain when their pain is not improved with other nonnarcotic pain relievers. Pain relief from methadone lasts about 4 to 8 hours. However, methadone stays in the body much longer, from 8 to 59 hours after it is taken. As a result patients may feel the need for more pain relief before methadone is gone from the body. Methadone may build up in the body to a toxic level if it is taken too often, if the amount taken is too high, or if it is taken with certain other medications or supplements."1,2

¹http://www.fda.gov/CDER/drug/advisory/methadone.htm



²Emphasis added

Risks Factors for QTc Prolongation

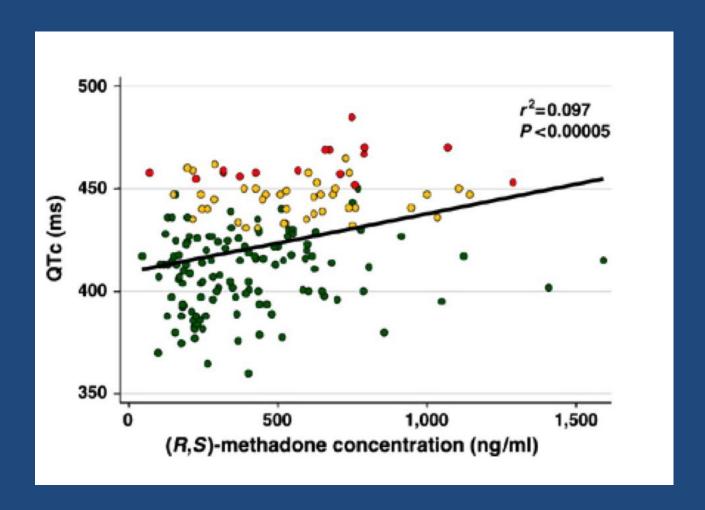
- Older age; esp. women
- Co-occurring cardiac disease
 - Advanced heart disease
 - Congenital and acquired long-QT syndromes
 - Family history of sudden death
- Low K⁺, Low Mg⁺⁺

>450-499 msecs: Monitor more frequently ≥500 msecs: Consider discontinuation

- Concomitant use other QTc prolonging Rx
 - Ca⁺⁺ blockers,
 propafenone, quinidine
 - Tricyclics, SNRIs, and SSRIs
 - Erythromycin,
 azithromycin,
 clarithromycin,
 quinolones,
 pentamidine
 - Ondansetron, risperidone



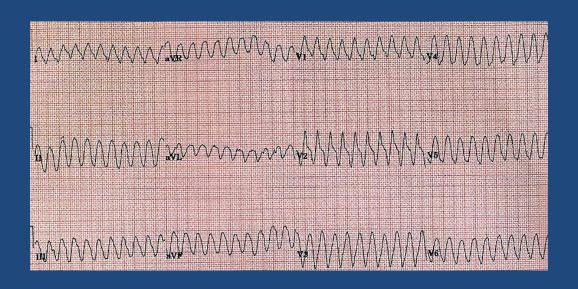
Methadone Levels and QTc Prolongation



Red dots:
prolonged QTc
Yellow dots:
borderline QTc
intervals
Green dots:
normal QTc values



Torsade de Pointes



Methadone dose range 65-1,000 mg (780-12,000 MED)

Most doses >250 mg (>3000 mg MED)

Review of case series and reports



Drug-drug interactions

CYP 3A4 *inhibitors* (*RAISE* methadone levels)

Use with caution-<u>moderate risk</u>:

Antibiotics

Protease inhibitors (ritonavir, nelfinavir, indinavir)

Macrolides (erythromycin, clarithromycin)

Azole antifungals (ketoconazole, itraconazole)

Quinilones (ofloxacin, moxifloxin)

Others (tetracycline, metronidazole, pentamidine)

Other often used drugs

Trazodone, haloperidol, respirdone, ondansetron, chlorpromazine, droperidol



Less potent CYP 3A4 *inhibitors*

Still use caution: may <u>RAISE</u> methadone blood level

Antibiotics

saquinavir, fluconazole, clotrimazole

Psychiatric Rx

- amitriptyline, desipramine, fluoxetine, fluvoxamine, imipramine, sertraline, venlafaxine
- olanzapine, quetiapine

Foods & beverages

grapefruit (especially juice)

Naturopathics

St. John's wort, valerian



CYP 3A4 *Inducers*

LOWERS methadone blood levels

May need to dose increase to maintain analgesia and/or prevent withdrawal

- Carbamazepine
- Diphenylhydantoin
- Rifampin



Other drugs associated with *Torsade de Pointes*---Avoid concurrent use with methadone---

Cardiac

- amiodarone, bepridil, disopyramide, dofetilide, ibutilide, procainamide, quinidine, sotalol,
- GI motility & antinausea
 - Chlorpromazine, cisapride, domeperidone, droperidol
- Antibiotics
 - clarithromycin, erythromycin, sparfloxacin
- Antipsychotics
 - Haloperidol, mesoridizine, thioridazine, pimozide



Common Clinical Methadone Concerns

- Anticholinergic
 - Urinary retention
 - Constipation
 - Dry mouth
- Weight gain
- Heavy sweating
- Reduced motor coordination
- Cognitive impairments

- Reduced sex hormone release
- Pregnancy cat. C
 - Withdrawal precipitated miscarriage
 - Neonatal abstinence
 - For opioid addicted pregnant women methadone maintenance is standard of care¹
 - Volume of distribution increases in 3rd trimester usually dictating need for a dosage increase¹



Overview of Methadone Dosing

- "Go low and slow":
 - Start: 2.5 mg/day BID-TID
 - Increase: at 5-10 day intervals
- Use in opioid-naïve patients: probably <u>never</u>
 - Risk of accidental OD when not tolerant
 - When committing to COT
 "when... pain is not improved with other non-narcotic pain relievers"¹
- Age ± disease related metabolic adjustments: <u>always</u>
- Drug-drug interactions: when appropriate



Dosing Recommendations VA/DoD Guidelines Up-Titration

- ❖Dose increments of <u>2.5 mg</u> q 8 h made every 5-7 d
- Dose increases after <u>5 to 74 days</u> if no problem with daytime sedation

NOTE: Half-life longer than duration of analgesia



Washington State Agency Medical Directors Group: Opioid Dose Calculator

120 mg MED dose threshold for

"specialty consultation"

OPIOID DOSE CALCULATOR				
Optional:	Patient name:			
	Today's date:	April 8, 2012		
Instructions:	Fill in the mg per day* for whichever opioids your patient is taking. The spreadsheet will automatically calculate the total morphine equivalents per day.			
Opioid (oral or transdermal):	mg per day*:	Morphine equivalents:		



	Opioid (or	ai oi dansaciinaij.	ing per day	•	
methadone					
up to 20mg per day		20			
21 to 40mg per day		40			
41 to 60mg per day		60			
>60mg per day		80			
	evergedene		90		

oxymorphone

960 120

2720

80 320

if high risk and/or adverse effects or lack of functional response

* Note: All doses expressed in mg per day with exception of fentanyl transdermal, which is expressed in mcg per hour

If this value is less than 120mg Morphine Equivalent Dose (MED), please follow Part I of the AMDG Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. Referral for pain management consultation is required before exceeding 120mg MED daily. See:

www.agencymeddirectors.wa.gov/opioiddosing.asp www.doh.wa.gov/hsqa/professions/painmanagement/

If this value is greater than 120mg MED, please follow Part II of the AMDG Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. See: www.agencymeddirectors.wa.gov/opioiddosing.asp

www.agencymeddirectors.wa.gov/guidelines.asp

TOTAL daily morphine equivalent dose (MED) =

j a one eti

Conversion Dosing Recommendations Morphine into Methadone

- 50-67% of calculated equianalgesic dose is conversion dose
- Calculation varies with the total daily dose
- Dose proportion is dependent on MED of previous opioid (PO)

- Morphine < 200 mg/day:Methadone 5 mg q8 hr*(*in opioid tolerant patient)
- Morphine 200-500 mg:

5-10% of oral MED, given in divided doses q 8 hr

MED > 500 mg/day:Get expert help

VA/DoD Clinical Practice Guideline for the Management of Chronic Pain 2003 v.1



"Rotation" onto Methadone

- Typically can reduce dose to 10-50% of current MED
- High but ineffective doses of previous opioids may overestimate the methadone dose¹
- Analgesic effects can range 4-13 days to stabilize
 - Repetitive dose equianalgesia at just 10-20%²
 - Reduction in the calculated equianalgesic dose in all cases³
- Conversion ratios are <u>not</u> bi-directional
- Specific reduction formula based on the MED of the opioid taken at the time of the switch
 - Methadone potency rises as its dose is increased!!

¹VA/DoD Clinical Practice Guideline for the Management of Chronic Pain 2003 v.1

²Lawlor PG., Turner KS., Bruera HJ. Cancer 1998; 82:1167-1173.

³Knotkova H., Fine PG., MD, Portenoy RK., J Pain Sympt Manag 2009; 38 (3): 426-439.



Methadone Risk Monitoring

- Similar to Other Long-Acting Opioids
 - Opioids are High Risk Drugs
 - Highest doses given to highest risk patients "Principal of adverse selection"
- Chronic Opioid Therapy Risk Assessment Tools- *Use prior to initiation of COT*:
 - ORT, or SOAPP-R or DIRE
 - CAGE-ID or AUDIT



Opioid Risk Tool (ORT)

Physician Form

With Item Values to Determine Risk Score

Name	Date
-	

Mark each box that applies		Female	Male
1. Family history of substance abuse	AlcoholIllegal drugsPrescription drugs	[] 1 [] 2 [] 4	[] 3 [] 3 [] 4
2. Personal history of substance abuse	AlcoholIllegal drugsPrescription drugs	[] 3 [] 4 [] 5	[] 3 [] 4 [] 5
3. Age (mark box if 16-45 years)		[] 1	[] 1
4. History of preadolescent sexual abuse		[] 3	[] 0
5. Psychological disease	 Attention-deficit/ hyperactivity disorder, obsessive- compulsive disorder, bipolar disorder, schizophrenia Depression 	[] 2 [] 1	[] 2 [] 1
Low (0-3) Moderate (4-7) High (≥8)	Scoring totals	[]	[]

10 Questions to Administer:

- On initial visit for ALL new or inherited COT patients
- Prior to LA Opioid Therapy

Scoring

- 0-3: low risk (6%)
- 4-7: moderate risk (28%)
- ≥ 8: high risk (> 90%)



Adherence Monitoring Urine toxicology based on risk assessment score

Risk Category	UDT Frequency
Low Risk by ORT	Periodic
	(e.g. up to 1/year)
Moderate Risk by ORT	Regular
	(e.g. up to 2/year)
High Risk by ORT or opioid	Frequent
doses >120 mg MED/d	(e.g. up to 3-4/year)
Aberrant Behavior (lost	At time of visit
prescriptions, multiple	
requests for early refills,	(Address aberrant behaviors
opioids from multiple	in person, not by telephone)
providers, unauthorized dose	
escalation, apparent	
intoxication, etc.)	

From: WA State AMDG Guidelines www.agencymeddirectors.wa.gov/guidelines.asp



Methadone Urine Monitoring

Point of Care

- Generally reliable
- Detection for 3-14 days
- Expect 20+% false results¹

False positives²:

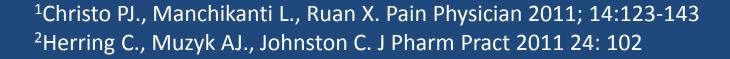
Chlorpromazine Clomipramine Diphenhydramine Doxylamine

Quetiapine Thioridazine

Verapamil

Confirmation testing by LC or GC/MS

- When results are unexpected AND patient does not admit to use of drugs identified on initial testing
- Can request reflex confirmation when false positives and negative results are expected
- Adulterants can interfere with confirmation assay

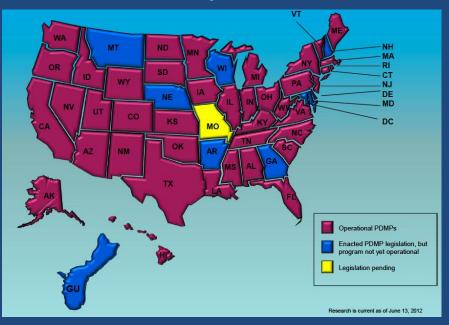




Adherence Monitoring Currently Available Solutions

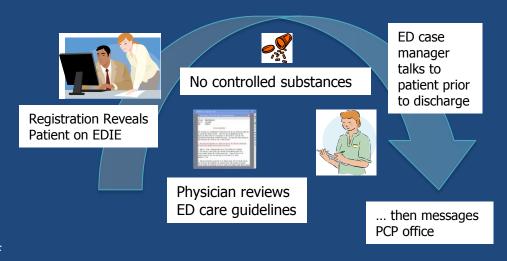
Prescription Monitoring

State level programs capturing all scheduled medication prescribing, even cash purchased



Emergency Department Information Exchange(s)

Save \$70-100,000/year in reduced admissions, labs, excessive exposures to CT imaging in emergency rooms by utilizing this system



Monitoring Co-occurring Conditions

- Sleep apnea
 - STOP-BANG screening tool¹
- Depression, Anxiety, PTSD
 - PHQ-9, GAD-7, PCL-C²
- Drug-drug interactions/poly-pharmacy
 - Rx Reconcilation and/or shared EMR system
- Cardiac
 - Advanced heart disease or h/o sudden death
 - ".. To ECG or Not to ECG... That Is Still the Question"

¹Chung F., Yegneswarian B., Liao P., et al. Anesthesia 2008; 108:812-821 ²UW Pain Toolkit http://depts.washington.edu/anesth/education/pain/index.shtml ³Cruciani RA., J Pain Sympt Manage 2008; 36: 545-552



Guidelines for Tapering Methadone

- Decrease 20-50% until 30 mg; then by 5 mg/day q
 3-5 d until 10 mg/d; then by 2.5 mg/d every 3-5 d¹
- Decrease 10% weekly, use clonidine for symptom management^{2, 3}
- Taper 10% weekly until 30% of initial total MED, then resume by 10% less of new dose weekly⁴
- Taper 10% of daily dose/day to 30% of daily dose every 1-2 wks, once 1/3 of original dose is reached, slow taper to ½ of previous rate⁵

¹VA/DoD 2010

²WA AMDG Guidelines 2007

³Utah State Guidelines 2008

⁴WA State HCA NRP Program 2011

⁵Canadian Guidelines 2010



Tapering Methadone Some Clinical Caveats

- If "Addiction" (aka "Substance use disorder")
 - >90% relapse onto opioids, prescribed or otherwise
- Following prolonged epoch of high dose use
 - Many patients "de-stabilize" and demonstrate behaviors meeting DSM criteria for SUD (aka "Complex persistent opioid dependency")
 - Often requires protracted taper schedule with frequent plateaus based on clinical response
 - Best outcomes require significant behavioral health support



Prescribing Methadone Conclusions

- Effective analgesic
- Inexpensive
- Analgesic interval shorter than half-life
- Enormous inter-patient variability
- Accumulative potency/complex dosing
- Complicated DDI and metabolic interactions
- When used carefully--- both effective and safe





Centers for Disease Control and Prevention Atlanta, Georgia

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A - Z Index

Methadone for Pain Management: The Clinician's Role in Reducing the Risk for Overdose

CE = Free Continuing Education Credits

Date: Wednesday, August 1, 2012

Time: 2:00 - 3:00 pm (Eastern Time)

Join By Phone:

Dial-in Number: 1-888-790-6180

Passcode: 1281914

Join By Webinar: https://www.mymeetings.com/nc/join.php? i=PW7035569&p=1281914&t=c

Presenter(s):



🖓 🧥 Len Paulozzi , MD, MPH Medical Epidemiologist

Division of Unintentional Injury Prevention National Center for Injury Prevention and Control Centers for Disease Control and Prevention

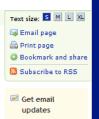


🖓 🦍 David Tauben, MD

👸 Clinical Associate Professor University of Washington Medical Director UW Center for Pain Relief Director of Medical Student Education in Pain Medicine Department of Anesthesia & Pain Medicine Department of Medicine

Overview:

CDC estimates that methadone was involved in 5,000 overdose deaths in the United States in 2009. Nonetheless, many methadone prescriptions are being written for conditions for which it might not be appropriate, and methadone is a preferred drug on many formularies. Prescribing methadone for chronic pain safely requires familiarity with its unique pharmacology and dosing recommendations. Join us for this COCA call where subject matter experts will review the epidemiology of methadone overdoses in the United States and discuss guidelines for appropriate opioid prescribing.



Contact Us:

Centers for Disease Control and Prevention 1600 Clifton Rd Atlanta, GA 30333

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- <u>cdcinfo@cdc.qov</u>



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