



American College of
Osteopathic
Family Physicians

Advocacy ♦ Education ♦ Leadership

AOA/ACOFP Osteopathic Medical Conference & Exposition (OMED)
San Diego, CA
October 7-11, 2012

**Risk Evaluation and Mitigation Strategies
For Controlled Substances**

William R. Morrone, DO

Tuesday, October 9, 2012, 1:00-2:30pm

CME/CEU Information

The American College of Osteopathic Family Physicians is accredited by the American Osteopathic Association Council to sponsor continuing medical education for osteopathic physicians.

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Please check where applicable and sign below. Provide additional pages as necessary.

Name of CME Activity: 2012 AOA/ACOFF Osteopathic Medical Conference & Exposition (OMED)

Dates and Location of CME Activity: October 7-11, 2012, The San Diego Convention Center, San Diego, CA

Topic: Risk Evaluation and Mitigation Strategies for Controlled Substance

Name of Speaker/Moderator: William R. Morrone, DO

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

A. Neither I nor any member of my immediate family has a financial relationship or interest with any proprietary entity producing health care goods or services.

B. I have, or an immediate family member has, a financial relationship or interest with a proprietary entity producing health care goods or services. Please check the relationship(s) that applies.

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| <input checked="" type="checkbox"/> Speakers' Bureaus* | <input type="checkbox"/> Employment |
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Please indicate the name(s) of the organization(s) with which you have a financial relationship or interest, and the specific clinical area(s) that correspond to the relationship(s). If more than four relationships, please list on separate piece of paper:

Organization With Which Relationship Exists	Clinical Area Involved
1. Rickett Benkheiser	1. OBOE training for physicians
2. Millennium Labs	2. Urine drug screens
3. AOAAM	3. monthly PCSS webinars
4.	4.

*If you checked "Speakers' Bureaus" in item B, please continue:

- Did you participate in company-provided speaker training related to your proposed topic? Yes; No;
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- A. The content of my material(s)/presentation(s) in this CME activity will not include discussion of unapproved or investigational uses of products or devices.
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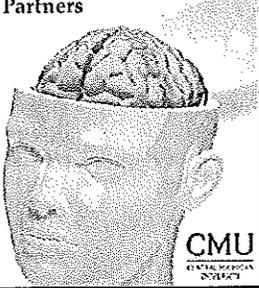
Signature: William R. Morrone DO Date: 8/13/2012
 William R. Morrone, DO

Please fax this form to ACOFP at 866-328-1839, or e-mail to judy@acofp.org as soon as possible.
 Deadline: Monday, August 13, 2012

**Opiate Management
in Patients w/ Pain**
REMS
Risk Evaluation Mitigation Strategy
San Diego OMED 2012
ACOPP and AOAAM
Central Michigan University College of Medicine
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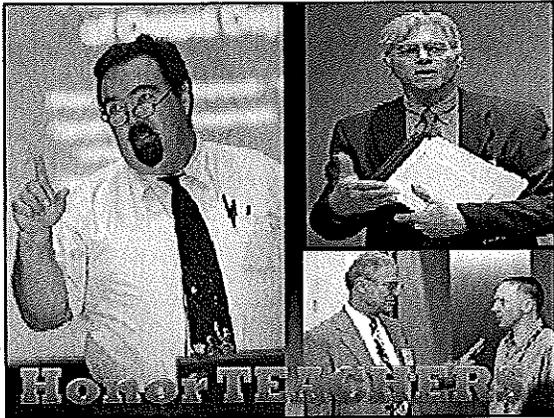


William R. Morrone DO, MS, ACOPP, ASAM, DAAPM
Medical Director, Hospice of Michigan CT 101
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Synergy Medical Education Partners
CMU College of Medicine
Queen of Angels Detox Unit
Recovery Pathways LLC
Deputy Medical Examiner
MidMichigan-MSUCHM
Advocate





**My
Parents
and
Historians
agree the
great
depression
ended with
WWII.**



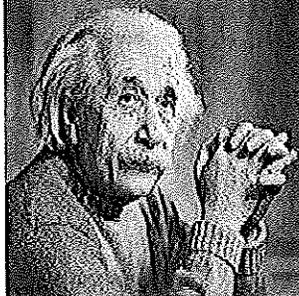
Who is speaking?

- ACOFP board certified *primary care physician*
- Family Medicine educator (CMU Medical Ed)
- Consultant appointment to *Dept. of Psychiatry*
- Certified in *Pain (AAPM)* and *Addiction (ASAM)*
- Credentials in *Forensics/Deputy Med Examiner*
- Armed Forces Institute of Pathology (AFIP)
- MS *Tox/Pharm* U. Missouri at KC/School of Pharm
- Active *pain consultant & Hospice Director*
- Activist, advocate & *addictionologist*



If you can't explain it simply, you don't understand it well enough.

— Albert Einstein



FREE YOUR MIND and THINK

Curriculum

- **DISCLAIMER**
- **ACGME/ACCME DISCLOSURE**
- **ACGME/ACCME CONFLICT of INTEREST**
- Needs & Gap PREVALENCE of PAIN
- Needs & Gap PREVALENCE of MISUSE and ABUSE
- **BODY of TEXT and TOOLS**
- **SUMMARY**
- **CLINICAL CASES**



Purpose of this curriculum and disclaimer

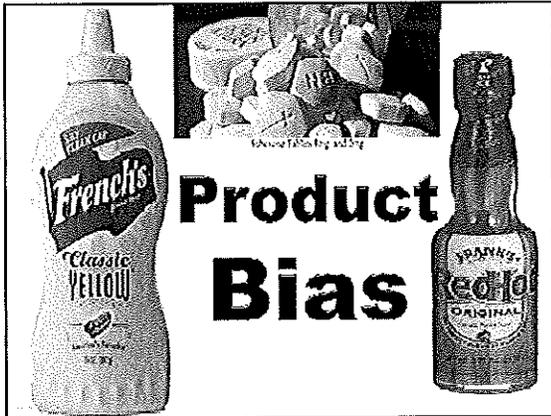
This curriculum includes the core information for the evaluation of patient risk for *opioids*. Treatment decisions should be made based upon the individual patient, the level of risk and available resources to reduce diversion.

The standard of care constantly evolves and this lecture will review the current status. Physicians who use opioids are responsible for their own decisions. Dr. Morrone does not assume any patient care responsibilities.



Disclosure & Conflict of Interest





What is Conflict and Disclosure?

- The intent of this disclosure is not to prevent a person with a relevant financial or other relationship from participating in the activity, but rather to provide participants with information on which they can base their own judgments.
- Dr. Morrone has identified conflicts of interest prior to the release of this activity.
- Dr. Morrone has indicated he has relationships with industry relative to the content of this CME activity

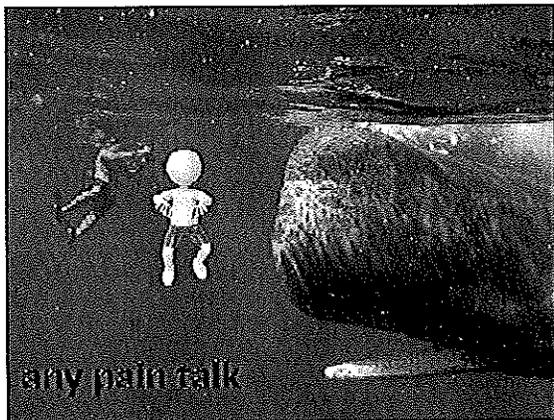
Dr. William Morrone has received honorarium from Reckitt-Benckiser for teaching and advocacy.



OBJECTIVES

- #1-Outline tools that providers can use to monitor patients: office urine drug screening, etc.
- #2-Discuss the importance of communication between the patient and the provider as it relates to the treatment of pain

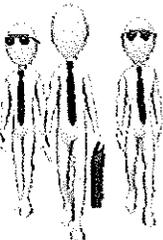
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Positioning Opioid Therapy for Chronic Pain

- Chronic non-cancer pain: weigh the influences

- What is conventional practice?
- Are there reasonable alternatives?
- What is the risk of adverse events?
- Is the patient likely to be a responsible drug-taker?



Fine PG, Portenoy RK. *Clinical Guide to Opioid Analgesia*, 2nd edition, 2007.
Jovey RD, et al. *Pain Res Manag* 2003;6(Suppl A):3A-28A.
Eisenberg E, et al. *JAMA*. 2005;293:3043-3052.
Gironi, et al. *N Engl J Med*. 2005;352:1324-1334.

FDAAA

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to **ensure that the benefits of a drug or biological product outweigh its risks.**

New authorities under FDAAA: (FDA) will now be implementing Risk Evaluation and Mitigation Strategies (REMS) for a number of offold products

Prevalence of Recurrent and Persistent Pain in the US

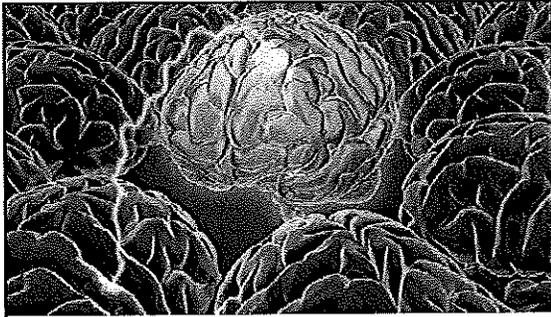
- 1 in 4 Americans suffer from recurrent pain (day-long bout of pain/month)
- 1 in 10 Americans report having persistent pain of at least one year's duration
- 1 in 5 individuals over the age of 65 report pain persisting for more than 24 hours in the preceding month
 - 6 in 10 report pain persisting > 1 year
- 2 out of 3 US armed forces veterans report having persistent pain attributable to military service
 - 1 in 10 take prescription medicine to manage pain

American Pain Foundation, <http://www.painfoundation.org> Accessed March 2010.

Patients must invest in their pain treatment & you must note **function**

University of Michigan, FSMB & AAPM:

- Treatment must be multi-dimensional, not only pharmacological and involve risk assessment.
- Effective therapy should control chronic pain in order to **improve function** at work, home, socially and in pleasurable pursuits.
- Complete analgesia is not possible for **many** patients.



Effective therapy should control chronic pain in order to **improve function** at work, home and socially.

M University of Michigan Health System **Guidelines for Chronic Pain**

Managing Chronic Non-Terminal Pain in Adults Including Prescribing Controlled Substances

OBJECTIVE: To provide an evidence-based clinical practice guideline for managing and treating patients with chronic non-terminal pain with special attention to specific principles of opioid management.

SCOPE: This guideline applies to all patients with chronic non-terminal pain who are being managed by a provider. It does not apply to patients with terminal cancer or end-of-life care, or to patients with acute pain.

DEFINITIONS: Chronic pain is defined as pain that persists beyond the expected period of healing. It is not defined by duration, but by the presence of pain that is not relieved by standard analgesics and that interferes with function. Chronic pain is a symptom, not a diagnosis. It can be caused by many different conditions, including injury, surgery, trauma, cancer, and degenerative diseases.

GOALS: The goal of this guideline is to provide a systematic framework for managing patients with chronic non-terminal pain, with special attention to the use of opioids. The goal is to improve function at work, home, and socially, while minimizing the risks of opioid use.

KEY PRINCIPLES:

- **Function vs. Effect:** The primary goal of pain management is to improve function, not just to reduce pain. Pain management should be evaluated based on its impact on the patient's ability to perform daily activities.
- **Individualized Care:** Pain management should be tailored to the individual patient, taking into account their medical history, current medications, and personal goals.
- **Non-Opioid First:** Non-opioid analgesics should be used as the first line of treatment for chronic pain, unless there is a clear indication for opioid use.
- **Lowest Effective Dose:** If opioids are prescribed, the lowest effective dose should be used for the shortest duration possible.
- **Regular Assessment:** Patients on opioids should be assessed regularly for pain, function, and side effects.
- **Education:** Patients and providers should be educated about the risks and benefits of opioid use.
- **Interdisciplinary Approach:** A multidisciplinary team approach, including medical, nursing, physical therapy, and behavioral health, is recommended for the management of chronic pain.
- **Documentation:** All pain management decisions and interventions should be documented in the patient's medical record.
- **Referral:** Patients who do not respond to medical management should be referred to a pain management specialist.

M University of Michigan Health System **What is the difference?**

FUNCTION vs. EFFECT

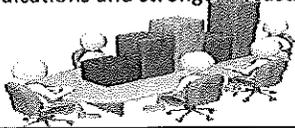
- **Objective:** To provide a systematic framework for providers to evaluate and manage patients with chronic, non-terminal pain with special attention to specific principles of opioid management.
- Not a guide for cancer or hospice management.

FUNCTION vs. EFFECT

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1000 S. TAPSCOTT DRIVE
ANN ARBOR, MI 48106-1000

Public Health Crisis

- **Opioids are at the center of a major public health crisis of addiction, misuse, abuse, overdose and death.**
- FDA is taking action to protect patients from serious harm due to these drugs. This represents a **careful balance** between **continued access** to necessary medications and **stronger measures** to reduce risks.

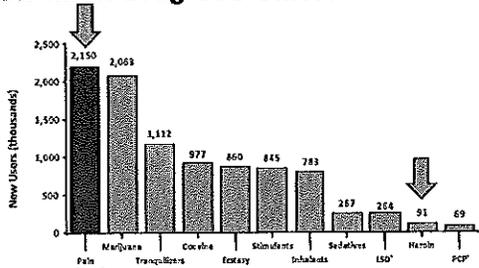


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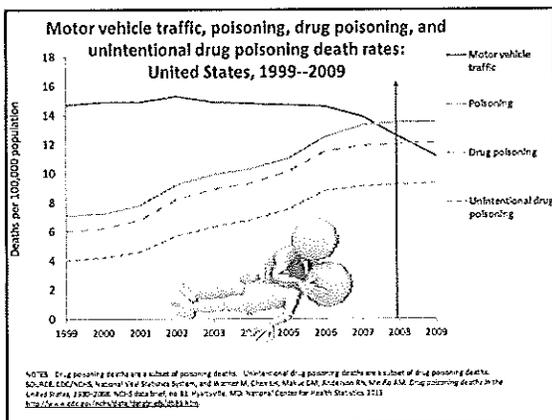
New Illicit Drug Use United States 2006

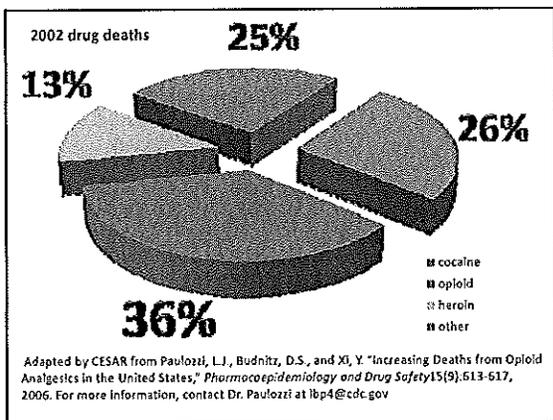


*\$33,000 new non-medical users of oxycodone aged ≥ 12 years. †LSO, lysergic acid diethylamide. ‡PCP, phencyclidine.

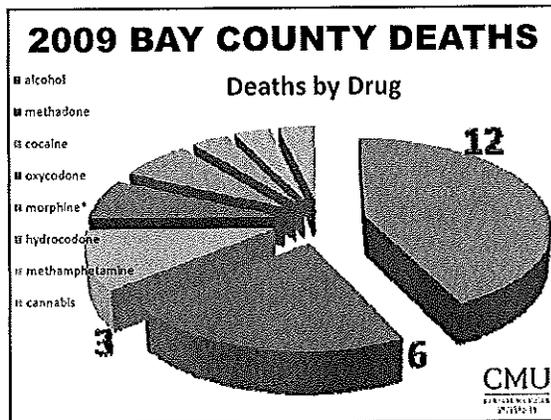
Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. 2006 National Survey on Drug Use and Health, Department of Health and Human Services Publication No. SMA 07-4233; 2007.

Some people can't read charts?
 In 8 to 10 years the number of **opioid overdose poisoning deaths** has **QUADRUPLED** from 4,000 to 18,000-20,000. In any other context this is referred to as an **epidemic**.



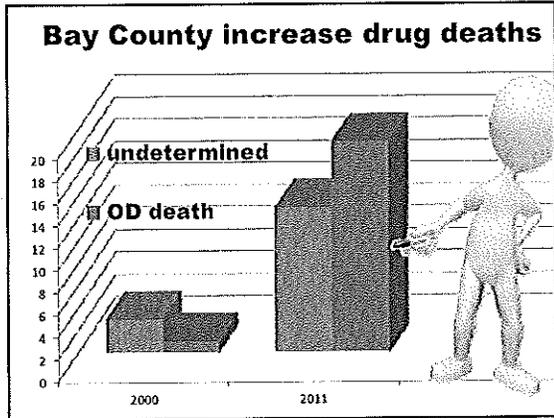


Natural	Semi-synthetic	Synthetic
(from opium 3%)	(derived from opium)	(man made)
Codeine	Buprenorphine	Meperidine
Morphine	Hydromorphone	Fentanyl
Thebaine	Oxycodone	Propoxyphene
	Oxymorphone	Methadone
	Hydrocodone	



Medical Examiner Data

- Saginaw Medical Examiner Data is not published to the internet like other counties. **Most counties do not make the data public** (Wayne, Kent etc...)
- I have access to data files in Bay County because I am a Deputy Medical Examiner.



Medical Examiners Office

MISSION
 To identify, investigate and determine the cause and manner of death of people who die in the County of Wayne under the circumstances or conditions described by Act No. 92 of the Michigan Public Acts of 1969.

The purpose of the Medical Examiner's Office is to provide forensic death investigations, autopsy, and toxicological services to the general public and medico-legal community so they can have documented, timely, and accurate cause and manner of death.

http://www.waynecounty.com/hhs_meo.htm

Bay County Autopsy Data

	Drug Intoxication deaths	Methadone in toxicology	Methadone likely cause of death	Methadone with a benzodiazepine
2010 (January to December)	18	5/18 = 28%	5/5 = 100%	3/5 = 60%
2011 (January to October)	19	6/19 = 32% *	6/6 = 100% *	4/6 = 67% *
Total	37	11/37 = 30% *	11/11 = 100% *	7/11 = 64% *

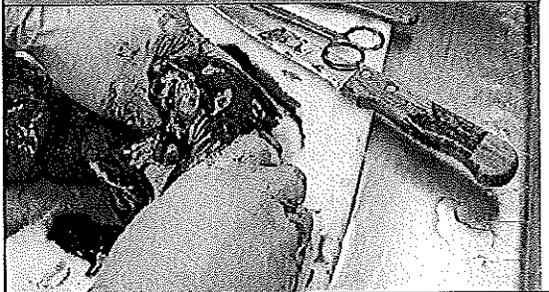
* = methadone clinic patient 37 y/o female [conc.] 2100 ng/mL ED07 = 470 ng/L

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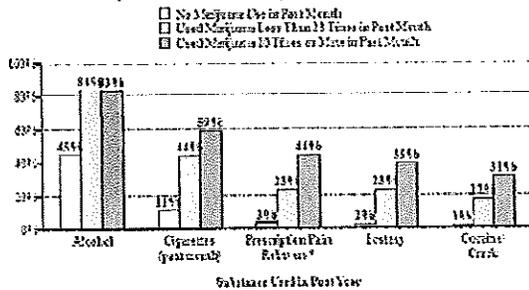
Opiate and Benzo INCREASED
DEATH - Based on AUTOPSY DATA

	LOCAL co-prescribed	NATIONAL co-prescribed
@ DEATH	63%	70%

lungs @ autopsy
>1,400 grams



Percentage of U.S. High School Students Reporting Past Year Substance Use,
by Past Month Marijuana Use (2011)



Who Misuses/Abuses Opioids and Why?

Medical
Pain patients seeking more pain relief

Nonmedical
Recreational abusers

Patients with disease of addiction

FOOD COURT

Risk Evaluation and Mitigation Strategies

Position of the FDA

- The **current strategies** for intervening [problems of prescription opioid addiction, misuse, abuse, overdose and death] are **inadequate**
- [FDA expects] all companies marketing these products to [cooperate] to get this done expeditiously. If not, [FDA] cannot guarantee that these products will remain on the market

Rappaport BA. REMS for Opioid Analgesics: How Did We Get Here? Where are We Going? FDA meeting of manufacturers of ER opioids, FDA White Oak Campus, Silver Spring, MD, March 3, 2009.

Multiple Types of Pain

Examples
<ul style="list-style-type: none"> • Strains and sprains • Bone fractures • Postoperative
<ul style="list-style-type: none"> • Osteoarthritis • Rheumatoid arthritis • Tendinitis
<ul style="list-style-type: none"> • Diabetic peripheral neuropathy • Post-herpetic neuralgia • HIV-related polyneuropathy
<ul style="list-style-type: none"> • Fibromyalgia • Irritable bowel syndrome

Adapted from Woolf CJ. *Ann Intern Med*. 2004;140:441-451.
1. Chong MS, Bawa ZH. *J Pain Symptom Manage*. 2003;25:S4-S11.

• Patients may experience multiple pain states simultaneously!

Breaking the Chain of Pain Transmission

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1. Otschalk A, Smith DS. *Am Fam Physician*. 2001;63:1979-1984. 2. Iyengar S, et al. *J Pharmacol Exp Ther*. 2004;311:576-584. 3. Morgan V, et al. *Gen*. 2005;24:671-697. 4. Reimann W, et al. *Anesth Analg*. 1999;89:141-145. Vanegas H, Schable HG. *Prog Neurobiol*. 2001;64:337-383. 6. Malberg AB, Yekich TL. *J Pharmacol Exp Ther*. 1992;263:136-146. 7. Stein C, et al. *J Pharmacol Exp Ther*. 1989;249:1269-1275.

S-HT = serotonin; NE = norepinephrine
TCA = tricyclic antidepressant

When do you use an opiate?

- Somatic and/or neuropathic pain
- Malignant origin of pain
- Non-malignant pain causing dysfunction including cessation of usual activities or employment
- Failure of non-opiate treatments including adjuvants
- Non-interventional treatments (lifestyle alteration, physical therapy, complementary medicine therapies) unsuccessful
- Interventional treatments not an option/unsuccessful
- Records reviewed verify the patient's history

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PAIN CENTER

Always quote your source

Russell K. Portenoy, MD

Department of Pain Medicine and Palliative Care
Beth Israel Medical Center, New York, NY
Neurology and Anesthesiology

Albert Einstein
College of Medicine

Equianalgesic Table

PO/PR (mg)	Analgesic	SC/IV/IM (mg)
30	Morphine	10
4-8	Hydromorphone	1.5
20	Oxycodone	-
20	Methadone	10
10	Oxymorphone	1

Richard K. Portney, MD, FRCPC, FRCPC
Department of Pain Medicine and Palliative Care

Opioid conversion chart

ANALGESIC	ORAL	PARENTERAL
Morphine	30	10
Codeine	200	120
Hydromorphone	7.5	2
Oxycodone	20	-
Hydrocodone	30	-
Methadone	20	10
Fentanyl	100-200 mcg [TM] 50 mcg [TD]	100 mcg
Meperidine	300	100
Propoxyphene	65-130	-
Tramadol	100-150	-

adapted from © Copyright 2003 American College of Physicians

- ## Adjuvants
- Adjuvants allow opioids to be anagetic or give greater analgesia at current/lower dose.
 - **Gabapentin** or Namenda or Amantadine
 - Valproic Acid or Phenytoin or Pregabalin
 - Amitriptyline or **Ketamine** or Benadryl
 - Promethazine or Dextromethorphan
 - **Baclofen** or Ranitidine or Clonidine
 - **Carbamazepine** 200-1600mg per day.

Adjuvant Analgesics for Chronic Headache

- Beta blockers
- Anticonvulsants
- Calcium channel blockers
- Alpha-2 adrenergic agonists
- Antidepressants
- Vasoactive drugs
- ACE Inhibitors

Department of Pain Medicine and Palliative Care

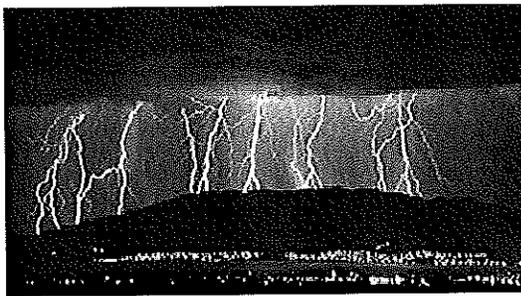
@ 20 minutes slide # 37

- Hand out case study.

CASE #4

- Spend 4 min. on case.

CASE #4



Get everybody ready for change

- Avoid long-term, daily treatment with **short-acting** opioids and opioid combinations (e.g., *Vicodin*, *Norco*, *Percocet*).

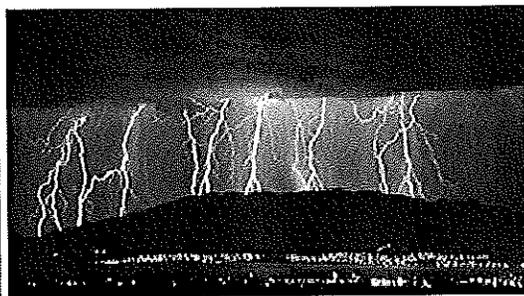
Write MS Contin not Vicodin

- Give 30 day notice. No phone refills.
- No exceptions No excuses

Opioid Formulations

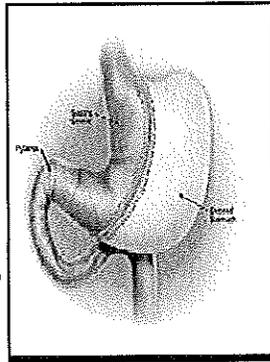
Type of Drug	Examples
Pure μ -opioid receptor agonists	Morphine, hydromorphone, fentanyl, oxycodone
Dual mechanism opioids	Tramadol, tapentadol, buprenorphine
Rapid onset (transmucosal)	Fentanyl, alfentanil, sufentanil, diamorphine
Immediate release	Tramadol, oxycodone, hydromorphone
Modified release (long acting)	Morphine, methadone, oxycodone
Available with co-analgesic	Oxycodone, tramadol, codeine
Only available with co-analgesic	Hydrocodone

CASE #5



Severe Metastatic Gastroadenocarcinoma

- 48 y/o white M
- Mercy Hospice
- (+) vomiting all day
- No stomach
- Stopped chemo
- Stopped radiation
- 90# (6ft 2in)
- hydromorphone pump
- Nursing Home doesn't take pumps.

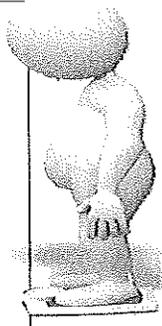


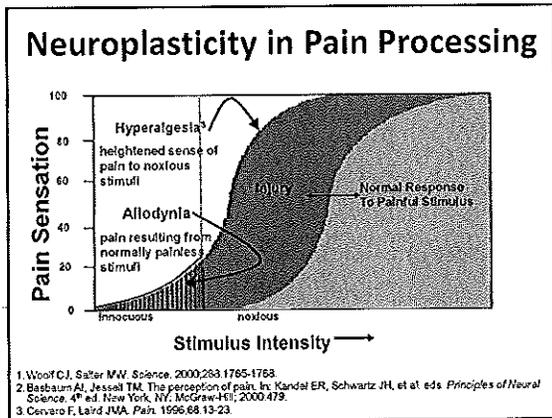
Hydromorphone pump PICC line to Methadone oral suspension

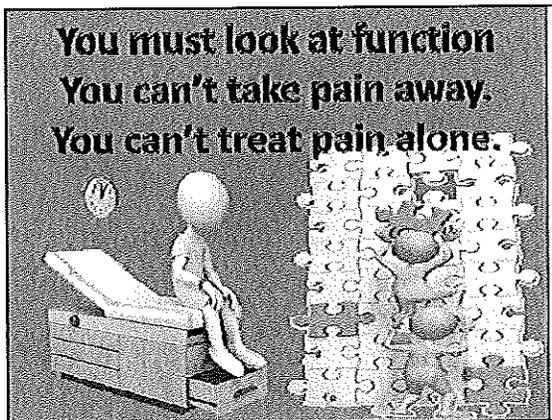
Date	Methadone PO	Hydromorphone IV	Hydromorphone/15 min
01/06	zero	15 mg	15 mg x 37
01/07	10 mg BID	10 mg	14 mg x 25
01/08	15 mg TID	9 mg	13 mg x 19
01/11	25 mg TID	7 mg	12 mg x 12
01/12	50 mg TID	3 mg	11 mg x 8
01/13	80 mg TID	zero	10 mg x 2
02/16	No change	expiration	

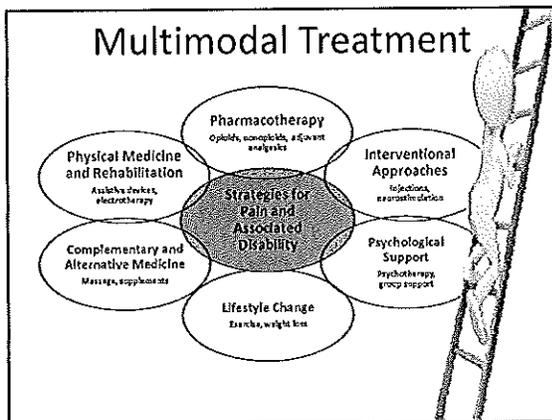
OPIOID ROTATION WORKS

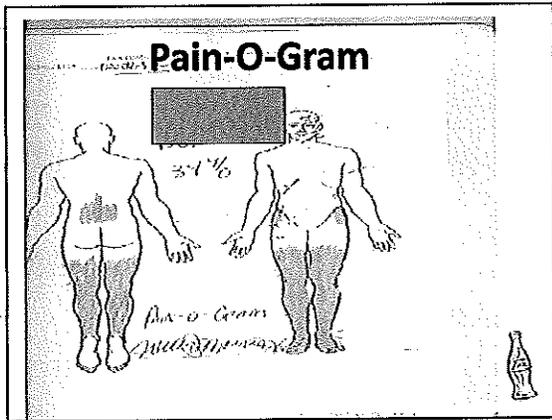
- On his 3rd day of the methadone conversion the hospice patient said it was the first time in 4 years he was **pain free**.
- He felt like getting up for a cigarette. That counts for **improved function**.

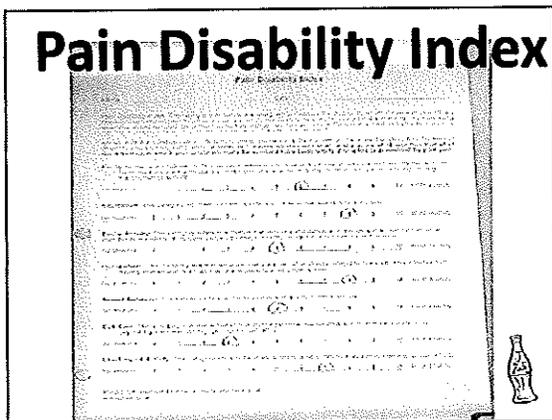


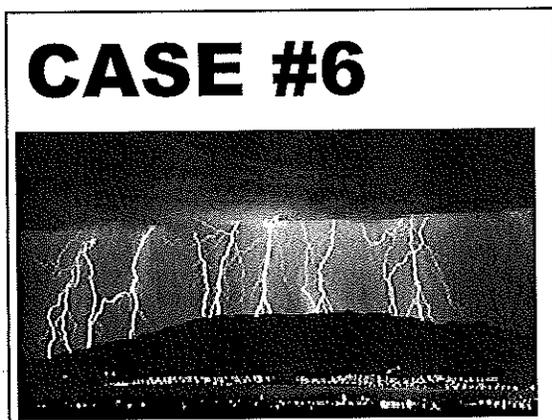












- **55 YEAR OLD white female**
- **Non-smoker**
- **Employed: County Court House**
- **Married w/ adult children gone**
- **Husband employed at VA**
- **HCV (+) and history of GI bleeds**
- **Fentanyl Patch 100 micgr / 1 hr**
- **# 10 hydrocodone/APAP / month**

Focus on function not pain

Encounter Diagnoses

- | Code | Name |
|-----------|--------------------------|
| • 338.29 | Other chronic pain |
| • 724.5AE | Back pain with radiation |
| • 724.2CA | Chronic lower back pain |
| • 723.1BC | Chronic neck pain |
| • 724.6AL | Sacral back pain |
| • 724.2U | Lower back pain |



Focus on function not pain

Refill has made a **big difference** with her increased **functionality** (analgesia is stable / No changes)

- **Not missing work this year (increased activity)**
- **4/5 days at work are good** (she kept garden)
- Patient had Thanksgiving & Christmas at her house this year (not done in > 5 years)
- Posture is better and there no adverse events
- **NO aberrant red flags (UDS) RTC ONE MONTH.**

**Domains for Pain Management Outcome:
The 4 A's**

- Analgesia
- Activities (ADL)
- Adverse Events
- Aberrant Drug Taking Behaviors



Passik SD, Weinreb HJ. *Adv Ther*. 2000;17:70-83.
Passik SD, et al. *Clin Ther*. 2004;26:552-561.

TERMS

- The terms addiction, physical dependence and drug tolerance must be accurately defined and used in the context of opioid therapy for chronic pain.
- Patients, family members, and medical providers and staff frequently misuse or misinterpret these terms.
- The presence of tolerance or physical dependence are *not* synonymous with addiction.

ELEMENTS of REMS

- Healthcare provider training & certification
- Pharmacy certification
- Drugs dispensed in only approved setting
- Drugs dispensed with documentation of safe use
- Patients will be monitored
- Patients will be in a registry



FDA: March 7, 2008 Wash DC

Implementation: Opioid REMS

- After notifying the sponsors of long-acting and extended-release opioid drugs that they were required to submit a risk evaluation and mitigation strategy (REMS), FDA has been working with the sponsors that market these products on the required REMS.
- The central component of the Opioid REMS is an **education program for prescribers** (e.g., physicians, nurse practitioners, physician assistants) so that opioid drugs can be prescribed and used safely.





US vs
BUCK

June
2010

United States Attorney's Office
Eastern District of Michigan
Richard L. Michaels
United States Attorney

PRESS RELEASE

FOR WEBSITE RELEASE
June 8, 2010

CONTACT: Chad Pulley (313) 224-2324
FOR MORE INFORMATION: (313) 224-2324

BAGANAW DOCTOR INDICTED FOR FIVE SCRIPTS IN BRACK OVERSHOOT

Dr. Alan Baganaw, M.D., of Baginaw, Michigan, was indicted on charges of unlawfully and being controlled substance, introduced to and State Attorney Richard L. Michaels (313) 224-2324 was present in the announcement by Special Agent in Charge (SAC) in Grand Haven, Michigan.

The indictment charges that from January 2009 through July 2009, Dr. Baganaw unlawfully and controlled prescription drugs (such as the course of controlled substances) and for no legitimate medical purpose. The indictment also charges that Dr. Baganaw provided over 13,000 single units of narcotic pain drugs (such as Vicodin, Oxycodone, hydrocodone, morphine, methadone, and Dilaudid). The indictment also charges that Dr. Baganaw provided these prescription drugs without and without medical supervision, despite being warned that national laws regarding the drugs, and for at least one of the legitimate needs of thousands of patients.

Special Agent in Charge (SAC) Grand Haven, Michigan, is involved in a joint effort with the U.S. Attorney's Office in Grand Haven to bring this case to a successful conclusion.

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- Occasionally, providers may be asked, or are tempted to prescribe opioid analgesics as therapy for opioid (illicit or prescription) addiction.
- **This is illegal** – special licensing is required to prescribe methadone, buprenorphine or other substances for the purpose of treating addiction.



Year	Patients who identify heroin as their addiction	Patients addicted to other opiates	Patients in methadone programs	COST of treatment
2010	11,358	8,448	6,970	\$7,448,574 *
2009	12,522	7,779	6,931	\$8,548,702 *
2008	10,499	6,250	6,248	\$5,248,842
2007	9,931	5,603	5,973	\$4,847,533
2006	9,958	4,918	5,875	\$5,438,545
2005	9,601	4,002	6,193	\$4,957,472
2004	8,726	3,246	6,380	\$5,340,845
2003	2,935 *	2,618	6,254	\$5,331,858
2002	6,517 *	1,929	NA	\$5,627,338
2001	7,857	1,882	NA	\$7,651,656
2000	7,264	1,292	NA	NA

Source: SAMSHA and MDCH, Dan Iacalano, Bay City Times, May 1, 2011



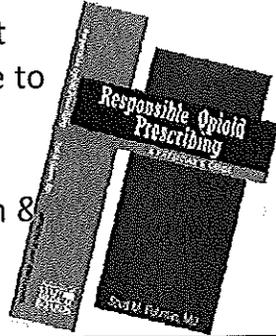
CONSULTATION

- For patients with opioid addiction who also have well substantiated moderate to severe pain, opioid analgesics have been used, but used with extreme caution, and under close supervision.
- Consultation for a pain/addiction management specialist is advised.



TOOL #1

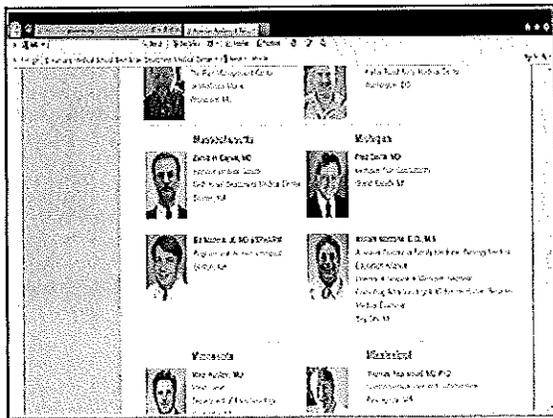
Outline tools that providers can use to monitor patients such as in office urine drug screen & improve function

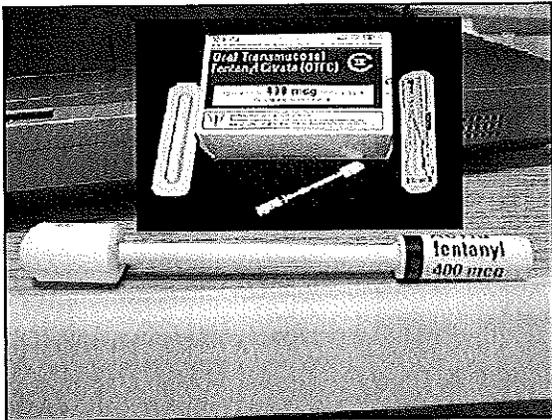


American Academy of Pain Medicine

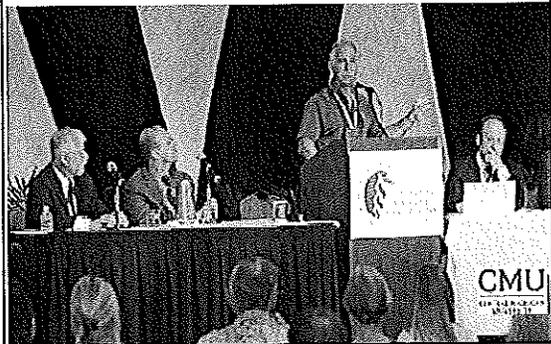


http://www.painmed.org/MemberCenter/Get_Involved_Locally.aspx#MI





Perry Fine invented fentanyl lollipop for cancer pain at University of Utah

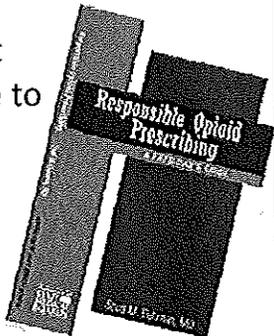


**The FISHMAN BOOK / FSMB
University of Michigan
MDCH / LARA
AAPM
APS
FDA REMS and
Dr. Morrone all teach the same**



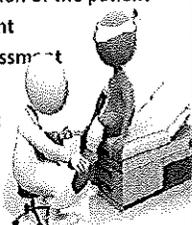
TOOL #1

Outline tools that providers can use to monitor patients such as in office urine drug screening

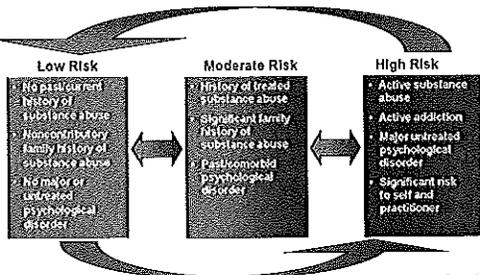


REMS: Initial Visits

- Initial comprehensive evaluation of the patient
- Risk assessment of the patient
- Prescription monitoring assessment
- Urine drug test
- Opioid treatment agreement
- Opioid consent form
- Patient education

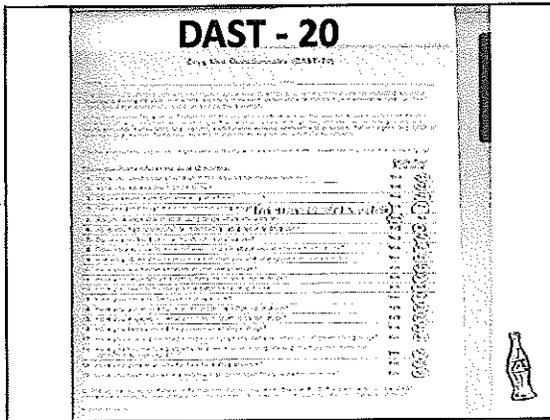


REMS: Stratify Risk TOOL #2



Webster LR, Webster RM. Pain Med. 2005;6:432-442.





ORT Validation

Mark each box that applies

	Female	Male	
1. Family history of substance abuse			• Exhibits high degree of sensitivity and specificity • 94% of low-risk patients did not display an aberrant behavior
- Alcohol	<input type="checkbox"/> 1	<input type="checkbox"/> 3	
- Illegal drugs	<input type="checkbox"/> 2	<input type="checkbox"/> 3	
- Prescription drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4	
2. Personal history of substance abuse			• 91% of high-risk patients did display an aberrant behavior
- Alcohol	<input type="checkbox"/> 3	<input type="checkbox"/> 3	
- Illegal drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4	
- Prescription drugs	<input type="checkbox"/> 5	<input type="checkbox"/> 5	
3. Age (mark box if 16-45 years)	<input type="checkbox"/> 1	<input type="checkbox"/> 1	
4. History of preadolescent sexual abuse	<input type="checkbox"/> 3	<input type="checkbox"/> 0	
5. Psychological diseases			
- ADD, OCD, bipolar, schizophrenia	<input type="checkbox"/> 2	<input type="checkbox"/> 2	
- Depression	<input type="checkbox"/> 1	<input type="checkbox"/> 1	

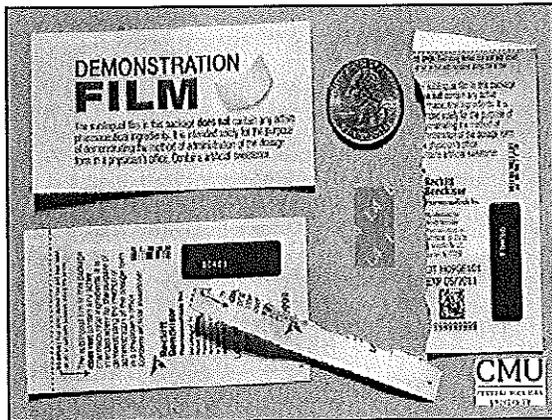
N = 185
 ADD, attention deficit disorder, OCD, obsessive-compulsive disorder.
 Webster LR, Webster RM. Pain Med. 2005;6:432-442

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Lynn Webster validated ORT

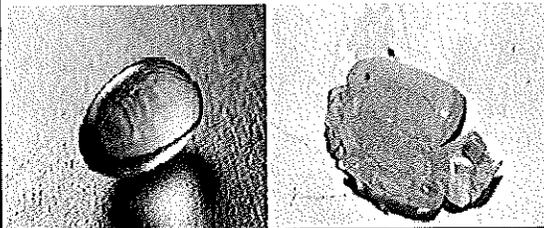
Reduce risk with tamper resistant formulation





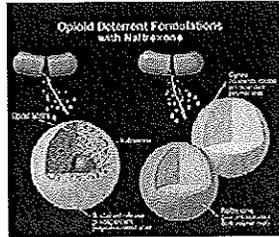
Viscous Gel Base

- SR oxycodone formulation: Remoxy™
 - Deters dose dumping
 - Difficult to crush, break, freeze, heat, dissolve
 - The viscous gel-cap base of PTI-821 cannot be injected
 - Resists crushing and dissolution in alcohol or water

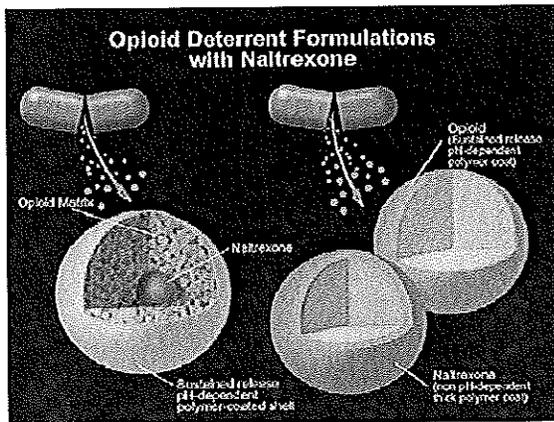


Pharmacologic Deterrent: Antagonist

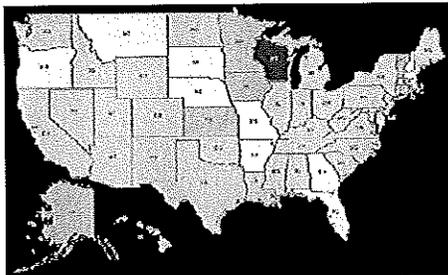
- Sequestered antagonist
- Bioavailable antagonist
- Antagonists are released only when agent is crushed for extraction
 - Oral formulation sequestered antagonist becomes bioavailable only when sequestering technology is disrupted; targeted to prevent intravenous abuse



Webster LR, Dove B. *Avoiding Opioid Abuse While Managing Pain: A Guide for Practitioners*. 1st ed. North Branch, MN: Sunrise River Press; 2007.



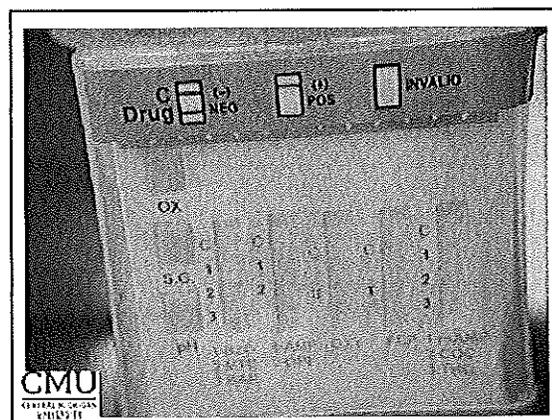
Tool #3 PMPs

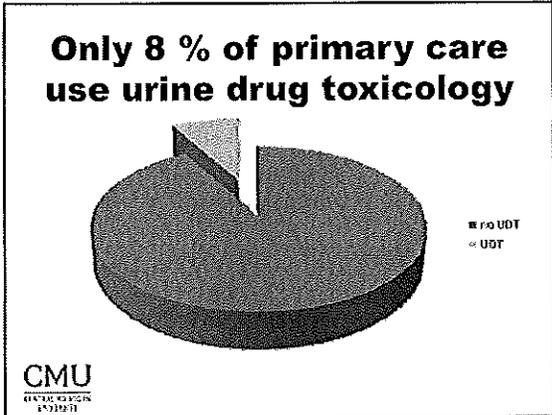


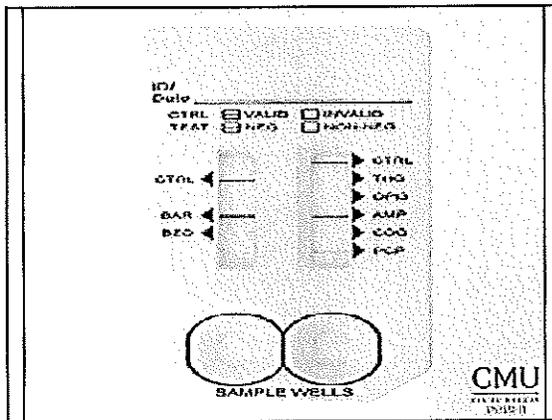
Office of Diversion Control, <http://www.dea.diversion.usdoj.gov/faq/monitoring.html#1>, Accessed March 2010.







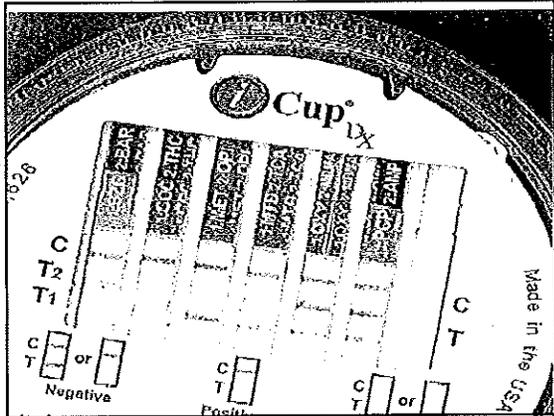




Identifying Who Is at Risk for Opioid Abuse and Diversion

- Predictive tools
- Aberrant behaviors
- Urine drug testing
- Prescription monitoring programs
- Severity and duration of pain
- Pharmacist communication
- Family and friends
- Patients

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FSMB text

RISK tool

MAPS online

UDS tox

RESULTS OF CONTROLLED SUBSTANCE UDT: WORKPLACE

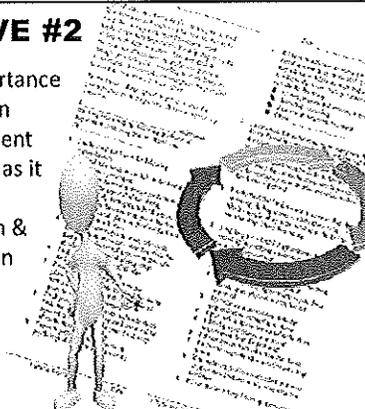
- Donor Name: Jack Squatt
Donor ID #: 1897221
Accession #: None assigned
Date collected: 04/11/2008
Date received: 04/15/2008
- Specimen ID #: 1897221-112
Reason for test: Random
Time collected: 1648
Date reported: 04/15/2008

Class or Analyte	Result	Screen Cut-Off
AMPHETAMINES	NEGATIVE	1,000 ng/ml
BARBITURATES	NEGATIVE	200 ng/ml
BENZODIAZEPINES	NEGATIVE	200 ng/ml
CANNABINOIDS	NEGATIVE	50 ng/ml
COCAINE	NEGATIVE	300 ng/ml
METHADONE	NEGATIVE	150 ng/ml
OPIATES	POSITIVE	100 ng/ml

Validity Test	Result	Normal Range
CREATININE	NORMAL at 33.4 mg/dL	≥ 20 mg/dL
SPECIFIC GRAVITY	NORMAL	≥ 1.003
pH	NORMAL	4.6-8.0

OBJECTIVE #2

Discuss the importance of communication between the patient and the provider as it relates to the treatment of pain & improved function



Opioid Treatment Agreement (OTA)

1. PURPOSE AND SCOPE

2. PATIENT RESPONSIBILITIES

3. PROVIDER RESPONSIBILITIES

4. MONITORING AND EVALUATION

5. DISCONTINUATION OF THERAPY

6. LEGAL DISCLAIMER

7. SIGNATURES

8. CONTACT INFORMATION

<http://www.in.gov/Clamstns/Files/OTAgreement.pdf>, Accessed March 2010.

SUMMARY

- #1-Outlined tools that providers can use to monitor patients: office urine drug screening, etc.....
- #2-Discussed the importance of communication between the patient and the provider as it relates to the treatment of pain



Online Resources	
Resource	Web Address
American Academy of Pain Medicine	http://www.painmed.org/clinical_info/guidelines.html
American Pain Society	http://www.ampain.org/pub/cp_guidelines.htm http://www.ampain.org/links/clinical1.htm
Federation of State Medical Boards	http://www.fsmb.org/RE/PAIN/resource.html
American Academy of Pain Management	http://www.aapainmanagement.org/literature/Publications.php
PMQ	http://www.permanente.net/homepage/kaiser/pdf/59761.pdf McGill Pain Questionnaire (Mezack R. Pain 1987;30:191-197)
Opioid Management Plan	http://www.aafp.org/aafp/20000301/1331.html
Opioid Treatment Agreement	http://www.hi.wa.gov/Claims/Files/OMA/Agreement.pdf

REMS CASE STUDY

- 24 year old white male new patient
- Missed scheduled appointment Monday
- Walk in Friday afternoon (to be seen)
- Requesting opiates by name
- UDS is blank for everything
- **Pain history is vague**
- **WHAT DOES MAPS (PMP) show???**



24 year old white male new Patient

- 30mg Adderall XR – Dr. Albert Yong (60#)
- 30mg Adderall XR – Dr. Kishore Kondapenini (90#)
- 30mg Adderall XR – Dr. Douglas Foster (90#)
- Accumulated 240# per month (2880#/year)
- Filled 3 different SAGINAW pharmacies
- \$15 x 2880 = \$ 43,200 tax free
- At the 35% tax bracket \$ 43,200 = **\$ 58,320**



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REMS Case Study # 2

A 56-year-old healthy male w/ acute back pain

Conservative therapy ineffective (failure)

Dx with acute thoracic compression fractures

Persistent pain 7/10 & activity pain 10/10

ORT 5

UDT consistent therapy

PMP: no opioids

Rx started with hydrocodone/APAP q 4 hours

Titrate to 50 mg CR morphine/naltrexone BID

REMS Case Study #2 (cont)

• **Monitoring**

Weekly visits until stable and document **function**

Prescribe only enough medication until next visit

• **Rx**

Short acting for BTP if needed (QD)

CR formulation (with less street attractiveness)

Consult out for Vertebroplasty that is partially effective

• **Six month follow-up**

Much improved; **pain 2/10**, => tapered of opioids by 70%

No aberrant behaviors in history

PMP showed no aberrant behavior and exam showed better function

Monthly UDT consistent with therapy



REMS Case Study #3

• 38-year-old female actress with ovarian cancer and peripheral neuropathy from therapy

• ORT score was 9

• Urine drug test: **THC**, amphetamines

• **History of oxycodone addiction, ADD, sexual abuse**

• **Smokes** 1 pack per day since the age of 12

• Consumes **18-20 drinks** per week

• PMP: **several** opioid prescriptions from different providers



REMS Case Study #3 (cont)

- RX
 - Instructed to DISCONTINUE THC (marijuana) IN THE CHART
 - OTA (OPIOID TREATMENT AGREEMENT) aka PAIN CONTRACT
 - Pregabalin 600 mg/day
 - Methadone was slowly titrated to 5 mg q/d, Education for Safe Use
- Two weeks later
 - Patient said she **couldn't tolerate methadone**
 - Asked for oxycodone and no UDS supplied
 - Pregabalin is causing confusion and severe memory impairment, can't remember her lines in performance (POSSIBLE DECREASED FUNCTION)

WAS THE PROBLEM METHADONE OR PREGABALIN ????

