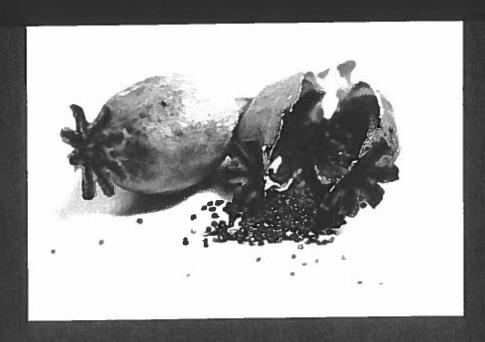
BENEFITS OF OPIOIDS FOR PAIN MANAGEMENT

DAVID S. ROGERS, M.D. Oaktree Medical Center



FOR	
PAIN MANGEMENT	
DAVID S. ROGERS, M.D.	

PAIN PREVALENCE

- 100 million adults in the U.S.
- 31 % of the adult population
- 34 % female adults
- 27 % male patients
- 26 % of adults in the U.S. with depression

N.I.H.

UNDERTREATMENT OF PAIN

42% E.D. patients present with pain
75 % leave the E.D. in mod-severe pain
40% never receive analgesics

□ 86% patients after surgery report modto severe pain

CONSEQUENCES OF UNTREATED PAIN	
"Unrelieved pain has negative physical and psychological consequences. Aggressive pain prevention and control that occurs before, during, and after surgery can yield both short-	
term and long-term benefits." AHCPR Clinical Practice Guidelines-Acute Pain Management	
"Unrelleved pain has enormous physiological and psychological effects on the patient. The Joint Commission	
component of good care. Research clearly shows that unrelieved pain can slow recovery credit by the care.	
care system."	
Dennis O'Leary, M.D. President, JCAHO	
	_
PAIN	
- WEBSTER'S Definition of PAIN	
 A: a state of physical, emotional, or mental lack of well-being or physical, emotional, or mental uneasiness that ranges from mild discomfort or dull distress to acute often unbearable agony, may be generalized or localized, and is the 	
consequence of being injured or hurt physically or mentally or of some derangement of or lack of equilibrium in the physical or mental functions (as through disease), and that usually produces a reaction of wanting to avoid, escape, or destroy	
the causative factor and its effects.	
B: a basic bodily sensation that is induced by a noxious stimulus, is received by naked nerve endings, is characterized by physical discomfort (as pricking, throbbing,	
or aching), and typically leads to evasive action.	
Ψ.	
OPIOID DEFINITION	
1. any synthetic narcotic that has opiate-like	
activities but is not derived from opium.	
2. any of a group of naturally occurring	
peptides, e.g., enkephalins, that bind at or otherwise influence opiate receptors either	
with opiate-like or opiate antagonist effects.	
1	

MOST WIDELY PRESCRIBED DRUG CLASS

- □ 1 OPIOIDS
- **2 ANTIDEPRESSANTS**
- **3 LIPID AGENTS**
- □ NIH NIDA data
- □ Science Daily April 6, 2011

This sort of press is a direct consequence of our refusal to take a hard, responsible, unblased view of these very strong.

very strong,
very problematic,
and potentially deadly

ampauti



The 2003 APS Abstract Database Perform a con search

> TREATHENT APPROACHES (Medical/Interpret Gall) EQL Canter Part Operati Poster #854

Rear of addiction and side effects continue to influence patriots' decisions whether or not to follow assignsts regimens

Autrorial to Pass, S. Cartor, I. Chry, E. Cleband; The University of Texas MD Anderson Cancer Carter, Houston, TX

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OPIOID CONCERNS

- □ Physical dependence
- Psychological dependence
- Addiction
- □ Abuse
- □ Diversion

Figure 1. Annual Humbers of New Normadical Users of Prescription Tyric Drugs, by Drug Category 1965–2000 7 900 Part Research Tilendauters Schalaters 1 900 1 1000 1 1000 Source: SAMHSA 1999-2001 NHSDAs

ABUSE AND ADDICTION

- □ Rare as a rule in chronic pain patients
- <u>but</u> ...no appropriate studies of chronic pain populations over long term.

Important Questions

- □ Risk:Benifit (Efficacy) ratio?
- Abuse and Addiction?
- □ Tolerance?
- □ Psychological Risks?
- D Cognitive Risks?
- □ Palliation vs. Rehabilitation?

Adverse Events (PDR)

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OPIOID FACTS

USED TO TREAT MODERATE TO SEVERE PAIN

USED FOR ACUTE AND CHRONIC PAIN

SAFE AND EFFECTIVE WHEN USED CORRECTLY

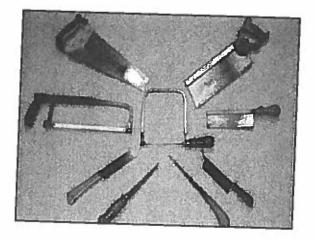
CAUSE LESS LONG-TERM DAMAGE TO BODY SYSTEMS THAN FROM OTHER DRUG GROUPS

ARE OPIOIDS REALLY **NECESSARY?**

Unfortunately, Opioids are clearly not the Panacea we had hoped; they are merely another set of tools, with substantial risk, mortality and morbidity

	OPIDIDS FOR CHRONIC NON-CANCER PAIN:
i	A META-ANALYSIS OF EFFECTIVENESS AND SIDE EFFECTS

- BOTH WEAK AND STRONG OPIOIDS OUTPERFORMED PLACEBO FOR PAIN AND FUNCTION OUTCOMES
- PAIN RELIEF WAS SUPERIOR WITH STRONG OPIATES COMPARED TO OTHER NON-OPIATE MEDICATIONS
- REDUCTIONIN PAIN INTENSITY WAS APPROXIMATELY 30%
- e Furlan, Sandoval, Mallis-Gagnon, Tunks Canadian Medical Journat May 23, 2006 vol. 174 no. 11 1589-1594



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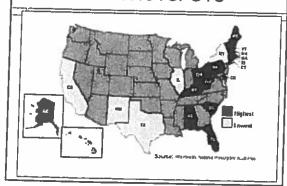
LIST OF MEDICATIONS I WILL NOT PRESCRIBE	
□ PROPOXYPHENE COMPOUNDS □ MEPERIDINE □ HYDROMORPHONE IR □ BUTALBITAL COMPOUNDS □ METHADONE □ NALBUPHINE □ CARISOPRODOL	
BUTORPHANOL PENTAZOCINE CODEINE	
	7
Methadone Gruws as Killer Drug. by pad section CHILANIA, No. — Introduce, a drug freg re and for trait g	
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FOOD FOR THOUGHT

WE SHOULD ALL RECOGNIZE THAT THERE IS A NATIONAL PROBLEM WITH DRUG USE OF ALL TYPES

CAFFEINE NICOTINE ETHANOL

DIVERSION HOTSPOTS



PROHIBITION

DEASY SOLUTION

OR

DRECIPE FOR DISASTER?

PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING - PROP	
PROPOSES MAXIMUM DAILY DOSE EQUIVALENT OF 100 MG. MORPHINE FOR NON-CANCER PAIN MAXIMUM DURATION OF CONTINUOUS DAILY USE FOR NON-CANCER PAIN OF 90 DAYS	
RUSSELL PORTNOY, M.D.	
□ OPIOID THERAPY □ FOR CHRONIC NON-MALIGNANT PAIN □ Journal of Law, Medicine, and Ethics □ 24 November, 1996 296-309	
"If you insist on regulation, then you are consigning my mother to live in chronic pain." Wall Street Journal 17 December, 2012	
LYNN WEBSTER, M.D. President of AAPM	
"We believe that the adoption of the recommendations in the PROP petition to lower doses or duration would provide a false sense of security for patients and practitioners."	
"In our view, a more effective means to address this problem would be enhanced prescriber education, and adherence to principles of education including appoint monitoring for aberrant	
behaviors and early signs of addiction." Balem News.com Aug. 26, 2012	

Steve Passik, P.h.D

Professor of Anesthesiology, Vanderbilt University

- a "I am not pro-opioid, I am anti B.S."
- "In pain management, no exposure of anyone at all means cutting off an avenue to relief for a subset of patients with pain that might otherwise do well. Safe opioid prescribing is the result of assessing the vulnerabilities in highly stressed people and accommodating the delivery of opioid therapy to them. We need to stop blaming the drugs..."
- www.reportingonhealth.org/2012/08/30

Pressure to Treat Pain*

- JCAHO Regulations
 - Pain must be monitored and treated appropriately.
 - n Patients have "right" to pain relief.
- Patient Advocates and Rights Groups
 - Demand opioids for benign pain. n Patient's Bill of Rights in many states.
- Litigation for Failure to Treat Pain
- a \$1.5 million largest judgment to date.
- a 18 suites in 11 states pending.
- Goal of winning a case in every state.
- * The implication being "treating pain"=Opioids

The rock and the hard place

- More pressure to prescribe opioids
- Lawsuits against physicians for not prescribing
- o Lawsuits against physicians for prescribing
- Criminal charges against physicians for patient diversion and abuse
- a Individual and Class Action suits against physicians for addiction / dependence
- Individual and Class action suits for death (usually accidental overdose)
- Individual suits for Accidents under the influence (usually MVA)

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amednews.com

PROFESSIONAL RELES

Florida physician guilty of manslaughter in OxyContin case

As word of the verdict to the OryConths-related case appendit, experts marry ductors will sky may from paid management.

By "anys Albert, Uthlore staff Marth 1 , 2007 Addressed information

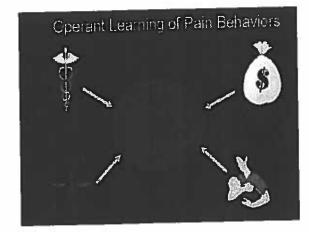
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ANESTHESIOLOGIST WINS DISABILITY BENEFITS FOR OPIOID ADDICTION

- a Julie Colby vs. Union Security Insurance Co.
- a Exclusion of the risk of drug abuse relapse was ruled an unreasonable interpretation of the insurance plan's coverage by the federal district court.
- Business Insurance 18 January, 2013



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Operant Issues Work Comp 54% 3rd Party Lawsuit 17% **Litigation Total** 71% IME'S 23% OPIOIDS MAY BE THE MOST POWERFUL OPERANT REWARD. INJURED WORKERS AND THE RISK OF NARCOTICS MISUSE 1 in 12 injured workers started on narcotics were still using them 3-6 months later Only 4-7% of injured workers with long-term narcotics use received psychosocial evaluation and treatment □ In the best state studied only 25% received

such care

states

□ Data based on 300,000 W/C claims in 21

Worker's Compensation Research Institute 2012

EARLY OPIOID PRESCRIPTION AND SUBSEQUENT DISABILITY AMONG WORKERS-WITH-BACK-INJURIES-

- Opioid use was a risk factor for long-term disability at 1 year
- n 14% (254 of 1843) received work disability compensation at 1 year
- p Franklin, Stover, Turner, et al.
- a Spine Jan. 2008 -vol.33 (2) 199-204

Change in Pain Effect of Workers' Comp 55 -No 50 WC 45 disch 1 3 eval Time: F (3.2, 481) = 11.37, p < .001, Group x Time: F (3.2, 481) = 3.2, p < .02 Gagnon C, Harden N et al Pain Practice 2012

COSTS AND POOR COMPLIANCE WITH BEST PRACTICES

1.4 BILLION DOLLARS SPENT ON NARCOTICS ANNUALLY BY EMPLOYEES AND INSURERS - 25% OF W/C EXPENSES

ONLY 1 IN 20 PHYSICIANS COMPLIED WITH BEST PRACTICES - RISK ASSESSMENT - SIGNED OPIOID AGREEMENT - OBTAINED RANDOM UDSI

TEXAS, MASSACHUSETTS, AND NEW YORK HAVE ESSENTIALLY BANNED PHYSICIAN DISPENSING BY GREATLY LIMITING THEIR ABILITY TO DO SO

Jospeh Paduda, President of CompPharma.LLC

OPIODS IN THE WORKPLACE

AMERICANS WITH DISABILITIES ACT AND DRUG ADDICTION TREATMENT ACT PASSED CONGRESS IN 2000

- Determined opioid addiction as a medical condition
- Encourage employers to support employees with opioid dependency

35 year-old Female with CLB on 20mg sustained release oxycodone BID

and several doses of immediate release "rescue" morphine a day.

Each Attempt to decrease opioids fail.

Vocation: School Bus Driver.

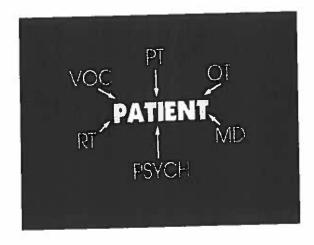
RTW Decision?

THE REAL OPIOID DILEMMA

- d More pressure to prescribe opioids
- Lawsuits against physicians for not prescribing
- Lawsuits against physicians for prescribing
- Criminal charges against physicians for patient diversion and abuse
- Individual and Class Action suits against physicians for addiction / dependence
- Individual and Class action suits for death (usually accidental overdose)
- Individual suits for Accidents under the influence (usually MVA)

	WHAT AMERICANS WANT AND EXPECT FROM HEALTH CARE	
	□ Cure □ Instant gratification □ Surgery □ Pills □ High tech solutions □ No effort in their recovery = Unrealistic goals in pain management	
L	WHAT DOES NOT WORK*	
	□ PROHIBITION □ NERVE BLOCKS* □ PAIN PUMPS* □ SPINAL CORD STIMULATORS* □ SURGERY* □ * FROM A COST/BENEFIT STANDPOINT	
֓֞֜֝֜֜֜֜֜֜֝֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜]
	WHAT DOES NOT WORK*	
	NERVE BLOCKS - \$25-\$100K per year for sometimes endless series of injections	
	□ SURGERY- \$25-\$200K for spinal surgery □ IMPLANTS- \$45-60K with up to \$1000/month	8
	maintenance (replacement in 4 years)	
	*essentially no evidence at all to support these procedures	
	Harden Pain Medicine 2012;(13) 987-988	

What doesn't work cont; Interventional Pain Management*	
Nerve Blocks Nerve Ablations	
Spinal Cord Implants	
□ Cortical Simulation □ Ketamine Coma	
Dead Rooster Comb Injections	
essentially no evidence to support any of these procedures	
Harden -Pain Medicine Vol.13(3) 196-197	
WHAT NOW?	
DO THE NECESSARY RESEARCH TO ANSWER THE OUTSTANDING QUESTIONS	
© EDUCATE PHYSICANS AND PATIENTS ABOUT RISKS	
□ RISK MITIGATION STRATEGIES	
□ ESTABLISH A RATIONAL PAIN MANAGEMENT POLICY NATIONALLY	
DISCUSS WHO ARE THE MOST APPROPRIATE PROVIDERS FOR CHRONIC	
PAIN MANAGEMENT	
WHAT DOES WORK?	
□ MULTIDISCIPLINARY APPROACH	
PSYCHIATRIC SUPPORT Cognitive Behavioral Therapy	
RATIONAL POLYPHARMACY	
□ WORK HARDENING PROGRAMS	
RISK MITIGATION STRATEGIES	



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Efficacy of	multidisciplinary pain treatment o	enters
	a meta-analytic review."	
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Interdisciplinary Team Model

- Patient Centered
- Team members work together toward a common goal
- B Make collective therapeutic decisions
- Communicate and consult with other team members, facilitated by planned face-to-face meetings
- Teams possess a combination of skills that no single individual demonstrates alone
- Team is able to achieve more than the sum of the individuals involved

Boon H, et al. BMC Health Services Research 2004,4:15; Cummings I The interdisciplinary team in: Doyle D, Henks GW, MacClonald N, editors, Oxford fastbook of pallative medicine Oxford Orient University Press, 1998; Parker GM, Cross-functional teams, working with allies, enersee and other strangers. San Francisco Jossey-Bess Publishers, 1994,7:31-40.

MULTIDISCIPLINARY PAIN CENTERS □ EFFECTIVE IN REDUCING PAIN AND OPIOID DECREASE HEALTH CARE SERVICES **a IMPROVE PATIENT FUNCTION** a EARLIER RETURN TO WORK □ CLOSING DISABILITY CLAIMS □ COST EFFECTIVE- ESPECIALLY WITH RECALCITRANT PATIENTS Drug Benefit Trends 2001; 13(9) 36-38 **Physical Therapy** o De-emphasizing high tech, passive modalities a Emphasizing low tech, self management and active modalities □ Reactivation a Stretch/strengthen a Tens units Psychotherapy Cognitive behavioral therapy o Stress management Coping skills

□ Relaxation techniques
□ Guided Imagery
□ Self hypnosis

WORK HARDENING	
EXAMINATION OF OUTCOMES IN DISABLED WORKER POPULATION	
SIGNIFICANTLY IMPROVED QUALITY OF LIFE	
UNLESS THERE WERE 2 OR MORE INJURIES MACK,et.al, Disability Medicine 2012,Vol.8 No.1 11-18	
SCREENING TOOLS	
SCREENING TOOLS IDENTIFY ADDICTIVE POTENTIAL	
□ IDENTIFY ADDICTIVE POTENTIAL	
DENTIFY ADDICTIVE POTENTIAL DIDENTIFY DEPRESSION -BAD	

RATIONAL POLYPHARMACY

- □ MULTIMODAL THERAPY
- USE OF OPIOIDS WITH OTHER MEDICATION CLASSES
- D MULTIPLE RECEPTOR SITES
- 0.1 + 1 + 1 = 5

Chemical Structure of Tricyclic Antidepressants		
Tertiary amines	CH-CH-CH-N CH Amitriplyline	
Secondary amines CHCH,CH,NHC Hs, Nortriptyline	CH ₁ CH ₂ CH ₂ NHC Desipramine	

Anticonvulsant Drugs and Neuropathic Pain*		
First-generation Carbamazepine ^A Divalproex sodium ^B Phenytoin ^A Valproic acid ^B Clonazepam ^B Phenobarbitol ^B	Second-generation o Gabapentin ^A a Lamotrigine ^A a Levetiracetam ^B o Oxcarbazepine ^A o Tiagabine ^B a Topiramate ^B o Zonisamide ^B	
*Published randomized controlled Irlais. *Clinical arecdotes and/or published case	"Not approved by FDA for this use.	

Mechanisms of Action		nugs
Na* channel blocker	 Carbamazepine Lamotrigine Oxcarbazepine 	Phenytoin Valproate Zonisamide
Ca** channel blocker	Ethosuximide Oxcarbazepine	Gabapentin Zonisamide
GABA receptors	• Barbiturates	- Benzodiazepine
GABA metabolism	Vigabatrin Valproate	Tiagabine (Gabapentin)
Giutamate receptors	 Carbamazepine Felbarnate 	Lamotrigine Topiramate
Glutamate metabolism	• (Gabapentin)	

Topical Medications

- o Capsalcin
 - a Inconsistent trial results; potential burning upon application
- o EMLA
 - m May help some patients with allodynia
- Clonidine gel
 - Pilot studies suggest efficacy; controlled trial in progress
- Unstudied custom compounds

 - a other TCAs, gabapentin, opioids, ketamine, guanethidine
 - Lidocaine/ Diclofenac Topical patches and gels

LONG ACTING OPIATES

- ARE MORE EXPENSIVE
- □ LESS PILL COUNT
- **B LESS OFF TIME REBOUND PAIN AND** ANXIETY
- **D LESS DIVERSION POTENTIAL**
- **LESS ABUSE POTENTIAL**

NEW FORMULATIONS

- □ IN OPIOID DEPENDENT PATIENTS TAKING NEW FORMULATION OXYCONTIN
- □ ABUSE DECLINED 35.6% TO 12.8%
- □ 66% OF SUBJECTS REQUESTED A CHANGE TO ANOTHER MEDICINE

Cicero, NEJM 2012- 367: 187-189

OPIOID SUMMARY	
USED TO TREAT MODERATE TO SEVERE PAIN	
USED FOR ACUTE AND CHRONIC PAIN	
SAFE AND EFFECTIVE WHEN USED CORRECTLY	
CAUSE LESS LONG-TERM DAMAGE TO BODY SYSTEMS THAN FROM OTHER DRUG GROUPS	