MANAGING CHRONIC PAIN WITH OPIOIDS: EMERGING CLINICAL SYSTEMS TO BALANCING SAFETY, EFFICACY, AND RISK

David Nowels, MD, MPH
Associate Professor,
Family Medicine UC Denver SOM
Faculty LQI

Objectives

- Recognize the nature of the public health and ethical crisis of under treatment of pain and of prescription drug abuse
- Identify the fundamental responsibilities of prescribers of controlled substances
- Identify components of clinical care for patients with persisting pain who receive opioids that may improve treatment, protect your practice, and protect patients

New Problems

Prevalence of Persisting Pain in US

1 in 4 Americans suffers from chronic pain

Higher in women, whites, and those who live in poverty

NCHS, Chartbook Heath Trends, Fig 28. 2006

Pathophysiology of Chronic Pain: Cortical Plasticity and Reorganization

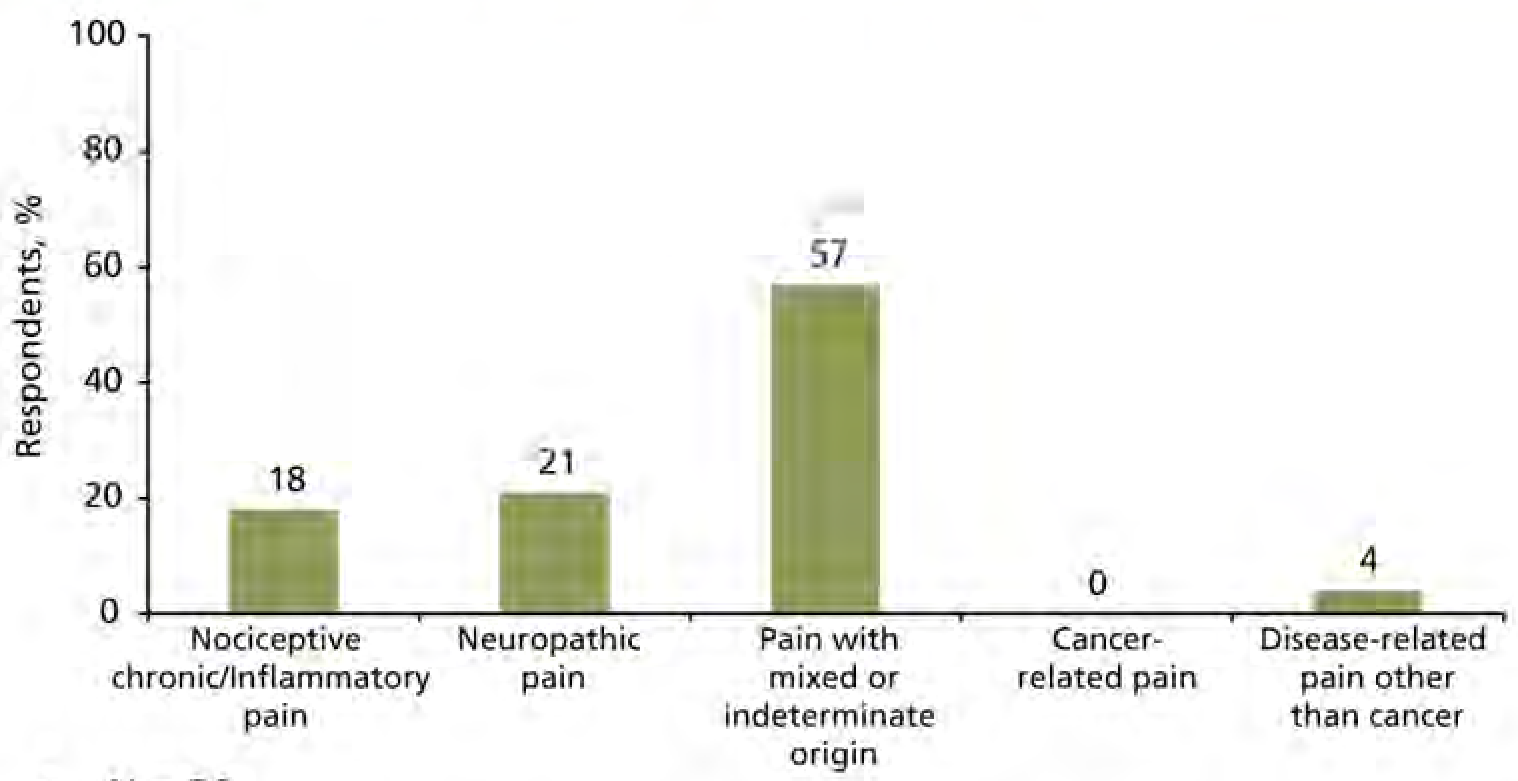
Injury

Early phase 1
LTP
Disinhibition/dis-LTD
Reduced GABA tonic current
2nd messengers, kinases

Late phase 2
Gene activation: CREB, egr1
Protein synthesis: NR2B
Trophic factors
Descending facilitation

Enduring phase 3
New cortical connections
Neuronal death of GABAergic neurons
Descending facilitation

Types of Chronic Pain Most Frequently Encountered by Practicing Physicians[1]



- N = 28
- Survey population consisted of pain medicine specialist, internal medicine specialists, and family practice physicians

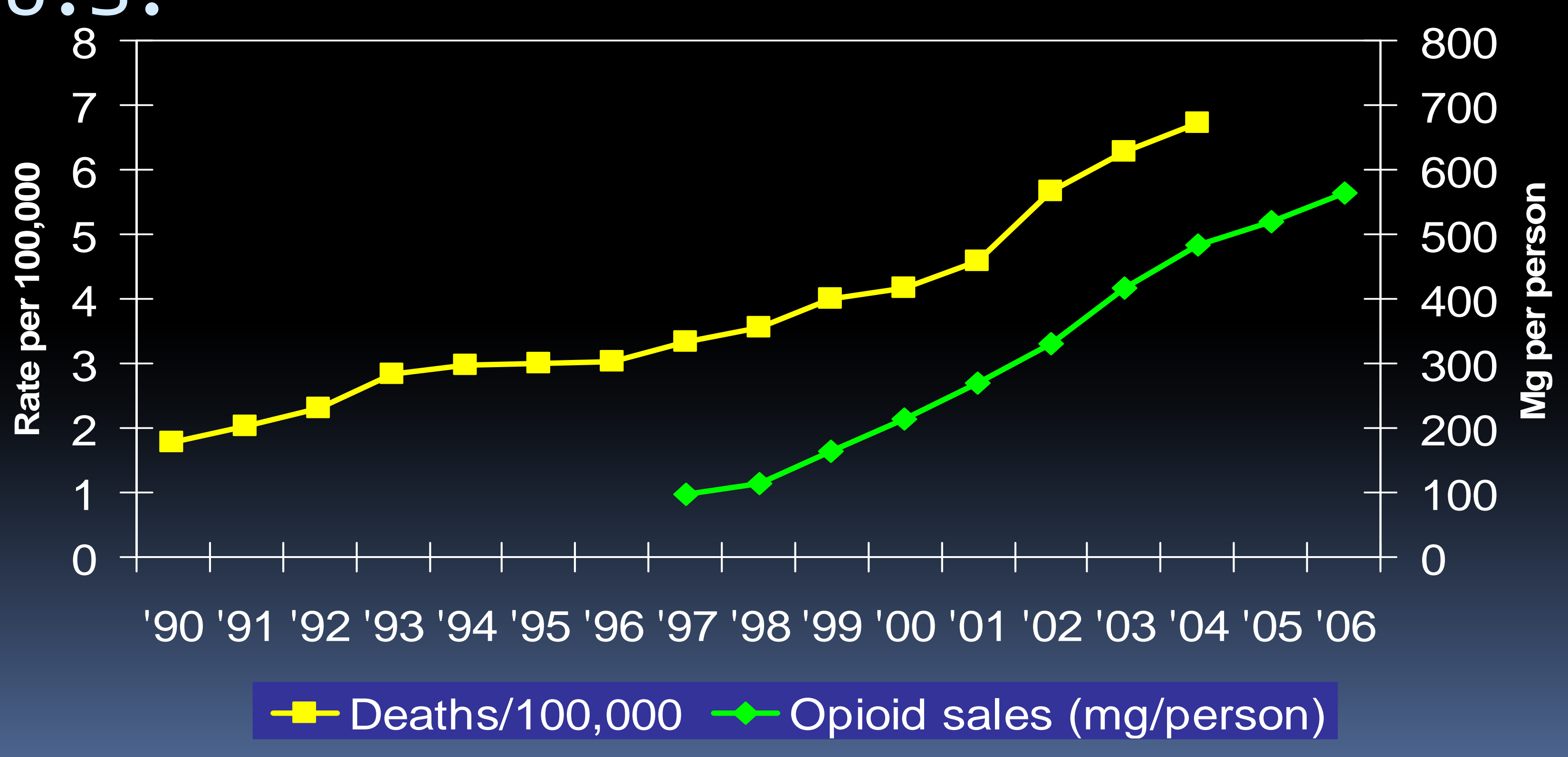
Impact of Unrelieved Pain

- Decreased productivity
- Impaired relationships
- Increased healthcare costs
- Depression
- Decreased functional capacity
- Anxiety/frustration
- Insomnia
- Sexual dysfunction
- Increased risk suicide
- Inability to concentrate
- Impaired driving ability
- Fatigue

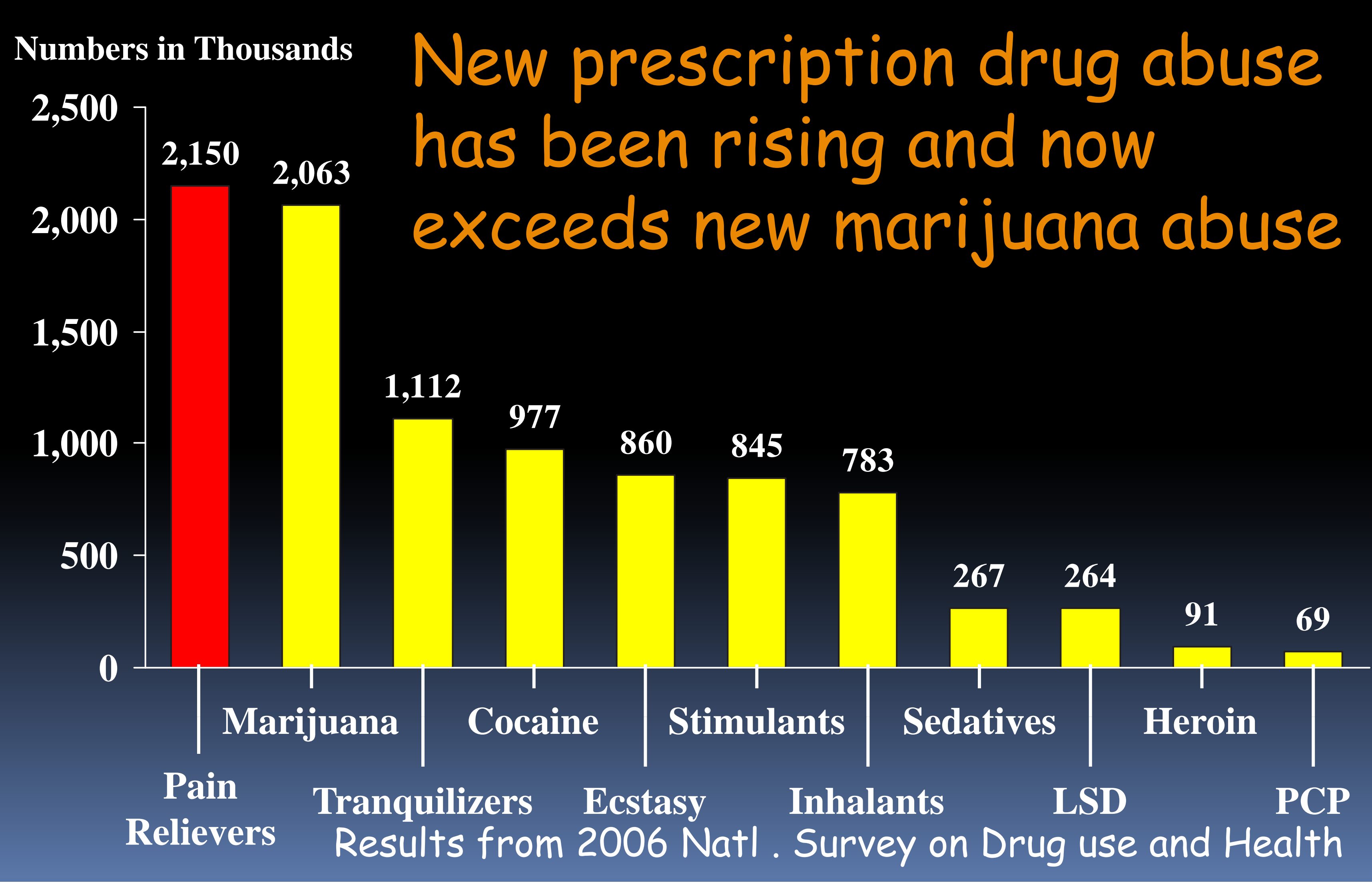
Opioid Use

- Opioids – the most broadly effective analgesics in medicine, used for millennia
- Effective and safe in both acute and persisting pain – if used properly
- Have liabilities of side effects and risks of abuse/diversion/misuse
- Both opioid use and opioid abuse are rising

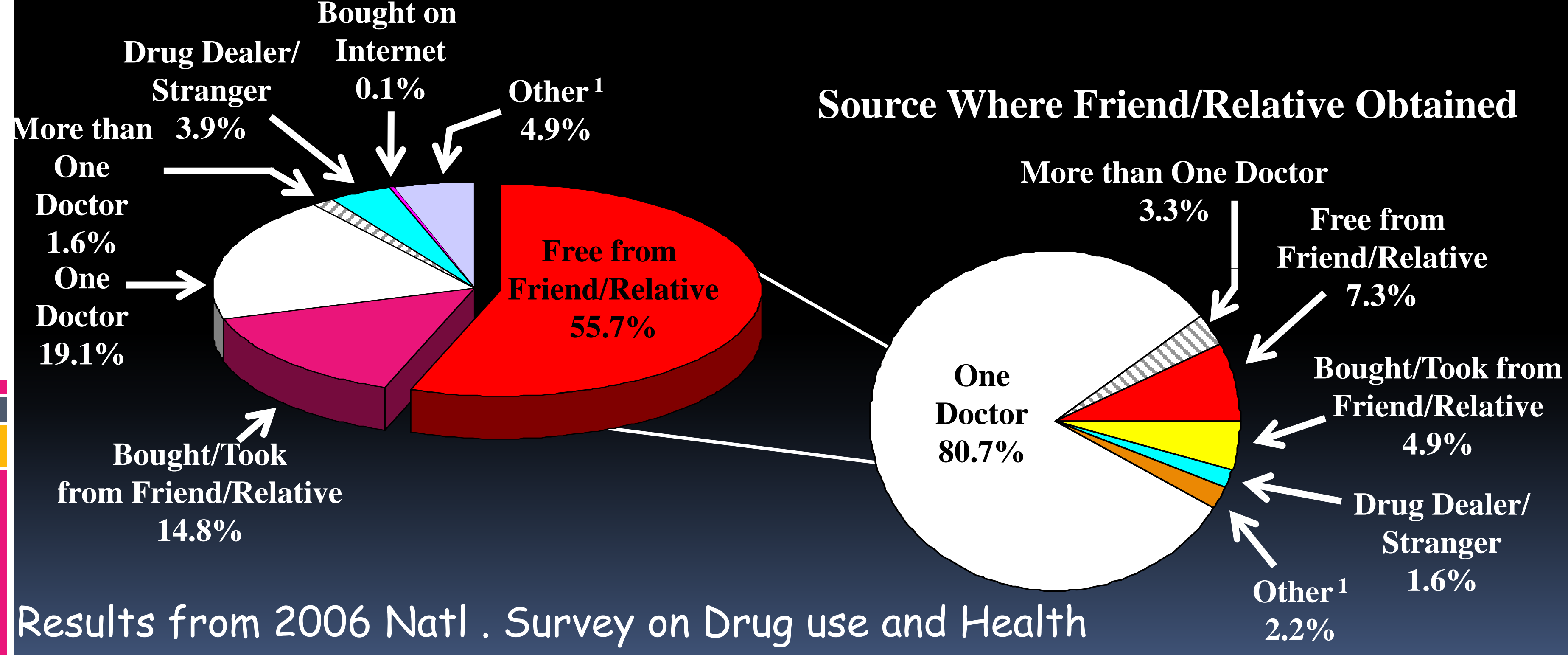
Unintentional drug poisoning mortality rates and total sales of opioid analgesics in morphine equivalents by year in the U.S.



New Illicit Drug Use in the US: 2006



Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2006



Results from 2006 Natl . Survey on Drug use and Health

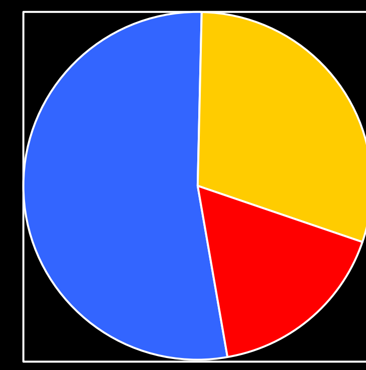
Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.

[1] The Other category includes the sources: "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Cost of Prescription Opioid Abuse in US

Total Cost 2001 = $8.6 Billion   Total Cost 2005 = $9.5 Billion

Workplace 53%;
$ 4.6 billion



Health Care 30%,
$ 2.6 billion

Criminal Justice 17%,
$1.4 billion

Prescription opioid abuse is a significant public health problem

Workplace costs include direct and indirect costs; Healthcare costs include Rx opioid abuse treatment costs and excess medical costs of abusers; Criminal Justice costs include direct costs to the criminal justice system and to victims as a result of Rx opioid abuse.

Birmbaum H, et al. Clin J Pain 2006; 22:667-676.

Physician Obligations

Numerous and occasionally conflicting:

- Treat pain adequately
- Do not cause harm
- Prevent prescription opioid diversion

http://www.painpolicy.wisc.edu

http://www.fsmb.org

http://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm (accessed 7/11/2008)

Conventional Opioid Use

- Potentially analgesic in all types of acute and chronic pain
  - First line treatment for severe acute pain
  - Recommended for moderate to severe pain in cancer, HIV/AIDS, and advanced medical illness
- The role of opioid therapy in persisting pain is in evolution and remains controversial

New Framework

The Framework

- Federation of State Medical Boards (FSMB)

  "Model Policy for the use of Controlled Substances for the Treatment of Pain"

  http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf (accessed 9/16/09)

  Adopted by > 22 state medical boards; CMBE has adopted

1. Evaluate the Patient

- Document
  - H&P
  - Pain hx
  - Comorbidities
  - Indication for opioid (mod/severe pain S,L)

- Risk assessment and management (S,L)
  - Asses risk for **all** patients considered for opioid trial
  - If decide to prescribe
    - Stratify risk of abuse or addiction
    - Structure treatment and monitoring

2. Develop and Document a Treatment Plan

Objectives used to determine success should be noted

- Functional goals
- QOL

Treatment adjusted over time to reflect changes in condition

Overall treatment plan should include additional evaluations and non-opioid therapies if indicated

Multiple Modalities (S,M)

- Pharmacotherapy
  - Non-opioids, adjuvant analgesics, opioid
- Psychological - CBT
- Interventional
  - Injections, neural blockade, implant therapies
- Rehab - PT/OT, modalities
- CAM – acupuncture, chiropractic, movement
- Lifestyle – wt loss, stretching

Potential Members of an Interdisciplinary Team for Chronic Pain Management

Conventional Opioid Use

- A **trial** of opioid therapy may be considered in all causes of moderate to severe pain

- The decision to pursue a therapeutic trial, with potential for long-term therapy, requires case by case assessment
  - Conventional practice
  - Availability of other therapies with their therapeutic index
  - Risk of adverse drug effects
  - Assessment of risk for drug abuse, addiction, diversion

Three Phases of Opioid Treatment Plan

- Initiation
  - Opioid naïve patients
  - Opioid tolerant patients
- Titration
  - Follow WHO guidelines
  - Pseudoaddiction
  - Appropriate frequency of visits
- Maintenance
  - Regular dose escalation is unusual

Here and on the Horizon

- Formulations to prevent ADE’s
- FDA plans to eliminate products with acetaminophen
- Risk Evaluation and Mitigation Strategies (REMs)
  - Certification
  - Patient registries
  - Controlled dispensing

3. Informed Consent and Treatment Agreement

- Discuss and document potential risks and benefits (S, L)
- If patient at high risk of abuse (perform risk stratification) consider written agreement (W,L)
  - Outline patient responsibilities
  - Include drug screening when requested
  - Number and frequency of all prescription refills
  - Reasons for which drug may be discontinued
- KEY message
  - **Partial pain relief and some functional restoration are typical outcomes in chronic pain therapy**

4. Periodic Review

- Continuation or modification of therapy should depend on progression toward treatment objectives (S,L)
  - Functional goals, improved QOL, lessened pain
  - **Verifiability** of objective indicators important
- **Reconsider therapy** if progress unsatisfactory
  - Exit strategy

Monitoring Outcomes – 4 "A"s

- Analgesia – average pain intensity
  - Use standardized tools
- Activities – functional assessment
  - Consider use of standardized tools
- Adverse effects – side effects
- Aberrant behavior – evidence of abuse, misuse, addiction

Pain Rating Scale© Mosby

No Pain 0 1 2 3 4 5 6 7 8 9 10 Worst Possible Pain

None Mild Moderate Severe

0 NO HURT
2 HURTS LITTLE BIT
4 HURTS LITTLE MORE
6 HURTS EVEN MORE
8 HURTS WHOLE LOT
10 HURTS WORST

Passik SD, Weinreb HJ. *Adv Ther.* 2000;17:70-80.

Monitoring Opioid -related Behaviors

Any misbehavior should be followed by: (S,L)

- Reassessment
- Decision about continuing prescribing
- Restructuring therapy if prescribing continues

Discontinuing Opioids (exit strategy)

- Based on ongoing risk assessment (S,L)
  - Comorbid condition making opioid therapy more likely to harm than help
  - No convincing benefit, needs attempt at optimizing therapy
- Other issues in risk:benefit analysis
  - Inability to tolerate opioids at sufficient analgesia
  - Persistent adherence problems despite agreement and limit setting

Discontinuing Opioids (exit strategy)

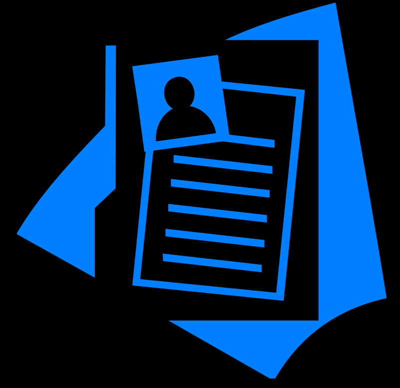
- Prevent acute abstinence and desperation
  - Opioid taper
  - Use clonidine to prevent autonomic sxs
  - Provide emotional support
  - Inpatient "detox"
  - Seek consultation

5. Consultation

Demonstrate willingness to refer
- Pt at risk for misuse, diversion, abuse

Consider consultation (S,L)
- Pt with hx substance abuse
- Co-morbid psychiatric disorder
- Diagnosis
- Progress toward treatment goals stalls

6. Medical Records



- H&P (old records)
- Diagnostic, therapeutic and lab results
- Evaluations and consultations
- Treatment objectives
- Discussion of potential risks/benefits
- Informed consent
- Treatments
- Meds (date, type, dose, quantity)
- Instructions and agreements
- Periodic reviews

7. Follow State and Federal Law/Regulations (S,L)

Nearly ½ of states have adopted the FSMB

Colorado has now adopted it

Colorado State BME current policy re use of controlled substances in treatment plan

- http://www.dora.state.co.us/medical/policies/10-14.pdf (accessed 7/28/08)

New Tools

Clinician Pain/Opioid Education

- AMA Pain Management – the online series
  - http://www.amacmeonline.com/pain_mgmt/

- ABFM Maintenance of Certification Process has a Self Assessment Module (SAM) in Pain Management
  - https://www.theabfm.org/MOC/part2.aspx

Initial and Follow-up Documentation Tools

- National Pain Education Council
  - http://www.npecweb.org/clinicaltoolbox.asp?id=26&selMenu=15,0 (accessed 7/29/08)

Opioid Risk Assessment/Stratification

- Several clinical tools are available that estimate risk of noncompliant opioid use (1-3)
- Results determine how closely a patient should be monitored during opioid therapy (3)

- **Scores implying a high risk of abuse are not reasons to deny pain relief** *(3)*

1. Webster LR, Webster RM. *Pain Med.* 2005;6:432-42.
2. Coambs RB, et al. *Pain Res Manage.* 1996;1:155-62.
3. Butler SF, et al. *Pain.* 2004;112:65-75.

Opioid Risk Tool –aberrant behavior

Risk Factor	W	M
Family hx substance abuse		
ETOH	1	3
Illegal drugs	2	3
Prescription drugs	4	4
Personal hx substance abuse		
ETOH	3	3
Illegal drugs	4	4
Prescription drugs	5	5
Age (> 14, < 45)	1	1
Hx preadolescent sexual abuse	3	0
Psychological dz		
ADD, OCD, Bipolar, Schiz	2	2
Depression, Anxiety	1	1

- Administration
  - Initial visit
  - Prior to opioid tx
- Scoring
  - 0-3 Low (6%)
  - 4-7 Medium (28%)
  - > 7 High (>90%)

Webster LR, Webster RM. *Pain Med.* 2005;6:432-42.

Urine Drug Screening

- Guides
  - http://www.familydocs.org/files/UDTmonograph.pdf (accessed 7/29/08)
  - Heit H. Jr Pain and Symptom Management. 2004.;27(3):260-267
  - Moeller, K. et al. Mayo Clin Proc. 2008; 83(1):66-76
- Clinical vs. Other Use
- Immunoassay vs. Gas Chromatography techniques

Medication Use Agreement

- American Academy of Pain Management
  - http://www.partnersagainstpain.com/printouts/A7012CT6.pdf (accessed 7/29/08)

Colorado State Prescription Drug Monitoring Program

http://www.dora.state.co.us/pharmacy/pdmp/index.htm (accessed 7/29/08)

Patient Education

- Emerging solutions in pain

http://www.emergingsolutionsinpain.com/ (accessed 9/1/09)

- Web MD

http://www.webmd.com/pain-management/guide/narcotic-pain-medications (accessed 7/29/08)

http://www.webmd.com/pain-management/guide/default.htm (accessed 7/29/08)

Treatment Guidelines

Clinical Guidelines for the use of Chronic Opioid Therapy in Chronic Non-cancer Pain,

For the American Pain Society/American Academy of Pain Medicine Opioids Guidelines Panel. Chou R, et al. 2009. J Pain 10(2):113-130.

Helpful Website

Emerging Solutions in Pain:

http://www.emergingsolutionsinpain.com/

(accessed 9/1/09)

Provider education

Tools for practice

Patient education materials

Conclusions

- Opioids are an irreplaceable but potentially problematic drug class for treatment of chronic pain conditions
- Long-term opioid therapy can be safe and effective for chronic non-cancer pain in appropriately selected and managed patients
  - Consider when warranted by severity and adverse impact of pain

Conclusions

- Safe and effective therapy requires clinician skills in assessment, opioid pharmacotherapy, and risk management
- Clinicians can acquire these skills and determine which patients to treat and how to optimize benefit while minimizing risk
- Many clinical tools exist to assist the clinician and practice to manage patients requiring opioid therapy
- When in doubt, seek consultation (2nd opinion or co-management)

Areas of Ethical Tension

- Prescriber's roles –
  - Personal clinician
  - Societal monitor – addiction, diversion
- Prescriber's education
- Multiple potential uses of opioid
  - Pain, recreation, addiction
  - Not uncommonly all in the same individual
- Emotionally Charged
- Common issue with little data re effectiveness of clinical management