OPIATE THERAPY AND TREATMENT OF CHRONIC NON-CANCER PAIN

A Clinical Perspective

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DISCLOSURES

- Individual stock in the following companies
  - J&J-Makers of fentanyl patch and tapentadol
    - .00000189% owner
  - Intuitive Surgical-Makers of robotic surgical equipment
    - .0000193% owner

OBJECTIVES

- Review evidence and guidelines surrounding opiate treatment of CNCP
- Share resources to help improve clinical outcomes and adherence to these guidelines
- Tips and tricks for transitioning/tapering opioids
- Review methods to avoid low-value prescribing

QUESTION #1

- Which of the following is true regarding prescription opiates?
  - A) Per capita sales of opiates in the US increased more than 3-fold between 1999-2009
  - B) There were 80% more deaths from opiate overdoses in Colorado in 2013 than there were drunk driving fatalities
  - C) Case series performed in the 1980s suggested that opiates could be prescribed for years for pain with little fear of addiction
  - D) All of the above

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PORTENOY'S COMPLAINT

- 1986 retrospective case series
- 38 cases non-malignant pain
  - All had failed more conservative measures for many years
  - About half received disability payments
  - 19/38 received opioids for > 4 years
  - 0 adverse events reported
  - 29% adequate pain relief
  - 34% partial pain relief
  - 37% continued to have severe pain intermittently
  - Only 2/38 posed "management problems"

- "Suggests that opioid maintenance therapy initiated for the treatment of chronic non-malignant pain can be safely and often effectively continued for long periods of time."
  - "Few" patients had dramatic improvement in functional status or psych status
  - 100% feared worsening pain if opioids withdrawn
  - Only 4/38 took more than 40 mg maintenance morphine/day

Portenoy, 1986

MY STORY

Why I’m interested in the management of CNCP

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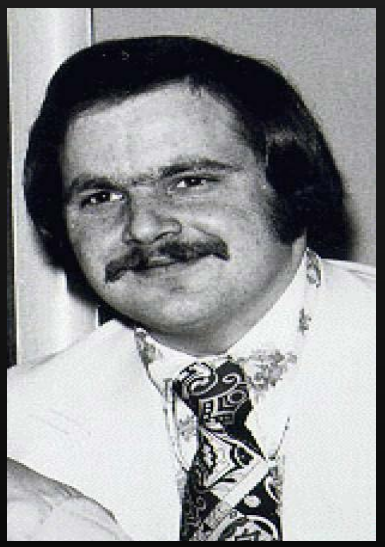
TODAY

- More than 12 million Americans reported abuse of prescription opiates in 2010
- 16,650 Americans died from prescription drug abuse in 2010

"Opium gives and takes away."

--Dequincy 1901, Confessions of an English Opium Eater



http://www.cdc.gov/homeandrecreationalsafety/rxbrief/

. Accessed online January 11, 2015

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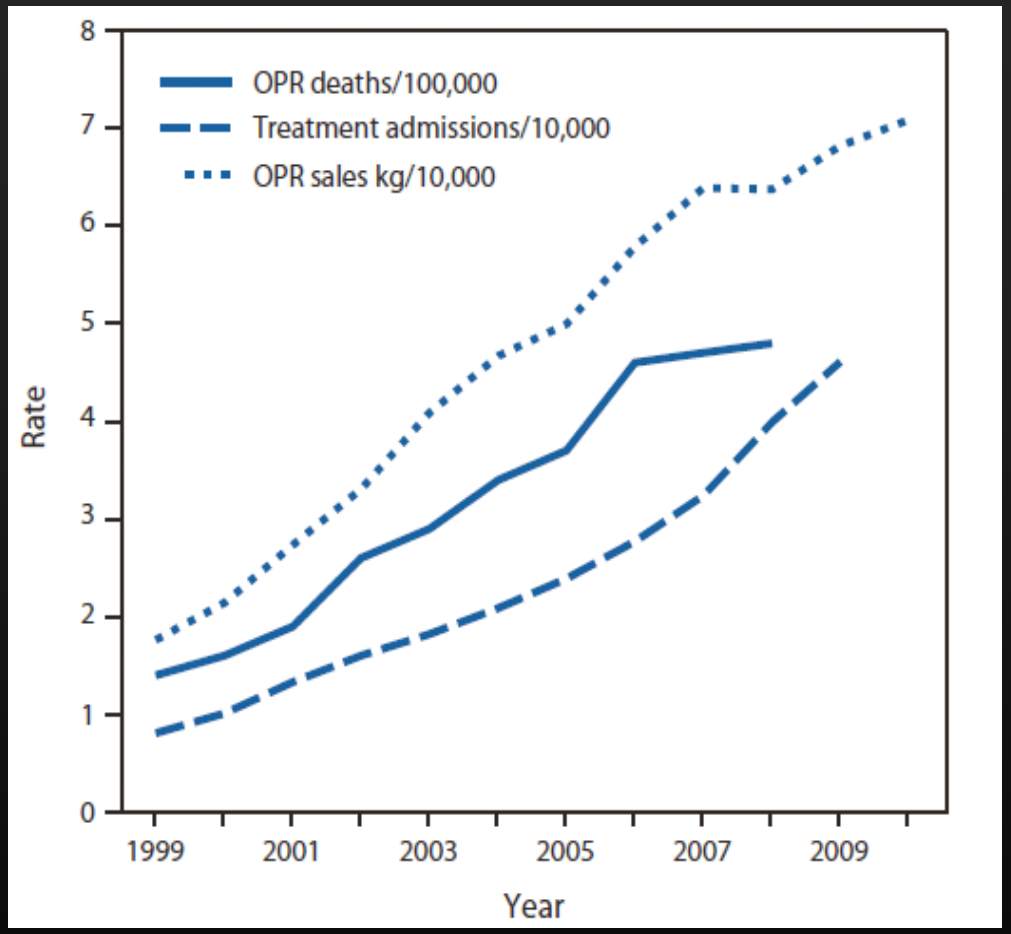
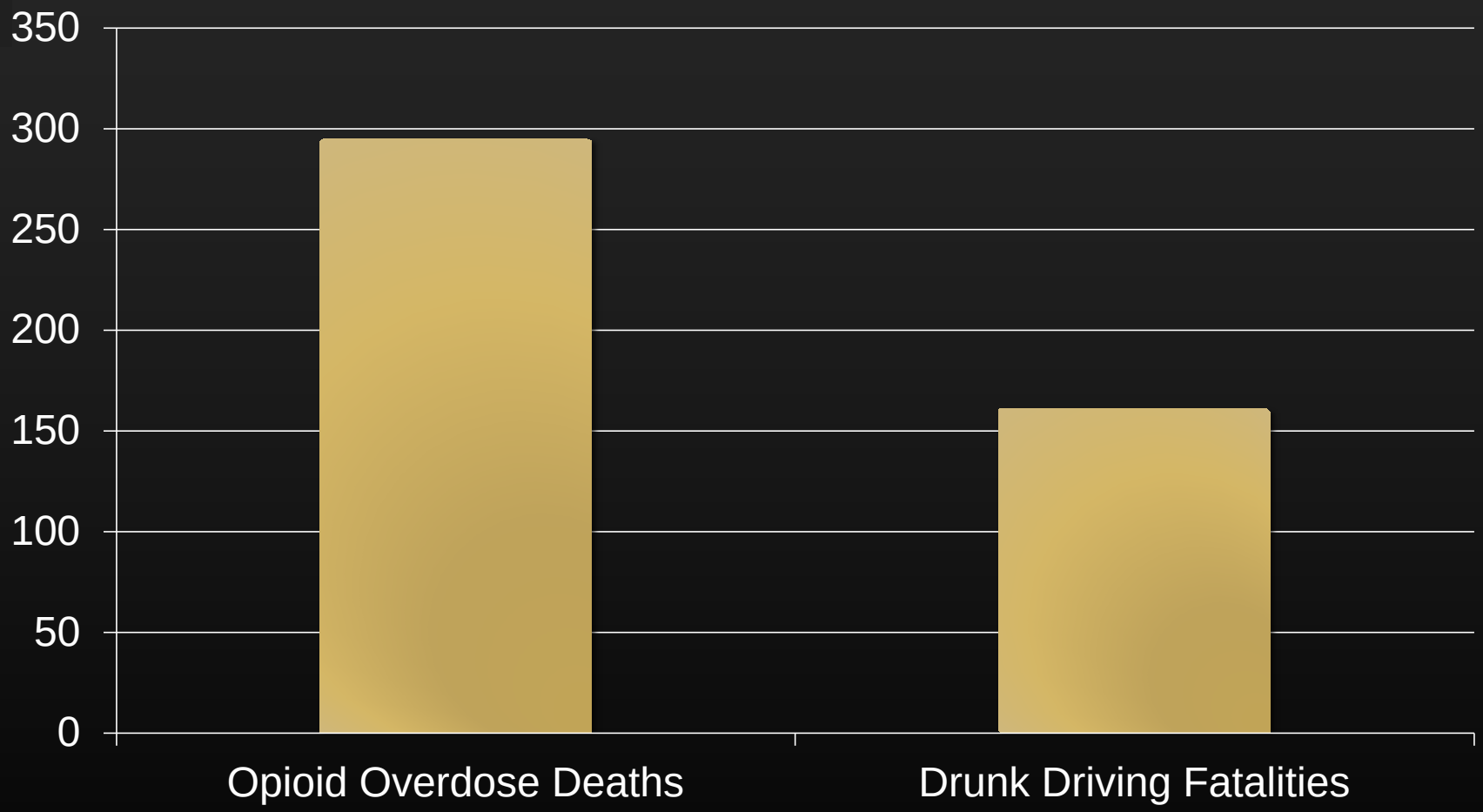
RATES OF OPIOID PAIN RELIEVER (OPR) OVERDOSE DEATH, OPR TREATMENT ADMISSIONS, AND KILOGRAMS OF OPR SOLD --- UNITED STATES, 1999—2010 (1)



MMWR. November 1, 2011. Vital Signs: Overdoses of Prescription Opioid Pain Relievers -- United States, 1999—2008. Accessed online November 3, 2011

2013 COLORADO DEATHS



http://peerassistanceservices.org/programs/prescription-drug-abuse-prevention/

(Retrieved Dec 3rd, 2014)

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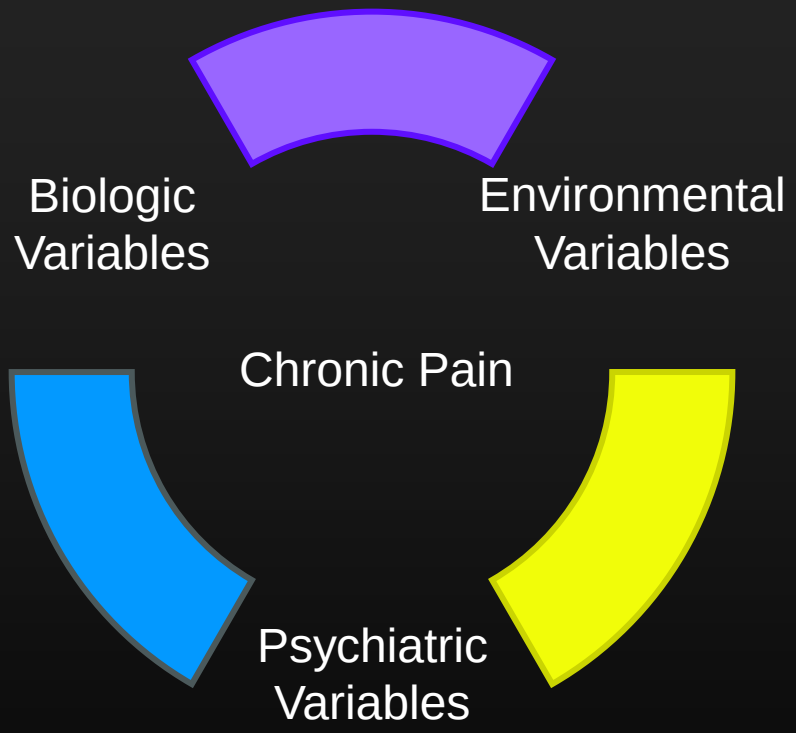
CLINICAL PEARLS

- Use of opiates has increased dramatically
- There is increasing evidence that opiates can be harmful
- Prescription of opiates for long term CNCP should be done cautiously

CHRONIC NON-CANCER PAIN

- State of pain which persists beyond the usual course of an acute disease or healing process
- A condition often with poor correlation between pain complaints and results of physical findings or diagnostic tests
- Complex condition with myriad of causes and perpetuating factors often including psychiatric co-morbidity



Expert Guide to Pain Mgmt, (McCarberg, Passik)

IDEAL GOALS OF TREATMENT

- Decrease pain
- Improve function
- Decrease reliance on health care system
- Increase physical activity
- Enhance relationships and psychological integrity
- Return to work

HOW DOES NON-CANCER PAIN DIFFER FROM TERMINAL CANCER PAIN?

- Treatment horizon much longer
- Treatment goals should differ (function vs. comfort)

Matthew Hollon ACP Meeting
April 8, 2006

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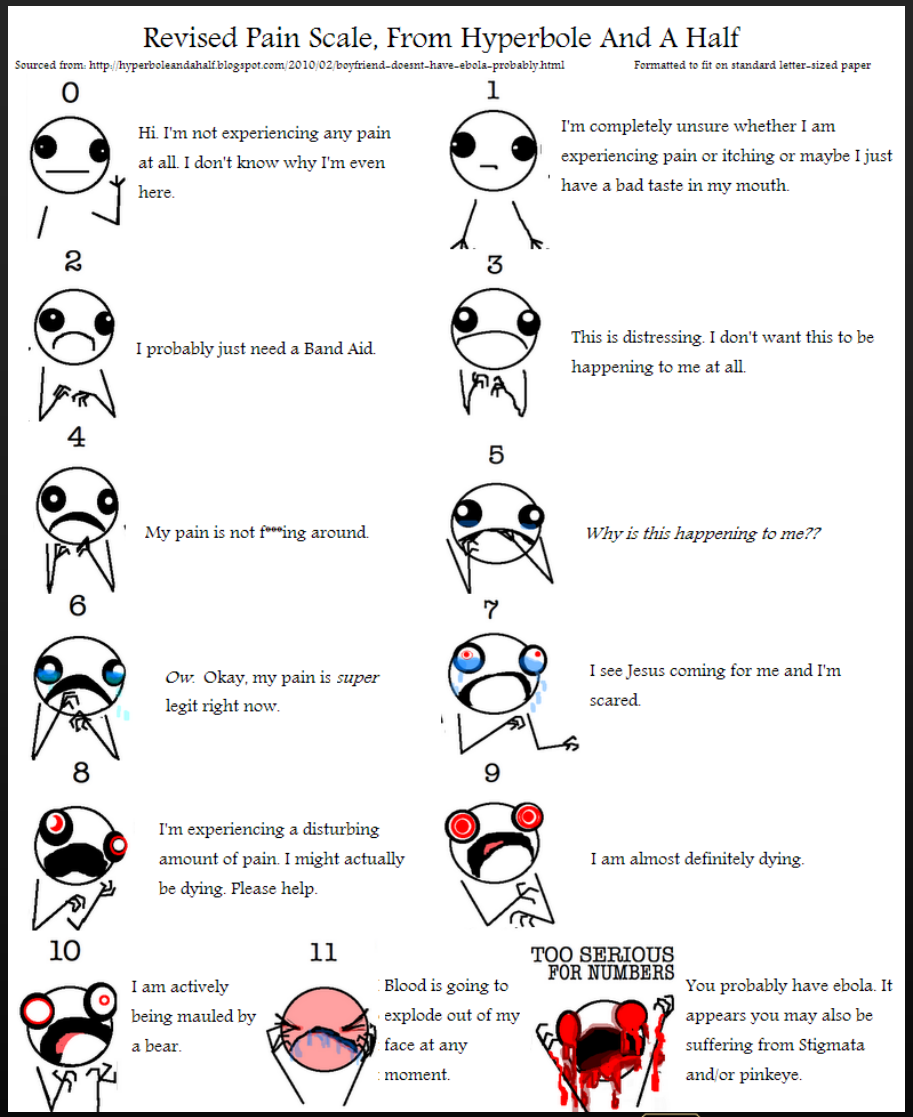
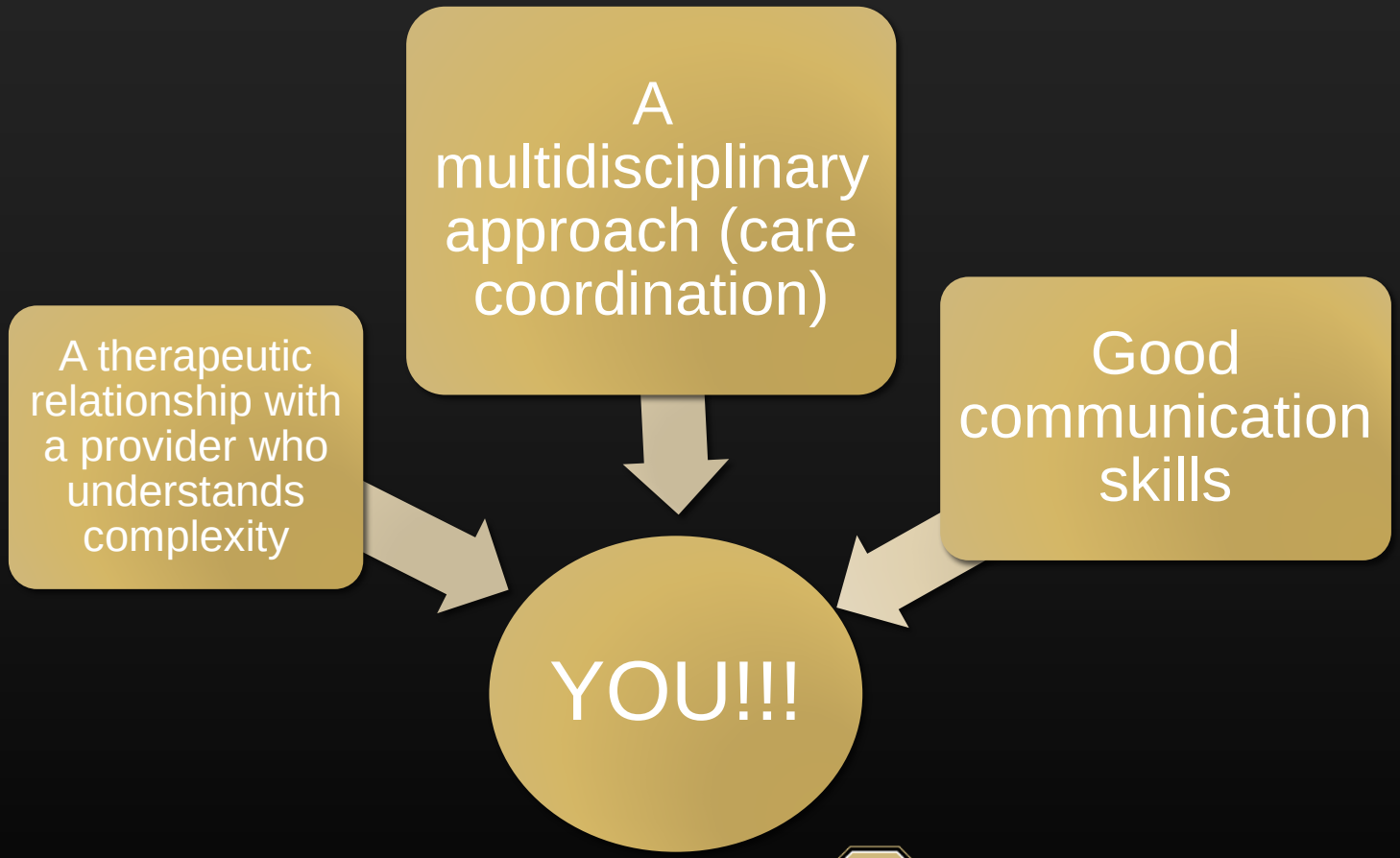
REVISED PAIN SCALE???



http://hyperboleandahalf.blogspot.com/2010/02/boyfriend-doesnt-have-ebola-probably.html

PCPS SHOULD TAKE THE LEAD MANAGING THIS CONDITION: WHY?



SUMMARY OF RCTS

- 14 RCTs, 1201 patients, approx 85/study
- Short follow-up
  - Most less than 14 weeks
- Most compared opiate vs. placebo
- Substance abusers generally excluded
- Usually well defined pain causes (OA, RA)
- 13/14 showed benefit vs. placebo for pain (Analgesia)
- 7/13 showed no benefit for function (ADLs)

Ballantyne, NEJM 2003

QUESTION #2

- Evidence-based guidelines have suggested using which morphine equivalent dose as an upper dosing threshold to minimize risk of overdose?
  - A) 30 mg
  - B) 60 mg
  - C) 100 mg
  - D) No evidence-based upper dosing threshold exists

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GUIDELINE RECOMMENDATIONS

- Annals Jan 7, 2014
  - Evaluated quality and content of guidelines for opioids for CNCP
  - Found 13 guidelines met selection criteria
  - Most recommendations based on observational data/expert consensus

Annals of Internal Med. Jan 7, 2014

RISK MITIGATION CONSENSUS

- Upper dosing thresholds (90-200 mg MED)
- Caution with certain medications (methadone)
- Use risk assessment tools
- Use treatment agreements
- Use urine drug testing
- Be especially careful of opioids with other sedative drugs (benzos)

Annals of Internal Med. Jan 7, 2014

WHY THRESHOLD DOSING?

- Cohort study of 10,000 patients
  - Followed for 42 months
- Risk of overdose and death increased with higher doses of opiates

Opiate Dose	Annual OD Risk	RR
1-20 mg	0.2%	1
50-99 mg	0.7%	3.7
>100 mg	1.8%	8.9

Annals of Internal Medicine, 2010 vol. 152 (2) pp. 85-92
Slide reprinted with permission from Josh Blum MD

THERAPY > 120 MG MED

- Associated with increased risk of:
  - Fracture
  - Death
  - Overdose
  - Dependence

J Gen Intern Med, 2011 vol. 26 (12) pp. 1450-1457

CLINICAL PEARL

- Based on recent data, it is reasonable to use a daily dose of 100 mg morphine equivalents/day as a threshold dose for CNCP treatment in the primary care setting

OPIOID TREATMENT GUIDELINES

- 25 recommendations
  - 21 supported by weak evidence
  - 4 supported by moderate evidence
- Unanimous consensus on “almost all” recommendations
- All recs we discuss are “strong”

The Journal of Pain, Vol 10, No 2 (Feb), 2009: pp 113-130

REC 1: PATIENT SELECTION AND RISK STRATIFICATION

- **“Before initiating opioids, clinicians should conduct a history… including an assessment of risk of substance abuse, misuse or addiction.”**
- SOAPP, ORT, DIRE
  - All published opiate risk screening tools that can be used in office

QUESTION #3

- According to validated opiate risk screening tools which of the following is a risk factor for predicting aberrant seeking behaviors in opioid treated patients?
  - A) Past history of smoking
  - B) History of prior victim of sexual abuse if male
  - C) 30-years of age
  - D) Current use of sleeping agent

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ORT-A Practical Tool

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
	TOTAL		_____	_____

Total Score Risk Category
Low Risk 0 – 3
Moderate Risk 4 – 7
High Risk ≥ 8

Reprinted by Permission: Lynn Webster, MD

Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk tool. Pain Med. 2005;6(6):432

CLINICAL PEARL

- If you are considering chronic opiate therapy for a patient there are several validated tools to assess potential risk of this therapy.
- The ORT is a 5 item tool that can be performed easily in the primary care setting

REC 2: HIGH-RISK PATIENTS

- **Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues or serious aberrant drug-related behaviors only if they are able to implement more frequent and stringent monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist.**

WHERE TO FIND HELP FOR PATIENTS

http://www.samhsa.gov/treatment/index.aspx

Substance Abuse Programs

Mental Health Programs

Buprenorphine providers

REC 3: INFORMED CONSENT AND OPIOID MANAGEMENT PLANS

- **When starting chronic opioid therapy (COT), informed consent should be obtained. A continuing discussion… should include goals, expectations, potential risks and alternatives to COT**
  - Complete relief of pain is not realistic
  - S.M.A.R.T goals should be documented

SMART GOALS

- Specific
- Measurable
- Attainable
- Realistic
- Timely

- Examples of SMART goals
  - Decrease pain so that I can get out of the house to visit the grandkids once a week
  - Decrease pain so that I can walk for 5 minutes most days during the week

QUESTION #4

- The 2009 American Pain Society Guidelines recommend opiate prescribers routinely assess which of the following at follow-up visits
  - A) Whether or not the patient is diverting opiates
  - B) Use of illicits with a urine toxicology screen
  - C) Depression score using PHQ-9
  - D) Progress towards achieving functional goals

QUESTION #4

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REC 4: MONITORING

- **Monitoring should include documentation of pain intensity, level of functioning, assessments of progress toward achieving goals, presence of adverse events and adherence to therapy**

CLINICAL PEARL: THE 4AS

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Pain Assessment Documentation Tool

Progress Note
Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Progress Note
Pain Assessment and Documentation Tool (PADT™)

QUESTION #5

- Which of the following is an indication for tapering opiate therapy?
  - A) Clear evidence of drug diversion
  - B) Failure to achieve any functional goals despite gradual uptitration of morphine to 60 mg PO bid
  - C) Presence of marijuana on a urine toxicology screen
  - D) All of the above

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CLINICAL PEARL: INDICATIONS FOR DISCONTINUATION OF THERAPY

- **Clinicians should wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse, experience no progress toward meeting goals or experience intolerable adverse effects**

HOW TO WEAN

- Weaning by 10% week should be tolerable
  - Can reduce wean to 5%/week when down to 1/3 of initial dose
- Clonidine can be used to help with withdrawal
  - 0.1 mg po qid for 2 days
  - 0.2 mg patch q 7 days
  - Repeat if symptoms persist
- Doxepin for sleep
  - 5-10 mg qhs

A TAPERING SPREADSHEET

- http://www.hca.wa.gov/medicaid/pharmacy/pages/toolkit.aspx

REC 6: USE OF PSYCHOTHERAPEUTIC COINTERVENTIONS

- **As CNCP is often a complex biopsychosocial condition, clinicians who prescribe COT should routinely integrate psychotherapeutic interventions, functional restoration, interdisciplinary therapy and other adjunctive nonopioid therapies (mod quality)**

PSYCHOTHERAPEUTIC OPTIONS

- Nonopiate medications
- Integrative Medicine
- PT
- SAMHSA website for counseling
- John Otis: Managing Chronic Pain: A CBT Approach
- This should be easier for us and our patients

MY SOAPBOX

Practical advice

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FINAL PRACTICAL SUGGESTIONS
1. THE INITIAL FEW VISITS ARE KEY

- -Take your time
- -Try to validate patient
- -Assess function
- -Review records
- -Review pain intensity
  - -Chronic pain is never an emergency
  - -You have no obligation to prescribe medication at the first visit

OTHER PRACTICAL SUGGESTIONS
2. IT IS OK TO SAY "NO"

-Offer alternative treatment for poor candidates

-Your job is to do no harm and do what you feel is best, not do only what the patient wants

-Listen to your inner voice.

-Frame decision to stop/taper as risk:benefit analysis

3: REQUIRE PATIENTS TO TAKE SOME OWNERSHIP OF ILLNESS

- At the very least patients on opiates need to:
  - Make the vast majority of clinic appointments
  - Define and agree to appropriate goals of care including function
  - Participate in some non-pharmacologic therapy for their pain
  - Agree to random urine tox screens

4: ADDICTION IS A CHRONIC DISEASE

- Stopping opiates is not addiction treatment
- Always offer substance abuse treatment for those patients who have a substance abuse problem

5. WEB-BASED AND LIBRARY RESOURCES ARE AVAILABLE TO HELP CLINICIANS AND PATIENTS

Provider Training
https://www.scopeofpain.com/

- Patient Resources

http://www.fmaware.org/

http://www.med.umich.edu/painresearch/

Caudill-Slosberg MA. *Managing Pain Before It Manages You.*

Thorn BE. *Cognitive Therapy for Chronic Pain: A Step-by-Step Guide*

CONCLUSIONS

- As PCPs, we should take the lead managing these patients
- Guidelines and consensus statements are available and should guide our care
- Documentation is key and should include pain history, psychosocial history, functional goals, risk assessment initially and 4As upon follow-up
- A multidisciplinary approach should be utilized when treating this illness

CONCLUSIONS (CONT)

- Patients on opiates with numerous red flags who fail to meet functional goals should not continue to receive opiates indefinitely
- Underlying psychiatric illness should be identified and treated
- Pain management requires art as well as knowledge and from time to time, we are likely to make the wrong decisions

Portenoy, 1996

QUESTIONS

2013 FSMB CONTROLLED SUBSTANCE MODEL POLICY STATEMENT

- "Since 2004… evidence for risk associated with opiates has surged, while evidence for benefits has remained controversial and insufficient."
- Will consider inappropriate management of pain, particularly chronic pain, to be a departure from best clinical practices including:
  - Inattention to initial assessment
  - Inadequate monitoring during use of medication
  - Inadequate attention to education and informed consent
  - Unjustified dose escalation w/o attention to risks/other options
  - Excessive reliance on opioids particularly in high doses
  - Not making use of available tools for risk mitigation (CPDMP)

FMSB CONTROLLED SUBSTANCE POLICY (CONT)

- "Criteria when evaluating the physician's treatment of pain"
  - Medical records should contain
    - Medical history and physical exam
    - Diagnostic test results
    - Evaluations and consultations
    - Steps taken in response to aberrant behavior
    - Results of risk assessment including screening instruments if used
    - Informed Consent and Treatment Agreement copies
    - Treatments
    - Medications
    - Patient instructions
    - Results of ongoing monitoring of progress on pain and function

A SAMPLE PATIENT

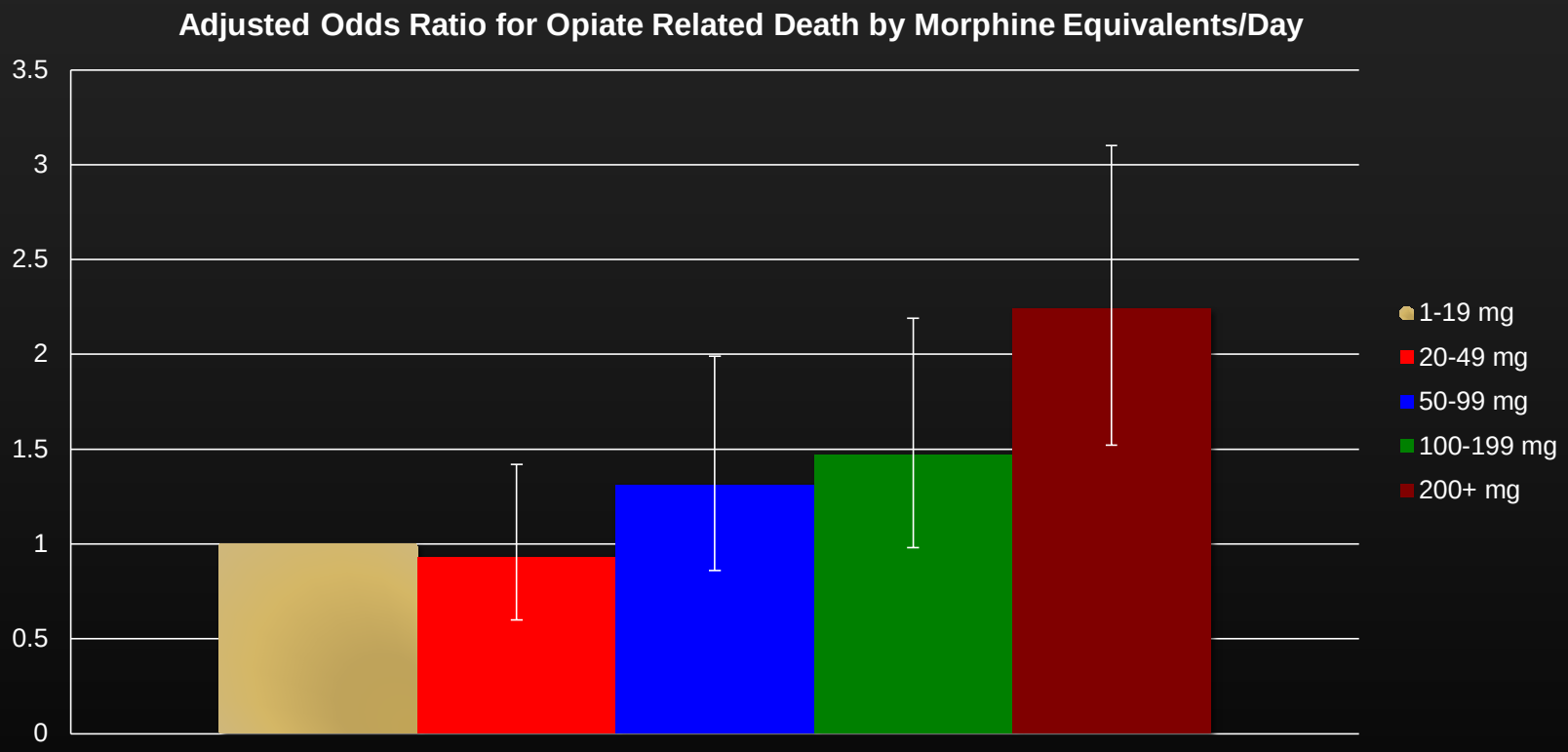
- Between 1996-2011, a middle aged female with a history IBD and polysubstance abuse presented to our resident clinic over 90 times with varied pain complaints
- There was ample evidence that her pain was not from IBD
- More than 26 residents and 29 attending physicians saw her
- Her pain was managed with escalating doses of opiates

EVIDENCE OF TREATMENT PROBLEMS

Documentation of aberrant seeking behaviors and major side effects

- 26 calls for early renewals between visits
- 4 reports of opiate theft leading to early refill requests
- 7 reports of falls as an outpatient during clinic visits

OPIOID DOSE AND DRUG RELATED MORTALITY IN PATIENTS WITH CHRONIC NON-MALIGNANT PAIN



Arch Intern Med,
2011 Vol 171 (7), pp.
686-691

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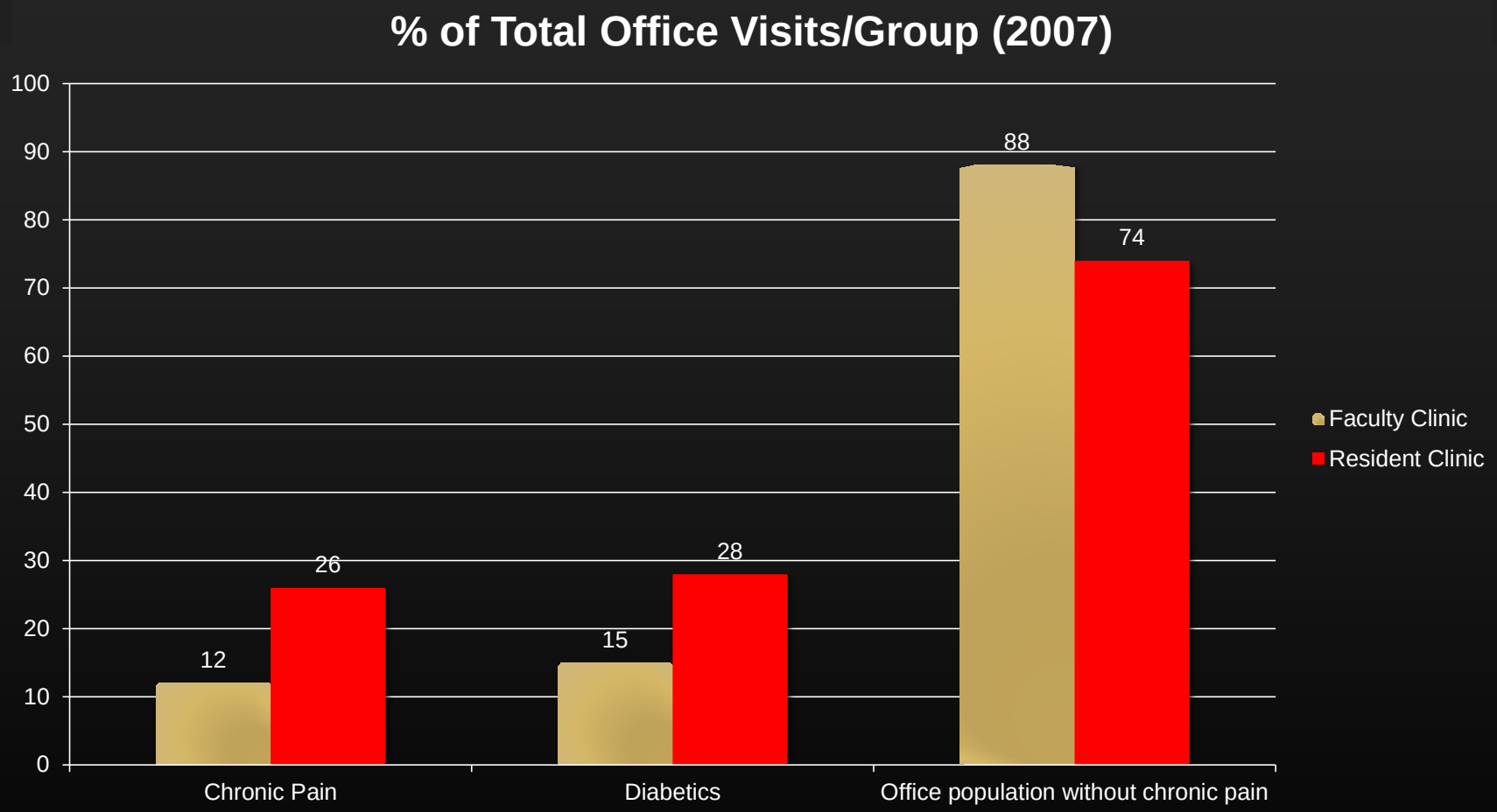
PATIENTS ON CHRONIC OPIATES COMPRISE A DISPROPORTIONATE SHARE OF OFFICE VISITS



Chronic Pain=3 or more scheduled opiate rxs during 12 month period

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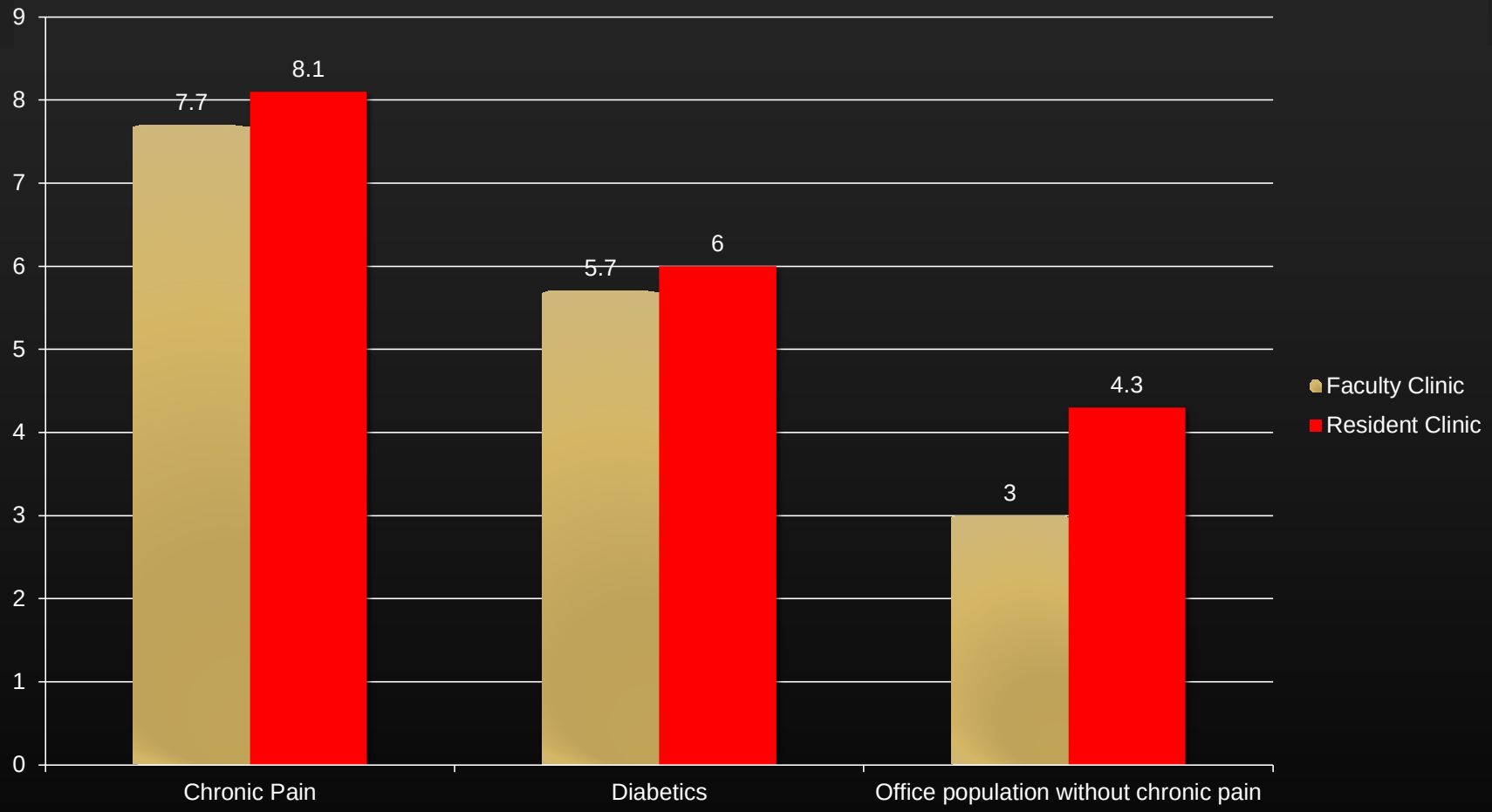
MEAN # OF OFFICE VISITS/PATIENT 2007



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A DAY AT THE OFFICE

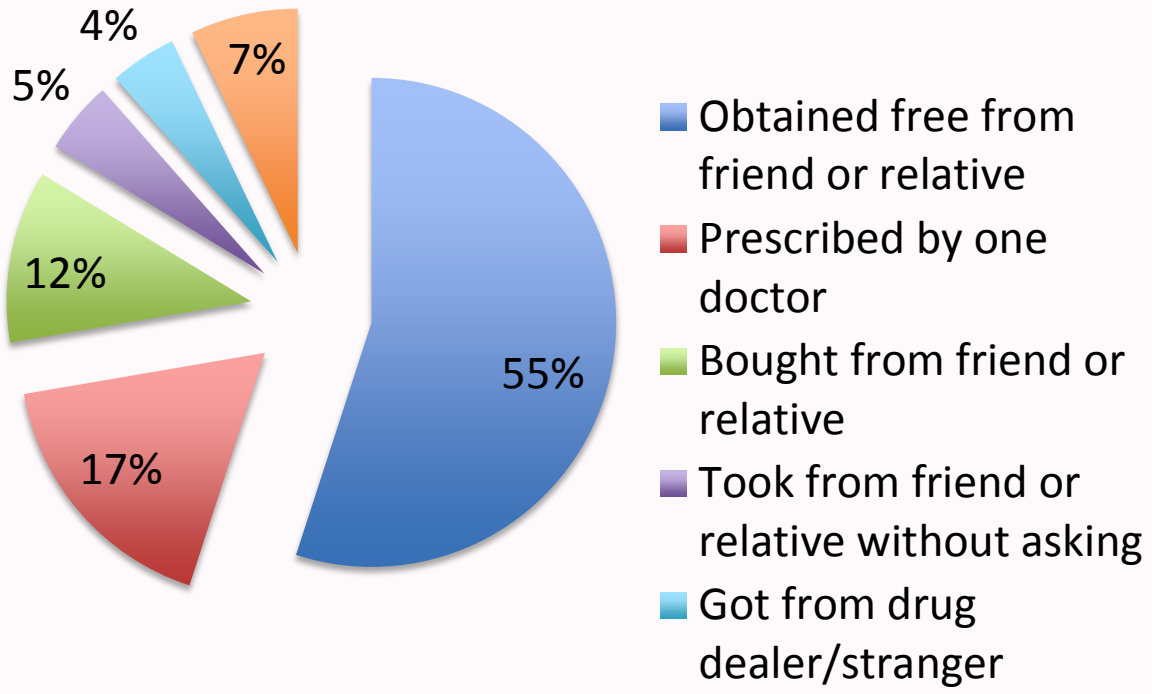
- http://www.youtube.com/watch?v=b6jKkFJkLrI

WHERE ARE THE HEROIN USERS COMING FROM?

- Heroin use rates among frequent non-medical opioid users increased from 62 to 95 per 1,000
- 75% of heroin users surveyed who initiated use after 2000 began with prescription opioids

Jones CM. *Drug Alcohol Depend* 2013
Cicero TJ et al. *JAMA Psychiatry* 2014

SOURCES OF DIVERTED OPIOIDS



PRESCRIBED OPIOIDS AND OVERDOSE RISK

- Overdose risk increased in patients with:
  - Substance abuse
  - Depression
  - ***Concomitant sedative-hypnotic use***
- Risk for events greatest after initiation of therapy or refill

OPIOIDS AND BENZODIAZEPINES

- BZDs rarely cause OD by themselves
- Frequently used together with opioids
- Benzodiazepines used for sleep, anxiety, muscle relaxation/pain
- Increased reward and reinforcing effects of opioids
- Patients seeking treatment for BZD abuse nearly tripled 1998-2008
- Effects on respiration are synergistic rather than additive
- Alprazolam #1 drug implicated in review of all overdose deaths in Georgia
- Avoid co-prescribing with opioids

Jones JD, Mogali S, Comer SD. *Drug Alcohol Dependence* 2012;125:8-18
Atlanta Journal-Constitution, August 14, 2012