Improving Safety in Opioid Prescribing: A Framework for Chronic Pain in Outpatient Practice

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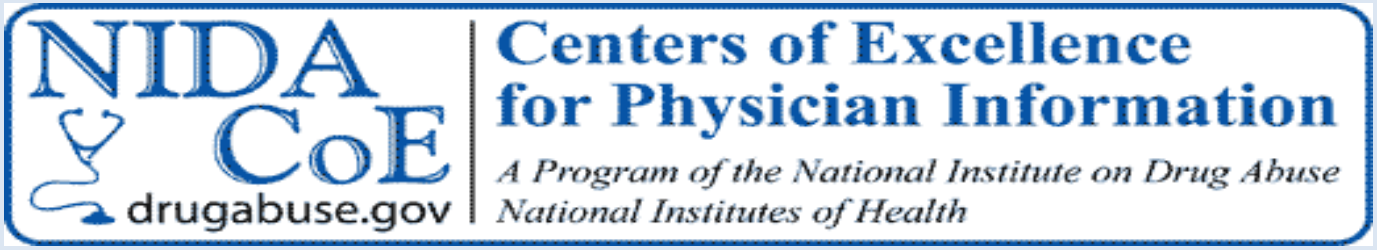
I have no actual or potential conflicts of interest in relation to this program/presentation

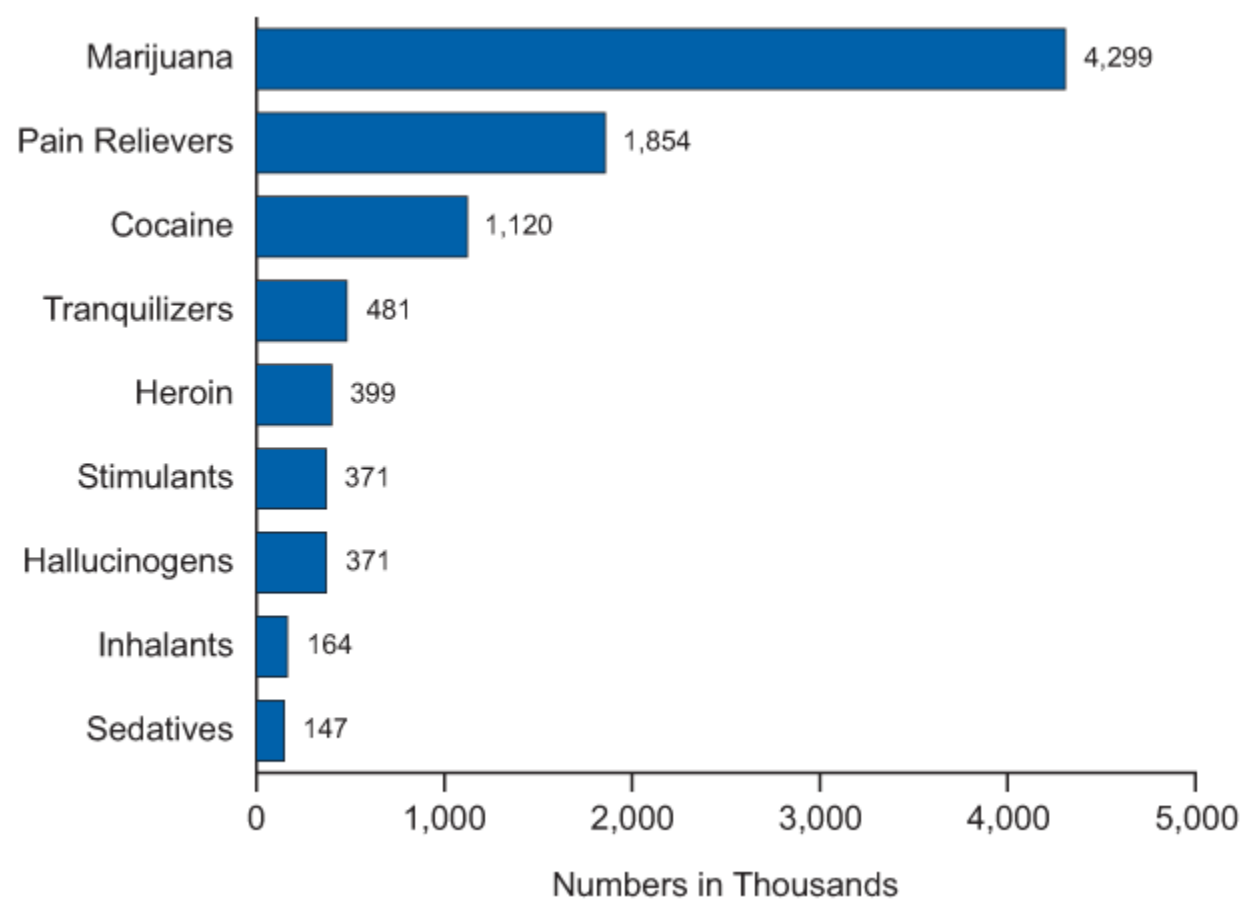


Objectives

- Discuss recent trends in the misuse of prescription opioids
- Describe screening procedures recommended prior to initiating opioids
- Describe The 4-A's structure of monitoring patients on chronic opioid therapy
- Discuss the differential diagnosis and management of aberrant drug-taking behaviors
- Describe the two techniques for urine drug testing
- Discuss procedures for minimizing diversion, including registries, drug monitoring programs, call backs and pill counts.

Fig 7.2

Dependence on/Abuse of Illicit Drugs in the Past Year among Persons Aged 12 or Older: 2009



Initiation of Drug Abuse: NSDUH 2009

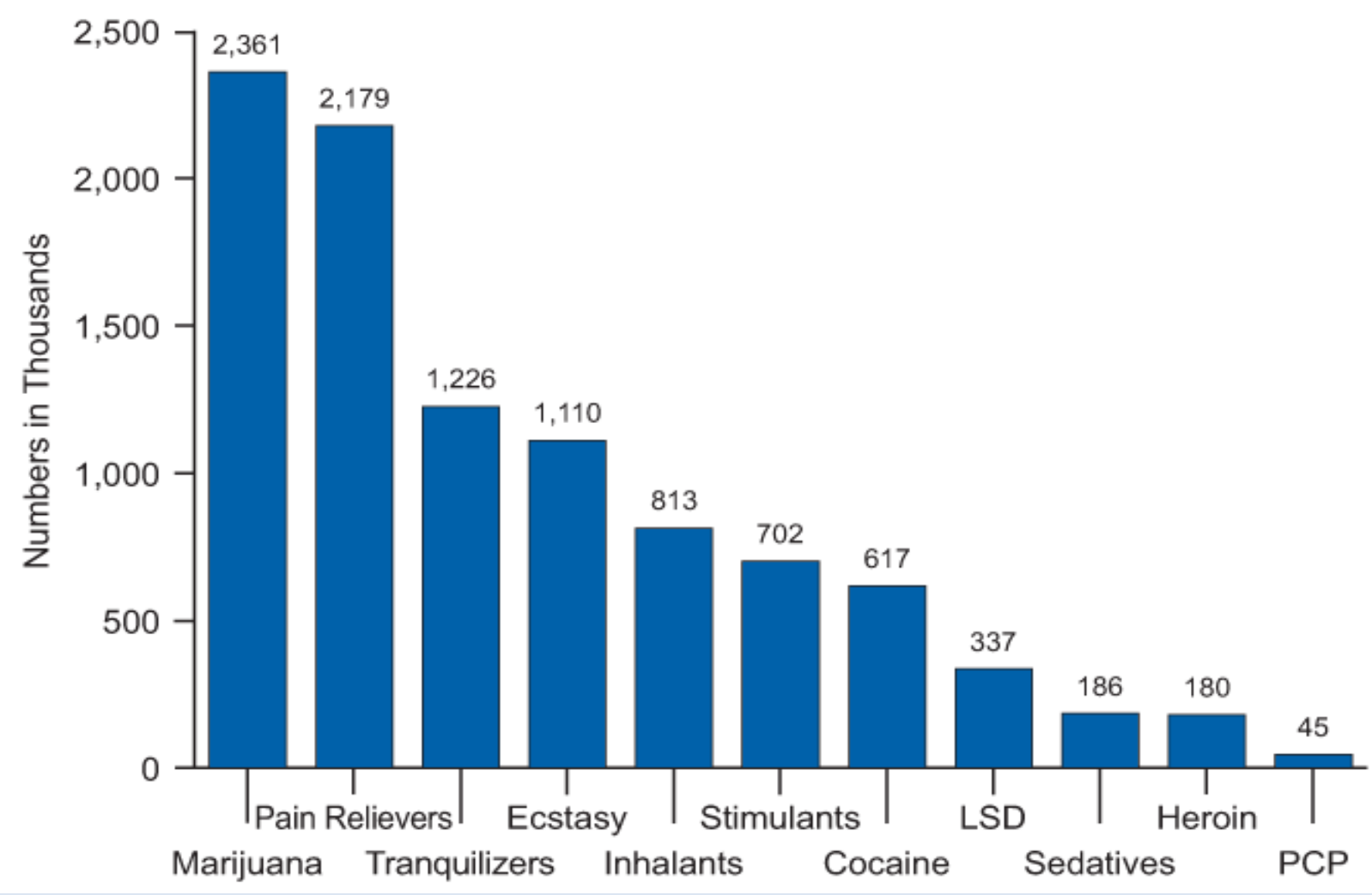
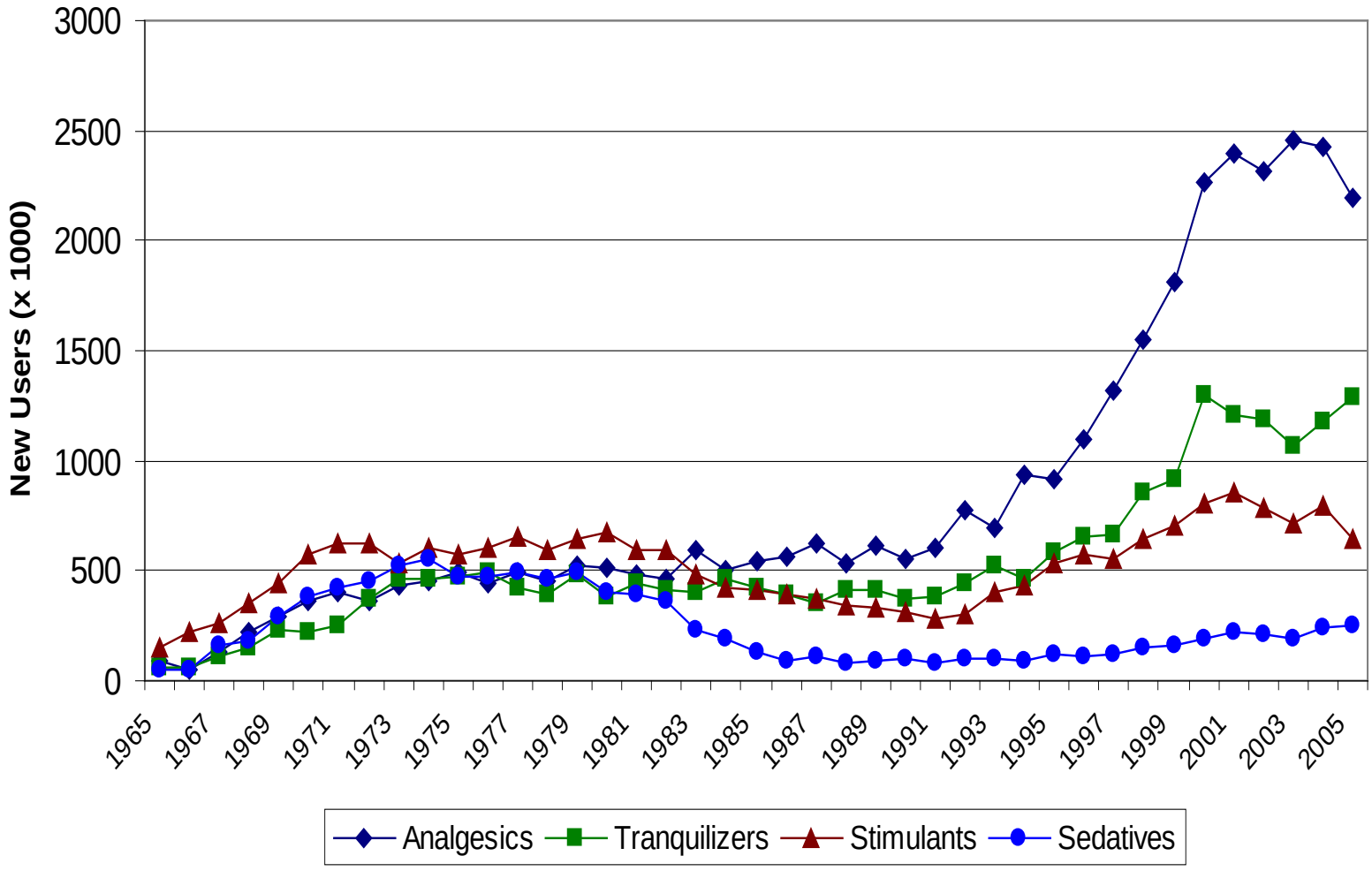
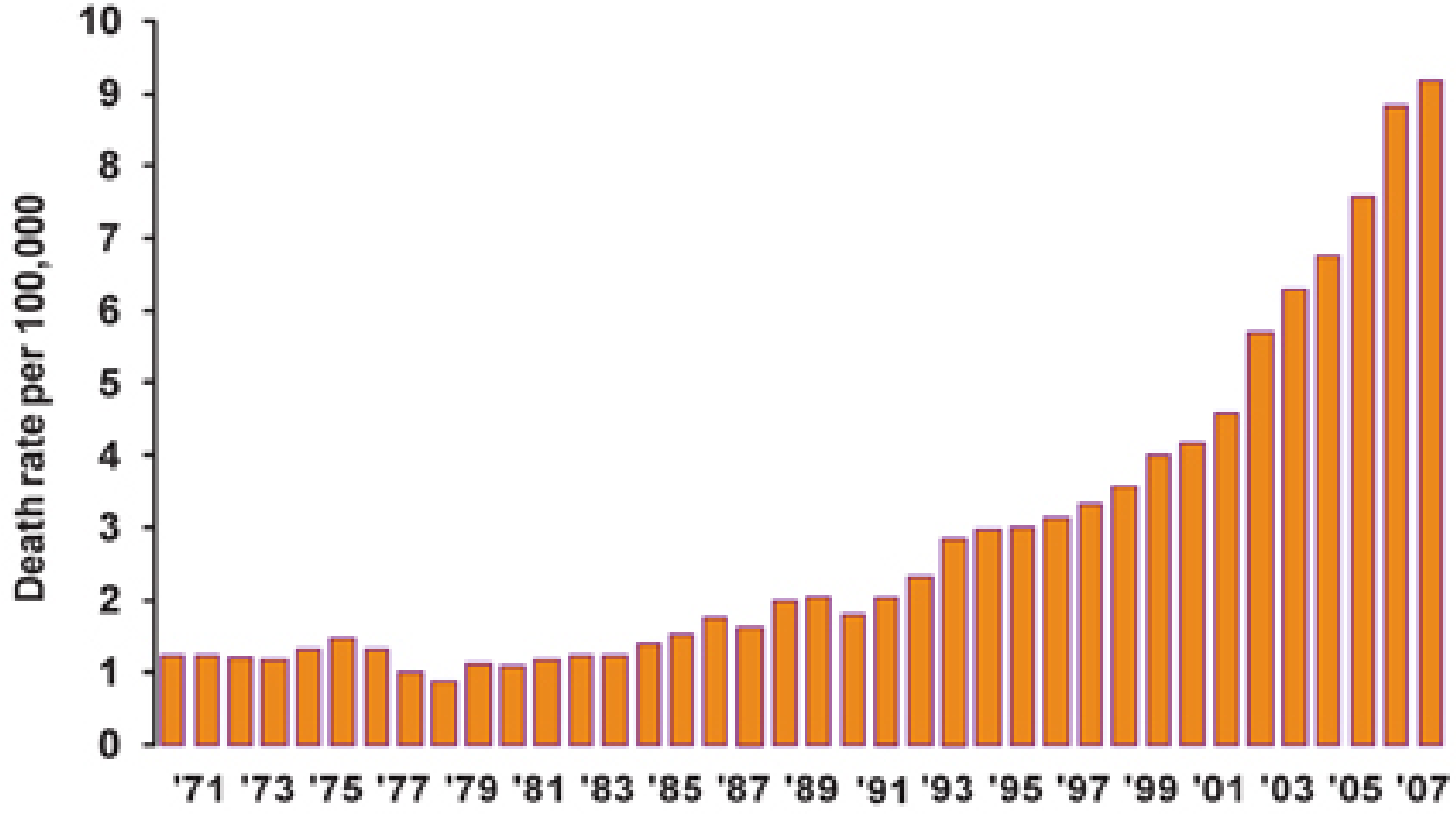


Exhibit 2: Past Year Initiation of Non-Medical Use of Prescription-type Psychopharmaceutics, Age 12 or Older: In Thousands, 1965 to 2005[1]



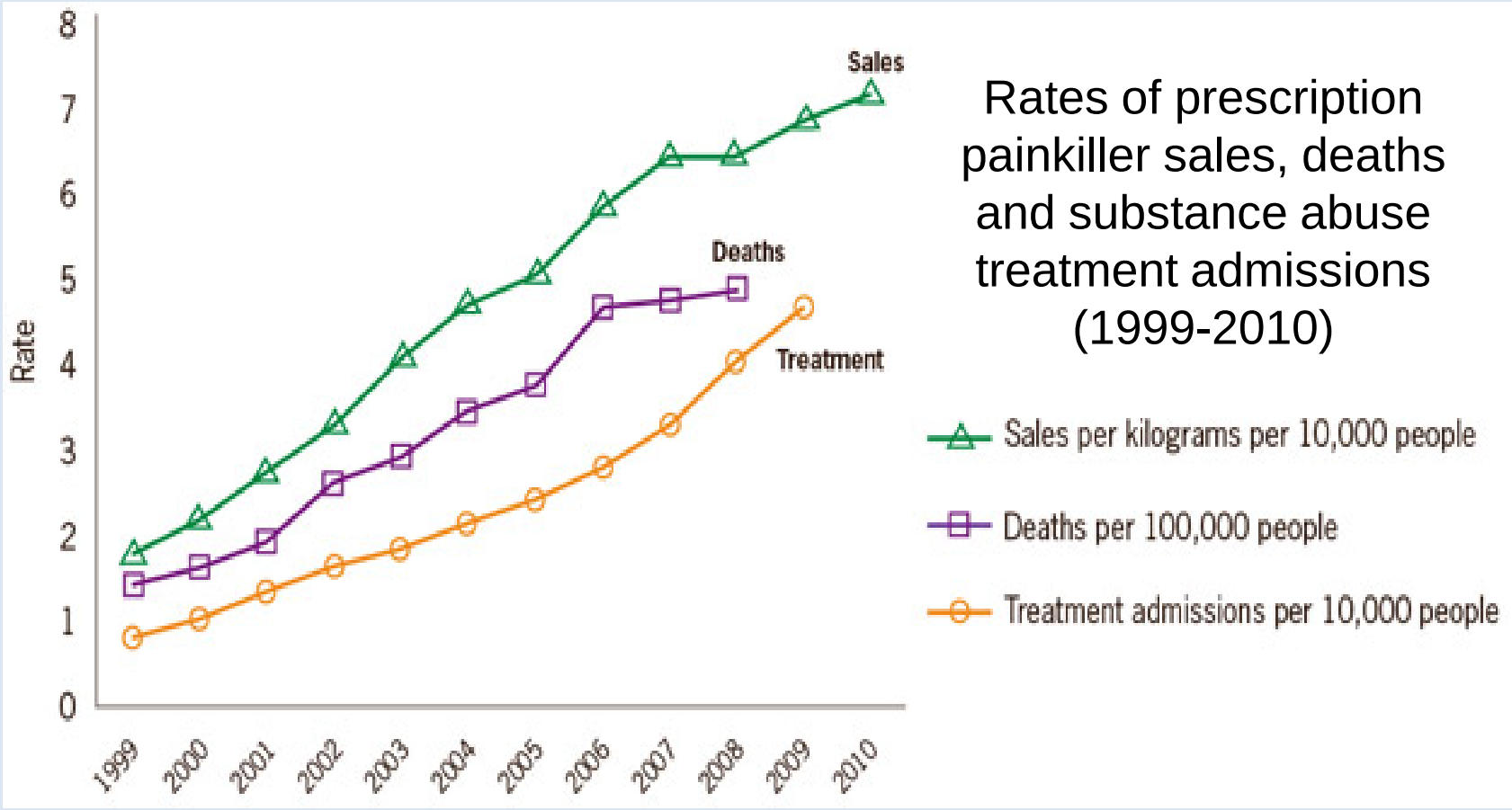
Source: SAMHSA, OAS, NSDUH data , 2005

Figure 1: Rate of unintentional drug overdose death in the United States, 1970-2007



Source: National Vital Statistics System

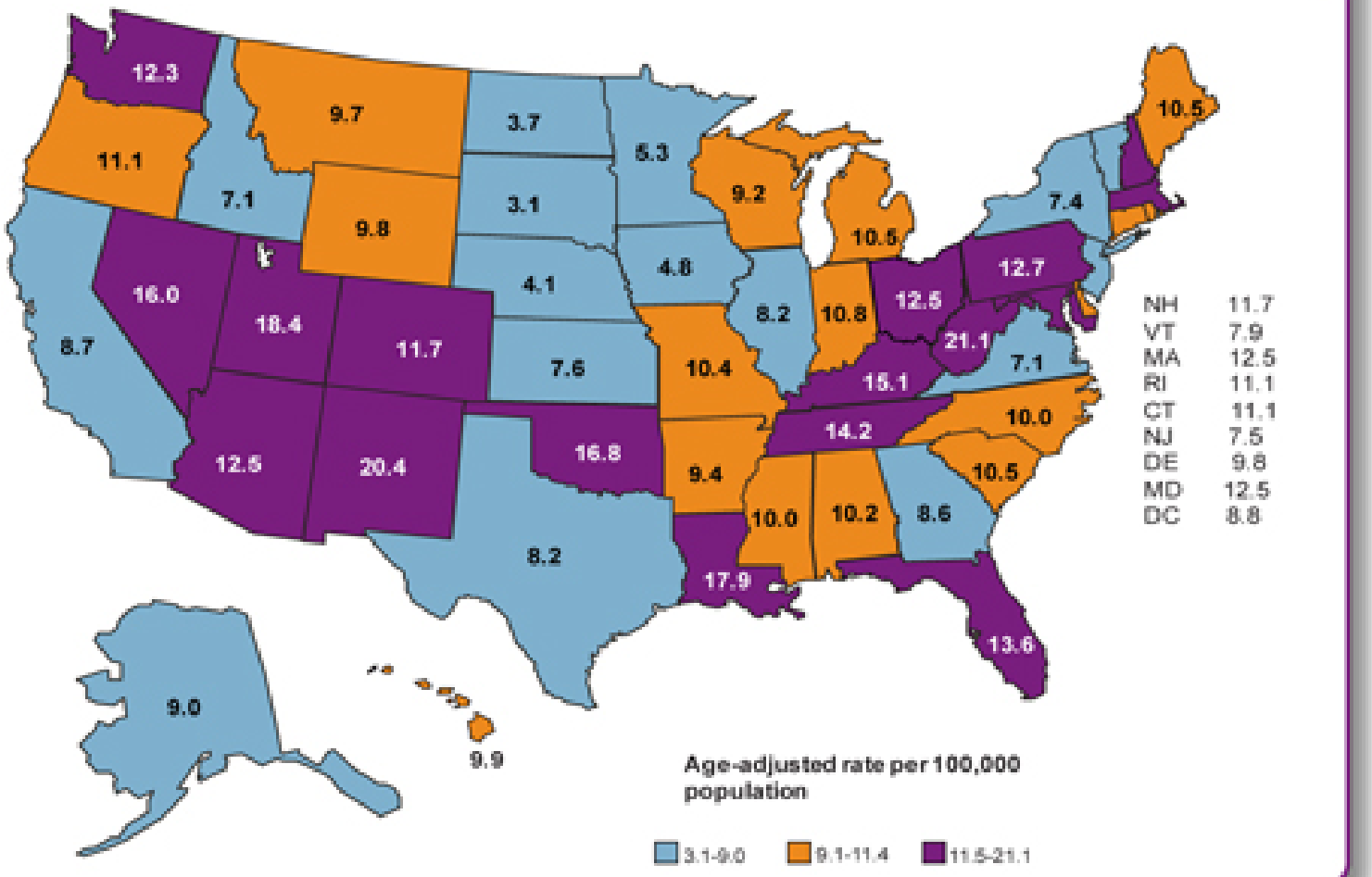
Opioid Overdose and Treatment Admissions Parallel Sales



SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

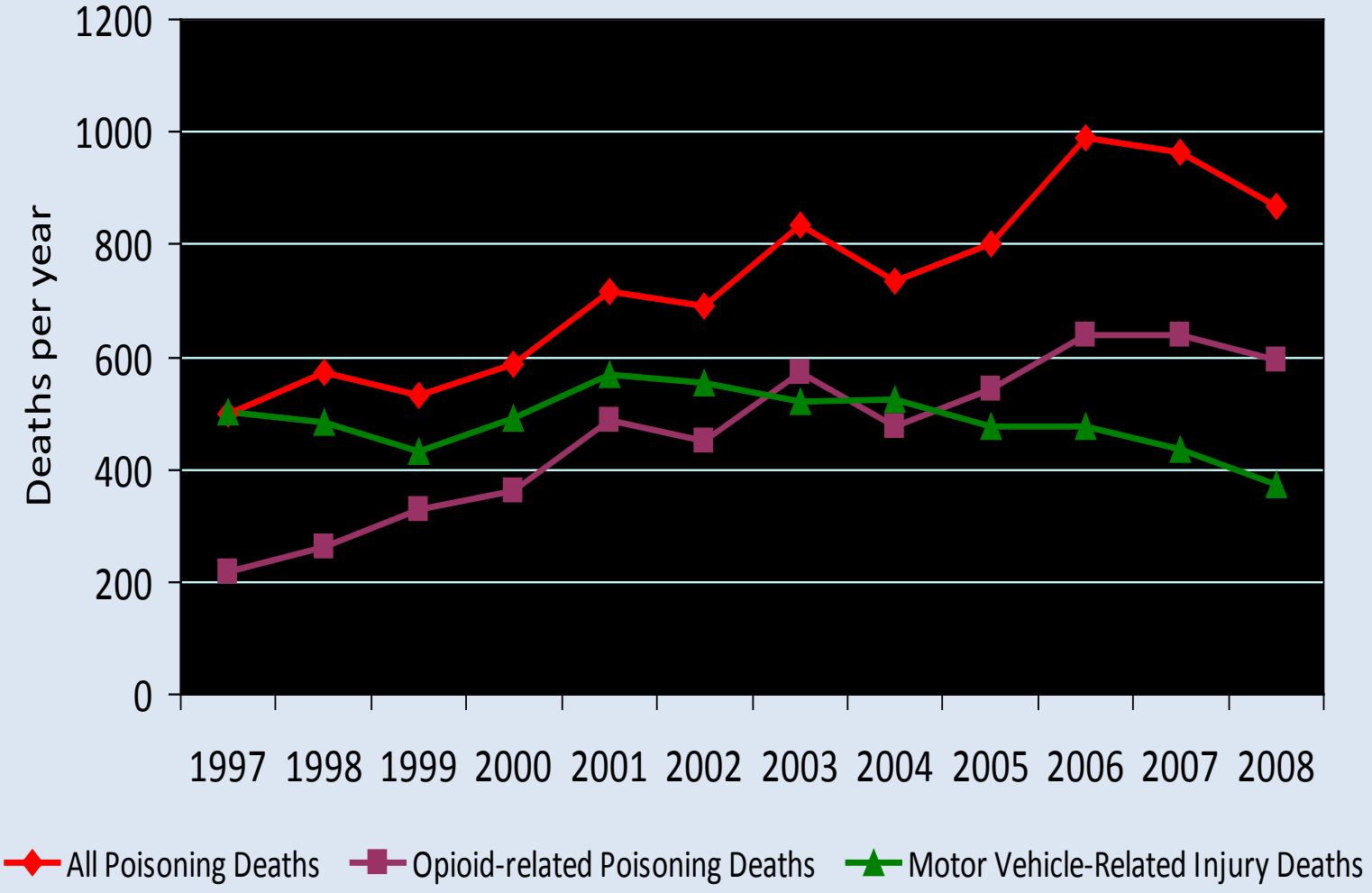
http://www.cdc.gov/VitalSigns/pdf/2011-11-vitalsigns.pdf

Figure 3: Drug Overdose Death Rates by State, 2007



Source: National Vital Statistics System

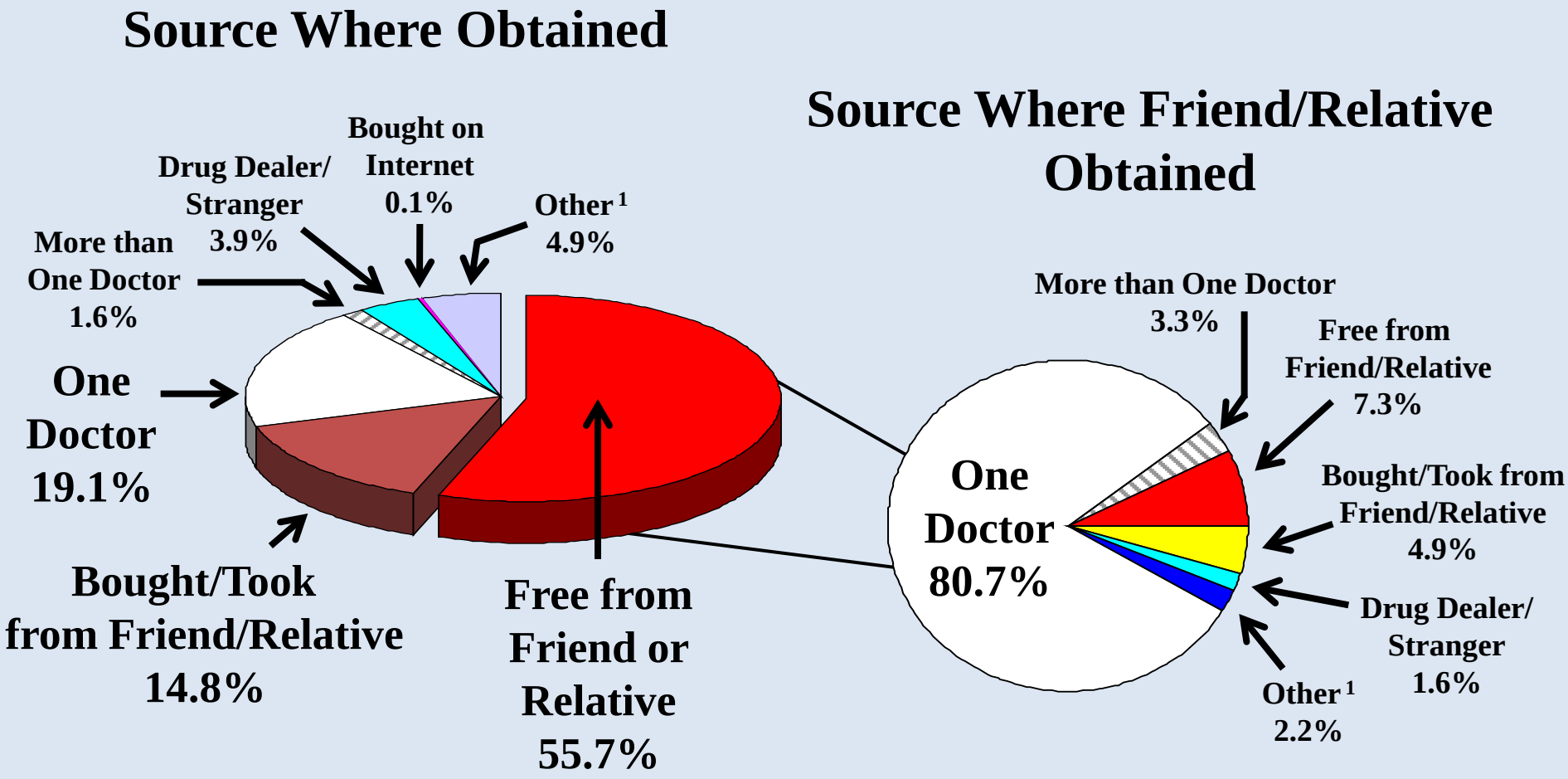
Poisoning Deaths vs. Motor Vehicle-Related Injury Deaths, MA Residents (1997-2008)



The source of the data is: Registry of Vital Records and Statistics, MA Department of Public Health

Source of Pain Relievers

NSDUH 2006



Chronic Pain and Opioids in Primary Care

- 20-40% of primary care visits have chronic pain complaints (Upshur 2006)
- Medical management of chronic pain falls to outpatient medical providers
  - Pain specialists often procedurally focused
- Pressures to aggressively treat pain
  - Advocacy groups, JCAHO's "fifth vital sign", big pharma
- Largest proportion of misused opioids from primary care providers
- Specific guidelines exist, but providers are unaware of recommendations
- Providers in all settings feel unprepared and unsupported in caring for pain patients
  - *Providers feel threatened…*

Goal: Practice and Documentation = Practice Guidelines

- Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain
  - Gourlay DL, Heit HA, Almahrezi A
  - Pain Medicine 2005:6(2);107-112
- Federation of State Medical Boards: Model Policy on the Use of Controlled Substances in the Treatment of Pain, 2004
  - www.fsmb.org
- Opioid Treatment Guidelines
    - Chou R, et al. Journal of Pain, 10(2), 2009

Case study

- 41 year old male, low back pain
- Electrician, fell from ladder
- Standard tx for acute LBP last 3 months
- MRI with DJD L4-S1, Disk herniation without nerve impingement
- Unable to work, sleep, function at home
- History of alcohol problems in his 20's
- Percocet from brother make the pain better, improve his function
- Out of money, needs to get back to work

Prior to the prescription of opioids for a new patient…

- Determine diagnosis: are opioids indicated?
- Character of pain and functional assessment
- Informed consent and treatment agreement
- Risk assessment for misuse of opioids
- Screen for mood disorders/mental illness
- Screen for alcohol/substance misuse
  - *Screening tools, urine toxicology, RX monitoring program*
- <u>Treatment planning</u>
  - Goals and expectations
  - Adjuvant meds and therapies
  - Monitoring plan that matches risk profile

Opioid Trials in Chronic Pain

- Moderate to severe pain
- In adequate response to non opioid medications and non-medication modalities
- Potential benefits outweigh the risks
- Patient informed and gives consent
- Clear measurable treatment goals established
- Quality of evidence: Poor

Opioid Efficacy in Chronic Pain

- Most literature surveys & uncontrolled case series
- RCTs are short duration <4 months with small sample sizes <300 pts
- Mostly pharmaceutical company sponsored
- Pain relief modest
  - Some statistically significant, others trend towards benefit
  - One meta-analysis decrease of 14 points on 100 point scale
- Limited or no functional improvement

Balantyne JC, Mao J. NEJM 2003
Martell BA et al. Ann Intern Med 2007; Eisenberg E et al. JAMA. 2005

Agreements (Contracts)

- Rationale and risks of treatment
- Treatment goals
- Adjuvant therapies
- Monitoring plan
- Refill and other office policies
- Action for aberrant med taking behaviors
- Conditions for discontinuing opioids

Fishman SM, Kreis PG. Clin J Pain 2002
Arnold RM et al. Am J of Medicine 2006
Starrels JL et al. Ann Intern Med 2010

Informed Consent

- Side effects (short and long term)
- Physical dependence, tolerance
- Risk of drug interactions/Over-sedation
- Risk of impairment:
  - driving/machinery/employment
- Risk of abuse, addiction
- Legal responsibilities
  - Disposing, sharing, selling
- Opioid Medication ***Trial—***
  - *If inadequate benefit, too much risk, will stop*

Paterick et al. Mayo Clinic Proc. 2008

"Failure to warn"
What are the limits to prescriber liability?

Coombes vs. Florio MA 2007

- family of child killed may sue patient's doctor for "failure to inform" patient of risks
- Impact of medication not just on individual patient, but on third parties?
- Implications for informed consent
  - side effects, discussion of possible impact on activities, risks to others?
  - Documentation standards
  - Mental capacity to give informed consent

Opioid Misuse Risk Factors

- Young age
- Personal history of substance abuse
  - Illicit, prescription, alcohol, smoking
- Family history of substance abuse
- Legal history (DUI, incarceration)
- Mental health problems

Ives, 2006; Akbik, 2006; Webster, 2005; Michna, 2004; Reid, 2002; Compton, 1998; Chabal, 1997; Dunbar, 1996; Passik, 2006

Opioid Risk Assessment
SOAPP® - SF
Screener & Opioid Assessment for Patients with Pain Short Form

Evaluate for relative risk for developing problems (e.g. aberrant medication taking behaviors) – 86% sensitive, 67% specific

0=Never, 1=Seldom, 2=Sometimes, 3=Often, 4=Very often

1. How often do you have **mood swings**?
2. How often do you **smoke a cigarette** within an hour after you wake up?
3. How often have you taken **medication other than the way it was prescribed**?
4. How often have you used **illegal drugs** (for example, marijuana, cocaine, etc) in the past 5 years?
5. How often, in your lifetime, have you had **legal problems** or been arrested?

≥ 4 is POSITIVE **< 4** is NEGATIVE

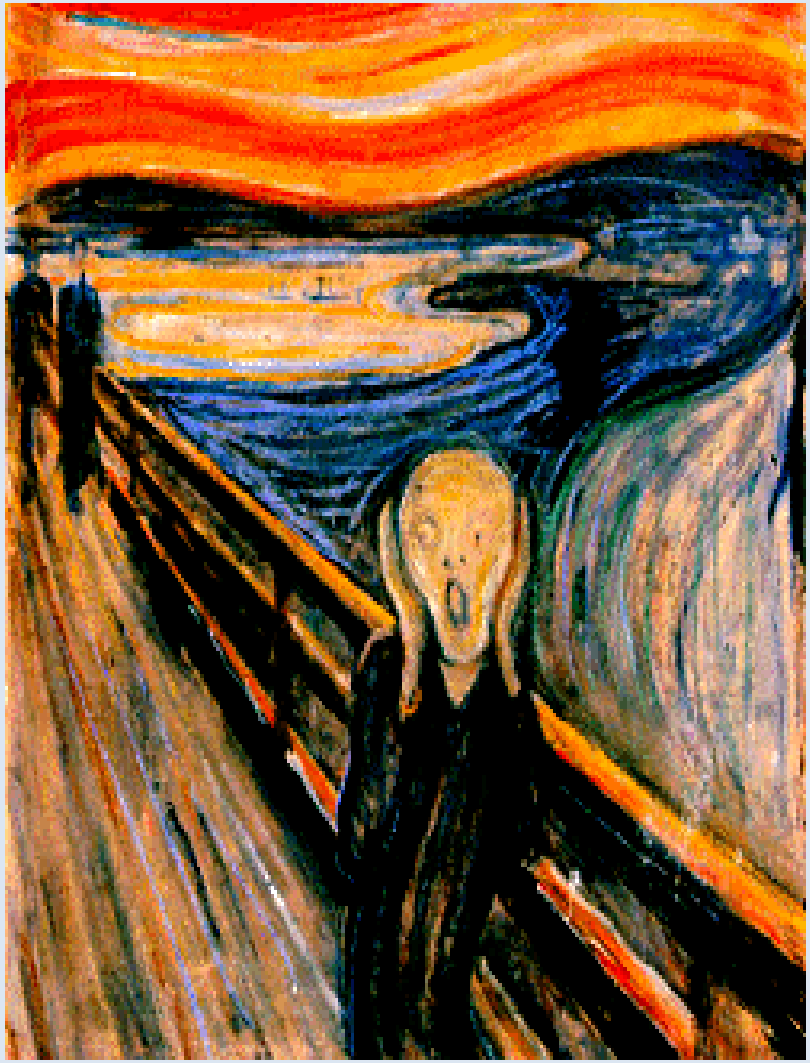
Screening for Substance Abuse Disorders Using 'Single' Questions

- "Do you sometimes drink beer wine or other alcoholic beverages? How many times in the past year have you had 5 (4 for women) or more drinks in a day?" *(+ answer: > 0)*

- "How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?" *(+ answer: > 0)*

Smith PC J Gen Intern Med 2010; 24(7):783-8
Smith PC Arch Int Med 2010;170(13):11155-1160

Screening for Mental Illness



- PHQ 9
- Other psychiatric history
- Mental status and competency
- Suicidality
- Careful medication history for interactions

While the patient is in treatment…

- Regularly assess the “4-A’s”
  - Analgesia
  - Activity
  - Adverse effects
  - Aberrant behaviors
  - Affect…?
- Specific strategies to detect/prevent diversion
  - Call backs, urine drug screening (random), pill counts
  - RX monitoring program
  - Prescription intervals/quantities
  - Refill policies and visit frequency

Passik SD et al. Clin Ther. 2004

PEG* Scale
(Pain, Enjoyment, General activity)

1. **What number best describes your <u>pain on average</u> in the past week?** *(No pain - Pain as bad as you can imagine)*

2. **What number best describes how, during the past week, pain has interfered with your <u>enjoyment of life</u>?** *(Does not interfere-Completely interferes)*

3. **What number best describes how, during the past week, pain has interfered with your <u>general activity</u>?** *(Does not interfere – Completely interferes)*

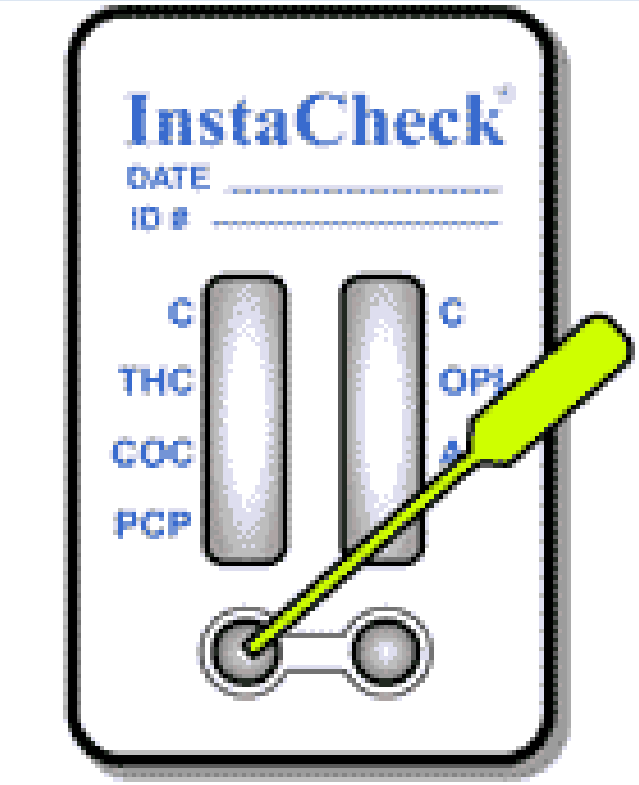
*Krebs EE, et al. J Gen Intern Med. 2009

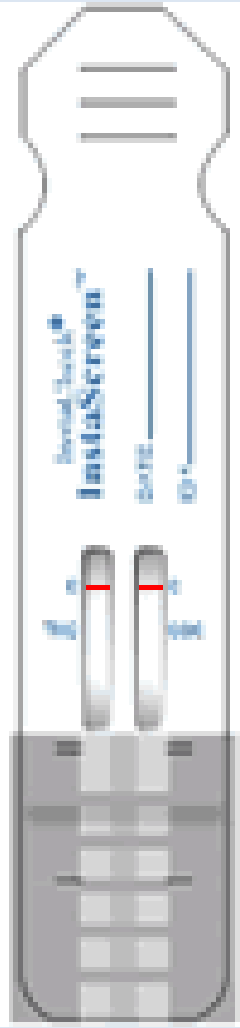
Monitoring: Urine Drug Tests

- Implementation Considerations
  - Know limitations of test and your lab
  - Be careful of false negatives and positives
  - Talk with the patient “If I check your urine right now will I find anything in it?”
  - ? Random versus scheduled
  - ? Supervised, temperature strips, check Cr
  - ? Chain-of-custody procedures

Gourlay DL, Heit HA, Caplan YH. Urine drug testing in primary care. Dispelling myths and designing strategies monograph (www.familydocs.org/files/UDTmonograph.pdf)

Office Drug Testing Options





Immunoassays

PROS:

- Point of care, or lab based
- Fast
- Easy
- Cheap
- Specific tests available for many drugs
  - Oxycodone
  - Buprenorphine
- Can be used as screening with option for confirmation

CONS:

- Qualitative tests
  - cutoff ng/ml
    - Opiates 2000
    - Cocaine metab 300
- False positives
  - Cross-reactivity
  - Contamination
- No non-morphine opioids
  - Unless specifically test
- No non-oxazepam benzos
  - Unless specifically test

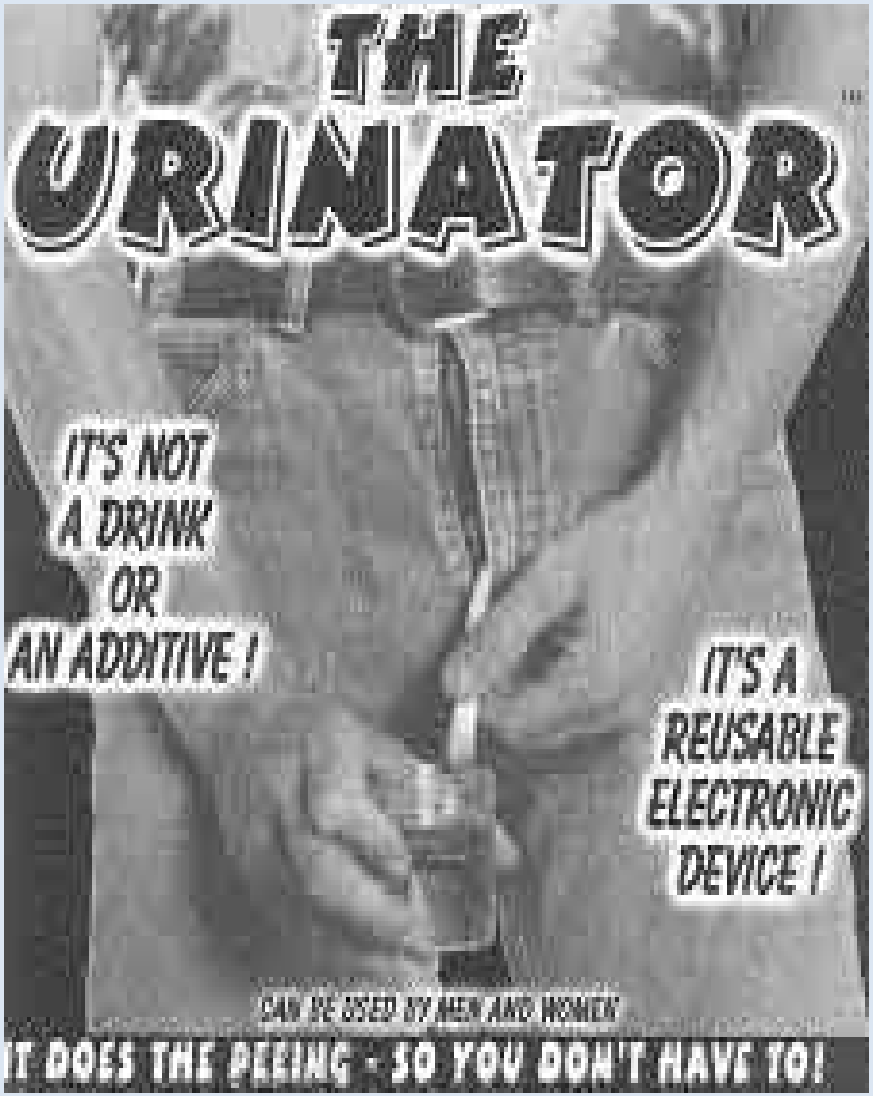
Drug Testing: Quality Control

Urine:

- Observation of samples
- Temperature
- Creatinine
- pH

Oral Swabs:

- Short detection window
- ? Any quality checks



Urine Detox and Adulterants

Consider Establishing a Lab Link

Lab may provide:

- Initial screens
- GCMS confirmation
- Observed testing
- Chain of custody
- On-site testing
- On line results
- Expert consultation

Pill & Patch Counts

- **Confirm medication adherence**
- **Minimize diversion**
- Bring pills to each visit
  - If patient “forgets” pills, schedule return visit w/in a week
- ***Consider random call backs for pill counts and drug screens***
- 28 day (rather than 30 day) supply
  - Prevents the weekend run out
  - Prescriber typically in clinic the same day of the week

Massachusetts Online Prescription Drug Monitoring Program

- Online database of prescriptions filled in MA
  - Oct 2009-Dec 2010: Schedule II
  - January 2011 onward: Schedule II-V
- Pharmacies report data weekly
  - Up to 4 week lag in uploading data
- Registered providers may access online
  - Requires patient first and last names, birthday
  - Only provider may access (not nurse, MA)
  - Only for patients for whom you are prescribing

Clinical Uses of PMP

- Screen patients prior to initiating controlled substances
  - Are they taking what they say they are taking?
  - Pattern of unsafe medication use?
- Monitor for prescriptions from other sources during treatment
- Coordinate care with other providers
- Monitor for medication interactions

Frequently Asked Questions

- Prescriptions filled out of state not recorded
- You may contact any provider on that report for purposes of coordinating care
- You may report concerns for diversion to DEA investigator, medical licensing board
- Not required to use PMP, but recommended
- Do not access records of individuals not in your care
- Do not delegate access to non-licensed, non registered staff

How do I sign up?

- Application packet
- Contact info and email
- Medical license number, state controlled substances number, federal DEA number, and expiration dates for each
- Create a PIN
- Notarize and send to DPH contact listed
- DPH will follow up by email with instructions to complete the process

An ounce of prevention: Opioids in acute pain

- Ask yourself: are opioids really needed?
- Consider lower potency agents:
  - Codeine, hydrocodone, tramadol
- Screen for substance use disorders (personal and family) and mental health problems
- **Informed consent**:
  - sedation, overdose, addiction
- Limit the number of pills dispensed
- Set a goal for the duration of treatment
- Do not refill without reassessing
- Do not use long acting opioids for acute pain

Outpatient Pain Case Continued.

- Fell on ice, says he's in extreme pain
- Out of meds: took month's prescription in 2 weeks
- Calling in for prescription refill early
- Demanding to see you, rude to the nurse
- Showing withdrawal symptoms

Provider Responses

- She has violated her treatment contract
- She is addicted to these medications
- We have to stop these meds now
- She should go to detox
- Every time this patient is on my schedule, I want to take a sick day

What's going on…

The Differential Diagnosis of Aberrant Behaviors

"Treatment Seeking"

- Pain
  - Under-treatment
  - Progression of known condition
  - New pain generator
- Physiological dependence
  - Tolerance
  - Withdrawal or 'abstinence syndrome'
- Hyperalgesia
- Pseudo-addiction

"Drug Seeking"

- Substance abuse
- Addiction
- Criminal activity
  - Self or others
- Psychiatric condition
- Cognitive impairment

Next steps

Dr. Easy

- Provide early refills
- Provide early refills with additional opioid medication to treat acute pain

Dr. Hard Core

- Provide no early refills
- Discontinue meds altogether

Dr. Middle Ground

- Provide early refills *once* +/-- additional meds
- Enhance/intensify treatment
- Evaluate “differential diagnosis”
- Screen mental health and addictoin
- Review agreement, treatment goals
- Involve family, other providers

What if…

- Patient had no acute injury, but still took more meds?
- Patient reported medication was stolen?
- Patient took entire supply of meds due to stress/anxiety?
- Review of MA PMP shows ongoing fentanyl RX from another provider
- You find your patient in the newspaper's "police blotter" arrested for selling oxycodone?

Aberrant Medication-Taking Behavior

<u>More Likely</u> to be Suggestive of Addiction

Red Flags

- Deterioration in functioning at work or socially
- Illegal activities – selling, forging, buying from nonmedical sources
- Injection or snorting medication
- Multiple episodes of "lost" or "stolen" scripts
- Resistance to change therapy despite adverse effects
- Refusal to comply with random drug screens
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians and pharmacies

Aberrant Medication-Taking Behavior

<u>Less Likely</u> to be Suggestive of Addiction

Yellow Flags

- Complaints about need for more medication
- Drug hoarding
- Requesting specific pain medications
- Openly acquiring similar medications from other providers
- Occasional unsanctioned dose escalation
- Non-adherence to other recommendations for pain therapy

Too little benefit

- Inadequate analgesia
- Not improving function
- Not meeting treatment goals
- Not all pain is opioid responsive
  - Acute > Chronic
  - Nociceptive > Neuropathic
  - Varies among individuals
- More is not always better
- Maximum opioid dose beyond which little benefit is seen (120 mg MSO4 equivalent?)

Too much risk

Opioid related

- Adverse events
  - Side effects; Toxicity
- Increasing dose without increasing benefit
  - Tolerance?
- Increasing dose without worsening condition
  - Hyperalgesia?
- Addiction
  - Loss of control
  - Use despite negative consequences
  - Compulsive use

Psychosocial

- Psychiatric instability
- Unsafe housing or storage
- Non compliance with monitoring procedures
- Non compliance with office procedures
- Use of other non opioid drugs of abuse
- Diversion or criminal behavior

Avoiding "Abandonment"

- Documentation of risk/benefit discussion and why treatment discontinued
  - *Allow for medically appropriate taper*
- Restate commitment to continue to work with patient on pain and addiction if needed
  - Refer to specialty pain treatment providers
  - Alert patient to addiction treatment resources
- See patient frequently and monitor for progress and safety
- Copy to patient and to chart

Challenges

- Involuntary Withdrawal
  - Set a reasonable schedule and stick to it
- Emergency Termination
- Recurrence of pain
  - Overlap of pain and withdrawal symptoms
  - Assess withdrawal intensity with scale
- Psychiatric instability
  - Overlap of pain and psychiatric symptoms
  - Suicidality
- Threatening behavior
  - “if you don’t prescribe this for me I will just have to get it on the street”
  - “I’m calling my lawyer”

Finding Treatment

- SAMHSA Treatment Facility Locator
  - http://dasis3.samhsa.gov/
- Massachusetts State Helpline 800-327-5050
  - www.helpline-online.com
- Buprenorphine Treatment
  - MA State hotline: 617-414-6926
  - http://buprenorphine.samhsa.gov/
  - www.naabt.org

Thank you!

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Drug Testing Reference Slides

Table: Drug Testing Techniques

Drug Testing Technique	Characteristics	Advantages	Disadvantages
Immunoassays	• Engineered antibodies bind to drug metabolites • Most commonly used technique in all settings, including hospital labs	• Easy to use in many settings including office-based testing • Less expensive • Available for specific drugs, or a panel of drugs	• Qualitative testing: positive or negative only • Often have high cut-off levels, giving **false negative** results • Risk of cross reactivity with other agents, giving **false positive** results
GCMS (Gas Chromatography, Mass Spectrometry)	• Directly measures drugs and drug metabolites	• Very specific, less cross-reactivity, minimizes **false positives** • Very sensitive, detects low levels of drug, minimizes **false negatives** • Quanititative testing	• Requires advanced laboratory services • Very expensive

1. Manchikanti L 2008 Pain Physician 11:s155-s180
2. Gourlay DL, Heit HA, Caplan YH 2010 4rth edition
http://www.familydocs.org/professional-development/cme-monographs.php

Table: Drug metabolites, typical cut-off levels and time of detection in urine

Drug	Primary metabolite	Typical cutoff ng/ml	Potential source of false positive	Time of detection in urine
Opiates	Morphine	300-2,000	Poppy seeds Rifampin Chlorpromazine Dextromethorphan	2-4 days
Cocaine	Benzoylecgonine	300	Very specific metabolite	1-3 days
Amphetamine Methamphetamine	Amphetamine	1,000	Ephedrine Phenylpropanolamine Methylphenidate Trazodone Buproprion Ranitidine	2-4 days
Marijuana	Tetrahydrocannabinol (THC)	50	NSAIDS Marinol Pantoprazole	1-3 days for intermittent use; up to 30 days in chronic use
Benzodiazepines	Standard assays measures oxazepam, diazepam *Poor detection of newer agents*	200	Oxaprozin	Varies with half-life of agent

Table: Natural and Synthetic Opioids

Natural Opiates *from opium*	Semi Synthetic Opioids *derived from opium*	Synthetic Opioids *Manufactured, not from natural opium*
Morphine Codeine Thebaine	Hydrocodone Oxycodone Hydromorphone Oxymorphone Buprenorphine Diacetyl-morphine (heroin)*	Methadone Propoxyphene Fentanyl Meperidine

Typical opiate immunoassays detect only natural opiates that are metabolized to morphine, and do not detect semi-synthetic or synthetic opioids

* Heroin is metabolized to morphine, and therefore can be detected using a standard opiate immunoassay.