

Interpreting Urine Screens and Serum Opioid Levels in the Chronic Pain Patient

Opioid Pharmacokinetics & Toxicokinetics

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Special Credits

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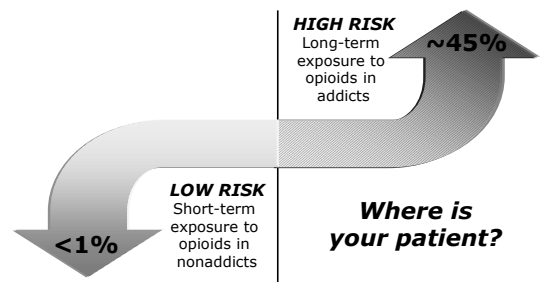
Disclosures

- This lecture is NOT specific to the Dept. of Veterans Affairs Institutions or any other Federal Institution.
- Information provided may be applied to any clinical setting as each attendee deems appropriate.
- Speakers Bureaus
 - Janssen, Merck, Ortho-Biotech, Ortho-McNeil, Pfizer, Purdue Pharma.

Presentation Outline

- Introduction
- Brief Overview of Pharmacokinetic Terms
 - Parameters and Definitions
- Need for monitoring
- Urine drug screen
- Medicinal Chemistry
- Analytical Chemistry
- Opiate serum predictability
 - See handout
- Conclusion
- Discussion, Cases, Questions

Risk of Addiction or Aberrant Behavior With Opioids



Porter, 1980; Dunbar, 1996; Passik, 1998

Important Definitions:

- **Pharmacokinetics:** The study of the mathematical relationships between a drug dosage regimen and the resulting serum concentration (what the body does to the drug).
- **Elimination:** The sum of all processes responsible for removal and/or transformation of drug in the systemic circulation. These processes are principally metabolism and excretion.
- **Elimination half-life:** The time required for serum or body drug concentration to decrease by 50%.
- **First-order kinetics:** A process where the rate of drug metabolism, excretion or transfer is directly proportional to the concentration of the drug.

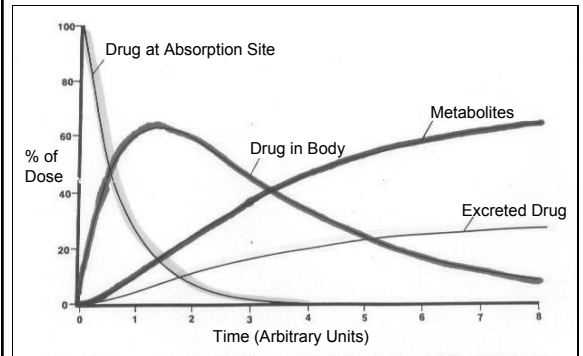
Definitions:

- **First-pass effect:** The removal of a portion of a drug dose by the liver prior to reaching the systemic circulation. (Important for which two opioids?)
- **Distribution:** The process by which drug is transferred from the vasculature to body tissues. (Important for which two opioids?)
- **Metabolism:** The process by which drugs (or endogenous compounds) are transformed into their respective metabolites. A principle mechanism for drug elimination.
- **Excretion:** The elimination of drug or metabolite from the body into urine, feces, sweat, etc., (principally urine for unchanged drug or metabolites).

Definitions

- **Clearance:** A measure of efficiency of removal of drug from the body (elimination). It is defined as the volume of blood, serum, or plasma that is totally cleared per unit time.
- **Saturation Kinetics:** Also known as Michaelis-Menten or capacity limited kinetics whereby increases in dose rate result in disproportionate increases in serum concentration due to saturable metabolic pathways.
- **Steady State:** A condition of equilibrium achieved during chronic dosing when the rate of drug input equals the rate of drug elimination.
 - How many half-lives until steady state?
 - Why is this important for opioid screening?

Relative Concentrations:



Opioid Analgesic P-Kinetics

AGENT	TIME TO PEAK (HR)	HALF-LIFE (HR)	ANALGESIC ONSET (MIN)	ANALGESIC DURATION (HR)
MORPHINE (IM)	0.5-1	2	10-20	3-5
HYDROMORPHONE (IM)	0.5-1	2-3	10-20	3-5
LEVORPHANOL (IM)	0.5-1	12-16	10-20	5-8
HYDROCODONE (PO)	1	4	30-60	4-6
CODEINE (IM PO)	0.5-1	3	10-20	4-6
OXYCODONE (PO)	0.5-1	2-3	30-60	4-6
MEPERIDINE (IM)	0.5-1	3-4	10-20	2-5
FENTANYL (PATCH)	24-72	16-22	12-18	48-72
FENTANYL (IM)	1-2	3-4	7-15	1-2
METHADONE (IM PO)	0.5-1	15-30	10-20	>8 (chronic)
PROPOXYPHENE (PO)	2-2.5	6-12	30-60	4-6

Combined data from: Reisine T, Paternak G 1995 and Pasero C, Portenoy RK, McCaffery M. 1999
Drug Facts and Comparisons 2004 Facts and Comparisons. A division of Wolters Kluwer Health, Inc.

Metabolic Pathway from Drug Elimination

DRUG	OPIOID CLASS	MAJOR METABOLIC PATHWAY
Morphine	Phenanthrene (w/-OH)	Glucuronidation
Hydromorphone	Phenanthrene	Glucuronidation
Codeine	Phenanthrene (w/-OH)	Demethylation, glucuronidation
Levorphanol	Phenanthrene	Glucuronidation
Oxycodone	Phenanthrene	Demethylation, glucuronidation, keto-reduction, minor 3A4/2D6
Oxymorphone	Phenanthrene	Glucuronidation
Meperidine	Phenylpiperidine	Oxidation, hydrolysis, demethylation, glucuronidation
Fentanyl	Phenylpiperidine	Oxidation, hydrolysis, minor 3A4
Alfentanil	Phenylpiperidine	Oxidation
Sufentanil	Phenylpiperidine	Dealkylation, demethylation
Methadone	Diphenylheptane	Demethylation, 3A4 substrate (significant)

Volles DF, McGory R. Pharmacokinetic considerations. 15.5.Jan 1999.

Need For Opioid Compliance Monitoring

- **Improper use of Opioids**
 - Drug abuse
 - Overdose
 - Pt taking more than prescribed
 - Pt taking less than prescribed
 - Drug diversion
 - Illicit drug use
 - Illicit drug sale
- **Legal implications**
 - Practitioner
 - Institution

Katz N, Fanciullo GJ. Clinical Journal of Pain. July/August;18(4):s76-s82. 2002.
"Blood and urine testing for opioids." Cpmmission.com. Ed. Brian Fisher MD. 6 Mar 2005. <http://www.cpmmission.com/main/Fblood.html.

Current Opioid Use Monitoring

- **How can I convince managed care to pay for this service?**
- **Serum drug level**
 - Quantitative analysis
 - How much drug is present in serum?
 - Can I accurately predict how much drug the patient is taking?
- **Urine drug screen**
 - Quantitative analysis
 - How much of which drug(s) are present in the urine?
 - What metabolites can be expected and what do they mean?

Katz N, Fanciullo GJ. Clinical Journal of Pain. July/August;18(4):s76-s82. 2002.
Vanderveen M, Vandebussche H, Verstraete A. Detection time of drugs of abuse in urine. Acta Clin Belg. Nov-Dec;55(6):323-33. 2002.
"Blood and urine testing for opioids." Cpmmission.com. Ed. Brian Fisher MD. 6 Mar 2005. <http://www.cpmmission.com/main/Fblood.html.

Urine Specimen Collection Handbook for the Federal Workplace

- Observed urine collection
 - Collection done in clinic (or picture ID)
 - No significant other or children allowed in collection area
 - No clothing, wallets, handbags allowed in collection area
- Prevention of specimen tampering by clinic personnel
 - Chain of custody documentation
 - Collect vial sealed until opened by lab processing the specimen

<http://workplace.samhsa.gov/resourcecenter>

Slide adopted from Virginia L. Ghafoor, Pharm.D. as presented at 2004 Annual ACCP Meeting, Dallas TX.

Urine Drug Screen

- **Most often used**
 - **Convenient, inexpensive**
- **Identifies various substances of abuse**
 - **Amphetamines (not ?)**
 - **Benzodiazepines**
 - **Barbiturates**
 - **Cocaine**
 - **Opiates**
 - **Cannabinoids**
 - **PCP**

Katz N, Fanciullo G.J. Clinical Journal of Pain. July/August;18(4):s76-s82, 2002.

Vandevenne M, Vanderbussche H, Verstraete A. Detection time of drugs of abuse in urine. Acta Clin Belg. Nov-Dec;55(6):323-33, 2002.

"Blood and urine testing for opioids." Cpmision.com. Ed. Brian Fisher MD. 6 Mar 2005. <<http://www.cpmision.com/main/Fblood.html>>.

Smith ML, Shimomura ET, Summers J, et al. J Anal Toxicol. 2000 oct24(7):522-9.

Immunoassay Method aka, Urine Screens

- Antibody binds to drug substrate (competitive binding)
- A known quantity of antibody and enzyme-labeled antigen containing either drug or metabolite added to the patient's urine specimen
 - Drug or metabolite in the patient's urine specimen will compete with the labeled drug complex to form antigen/antibody complexes
 - The amount of enzyme-labeled antigen that binds to antibody is inversely proportional to the amount of drug and/or metabolite in the urine
- Potential for cross-reactivity with drugs containing similar chemical composition to assay targets

Clinics in Laboratory Medicine, 21(2):363-374, 2001.

Slide adopted from Virginia L. Ghafoor, Pharm.D. as presented at 2004 Annual ACCP Meeting, Dallas TX.

Gas Chromatography Mass Spectrometry (GCMS)

- Dilute urine will often yield results below analytical detection point
- Must request "no threshold testing" for dilute specimens or low opioid concentrations
 - PRN use of opioids
 - Fentanyl 25 mcg/hr patch
- Can not indicate:
 - Amount of drug taken
 - When the last dose was administered
 - Drug source

Therapeutic Drug Monitoring, 25(6):723-272, 2003

Slide adopted from Virginia L. Ghafoor, Pharm.D. as presented at 2004 Annual ACCP Meeting, Dallas TX.

Problems With Urine Drug Screen

- **Quantitative**
 - **Predictability vs. accuracy**
- **Does not assess entire clinical picture**
 - **Cutoff level for opiates is high**
 - **2000 ng/mL vs 300ng/mL**
 - **Patient dose and frequency**
 - **Long-acting vs. short-acting vs. extended release vs. time of last dose**
 - **Specific opiate being monitored**
 - **Synthetic opiates not as accurate**
 - **Water solubility vs. lipophilicity**
- **Excessive false positives or false negatives**

Katz N, Fanciullo G.J. Clinical Journal of Pain. July/August;18(4):s76-s82, 2002.

"Blood and urine testing for opioids." Cpmision.com. Ed. Brian Fisher MD. 6 Mar 2005. <<http://www.cpmision.com/main/Fblood.html>>.

Urine Creatinine Validation

- Creatinine is spontaneously and irreversibly formed from creatine in the muscle (it is a waste product not reused by the body)
- Excreted by renal tubular secretion at a constant rate
- Random urine creatinine level ranges from 18-200 mg/dL
- Theoretical urinary dilution limits
 - < 20mg/dL (potentially fatal water intoxication with death due to hyponatremia and cerebral edema)
 - < 5mg/dL (not physiologically possible; specimen was adulterated by a chemical agent)

Journal of Analytical Toxicology, 24:579-588, 2000

Slide adopted from Virginia L. Ghafoor, Pharm.D. as presented at 2004 Annual ACCP Meeting, Dallas TX.

Internet Search for "Clean Urine"

1. **You're Clean** Provides drug testing and detox products designed to help people prepare for and pass a urine or hair drug test. Find out about the company's guarantee.
www.youreclean.com
2. **pass a drug test urine** Drug testing products and information to help you pass urine and hair follicle drug test.
www.cheerful.com
or hair - **Cheer Test**
3. **You're Clean** Drug testing. Drug test. Pass a urine drug test, pass a hair drug test. Info for helping people pass the urine drug test & hair drug test. Protect your rights. Don't be a victim of drug testing. Use our proven drug.
www.youreclean.com/index2facts.html#clean:drug_testing_solutions Pass a urine drug test & hair test
4. **pass a drug test Be Negative** pass testing Clean pass a drug test. "Be Negative Coat" Drug Testing Solutions "Be Negative" can provide you with products to help you pass a drug test. You can pass a hair follicle drug test, blood or urine test. We carry detox products and hair cleaners at low prices.
www.beegative.com
5. **Terminader Gold 60 Clean Detox Urine Drug Testing** terminader gold 60 clean detox urine testing drink.
www.webpage.com/users/Terminader
6. **anti drug testing products - for urine and hair follicle drug tests** Drug testing products and information to help you pass hair follicle and urine drug tests.
www.cheerful.com/products
7. **Drug Testing Marijuana - Self Test Drug Kits** Unbiased providers of drug and alcohol self / home test kits for people who want to test themselves for marijuana and other drugs.
www.drugtestingmarijuana.com
8. **Always Test Clean** Soils capsules, drinks, and shampoos designed to remove the toxins that cause positive results on urine, hair, or blood drug tests. Find out how each product works.
www.always-test-clean.com
9. **Passing a drug test. Pass a drug test. Pass a drug test. Passing a drug test. Products to help you pass a drug test.** Marijuana, cocaine, drug test, Pass meth drug test, False positive amphetamine drug testing information, Passing drug testing, Ways to pass a drug test, Passing a drug test
www.passdrugtesting.com
10. **Hair Drug Testing, Urine Drug Testing, Pass Your Drug Testing** has many resources to help drug testing, pass a drug test, Hair Drug Testing, Urine Drug Testing, Urine Drug Testing, urine drug testing, hair drug testing, Urine Drug Testing, Urine Drug Testing.
www.passyourdrugtesting.com/hair-drug-testing-urine-drug-testing.htm
11. **passing urine drug testing, pass a drug test** www.PassDrugTesting.com DRUG TEST ? Pass any drug test. Pass urine drug testing. Pass saliva drug test. Pass hair drug testing. Pass blood drug testing. All products formulated for high toxin levels. We also have drug test kits.
www.passdrugtesting.com/urine_drug_test.html
12. **Drug Testing Products - Marijuana Information - Home Test Kits** Drug testing kits, products and

www.passdrugtest.com/blood_drug_test_information..html



www.PassDrugTest.com

Help to pass a drug test. Pass urine drug test. Pass blood drug test. Pass saliva drug test. Pass hair drug test. We also have to it yourself drug test kits. For drug test information and list of toxins that cause false positive see Drug Test Q&A button lower left.

Order Today Receive Shipment Tomorrow.

Toll Free 1-877-345-5555

Carbo Cleansing Shake

Pass Urine Drug Test.

Pass Blood Drug Test.

Pass Saliva Drug Test.

<http://www.csun.edu/~hbcs096/dt/ftbc.html/node114.html>
Where to Get Clean Urine

- Urine From A Donor
- Powdered Urine
- Making Your Own Powdered Urine
- Dog Urine

I heard from Dr. Grow that dog urine (of all things) can be substituted, and will pass the test! However, I don't know how an age, gender, pH, or creatinine test would result. Someone was able to use dog urine for several months to pass the test. This subsection assumes you have a clean dog. I know my dog's urine wouldn't pass; he eats more weed than humans do. It would make more sense to use human urine, but dog urine provides a workable substitution in an emergency.

<http://www.csun.edu/~hbcs096/dt/ftbc.html/node114.html>

The Clean Whiz Kit



<http://www.cleanwhiz.com/cleankit.html>

Chemical Adulterants

HOUSEHOLD PRODUCTS	
Adulterant	Drug Test Affected
Chlorine Bleach	Marijuana, Morphine, Amphetamine
Liquid Drain Cleaner	Morphine, Amphetamine
Vinegar	Amphetamine
PROMOTIONAL PRODUCTS	
Adulterant	Drug Test Affected
Pyridinium Chlorochromate (PCC)	Amphetamine, Cocaine, Morphine Marijuana, Phencyclidine
UR'n Kleen	All of the above except Amphetamine
Instant Clean and Stealth	Marijuana, Phencyclidine, Cocaine

American Clinical Laboratory, 21(1):37-39, 2002

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



Appropriate Interpretation of Urine Drug Screens

- **TEST RESULTS**
 - **False negative**
 - **Assess patient current opioid dose**
 - Amount and type of opioid
 - As needed dosing
 - **Inquire about quantitative data**
 - **False positive**
 - **What opioid is patient taking?**
 - Synthetic opioid
 - Metabolites present
 - **Additional as needed doses vs. no BT meds**

Katz N, Fanciullo GJ. Clinical Journal of Pain. July/August;18(4):376-82, 2002.

"Blood and urine testing for opioids." Cpmisson.com. Ed. Brian Fisher MD. 6 Mar 2005. <<http://www.cpmisson.com/main/F3blood.html>>

Chemical Classes of Opioids

	PHENANTHRENES	BENZOMORPHANS	PHENYLPIPERIDINES	DIPHENYLHEPTANES
Rx EXAMPLES >	 <p>MORPHINE morphine codeine hydrocodone* hydromorphone* levorphanol* oxycodone* oxymorphone* buprenorphine* nalbuphine butorphanol* naloxone* heroin (diacetyl-morphine)</p>	 <p>PENTAZOCINE pentazocine phenazocine isoperamide</p>	 <p>MEPERIDINE <u>meperidine</u> fentanyl alfentanil remifentanyl</p>	 <p>METHADONE methadone propoxyphene</p>
X-SENSITIVITY >	PROBABLE	POSSIBLE	LOW RISK	LOW RISK

*These agents lack the 6-OH group of morphine, possibly decreasing cross-sensitivity within the phenanthrene group.
Reisner T, Pasternak G. Opioid analgesics and antagonists. In: Hardman JG, Limbird LE, Molinoff PB, Ruzkin RW, Gilman AG, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th ed. New York, NY: McGraw-Hill Companies; 1996:521-555.
Wittke RE. Analgesic Agents. In: Detelido JN, Bannan WA, eds. Wilson and Gilvold's Textbook of Organic Medicinal Chemistry, 9th ed. JB Lippincott Company, Philadelphia, Pa. 1991:629-654.

Sample Urine Drug Screen Cutoff Levels

Screen	Cutoff (ng/mL)
Amphetamine	1000
Barbiturate	200
Benzodiazepine	200
Cocaine	300
Opiates	2000
Cannabinoids	50
Methadone	300
PCP (phencyclidine)	25

Example: Beckman Synchron CX5CE at Memphis VAMC.

Interpreting Urine Screens: Clinical Examples

Patient on fentanyl transdermal system with no BT opioids and urine screen is negative.

What does it mean?

- Pt is not likely to be using the patch.
- Pt is on too low of a dose.
- Something went wrong with the lab test.
- Most phenylpiperidines are not included in urine toxicology screens.

Interpreting Urine Screens: Clinical Examples (cont'd)

Patient on fentanyl transdermal with no medication for breakthrough pain and the urine screen is positive.

What does it mean?

- Pt may be taking fentanyl as prescribed.
- Pt may be injecting heroin or hydromorphone.
- Pt may be snorting sustained released oxycodone.
- All of the above

Interpreting Urine Screens: Clinical Examples (cont'd)

- Patient on methadone with no BT opioids and urine screen is negative. What does it mean?
 - Pt is likely diverting the methadone.
 - Pt is on too low of a methadone dose.
 - Something went wrong with the lab test.
 - Methadone is not included in urine toxicology screens.

Interpreting Urine Screens: Clinical Examples (cont'd)

- Patient on methadone with no BT opioids and urine screen is negative. What does it mean?
 - This is what we would expect.
 - Pt could be selling methadone and using propoxyphene instead.
 - A and B above are true.
 - None of the above

Serum Opioid Levels

- More accurate monitoring tool
- Advantages
 - Specific for opioid (and metabolites) being monitored
 - Predictability
 - Based on existing pharmacokinetic data
 - Can accurately estimate what appropriate levels should be after steady state is achieved
 - More difficult for patient alter
 - Require picture ID outside of clinic setting
 - Better indicator of opioid use
 - Dose related pharmacokinetics

"Blood and urine testing for opioids." Cpmision.com. Ed. Brian Fisher MD. 6 Mar 2005. <http://www.cpmision.com/main/Fblood.html.

Serum Opioid Levels

- Disadvantages
 - More invasive
 - Expensive
 - Time until results vs. RX supply
 - Data correlating serum opioid levels is mathematically challenging and scant
 - Need for steady-state data
 - Consider drug interactions
 - Lack of access to practitioners with expertise in pharmacokinetics

"Blood and urine testing for opioids." Cpmision.com. Ed. Brian Fisher MD. 6 Mar 2005. <http://www.cpmision.com/main/Fblood.html.

Pharmacokinetic (PK) data for commonly prescribed opioids

See Chart in handout!

- Plasma half-life
- Time to peak concentration
- Time to steady-state
- Metabolites
- Steady-state (PK)
 - 24 hour dose vs. expected serum level
 - Average time of expected serum level

OXYCODONE-1

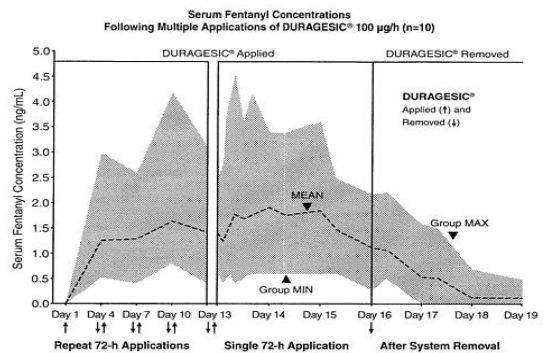
Calculating Patient's Ingested Dose based on Serum Levels

- Dose proportionality and/or bioavailability has been well established for 10mg, 20mg, 40mg, 80mg, and 160mg tablets strengths for both peak plasma levels (C_{max}) and extent of absorption (area under the curve).
- At a dose of 10mg sustained release oxycodone PO q12h, the mean maximum serum concentrations (+/- SD) for sustained release oxycodone has been reported as 15.1 +/- 4.7 ng/mL.
 - (We can expect 90% confidence levels with these numbers (Reder RF, Oshlack B, Miotto JB, Benziger DD, Kaiko RF)

Calculating Patient's Ingested Dose based on Serum Levels

- Sustained-release oxycodone 40 mg PO q8h, we can calculate a C_{max} (or maximum serum concentration).
- The absolute high average serum concentration we should expect in this patient at his current dosage is 90.6 ng/mL (+/- 4.7ng/mL)
 - Assuming that the blood was drawn exactly at the peak of 3.2 hours after the patient's last dose

Fentanyl Transdermal



Fentanyl - MICROMEDEX® Healthcare Series, Thomson MICROMEDEX, Greenwood Village, Colorado Copyright © 1974-2005.

Fentanyl Transdermal

TABLE A
FENTANYL PHARMACOKINETIC PARAMETERS
FOLLOWING FIRST 72-HOUR APPLICATION OF
DURAGESIC®

Dose	Mean (SD) Time to Maximal Concentration T max (h)	Mean (SD) Maximal Concentration C max (ng/mL)
DURAGESIC® 25 µg/h	38.1 (18.0)	0.6 (0.3)
DURAGESIC® 50 µg/h	34.8 (15.4)	1.4 (0.5)
DURAGESIC® 75 µg/h	33.5 (14.5)	1.7 (0.7)
DURAGESIC® 100 µg/h	36.8 (15.7)	2.5 (1.2)

NOTE: After system removal there is continued systemic absorption from residual fentanyl in the skin so that serum concentrations fall 50%, on average, in 17 hours

Fentanyl - MICROMEDEX® Healthcare Series, Thomson MICROMEDEX, Greenwood Village, Colorado Copyright © 1974-2005.

All Chronic Pain Patches Are Not Created Equal*

DURAGESIC® Reservoir Fentanyl Delivery System

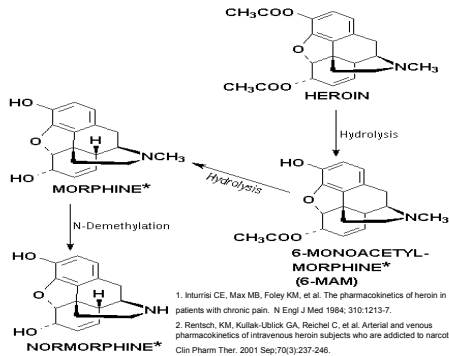


Matrix Delivery System



*No conclusions regarding comparative safety or efficacy can be drawn from this comparison.

Heroin



- Inturrisi CE, Max MB, Foley KM, et al. The pharmacokinetics of heroin in patients with chronic pain. *N Engl J Med* 1984; 310:1213-7.
- Rentsch, KM, Kullak-Ublick GA, Reiche C, et al. Arterial and venous pharmacokinetics of intravenous heroin subjects who are addicted to narcotics. *Can Pharm Ther*. 2001 Sep;70(3):237-246.
- Heroin - MICROMEDEX® Healthcare Series, Thomson MICROMEDEX, Greenwood Village, Colorado Copyright © 1974-2005.

Heroin 25,26,27

- **Half-life**
 - ~3 minutes (1.7-5.3 minutes)
 - **Time to steady state**
 - ~15 min
 - **Time to peak concentration**
 - Can detect heroin and 6-acetylmorphine
 - within 10-15 minutes after parenteral administration
 - **Serum Predictability**
 - Yes
 - Heroin is rapidly metabolized to morphine
 - Better if apply morphine pharmacokinetics
 - Not studied exclusively
- References: See previous slide

Monitoring Recommendations

- General considerations
 - Patients sign an Controlled Substance agreement
 - Advised patient of risk of addiction, tolerance, etc.
 - Classify patients by potential for aberrant medication misuse
 - High Risk
 - Urine appropriate screens at frequent office visits
 - Use less abusable formulations
 - » Long-acting, transdermal
 - Medium Risk
 - Random urine opioid screens
 - Reduce frequency of visits
 - Low risk
 - Monitor less frequently

Conclusions-1

- Chronic pain is common and under-treated
- Identify chronic pain patients who would most likely benefit from opioid therapy and use it responsibly
- Implement opioid treatment with a plan for ongoing monitoring
- Assess and monitor pain, side effects, and drug-related behaviors
- Prospectively choose opioid therapies commensurate with potential diversion risk
- Adjust dosage
- Manage side effects

Conclusions-2

- Need to monitor patients using opioids
 - Medical
 - Legal
- Monitor patients appropriately for opiate use
 - Urine screen as a preliminary indicator
 - Investigate further with serum opioid levels PRN
 - Correlate patient specific values with known pharmacokinetic data
- React appropriately to lab results
 - Do not jump to conclusions
 - Investigate appropriately with appropriate lab tests

Questions

www.paindr.com