

MRO Update 2008

1. Regulatory update
2. Testing for prescription drugs
3. Alternative specimens

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1. Regulatory Update

*Hell, there are no rules here –
we're trying to accomplish something!*

Thomas Edison

*Famous inventor...
not an MRO.*

1. Regulatory Update - DHHS

- Proposed alternative specimen test procedures issued in April 2004.
- Final revised procedures sent to OMB for clearance in 2006 but withdrawn without action.
- Final revisions to DHHS Guidelines on specimen validity testing took effect 11/04.
- Interim final rule from DOT to apply DHHS SVT procedures to DOT-mandated testing issued in late 2004.

Regulatory Update - DOT

- SVT procedures affecting "substitution criteria" and actions on very dilute specimens (creatinine 2-5) implemented in 2004
- Final rule on SVT and other revisions to Part 40 issued June 2008, e.g.,
 - Mandatory SVT for all DOT specimens
 - More explicit direct observation procedures
 - Direct observation for all reasonable suspicion and follow up tests
 - Procedures in case of consecutive invalids

Regulatory Update - USCG

- USCG is part of Homeland Security Department but still uses Part 40 Procedure for its drug testing
- Increased emphasis in recent years on serious marine incident testing;
 - Urine drug testing, saliva or breath alcohol testing;
 - SMI alcohol testing does not have to conform to Part 40 procedures; action can be taken on ASD result without requirement for confirmation EBT.

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USCG, cont.

- Clarification issued on return to duty requirements:
 - MRO return to work letter required;
 - MRO needs to coordinate with SAP and treatment provider before issuing letter.
- SAP return to duty process also required
- Periodic drug test required for license renewal;
 - Must be signed by DOT-qualified MRO;
 - The individual is often the "employer."

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Regulatory Update - NRC

- Substantially revised Fitness for Duty regulation in April 2008;
- In general, the new rule includes more detailed drug and alcohol testing procedures aligned with DHHS and DOT rules;
- Urine drug testing retained; including option for conducting on-site screening tests;
- Blood alcohol tests removed, except employee can request blood alcohol following a positive EBT result.

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NRC, cont.

- Changes in drug testing
 - Minimum specimen volume reduced from 60 to 30 mL;
 - Direct observation collections must be approved by DER or MRO and use the "bare body chest to knees" procedure; and
 - Dilute specimens may be tested to LOD for drugs.
- Refusal to test, including adulteration or substitution, is cause for a permanent bar from working in nuclear industry
- Can test for additional drugs beyond HHS 5

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NRC, cont.

- MRO may authorize alternative specimens for "shy bladder" and inability to provide saliva or breath specimens;
- MROs to make additional interpretation of return to duty tests to determine if positive is from new use or residual excretion;
- MROs can verify non-contact positives after one day; and
- MRO and other FFD program personnel (e.g., DER) are subject to NRC D&A tests.

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2. Testing for Prescription Drugs

- Trends
 - Positive test rates for illicit drugs are low;
 - Per surveys, increased prescription drug abuse;
 - Workplace drug testing is a mature market; to expand, sell new services.

Why test for drugs?

- 70's military programs to identify addicted soldiers and steer them to treatment
- '80s Federal workplace testing to deter use of illegal drugs
- '90s DOT and NRC testing for safety reasons
- '90s More drug testing by pain clinics and impaired professional monitoring
- 2008 For safety reasons, MSHA proposes
 - 5-panel plus benzos, barbs, and Rx opioids
 - MRO to determine if Rx used "as prescribed"

Why test for prescription drugs?

- Identification and referral to treatment?
- Deterrence (social engineering)?
- Safety?
- Better employees?

Which prescription drugs?

Q. Would you test for this drug?

Manufacturer's Warning:
When using this product do not use more than directed. Marked drowsiness may occur. Avoid alcoholic drinks. Alcohol, sedatives, and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery.

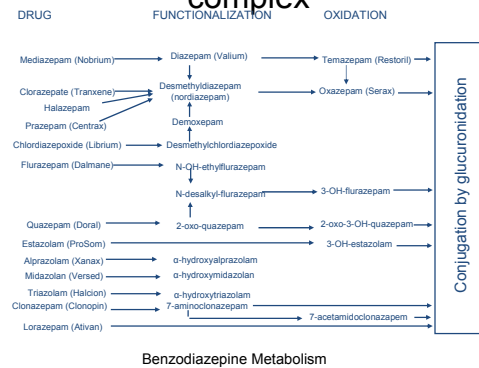
Which prescription drugs?

- >700 drugs in *PDR* with impairment warnings
- No evidence associating prescription drug use with accidents;
- Some evidence of impaired performance after 1st dose of benzos or Schedule II Rx opiates;
- FMCSA allows Rx drugs (except methadone and insulin) if the prescriber says so;
- Does controlling pain improve performance?
- Is this just about hydrocodone and oxycodone? Alcohol?

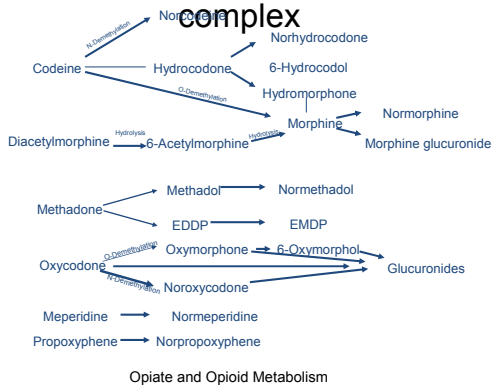
Interpretation can be complex

- Some metabolic pathways are complex
- Ambiguity about medicine that is:
 1. Borrowed
 2. Prescribed/purchased via Internet
 3. Foreign
 4. Old
 5. Taken for reason other than prescribed
 6. Detected at extremely high concentration
 7. Self-prescribed

Metabolic pathways can be complex



Metabolic pathways can be complex



Rx Drug review #1

- Borrowed. Jill tests positive for hydrocodone. Jill says she had a root canal and her roommate gave her a Vicodin.

MRO's Determination:

Positive Negative

Rx Drug review #1

- Borrowing medicine is:
 - Illegal;
 - Admitted to by >30% of those surveyed [Peterson et al. *J Womens Health*;2008;17:1-6, and Goldsworthy et al. *Amer J Public Health*. 2008;111:1167-70.]
- Is this an appropriate target for workplace testing?

Rx Drug review #2

- Prescribed/purchased via Internet. Alex takes Adderall. His doctor prescribed it 2 yrs ago for ADD. Alex started buying it over the Internet after he left for college. His preemployment test for a summer job is amphetamine-positive.

MRO's Determination:

Positive Negative

Rx Drug review #2

- DOT says medicine prescribed/obtained over the Internet does not involve a doctor-patient relationship and is not an acceptable explanation for a DOT positive drug test ;
- The Internet is a common source of drugs for legitimate and illegitimate purposes;
- Is this an appropriate target for workplace testing?

Rx Drug review #3

- Foreign. Jack tests positive for codeine. He says some clinic gave him codeine when he burst his ear drug scuba diving in Cancun two days before the test.

MRO's Determination:

Positive Negative

Rx Drug review #3

- FDA says ok to import controlled substance in personal use amount, i.e., up to 90 days;
- Some people purchase their drugs in Canada to save money;
- Hard to corroborate purchase and/or use of drugs abroad;
- Is this an appropriate target for workplace testing?

Rx Drug review #4

- Old. Jane tests positive for oxycodone. She has a 3-year-old prescription for Percocet.

MRO's Determination:

Positive Negative

Rx Drug review #4 – old medicine

- If a donor took a medicine from long ago, is it still legitimate?
- It's not illegal;
- Expiration dates refer to shelf life;
- Drug abusers use, don't store, drugs;
- Is one prescription a life-long free pass?
- What's in *your* medicine cabinet?
- Is this an appropriate target for workplace testing?

Rx Drug review #5

- Taken for reason other than prescribed. Jane tests positive for oxycodone. She has a 3-month old prescription for Percocet received after surgery, and took one recently for a headache.

MRO's Determination:

Positive Negative

Rx Drug review #5 – medicine taken for reasons other than prescribed

- No law prohibits a patient from taking a medicine for a different reason than prescribed;
- We may want to discourage self-medicating with prescription drugs, but should people lose jobs and careers over this?

Rx Drug review #6

- Detected at extremely high concentration. Jeff tests positive for morphine at 30,000 ng/mL. He has a prescription for MSIR and says he takes it as needed for chronic low back pain.

MRO's Determination:

Positive Negative

Rx Drug review #6 – high concentration(s)

- If the donor took more (or less!?) of the prescribed dose, is that a valid medical explanation?
- Workplace drug tests do not measure dose;
- MRO could accept the explanation and notify the employer of any safety concerns – but, how would the MRO if there are safety concerns?
- Is this an appropriate target for workplace testing?

Rx Drug review #7

- Self-prescribed. Dr. Jacobson tests positive for oxazepam. He presents his wife's Serax, which he prescribed. He says he took one before his redeye flight from Phoenix to Boston two days before he took the drug test.

MRO's Determination:

Positive Negative

Rx Drug review #7 – self-prescribed

- Mostly an issue for testing in healthcare settings;
- Some states discourage or prohibit self-prescribing;
- Is this an appropriate target for workplace testing?

Probability of “false positive”

- Bayes’ theorem and workplace drug testing.
Given,
 - low rates of drug abuse (true positives), and
 - possible “false positives,” then
 - many positives will be “false positive.”
- Of particular concern re: amphetamine, barbiturates, benzodiazepines, and codeine.

Testing for prescription drugs – consequences to employee

- Employers treat all positives the same;
- If MRO downgrades to “negative” and reports possible safety risk, how does one assess that risk?
- Do safety needs outweigh the intrusion on personal privacy?
- If treatment is mandated for return to work, what is the appropriate treatment in these situations?

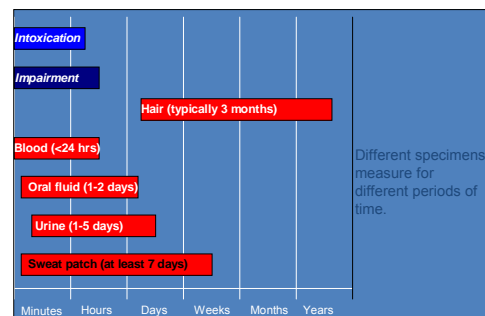
Testing for prescription drugs

- ✓ Chain of custody collections can reliably link the donor and specimen;
 - ✓ Laboratory analyses can fingerprint the drug;
 - ✗ MRO decisions can vary widely.
- Workplace testing for prescription drugs:
- Labs can do them;
 - Many employers (and some regulators) want them;
 - Service agents can sell them;
 - Cause collateral damage.

2. Alternative specimens

- Laws
 - Some state laws of yes/no type
 - Federal guidelines drafted in 2004
- Many employers already test hair and oral fluid

Comparisons between specimens – windows of detection



Comparisons between specimens – specimens and reasons for testing

Specimen	Pre-emp.	Random	Post-accident	Reasonable Suspicion	Return to Duty	Follow Up
Hair					*	
Oral Fluid						
Sweat						
Urine						

*Should wait at least 3 months since last use.

Hair and oral fluid are *worse* than urine because:

- Lower drug/metabolite concentrations than in urine;
- Specimen often used up in the analysis;
- Lack of standardization;
- No “SAMHSA certification” or external blind performance testing of laboratories;
- Limited knowledge base, service vendor experience, laboratory choice; and
- Uncertainties in interpretation.

Hair and oral fluid tests are *better* than urine because:

- Less prone to adulteration and substitution;
 - Collected under direct observation
 - Fewer products and techniques for cheating
- Hair has a longer window of detection; and
- Oral fluid has a shorter window of detection, and thus some consider it more closely tied to blood levels, i.e., to impairment.

Medical review of hair and oral fluid

- Accuracy of confirmed positive lab result is assumed
- MRO considers window of detection
- Limited information re:
 - Poppy seeds and opiate positive results
 - Vicks inhaler
 - Passive exposure
- Specimen validity testing varies between labs

Hair tests

- Passive exposure
- Poppy seeds
- Split tests, retests
- Specimen validity

Hair tests – passive exposure

- Environmental residues deposit on hair;
- Laboratory wash(es) are intended to remove them;
- Issue also addressed by reporting requirement for co-presence of metabolite to declare result “positive,” but:
 - Not all labs do this;
 - Environmental residues can contain “metabolites.”

Hair tests – poppy seeds

- Psychomedics' study: 10 people ate poppy seeds over 3 wks, highest morphine conc was 48 pg/mg (Hill V, et al. JAT. 2005;29:696-703)
- Given limited data, poppy seeds are a potential explanation for morphine (+)/codeine (-) hair tests near 200 pg/mg cutoff

Hair tests – split tests, retests

- Atypical
- Usually too little hair available for retest(s)
- Labs suggest collecting a second specimen for the second test, thus testing for approximately the same period of time

Hair tests – Specimen Validity

- Scope and interpretation of specimen validity tests varies between labs;
- Terminology (e.g., “invalid”) varies between labs; and
- Despite directly observed collection, specimens are not always valid.

Hair tests – substituted specimen

From: McCloy, Steven
To: mro@mail.rochester.edu
Sent: Tuesday, April 26, 2005 1:26 PM



A young man presented here this morning for a repeat hair sample. He insisted that there was no reason for his positive test the first time. He directed the medical assistant to a tuft of hair on his right scalp. She could not cut the sample because of a glue-like material at the base. He then directed her to a similar tuft in the right armpit. The texture of that hair differed from that of his left armpit. We took the samples from where he asked us to from the scalp and armpit locations. A picture of those samples is attached. We also took samples from the vertex area, where the hair seemed normal, and sent those samples to the lab.

Steven G. McCloy, MD
Providence, RI

Oral fluid tests

- Passive exposure
- Poppy seeds
- Specimen validity
- Window of detection

Oral fluid tests – passive exposure

- Exposure to marijuana smoke can cause THC to briefly appear in oral fluid;
- Non-issue if enough time elapses prior to collection. Ten minutes is usually enough. Sixty minutes erases all doubt.

Oral fluid tests – poppy seeds

- One published study. Opiate (+) results with 40 ng/mL cutoff for up to an hour after poppy seed ingestion. Peak concentration just over 200 ng/mL. (Rohrig T, Moore C. JAT. 2003;27:449-52)
- Poppy seeds are a potential explanation for morphine (+)/codeine (-) oral fluid tests

Oral fluid tests – specimen validity

- Test for IgG – present in human urine
- IgG thresholds vary by lab
- IgG in nonpreserved oral fluid is gone within a week. Preservative added at the time of collection counteracts this.

Oral fluid – window of detection

- Detection starts within minutes after dose;
- Detection ends in 24 hours or less after stopping;
- Closely parallels blood concentrations; thus, more likely to parallel impairment.

What should you collect?

"I saw three of my colleagues sitting in a car parked outside the hotel during lunch break at the seminar. I think they were smoking dope, but they deny it..."

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What should you collect?

"John's performance has been decreasing for some time now. He hasn't identified any problems in our discussion, but I'm concerned..."

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What should you collect?

"Ed is acting crazy today. He is more agitated and arguing more than I have ever seen him before..."

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What should you collect?

"We're missing some painkillers from the meds cabinet. Three employees had access, and the shortage occurred over the past few hours ..."

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What should you collect?

"Tom is returning to duty following a 6-week absence for drug rehabilitation. He also has a history of alcohol abuse ..."

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