COMPLIANCE MONITORING FOR CONTROLLED SUBSTANCES

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OBJECTIVES

- Update on Opioid and other drug overdose epidemic
- Discuss need for compliance monitoring for all controlled substance prescriptions
- Review drug test options and rationale for testing

UPDATE ON DRUG OVERDOSE EPIDEMIC

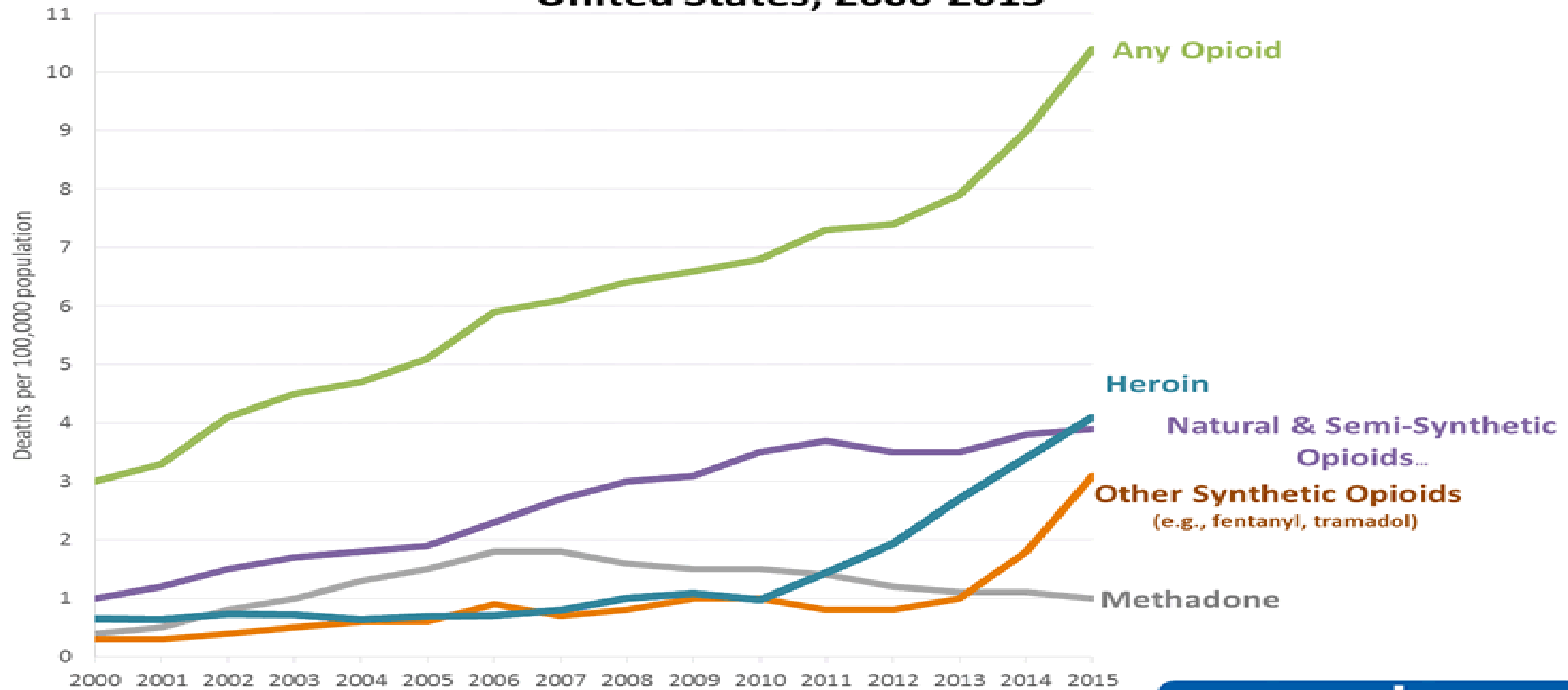
- 72,000 drug overdose deaths in 2017
- Increased funding for treatment
- Increased, but still severely lacking, access
  - Need for Medicaid expansion in all states (are you listening Texas and Florida?)
  - Reducing Stigma and integrating care into primary care setting
  - Access at point of need (ER, Community Health Centers, Primary care)

OPIOID OVERDOSE EPIDEMIC

- Opioids – prescription and illicit – are the main driver of drug overdose deaths.
- 42,249 opioid involved deaths in 2016
- 33,091 opioid involved deaths in 2015
- 28,647 opioid involved deaths in 2014
  - 27.7% increase in 1 year.
  - 47.5% increase in 2 years.
  - This is on top of the widely reported 400% increase from 1999-2015
- www.cdc.gov

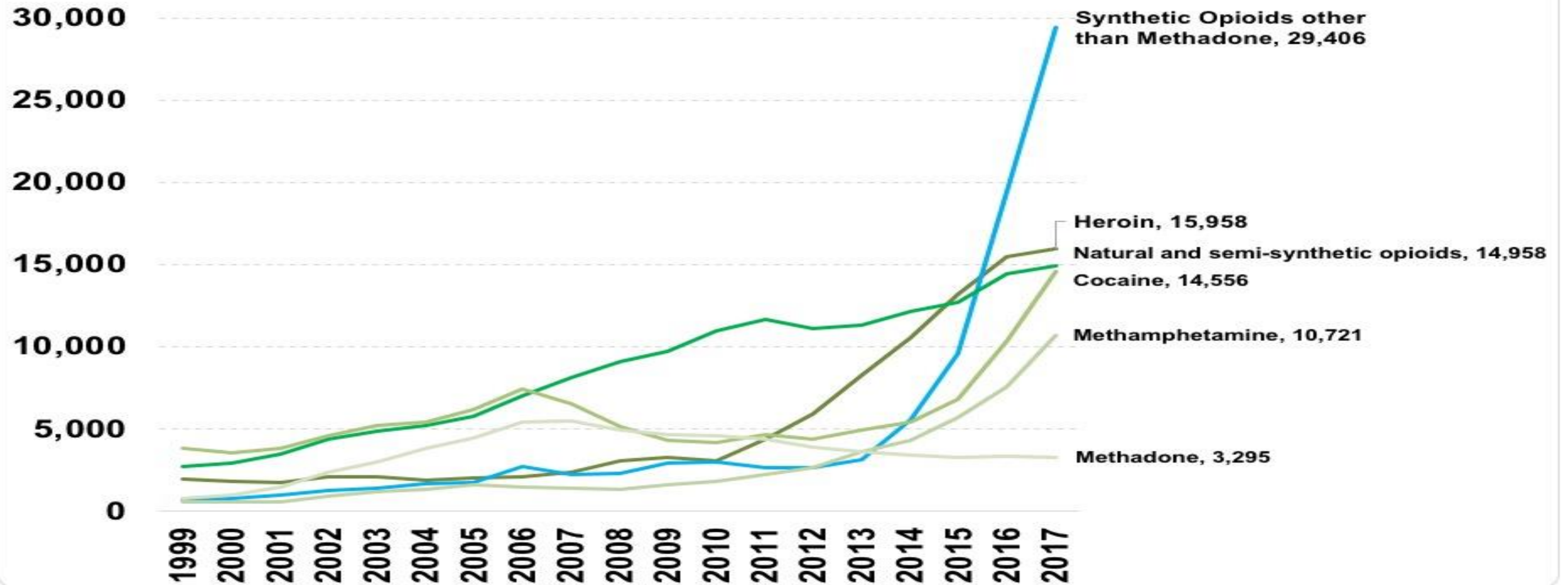
MORE STATISTICS

- 116 deaths per day in 2016 due to opioids
- Most common cause of accidental death
- More deaths in 2015-2016 alone than from Vietnam War
  - 75,340 vs 58,220 (U.S. military fatal casualties)
- As many as 1 in 4 people who receive prescription opioids long term for noncancer pain in primary care settings struggles with addiction.
  - Despite the above, only 2% of physicians in the US have taken steps to provide office based care for opioid use disorder patients


Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2015
Deaths per 100,000 population
0
1
2
3
4
5
6
7
8
9
10
11
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
Any Opioid
Heroin
Natural & Semi-Synthetic Opioids...
Other Synthetic Opioids
(e.g., fentanyl, tramadol)
Methadone
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/.
www.cdc.gov
Your Source for Credible Health Information

DON'T FORGET ABOUT ADHD MEDS

- Reduced supply and prescribing of opioids is a good thing, however there is now …
- Increased use of methamphetamine and cocaine



Drugs Involved in U.S. Overdose Deaths, 1999 to 2017
30,000
25,000
20,000
15,000
10,000
5,000
0
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
Synthetic Opioids other than Methadone, 29,406
Heroin, 15,958
Natural and semi-synthetic opioids, 14,958
Cocaine, 14,556
Methamphetamine, 10,721
Methadone, 3,295

RISK ASSESSMENT AND COMPLIANCE MONITORING

- CDC opioid prescribing guidelines are a good start
  - Assess risk vs. benefit of prescribing; especially to children, adolescents and young adults
  - In my opinion opioid risk will almost always outweigh benefit in children and adolescents.
- use DIRE score or opioid risk tool
- MAPS Reports
- Drug testing
- Need for controlled substance agreements

CHRONIC DISEASE MODEL

- Substance Use Disorder is a disease, not a choice.
- Common addictions
  - Alcohol
  - Nicotine
  - Opioids
  - Benzodiazepines
  - Stimulants
  - Cocaine
  - Marijuana
  - Overeating

OBJECTIVE INFORMATION NEEDED

- For HTN patients we check blood pressures
- For diabetic patients we check blood sugars
- For pain patients …
  - We get a number from 1 to 10!

NEED FOR A BETTER SYSTEM

- The Institute of Medicine (IOM) has noted that health policy and reimbursement processes need to be improved.
  - Improved outcomes will come more readily from improving the system than by trying to improve the skills of the practitioners.
    - Chapter 31, Principles of Addiction Medicine, The Essentials. 2011.

NEED FOR DRUG TESTING

- If you don't check you will have no idea.
- Many controlled substances that are prescribed are:
  - Taken incorrectly (snorted, injected, etc.)
  - Shared
  - Sold
- Many substances are available for illicit use
  - Other people's prescription
  - Illicits (Methamphetamine, cocaine, heroin, etc.)

NEED FOR OBJECTIVE DATA WHEN PRESCRIBING CONTROLLED SUBSTANCES

- Ignorance is not bliss.
- Review of 725,679 UDS from individuals 50 and over:
  - 28.1% of UDS contained non-prescribed drug
  - 31.8% of UDS where prescribed drug was not detected
  - 7.6% contained illicit drug
    - R. Frei. Study: Potential Medication Misuse in Older Pain Patients. Pain Medicine News. Aug 2012.10-8:1,16.

DRUG TESTING

- Qualitative ("urine drug screen" or saliva test)
  - Test either positive or negative
  - Immunoassay
- Quantitative (send out)
  - Test measures concentration of drug
  - GC/MS or LC/MS
  - Urine, Blood or Saliva
- In office testing
  - Urine Drug Test: Witnessed or unwitnessed
  - Saliva Test: Witnessed (point of care or send out)
  - Breathalyzer (Alcohol)

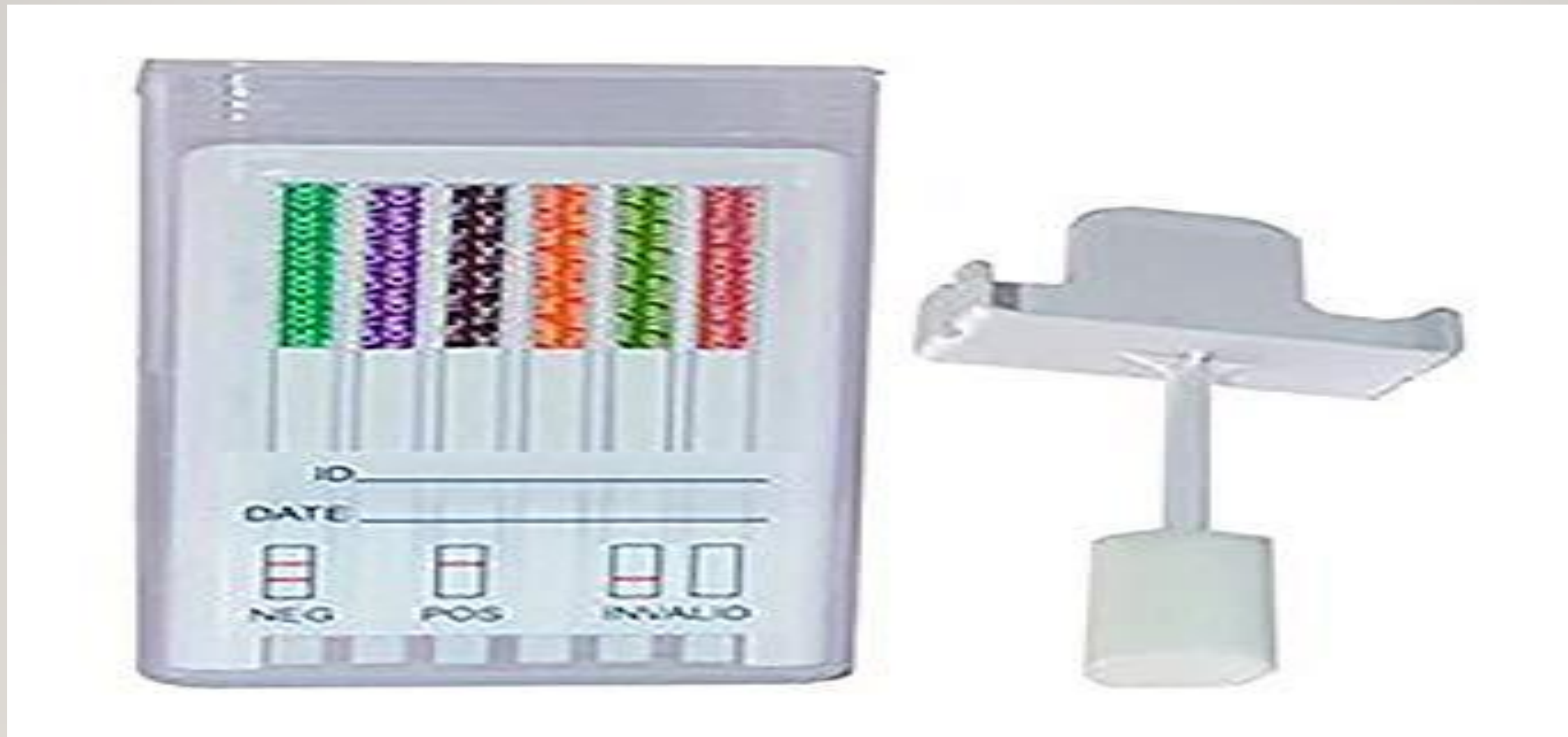
IN OFFICE TESTING

- Urine Test: Immunoassay
  - Inexpensive. Results at time of care!
  - Detection Window: 3-10 days or more
    - Ameritox Medication Monitoring Solutions
  - Qualitative
- Oral Swab Test: Saliva test
  - Point of care or send out.
  - Detection Window: 1-4 days
  - Qualitative or Quantitative

CLIA Waived
Drug Test Cup
Authorized Personnel Only
Remove Label for Results

Single -Drug
Screen Test
C
T

POINT OF CARE SALIVA TEST



ELEMENT
WAIT START
0.020
BAC
BACtrack

MEDICAL NECESSITY OF TEST

- Need to be able to justify reason for doing specific test
  - Why was the test ordered?
  - What results were obtained?
  - What (if any) changes in clinical course were made as a result of these test results?
- Failure to ask, answer and document these elements of medical necessity may eave clinician open to medicolegal exposure.
    - Urine Drug Testing in Clinical Practice, Edition 6, Center for Independent Healthcare Education, 2017.

PROS AND CONS

- Pros of In Office Urine Drug Testing
  - Low Cost, instant results
- Cons of In Office Urine Drug Testing
  - Higher detection limit, not definitive
  - False positives and negatives
- Pros of send out urine or saliva test
  - Lower detection limit, definitive.
- Cons of send out test
  - Cost can be very high and medical necessity comes in to question
  - Test for too many drugs greatly increases cost

MORE PROS AND CONS

- Urine is susceptible to adulteration or substitution by the donor
  - Witnessing test can mitigate this risk
- Saliva and blood are observed collections
- Saliva and blood detect recently taken substances
- Blood is the preferred specimen for correlating signs and symptoms with drug concentrations in real time

POINT OF CARE/UDS/IMMUNOASSAY

- Cost for 12 panel, CLIA waived specimen cup is $3-6
- Re-imbursement
  - Medicaid: $0-11
  - Commercial or Medicare: about $12-15
- CPT Code: 80305

IMMUNOASSAY

- Compared to quantitative tests are more likely to give false test results due to lack of sensitivity and specificity.
- A false positive occurs when the screen is positive but the drug is <u>not</u> actually present,
  - False positives often occur when drugs present in the sample are chemically related to the target drug.
- A false negative occurs when the drug <u>is</u> actually present but the screen is negative.
  - False negatives often occur because screening cutoff levels are unable to detect positive samples at low concentration levels.

FALSE POSITIVE AND NEGATIVE EXAMPLES WITH UDS

- Sertraline can cause false positive
- Clonazepam not detected as a benzodiazepine; false negative
- Methamphetamine false positive with cold medications
- When in doubt send out.
- Document patient reaction to results.
  - Patient will either admit to use or deny.
  - Recommend follow-up in 1 week to review confirmation

RATIONALE FOR SALIVA TESTING

- **Eliminate Adulteration**
- Urine testing is incredibly easy to cheat, beat, or otherwise falsify. Such techniques involve adulterants that interfere with the test results or take advantage of the opportunity to cheat due to the privacy required when collecting a urine sample which is not the case with oral fluid.
- All oral fluid drug tests are administered under supervised observation, making concealed tampering with the test sample virtually impossible. We have tested a wide range of adulterants that are available on the market and have not found any that can interfere with an oral fluid test when properly conducted.
- **How do you cheat or beat a saliva drug test? The short answer is: you can't; if it is done correctly.**

Source: Forensic Fluids Laboratories

SEND OUT DRUG TESTS

- Send out urine specimen
  - Obtained witnessed or unwitnessed?
- Used for Confirmation of urine drug screen.
- Used for quantitative testing
- Much More expensive
- Gas Spectrometry/Mass Spectrometry

CONFIRMATORY TESTING

- Definitive testing is commonly performed to "confirm" positive screening results, negative screening results for expected drugs or to test for drugs that do not offer screening options.
- Confirmation testing uses highly specific and sensitive analytical methodology such as LC-MS (for "liquid chromatography–mass spectrometry") or GC-MS (for "gas chromatography-mass spectrometry").
- These instruments provide a molecular fingerprint of the drugs that are present in the sample and provide corresponding measured drug concentrations with detection limits much lower than screening assays. Compared to screening, confirmation testing has many advantages.
  - http://cordantsolutions.com/getting-answer-screening-vs-confirmation-testing/

WHICH TYPE OF TESTING METHOD IS BEST?

- It depends on what you're testing for and why. If a doctor only needs a quick yes or no about a low-risk patient, a screen test might be considered sufficient.
- A chronic pain patient who continues to complain about pain levels despite her current prescriptions probably needs more definitive testing to try to determine what's really going on.
- Screening and confirmation testing in combination is required for cases in the criminal justice system, because a positive preliminary result must be confirmed using a different method than the initial test.
  - This method valuable for office based compliance procedure as well

GOAL OF TESTING

- Compliance Monitoring vs tool to kick patients out of your clinic
- How to respond to inconsistent test when you start actually looking
- Increase frequency of visits and re-establish "ground rules"
- Harm reduction and risk vs. benefit discussions need to be considered
- Medication changes may be needed
  - Adderall XR, Concerta or Vyvanse vs. short acting stimulants
  - Buprenorphine maintenance treatment if patient found to have opioid use disorder and has inability to properly take opioid pain medications
  - Discontinue benzodiazepines and focus on non-narcotic medications (SSRIs, mood stabilizers, Tri-cyclics, other)

HARM REDUCTION APPROACH (REASON TO NOT KICK PEOPLE OUT OF YOUR CLINIC!)

- Harm reduction benefits people who use drugs, their families and the community.
  - Is not mutually exclusive of efforts to promote abstinence.
- Harm reduction reminds clinicians of the supreme importance of keeping drug users alive and avoiding irreversible damage.
  - Chapter 30, Principles of Addiction Medicine, The Essentials. 2011.

Compliance Monitoring Policy - Word

David Best

File Home Insert Design Layout References Mailings Review View Help Tell me what you want to do Share

Buprenorphine Maintenance Treatment Compliance

Inconsistent Drug Screen Procedure

Goal: This will provide consistency in dealing with patients struggling with medication compliance.

1.Inconsistent drug screen results in conformation test and at least weekly witnessed test. (for a minimum of two weeks)

2.Only one week prescription given at a time.

3.Go to two weeks after two consecutive consistent tests. (only two week prescription given)

4.After three consecutive consistent tests at every two weeks, then go to monthly.

5.Patient agrees to respond to clinic request for random drug testing. Expectation is that test be performed within 24 hours.

6.Patient has responsibility to keep Best Medical Services aware of current address, phone and email.

Patient Name ____________________ Signature ____________________

Date ____________________

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QUESTIONS

- Drug test scenario questions?
- Clinic challenge questions?

THANK YOU

- **“A great many people think they are thinking when they are merely rearranging their prejudices.”**
- **“I will act as if what I do makes a difference.”**
-

William James
(1842-1910)