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Urine Drug Testing in Addiction Medicine

A Paradigm To Improve Outcomes and Reduce Costs

Andrea G. Barthwell, M.D., FASAM
Director, Two Dreams
(@DrAGB)

Michael C. Barnes, Esq.
Executive Director, Center for Lawful Access and Abuse Deterrence (CLAAD)
(@MCBtweets)

Disclosures

Andrea G. Barthwell, M.D., FASAM

- Alvee Laboratories: Consultant
- Braeburn Pharmaceuticals: Consultant
- Caron Foundation: Collaborator
- EMGlobal LLC: Partner
- Encounter Medical Group, PC: Medical Director
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Preview

- Terminology
- Policy Landscape
- Responses
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  - Government Enforcement
    - Legal Bases
    - Factual Bases
- Policy Recommendations
- Practice Recommendations for Addiction Medicine
  - General
    - Medication misuse and abuse
    - Other substance use
  - Test Selection and Frequency
    - Diagnosis
    - Active Treatment
    - Chronic Care
- Conclusion

Terminology

- “Substance use” herein refers to medication misuse and abuse, and other substance and alcohol use (tobacco excluded)

Preliminary	Definitive
Immunoassay	Chromatography – mass spectrometry
Presumptive	Confirmatory
Qualitative	Quantitative
Point-of-care / in-office / lab-based	In-office / lab-based
Screen	Confirmation
Semi-quantitative / quasi-quantitative	Absolute level, creatinine corrected
Simple test (cup / strip / dip / cassette)	Complex test
Class or specific drug identification	Specific drug identification

Policy Landscape

- 21.5 million Americans with SUDs; 90 percent untreated[1]
- 43,982 people die every year of overdoses (120 per day)[2]
- 16,235 Rx opioid-related deaths + 8,257 heroin-related deaths = 24,492 total year (67 per day)[2]
- Stigma affecting people with pain and addiction
  - Social
  - Structural

1. Briefing on Substance Use Treatment and Recovery in the United States Executive Summary, Partners for Recovery, Substance use and Mental Health Services Administration, available at http://partnersforrecovery.samhsa.gov/docs/Briefing_Substance_Use_Treatment.pdf.
2. Centers for Disease Control and Prevention. National Vital Statistics System mortality data, 2015, available at http://www.cdc.gov/nchs/deaths.htm.

Policy Landscape

- Confusion w/ forensic model and lack of knowledge about therapeutic uses
- Backlash against testing for substance use
  - Predominantly based upon **profiling** and **suspicion**
  - Associated with stripping away rights and benefits
    - Treatment and medications
    - Participation in sports and extracurricular activities
    - Public assistance
    - Child custody
  - Injustices exacerbated by erroneous results
- National debates
  - Mandatory testing as part of safer-prescribing standards
  - Drug testing for public benefits (cutting a hole in the social safety net vs. adding another layer of protection)

Policy Landscape

- Lack of understanding
  - Methodologies' benefits, shortcomings, and appropriate uses
  - Frequency of testing
  - Confusion between medical practice areas (*e.g.*, pain and addiction)
- Significant UDT expenditures in health care
  - Medicare paid $457 million for 16 million tests (2012)
  - Sales at UDT labs reached an estimated $2 billion (2013)
- Unethical practitioners have seized on the surge in spending

Payer Response:
Ill-Advised Cost-Saving Measures

- Restrictions on coverage
  - BCBS of Alabama proposed to deny coverage of *all* definitive testing
  - Medicaid per-member limits on testing
    - GA: 25 per year
    - NJ: 24 per year
    - NY: 104 per year
    - VT: 96 per year
- UDT costs used to argue against the use of opioids (methadone and buprenorphine) in medication-assisted treatment

Government Response: Enforcement (Legal Bases)

- Aggressive government action to reduce healthcare fraud and abuse
- $4.3 billion recovered (2013) under various federal and state laws
  - **Stark law**: prohibits referrals of Medicare/Medicaid patients if physician or family member has financial interest
  - **Anti-kickback statute**: prohibits exchange of value to induce/reward a referral of federal health care program business
  - **Criminal health care fraud statute**: prohibits schemes to defraud health benefit programs, including private plans
  - **False Claims Act**: prohibits claims for payment/approval to gov't known to be false
  - **Bank, mail, wire fraud**: prohibits schemes to defraud using a financial institution, postal service, or wire

Government Response: Enforcement (Factual Bases)

- Non-compliant physician-owned or family-owned labs*
  - Can include management firms
    - Physician owns firm
    - Firm owns lab
  - Can include requiring employees to refer
- Leasing
  - Office space to lab
  - Lab equipment to physician

*Stark Law exceptions are complex and require strict compliance, *e.g.,* in-office ancillary services exception: group practice can refer ancillary services if three tests are met:

- Practitioner test (who furnishes the services)
- Location test
- Billing test

Michael C. Barnes & Stacey L. Worthy, *Evaluating Motives: Two Simple Tests to Identify and Avoid Entanglement in Legally Dubious Urine Drug Testing Schemes*, 11 J. OPIOID MANAG. 89 (2015).

Government Response: Enforcement (Factual Bases)

- Clinical trials and registry arrangements: paying to submit patient data, answer patient questions, or review registry report
- Free supplies or services to a referral source, including labs reviewing doctors' orders and determining whether there is a need for UDT

Michael C. Barnes & Stacey L. Worthy, *Evaluating Motives: Two Simple Tests to Identify and Avoid Entanglement in Legally Dubious Urine Drug Testing Schemes*, 11 J. OPIOID MANAG. 89 (2015).

Government Response: Enforcement (Factual Bases)

- Improper markups, coding, and billing
  - Interpretation of results that a lab performed but for which the practitioner bills
  - Using codes to circumnavigate prohibitions against more expensive tests
- Medically unnecessary tests, including not using results to assess treatment plan

Michael C. Barnes & Stacey L. Worthy, *Evaluating Motives: Two Simple Tests to Identify and Avoid Entanglement in Legally Dubious Urine Drug Testing Schemes*, 11 J. OPIOID MANAG. 89 (2015).

Evaluating UDT Proposals

- Does the patient's health depend on the service?
- Will my decisions be influenced by the potential for profit?
- Does the proposal appear to avoid the spirit of the law while possibly complying with the letter of the law?
  - Circumvention schemes are disfavored if not expressly illegal
  - Do you want to serve as the test case?

Policy Recommendations

- Screenings for substance use in most health care settings
  - Distinguish screening (history, physical, and interview) from UDT
  - **Eliminate** profiling and suspicion-based model
- Expand *non-punitive* interventions
  - Referrals to higher levels of treatment
  - Greater social supports (strengthening the safety net)
- Educate the uninformed
  - To identify and avoid participating in legally dubious UDT schemes
  - To follow best practices
- Isolate and support enforcement against bad actors

Policy Recommendations

- Control costs by advancing ethics, efficiency, and transparency
  - Eliminate wasteful practices, including duplicative model
  - Use methodologies appropriately
  - Apply reason to frequency
  - Document medical necessity, the bases of UDT selections, and clinical responses to results
- Coverage policies must reflect best practices and control costs
- Help patients appeal unjust denials of care

Addiction Treatment Context

- Guidelines for testing for substance use in pain management are well established
- Pain guidelines are inadequate for addiction medicine
  - Do not address overlap of people in pain who also have substance use disorders (SUDs)
  - Do not support testing frequently enough

Test Selection

- Individualized testing based on clinical evaluation (no blanket orders)
  - Patient history
  - Prescribed medications
  - Trends
    - Local community
    - Patient population
  - Circumstantial considerations, *e.g.*, introduction of a substance into a treatment facility
- Document in medical record
  - Bases for decisions
  - Medical response to result

Test Selection

- Utilize preliminary tests when rapid result is necessary
  - Point-of-care/cup test
  - Rapidity and cost savings are lost if sample must be sent to lab
- No “confirmation” of preliminary w/ preliminary
- Utilize definitive tests when accurate information is necessary (and not available using preliminary)
- Sample integrity checks can help identify deceptive behaviors

Screening & Diagnosis

- Early diagnosis can lead to improved outcomes
- Universal & routine clinical *screening* (distinguish from testing)
  - Primary care
  - Urgent care
  - Pain
  - Psychiatry
  - Obstetrics
  - Peri-operative
  - Addiction
- Conduct a H&P and interview
- Add testing *as necessary*

Screening & Diagnosis

- Review patients for substance use during first consult and periodically thereafter
- Clinical considerations in choosing when and how to test
  - Indicators of risk (*e.g.*, family history or legitimate Rx for a controlled substance)
  - Evidence of use (*e.g.*, self report or needle marks)
  - Information necessary to direct care
  - Cost constraints
- Substance use alone is insufficient to substantiate presence of SUD

Screening & Diagnosis

If.. .	Then…
Patient exhibits no indicators of risk	Preliminary or forego testing
Patient exhibits one or more indicators of risk	Definitive
Patient exhibits evidence of use	Definitive
Definitive test results indicate abstinence	Test again if risk or presentation changes; test no more than once per year if no change
Definitive results indicate use	Intervene and establish a treatment plan

Active Treatment

- Test on regular basis and at random intervals
- Frequency influenced by stage of care
  - ≤30 days
  - 31 – 90 days
  - 91 days – 2 years
- Give same quality of care, regardless of whether patient is in MAT
- If results show use after period of abstinence, resume testing schedule for abstinence of $\leq$ 30 days
- May need to intensify treatment

Active Treatment

Duration of abstinence	Frequency of testing
≤30 days	Once per week* One in every three should be definitive quantitative
31 to 90 days	Once per week* No more than three definitive quantitative per month
91 days to 2 years	One to three times per month No more than three definitive quantitative per quarter

*Testing may be conducted up to three times per week, based on clinical considerations.

Chronic Care Management

- Patients with >2 years of abstinence
  - Often self-directed in recovery
  - Testing is less prescriptive and may be driven by individual's self-identified need
- Test on regular basis & at random intervals
- If test is positive, establish an active treatment plan appropriate to recent use

Chronic Care Management

Duration of abstinence	Frequency of testing
2 to 5 years	Definitive no more than once per year
>5 years	Definitive based on clinical considerations

Summary

- Decisions should be individualized
- Preliminary (point-of-care/cup) for rapid result
- Definitive for highest accuracy and thoroughness
- Document in medical record
  - Bases for decisions
  - Medical response to result

Conclusion

- Thanks to NAADAC and sponsors
- Contact
  - LinkedIn.com/in/DrAndreaBarthwell
  - @DrAGB
  - LinkedIn.com/in/MichaelCBarnes
  - @MCBtweets
- Thank you
- Questions and discussion