Urine Drug Testing in Addiction Medicine
A Paradigm To Improve Outcomes and Reduce Costs

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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
- GW Pharmaceuticals: Former Consultant
- Millennium Laboratories: Consultant
- The Parents Academy: Founder
- Treatment Partners LLC: Managing Partner

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Preview

• Terminology
• Policy Landscape
• Responses
  • Payer Restrictions
  • 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)

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

• 21.5 million Americans with SUDs; 90 percent untreated¹
• 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

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

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

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
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

<table>
<thead>
<tr>
<th>If...</th>
<th>Then...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient exhibits no indicators of risk</td>
<td>Preliminary or forego testing</td>
</tr>
<tr>
<td>Patient exhibits one or more indicators of risk</td>
<td>Definitive</td>
</tr>
<tr>
<td>Patient exhibits evidence of use</td>
<td>Definitive</td>
</tr>
<tr>
<td>Definitive test results indicate abstinence</td>
<td>Test again if risk or presentation changes; test no more than once per year if no change</td>
</tr>
<tr>
<td>Definitive results indicate use</td>
<td>Intervene and establish a treatment plan</td>
</tr>
</tbody>
</table>
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 ≤ 30 days
- May need to intensify treatment
# Active Treatment

<table>
<thead>
<tr>
<th>Duration of abstinence</th>
<th>Frequency of testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤30 days</td>
<td>Once per week*</td>
</tr>
<tr>
<td></td>
<td>One in every three should be definitive quantitative</td>
</tr>
<tr>
<td>31 to 90 days</td>
<td>Once per week*</td>
</tr>
<tr>
<td></td>
<td>No more than three definitive quantitative per month</td>
</tr>
<tr>
<td>91 days to 2 years</td>
<td>One to three times per month</td>
</tr>
<tr>
<td></td>
<td>No more than three definitive quantitative per quarter</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Duration of abstinence</th>
<th>Frequency of testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 to 5 years</td>
<td>Definitive no more than once per year</td>
</tr>
<tr>
<td>&gt;5 years</td>
<td>Definitive based on clinical considerations</td>
</tr>
</tbody>
</table>
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

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  • LinkedIn.com/in/DrAndreaBarthwell
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  • LinkedIn.com/in/MichaelCBarnes
  • @MCBtweets

• Thank you

• Questions and discussion