Medication adherence testing

For patients prescribed controlled substances

Presented by:

Dr Jeff Gudin, Board-Certified Pain Specialist, Senior Medical Consultant Dr Jack Kain, Director-Medical Science Liaison, Drug Monitoring & Toxicology

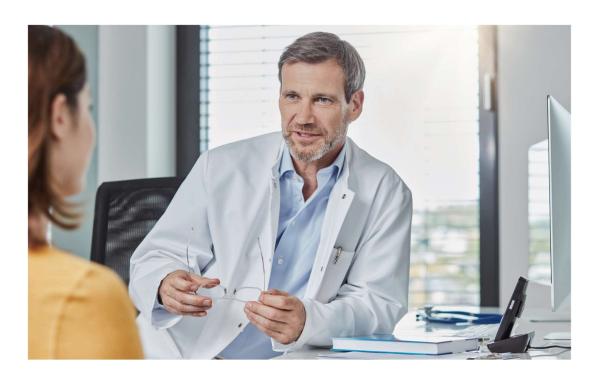
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Clinical Drug Monitoring is a critical tool to help combat the evolving drug misuse epidemic

Monitoring patients for medication adherence can help:

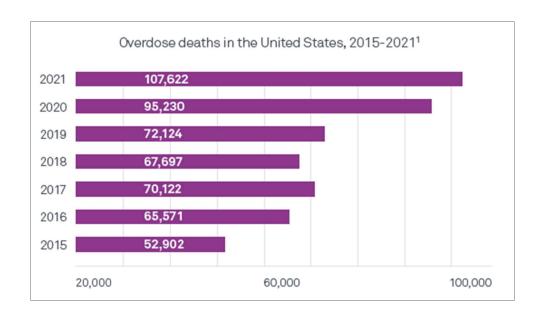
- Identify prescribed and nonprescribed substances
- Prevent harmful drug interactions
- Assist in the early detection and prevention of substance use disorder





Drug overdose deaths have been increasing

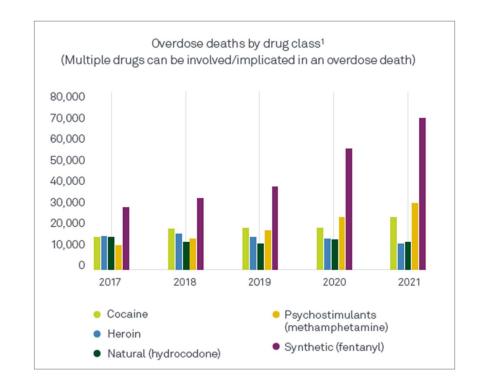
- Nearly 108,000 people died of drug overdoses in 2021, and about twothirds of those deaths involved fentanyl or another synthetic opioid¹
- That's an increase of nearly 50% vs the same time period in 2019, pre– COVID-19 pandemic





Worsening drug misuse epidemic

- Overdose deaths involving synthetic opioids, including fentanyl, psychostimulants such as methamphetamine, and cocaine all increased between 2020 and 2021²
- These troubling data are compounded by new warnings from the DEA about a sharp increase in fake prescription pills containing fentanyl and methamphetamine³
- The COVID-19 pandemic has worsened drug misuse and the overdose death rate,⁴ and the CDC is calling for implementing strategies to combat this serious public health issue⁵





There has been a significant increase in patients suffering from mental health conditions in the United States

Majority of treatment / prescribing is coming from PCPs/NPs/PAs

State of mental health in America

1 in 4



people over 18 years of age are prescribed mental health medications⁶ representing

nearly 50 million Americans

20%

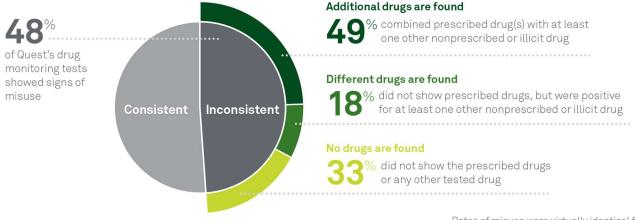
The average number of people taking prescription mental health medication has gone up by nearly 20% in the last year⁶

Drug testing is a critical tool to help monitor medication adherence for these controlled substances



Data from Quest Diagnostics Health Trends® report show that nearly half of patients misuse their medications⁷

Misuse remains high across sexes and among all age groups



Rates of misuse were virtually identical for males and females

↑48.7 male misuse rate

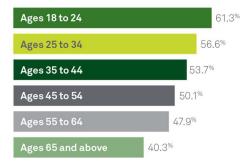
‡47.0% female misuse rat

Misuse rates were higher for men and women of reproductive age (15-45 years)

56.2 male misuse rate



Misuse remains high across all age groups





Drug misuse continues to be a leading public health issue. This may be attributed to a number of factors, including patients who:

- Don't follow prescription instructions
- Underestimate the addictiveness of pain medication and other controlled substances
- Assume prescriptions are safe under all circumstances
- Share prescription drugs with friends or family
- Allow other people access to medications by failing to secure them

- Increase dosage without a physician's approval
- Forget to notify their doctor of prescriptions from other healthcare providers
- Fail to consider the dangers of dangerous drug combinations when using prescriptions and/or illicit drugs
- Turn to counterfeit pills or purchase prescription drugs outside of a licensed pharmacy



The important role of Drug Monitoring

Using drug testing to monitor medication adherence can help to:

- Identify prescription drug use or non-use (medication adherence)
- Detect use of illicit substances
- Complement Prescription Drug Monitoring Programs (PDMPs) to provide a fuller picture of patient status
- Identify potential drug-drug interactions and harmful poly-substance use
- Identify drug diversion

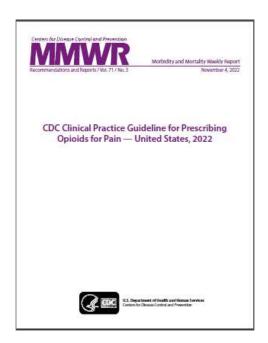
- Meet expectations of medical boards and regulatory agencies
- Maintain patient access to prescription therapies
- Mitigate risk and keep patients and communities safe while protecting clinician practices
- Provide insights to inform early detection of drug misuse leading to prevention, intervention, and treatment

Clinical Drug Testing is the only objective tool available to determine which substances patients are actually taking



Drug testing is supported by guidelines

- —The CDC issues new clinical practice guidelines for prescribing opioids for pain in November 2022
- Before starting opioids and periodically (at least annually) during opioid therapy, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances
- Additional considerations:
 - Clinicians, practices, and health systems should aim to minimize bias in testing and should not apply this recommendation differentially. Practice policies regarding testing and frequency can help minimize bias
 - If unexpected results from toxicology screening are not explained, a confirmatory test should be performed on the same sample using a method selective enough to differentiate specific opioids and metabolites
 - Limited toxicology screening can be performed with a relatively inexpensive presumptive immunoassay panel. Confirmatory testing should be used when toxicology results will inform decisions with major clinical or nonclinical implications for the patient



CDC Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 20228



Implementing a responsible drug monitoring protocol

What steps to take?



Considerations for implementing a responsible testing protocol

Key elements of a drug monitoring protocol when prescribing controlled medications⁹:

- 1. Establish which individuals to monitor
- 2. Evaluate patient risk factors using validated tools. Examples include
 - Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R)
 - Opioid Risk Tool (ORT)
- 3. Review the state PDMP
- 4. Create written treatment agreements

- 5. Discuss the risks and benefits of therapy
- 6. Review patient responsibilities
- 7. Conduct baseline testing
- Conduct periodic, risk-based drug monitoring



Initiating testing

Who to test?

Consider drug testing all patients:

- Who are prescribed controlled substances or scheduled drugs as well as those suspected of or at risk for drug misuse disorders
- With mental health conditions including anxiety, depression, schizophrenia
- With substance use disorder
- With medication-assisted treatment
- With chronic pain
- With ADHD



Initiating testing

How to test?

Best practices include presumptive testing and confirmation of positives with definitive testing. This helps minimize over-testing while providing the right level of information needed to make informed decisions

Presumptive drug testing

- Includes rapid point-of-care (POC) devices as well as more sensitive laboratory immunoassays
- While presumptive testing provides rapid and inexpensive qualitative results, it often has lower sensitivity, which may lead to false-negative and false-positive results

Definitive drug testing

- Uses highly complex laboratory instruments to identify and quantify prescription medications, illicit substances, and specific parent drugs and their metabolites often missed by POC testing
- Definitive testing provides greater sensitivity, can confirm or refute presumptive test results, and reduces the occurrence of falsepositive/false-negative results



Completing the protocol

How to determine which drugs to test

Drugs should be selected based on patient history, treatment plan, health condition, and community usage. Common drug class tests may include but are not limited to the following⁹

- Alcohol metabolites
- Amphetamines
- Barbiturates
- Benzodiazepines
- Buprenorphine
- Cocaine

- Fentanyl
- Heroin
- Marijuana
- Methadone
- Opiates
- Oxycodone





Completing the protocol (continued)

Determining frequency of testing



How to determine frequency of testing

Identify patients at high risk for opioid abuse, misuse, or diversion for whom more intensive monitoring may be appropriate⁹

- Validated risk assessment and stratification
- Clinician's documented medical necessity
- Patient history, clinical presentation, and/or community usage



Conclusions

- Clinicians who prescribe controlled substances must develop risk management strategies including skill sets in drug testing as well as mitigation of drug misuse and abuse
- Drug monitoring is standard of care when managing patients on controlled substances
- Communicate with your laboratories and toxicologists to ensure proper test selection and interpretation of test results
 - 1.877.40.RX.TOX (1.877.407.9869)
- More structured therapy with comprehensive monitoring plans can help patients adhere to treatment regimens, especially those who are higher risk or display aberrant behaviors



Thank you for joining us today!



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