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Ask The Pharmacist: Risk Assessment for Opioid Use Disorder (OUD)

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How does genetic testing enhance risk assessment for opioid use disorder (OUD)?

On December 19, 2023, the [U.S. Food and Drug Administration](#) (FDA) approved the first test ([AvertD](#)) that uses DNA in assessing whether certain individuals may have an elevated risk of developing [opioid use disorder](#) (OUD). The Diagnostic and Statistical Manual of Mental Disorders (DSM 5-TR) describes opioid use disorder as a problematic pattern of opioid use leading to problems or distress with at least two of the following occurring within a 12-month period:

1. Taking larger amounts or taking drugs over a longer period than intended.
2. Persistent desire or unsuccessful efforts to cut down or control opioid use.
3. Spending a great deal of time obtaining or using the opioid or recovering from its effects.
4. Craving, or a strong desire or urge to use opioids
5. Problems fulfilling obligations at work, school or home.
6. Continued opioid use despite having recurring social or interpersonal problems.
7. Giving up or reducing activities because of opioid use.
8. Using opioids in physically hazardous situations such as driving while under the influence of opiates.
9. Continued opioid use despite ongoing physical or psychological problem likely to have been caused or worsened by opioids.
10. Tolerance (i.e., need for increased amounts or diminished effect with continued use of the same amount).
11. Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

FDA-approved treatments for OUD include methadone, buprenorphine and naltrexone, complemented by cognitive behavioral approaches and counseling. Effective OUD treatment involves personalized diagnosis,

individualized treatment plans and long-term management with ongoing recovery support services.

Traditionally, standardized clinical examinations and ongoing monitoring, like urine drug screening, were employed, along with risk assessment tools such as Current Opioid Misuse Measure (COMM), Opioid Risk Tool (ORT), Patient Medication Questionnaire (PMQ) and Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), to gauge the risk of OUD development. Notably, these tools did not incorporate genetic testing, a capability now present in AvertD.

Manufactured by [AutoGenomics, Inc.](#), the AvertD test is designed for use before the initial exposure to oral opioid pain medications, particularly when considering a 4–30 day prescription for acute pain treatment. It is a prescription-only genetic lab test for patients aged 18 and older. The test is suitable only for patients who consent to it and have no prior history of opioid use. The test involves a simple cheek swab to collect the patient's DNA, which is then analyzed to identify potential genetic variants associated with elevated risk of developing OUD. AvertD assesses 15 genetic markers linked to brain reward pathways, providing insight into the patient's genetic predisposition to OUD.

Traditional standardized clinical tools, proven superior in multiple studies over subjective caregiver assessments, will continue to complement AvertD. AvertD will not replace or stand alone in making clinical treatment decisions, partly due to the risk of false-negative results. Combining AvertD with established tools is crucial to avoid a false sense of security for patients at risk of OUD and for health care providers making opioid prescription decisions. Importantly, AvertD is not intended for use in patients receiving chronic pain treatment.

Genetic testing is another step forward in preventing OUD and further expanding upon proper opioid prescribing guidelines for safety and efficacy. Current practices, guidelines, and assessments for OUD will still be utilized and AvertD will provide an additional supplemental option to providers to further determine the potential risks of OUD in their patients.

This information is meant to serve as a general overview, and any specific questions should be more fully reviewed with your health care professional such as the prescribing doctor or dispensing pharmacist.

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