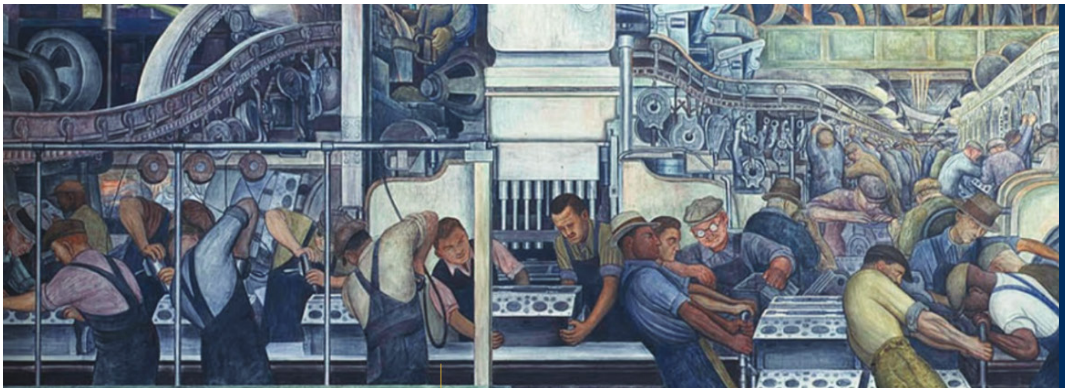

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Oral Fluid Drug Tests: Concerns and Recommendations

NOVEMBER 2024

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Executive Summary

Approximately 1 million arrests are made in the United States each year for driving under the influence of alcohol and/or drugs.[1] The National Institute of Justice reports that 13.6 million people drove under the influence of illicit drugs in 2021.[2] There is a strong policy argument for interventions to keep impaired motorists off the road and for law enforcement to test for drugs like they do for alcohol. Portable handheld devices for roadside drug testing, called oral fluid tests, claim to have advantages like being non-invasive and providing timely results. However, there are serious concerns with these devices, including the unexpected challenge of distinguishing between the presence of drugs and impairment by drugs, lack of manufacturing standards, and inaccurate results. Responsible adoption of oral fluid tests requires industry standards, confirmatory testing, and additional research.

Key Findings

- Twenty-four states have statutes that authorize the use of roadside oral fluid tests.[3]
- Drugs do not affect users uniformly or in a manner that is easy to measure. Differing characteristics of the drug, of the user, and of the circumstances in which the drug is used renders distinguishing between presence of drugs and impairment by drugs an opaque endeavor.[4]
- There are no consistent standards in the manufacture of oral fluid tests. The lack of industry-wide consensus reflects research challenges like dearth of quality studies and information challenges.[5]
- Laws concerning the use of oral fluid tests are inconsistent across all 50 states.[6]
- Language in manufacturers' instructions states that oral fluid tests are presumptive in nature and must be confirmed with laboratory testing.[7] Additionally, cross-reactivity with other, legal substances can introduce errors into the testing process.[8]

Introduction

Impaired driving is an issue affecting Americans every day. A 2021 report found that fifty-six percent of drivers involved in car crashes that resulted in fatality or serious injury tested positive for at least one drug.[9] Polysubstance impaired driving—operating a vehicle while under the influence of more than one drug or using drugs and alcohol together—has increasingly become a concern, especially in the face of the ongoing opioid epidemic and increasing legalization of recreational marijuana.[10] These recent developments have led grassroots organizations and scholars to demand greater action to deal with substance-impaired drivers. For example, the National Alliance to Stop Impaired Driving (NASID) laments that drug and multiple substance-impaired drivers often go undetected due to data underreporting and a lack of standardized testing for drugs among impaired drivers involved in crashes.[11] There is growing interest in roadside drug tests to decrease preventable traffic fatalities and identify impaired drivers who may otherwise escape detection.

At the same time, the U.S. criminal legal system's approach to drug use is defined by a punitive ideology that privileges retribution over treatment and prevention. Over 360,000 people are in prison in the U.S. for drugs, mostly simply for possession.[12] The enforcement of laws criminalizing drug use has a disproportionate impact on communities of color and people experiencing poverty.[13] Any plan to address substance misuse ought to include a clear understanding of that broader context.

Oral Fluid Tests

Roadside drug tests are portable handheld devices that allow police officers to screen motorists for the presence of drugs during traffic stops. They can be administered orally, whereby a saliva sample is collected through a cheek swab then analyzed by a handheld device,[14] or chemically, whereby the suspected illegal substances are combined with a chemical solution that produces specific colors when in contact with drugs.[15] This report will focus on orally administered saliva tests, which will be referred to as "oral fluid" tests. When drugs are metabolized by the body, they accumulate in saliva or urine by passive diffusion from the blood.[16] Studies suggest that drugs detected in oral fluid are well correlated with positive results from the same drug when tested in the blood; this basis forms the justification for the use of saliva tests.[17] Oral fluid tests are most commonly designed to detect the presence of THC, cocaine, amphetamine, methamphetamine, benzodiazepines, and opiates.[18] Oral fluid tests can be laboratory-based or point-of-care (POC) tests. Laboratory-based tests involve sending a collected oral sample to a certified lab to be analyzed by a technician, while POC tests are completed without a lab and provide rapid results requiring subjective assessment.[19]

Oral Fluid Test Kit Market

Oral fluid drug tests are a category of substance use test kits, supplied and distributed to consumers by medical device manufacturers, medical technology companies, and test kit manufacturers. The market for oral fluid tests, comprising about 50 businesses that generated $3.7 billion in revenue in 2023, is inundated with suppliers.[20] This inundation has been buoyed by the ease of modifying existing drug-testing devices (e.g., urine tests) to target drug metabolites that would be present in oral fluid.[21] The drug and alcohol test kit manufacturing industry in the U.S. is competitive, evidenced by the fact that market concentration, the extent to which market shares within an industry are concentrated with a small number of firms, is low.[22] Most of the drug testing in the United States occurs in an employment context.[23] Aside from employers, test kit buyers include drug treatment centers, hospital emergency rooms, pain treatment clinics, sports organizations, and courts and other legal authorities.[24]

Though some of these companies manufacture lab-based tests, the oral fluid tests utilized in the criminal legal system are rapid, POC tests.[25] U.S.-based medical device company Abbott Laboratories, established in 1894, is this industry's largest and oldest player, with its $451.6 million in 2023 revenue granting it an 8% market share.[26] Abbott Laboratories manufactures the SoTaxa Mobile Test System.[27] Other American test manufacturing companies include OraSure Technologies (est. 1987), Advin BioTech (est. 2009), and Cartoli Instruments (est. 2016); these companies sell the Oraltox Rapid Oral Fluid Drug Test,[28] Aloft Oral Fluid Drug Test,[29] and the Alere DDS2 Mobile Test System,[30] respectively.

About 24 states have statutes that authorize the use of roadside oral fluid tests.[31] Oral fluid drug testing follows the standardized traffic stop approach to check for impairment.[32] First, the driver is stopped by officers for exhibiting what the officer considers unusual behavior. The subject is then asked to participate in field sobriety tests to satisfy the officer's suspicion of impairment. If during this process the officer suspects impairment by a substance other than alcohol, they may then ask the motorist to consent to an oral fluid test.

The test is performed by inserting a test strip into the subject's mouth, where it stays for five minutes to ensure that an adequate sample is collected.[33] If a digital POC test is used (e.g., SoTaxa, Alere DDS2), the sample is inserted into the screening machine for analysis, and the result is analyzed and interpreted into readable output by the machine (e.g., positive, negative).[34] If an analog POC test is used (e.g., Advin BioTech, OraSure), there is no mechanical screening device, and the results must be subjectively interpreted.[35] A positive result is reported when the sample contains at least the minimum cutoff of a drug for each specific panel. A negative result is reported when the

sample does not contain the minimum cutoff. Despite providing insights on the presence of drugs, these tests are only designed to return a positive or negative result, not to quantify how much of a substance is in a person's system or how long it has been there.[36]

Oral fluid testing has distinct advantages over other methods of drug testing that make it a useful tool in the criminal legal system. Unlike blood or urine tests, the procedure is non-invasive, quick, and establishes results proximate to a motorist being stopped.[37] However, there are reasons to be concerned about the use of this technology. First, despite providing insights on the presence of drugs, these tests do not establish impairment or intoxication.[38] Further, there are no industry standards for accuracy or sensitivity in the manufacture of these tests.[39] Finally, incidences of false positives and negatives cast doubt on the accuracy of these tests.[40]

Impairment

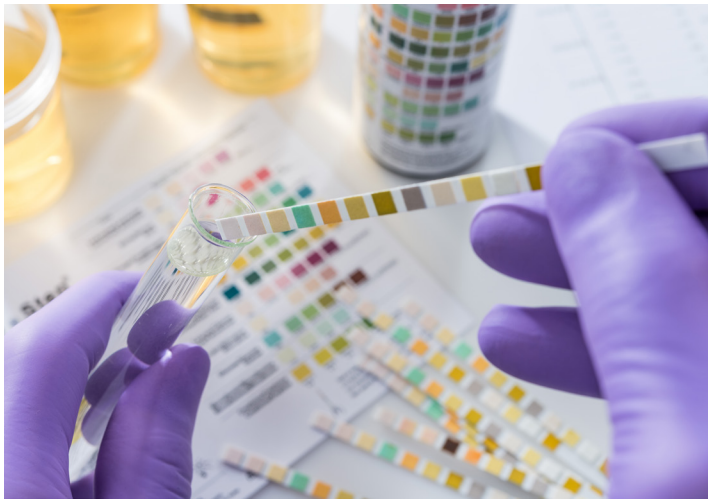
The safe operation of a motor vehicle requires thinking, reasoning, reflexes, and muscle coordination.[41] Any substance that adversely affects these physical and mental abilities in a motorist is said to "impair" them or to cause "impairment."[42] Thus, impairment is about the ability to exercise the functions essential to safe driving. Alcohol consumption, for example, has the documented effects of lowering alertness; decreasing muscle coordination (e.g., loss of balance, slurred speech, blurred vision); and negatively impacting reasoning and memory.[43] Impairment is a concern because diminished ability to exercise the cognitive functions essential to safe driving is associated with an increase in motor accidents and fatalities. There is a great deal of variability in how states approach the issue of drug-impaired driving. In some states, impairment-based statutes stipulate that prosecutors must prove the driver was impaired (for example, by driving recklessly or erratically). Some states have "per se" laws in which it is illegal to operate a motor vehicle if there are specific detectable levels of a prohibited substance in a driver's system.[44] Other states have "zero-tolerance" laws, which make it illegal to drive if there is any quantity of illegal substance detected.[45]

Concerns about Oral Fluid Testing

Oral Fluid Tests Do Not Establish Impairment

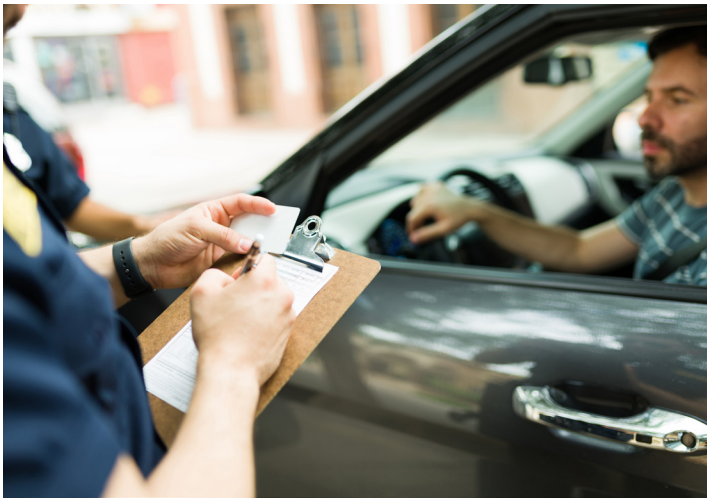
One particularly salient research problem has been distinguishing between the presence of drugs and impairment by drugs in the body. Roadside drug tests do not establish impairment by drugs. A Michigan report on the use of roadside oral fluid testing explains that "a positive or negative result by itself does not determine driver impairment. It merely provides an officer with additional information to consider during an investigation." [46] Oral fluid test manufacturers themselves recommend that the tests be followed up with confirmatory lab testing.[47]

Since blood alcohol testing has been a useful tool to identify impaired drivers, the impulse has been to create similar tests for other substances. However, alcohol affects the body uniformly in a manner that is easy to measure. Measuring the volume of alcohol in one part of your body can predictably tell you how much is in any other part of your body.[48] Furthermore, the time that alcohol concentration peaks in blood correlates to the onset of its most intense symptoms.[49] **It is a mistake to apply the expectations that have held true for successful alcohol detection to drug detection because drugs do not have as clear a correlation between concentrations and impairment.**



Different drugs may affect people differently depending on the characteristics of the drug, the characteristics of the user, and the circumstances in which the drug is used.[50] Take the example of marijuana. Unlike alcohol, marijuana is fat soluble.[51] The fatty parts of the body, including the brain, soak up THC such that it is possible to detect THC in the brain, even if it is no longer measurable in the blood.[52] Unlike alcohol, the height of intoxication after consuming marijuana isn't at the moment when blood THC levels peak, and the high doesn't rise and fall uniformly based on how much THC leaves and enters one's bodily fluids.[53]

Furthermore, the amount of THC in the system varies based on the frequency of use.[54] Occasional users would find a small amount of THC in their bloodstream after a few hours. Heavy users, however, build up so much THC in their body fat that it could remain detectable for weeks after the individual last consumed marijuana, such that they will have a constant, moderate level of blood THC even when they are not intoxicated.[55] This exact issue befell Abby McLean, a Colorado resident and frequent marijuana user, who was arrested at a DUI checkpoint for marijuana intoxication despite not having recently consumed marijuana.[56] Different drugs affect different people in inconsistent and unpredictable ways.



Lack of Standards in the Manufacture and Use of Oral Fluid Drug Tests

There are no consistent standards in the manufacture of oral fluid tests, and manufacturers have not reached industry-wide consensus in cutoff levels for the detection of illegal substances in oral fluid.[57] Partly, this reflects the reality that 1 ng/mL of an illegal substance in one medium, like blood, is not equivalent to 1 ng/mL of that illegal substance in another medium, like oral fluid or urine.[58] The many different oral fluid tests on the market have significant differences in the kinds of drugs they can detect, cutoff concentrations, and result interpretation and retention. For example, DrugWipe has a combined amphetamine/methamphetamine panel,[59] while the SoTaxa device screens for amphetamines and methamphetamines separately.[60] Furthermore, the cutoff threshold of Abbott SoTaxa device for detection of opiates is four times as high as that of the Securetec DrugWipe (40 ng/mL versus 10 ng/mL), yet the sensitivity, specificity, and accuracy of Securetec DrugWipe are 57.6%, 99.4%, and 78.3% compared to SoTaxa's 91.1%, 99.7%, and 96.7%.[61]

Additionally, **laws concerning the use of oral fluid tests are inconsistent across all 50 states.** For example, confirmatory lab testing is required by Alabama, not mentioned in law by Michigan, and mentioned in law by Oklahoma but ultimately not required.[62] Regardless, police departments in Alabama, Indiana, and Michigan have begun using roadside screening through oral fluid tests for identification of impaired drivers.[63] Evaluation over the years has generally concluded that the performance of these tests is variable. A Michigan report on a pilot of oral fluid testing devices concluded that oral fluid testing devices are "accurate to a certain degree" and demonstrated "varied percentages of accuracy." [64] Making matters worse, there are currently no federally approved model specifications for field screening devices in the United States.[65] **A tool that the legal system uses to make determinations about arrest and incarceration should meet basic standards for reliability and accuracy.** For some drugs, the tests are specific and reliable, and for others, predominantly marijuana and benzodiazepines, improvements in sensitivity are necessary.

Inaccurate Results

Language in manufacturers' instructions states that oral fluid tests are presumptive in nature and need to be confirmed with laboratory testing.[66] In 2021, Michigan State Police expanded a 2019 investigation into the SoTaxa Mobile Testing System, manufactured by Abbott Laboratories. While the report notes that each of the six drug classes demonstrated "varied percentages of accuracy when compared to the 'Gold Standard,' which is a blood test," **11% of all tests produced false positives or false negatives that did not match findings from follow-up blood tests.**[67] Similarly, a 2013 California study found that out of 50 oral fluid specimens tested by the Alere DDS2, 12 cases (24%) failed to return a valid result.[68]

Cross-reactivity with other, legal substances can also introduce errors into the testing process. A report on oral fluid testing found that chewing tobacco produced frequent false positive and false negative results across all five devices, while coffee, milk, soda, and wintergreen produced intermittent and inconsistent false positives or false negatives on one device or another.[69] Despite this report's noting that a 10-minute waiting period

eliminated the effects of the interferants,[70] the Michigan pilot study employed a five-minute processing time with the SoTaxa device when administering the roadside oral fluid tests.[71] Given the unpredictable nature of traffic stops, there are likely to be challenges in the field achieving the precision these tests require.

Recommendations

While oral fluid tests may be a useful tool in the larger fight against impaired driving, they require additional regulation, research and development, and testing. Furthermore, policymakers should resist relying on testing and punishment in their fight against impaired driving, and invest in prevention as well.

Recommendation 1: Establish industry standards for the manufacture and use of oral fluid tests.
Recommendation 2: Establish confirmatory testing to verify oral fluid test results.
Recommendation 3: Invest further research into best practices and science-based countermeasures to prevent drug-impaired driving.

Establish industry standards for the manufacture and use of oral fluid tests

Establishing industry standards for the manufacture and use of oral fluid tests will introduce greater consistency and reliability in their use. Two studies recommend industry cutoff levels. The Roadside Testing Assessment (ROSITA) recommends greater than 90% sensitivity and specificity and greater than 95% accuracy in oral fluid tests.[72] The Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) project recommends greater than 80% sensitivity, specificity, and accuracy.[73] However, no effort has been made to establish industry cutoff levels. Substance abuse and road safety scholars should team up with law enforcement and test kit manufacturers to agree upon industry standards guiding the creation of these tests.

Establish confirmatory testing to verify oral fluid test results

In May 2023, the US Department of Transportation (DOT) published a final rule that amends the DOT's regulated industry drug testing program to include oral fluid testing.[74] Despite the rule, oral fluid testing cannot be implemented until the Department of Health and Human Services (HHS) certifies at least two laboratories to perform confirmatory testing.[75] HHS must carry out the directive it has been given. At present, only Alabama performs confirmatory testing.[76] If oral fluid test results can carry criminal sanctions, confirmatory testing should be implemented in all cases to protect against inaccurate results. Though oral fluid testing is not currently common for most forensic laboratories and would require time, financial resources, and skilled personnel to develop and validate methods, the building of laboratory capacity is already and should be an important priority for many within the traffic safety field.

Invest in further research into best practices and science-based countermeasures to prevent drug-impaired driving

Further research ought to be undertaken to address the issue of drug-impaired driving at its source. There are several aspects of this issue—prevention, treatment, recovery, harm reduction—that can be strengthened with greater research into best practices and science-based countermeasures to prevent drug-impaired driving.

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