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DRIVING UNDER THE INFLUENCE OF DRUGS: ORAL FLUID TESTING

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Disclosures

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- President of 9-Delta Analytical LLC, a private laboratory specializing in the analysis of drugs in oral fluid and blood

Learning Objectives

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1. Discuss the advantages of oral fluid collection and analysis for drugs compared to blood
2. Understand the disposition of drugs into oral fluid and blood
3. Appreciate differences between roadside testing and laboratory-based analysis
4. Realize the wide range of commercially available rapid test oral fluid devices

Drugged Driving

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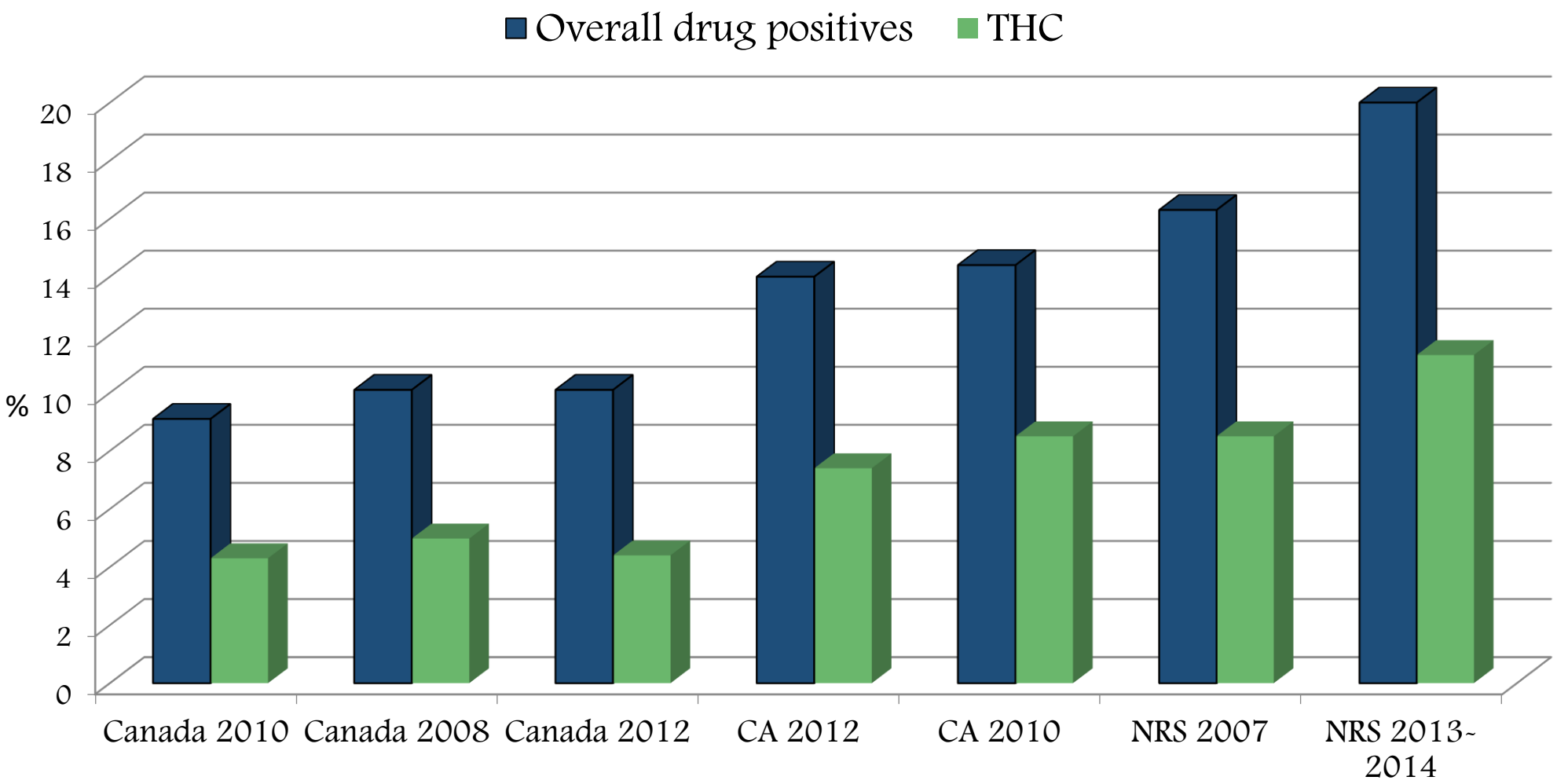
2017 report:

"Preventing Drug Driving in Europe" European Transport Safety Council (ETSC)

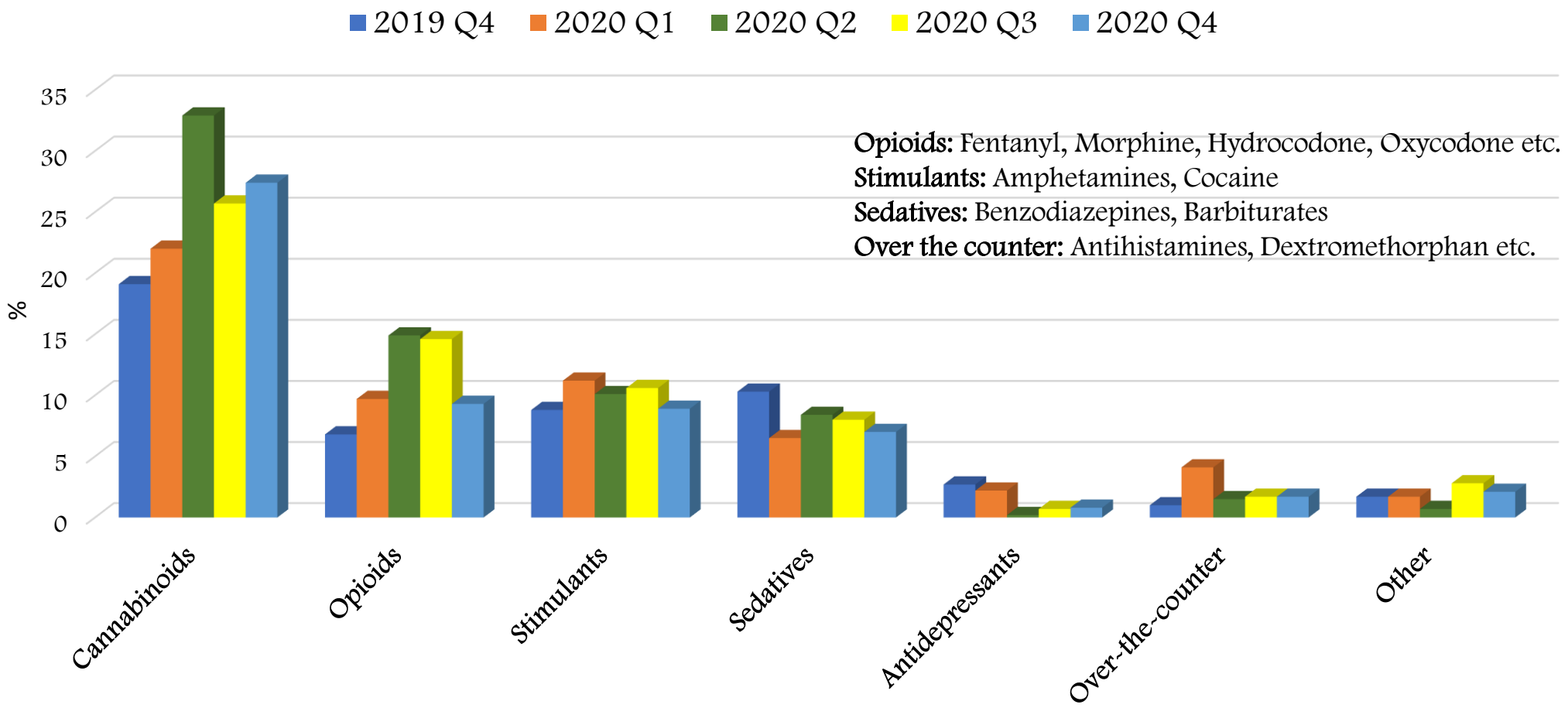
Relative risk of being killed or seriously injured in a collision for various drugs:

- Cannabis and illicit opiates: 1-3 times greater risk
- Cocaine: 2-10 times greater risk
- Amphetamines (alone): 5-30 times greater risk

Oral Fluid Analysis: North American Surveys



Fatally or Severely Injured Roadway Users



June 2021 NHTSA DOT HS 813 135
Update to Special Reports on Traffic Safety During the COVID-19 Public Health Emergency:
Fourth Quarter Data

2007 National Roadside Survey

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- 3,276 blood and oral fluid paired samples collected voluntarily from drivers
  - Not stopped for a driving offense
- 16.3% of drivers positive for drugs
  - Almost 50% for THC
- Paired positive samples in both blood and oral fluid
  - 75.7% were an exact drug match across all classes
  - 21.4% had at least one drug class match
- **97.1% correlation rate for paired specimens**
- Oral fluid is a viable alternative to blood, providing similar information on drug intake

Law Enforcement Options

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- Given the high rate of drug positive drivers, and if the driver is not under the influence of alcohol, what options are available for the police officer?
- DRE observations and evaluations, if DRE is available
- Would a person think twice about drugged driving if they knew there is a roadside solution to detect the presence of drugs?

- Technology that allows officers to test for the presence of drugs at roadside can:
  - Assist in the investigative process
  - Improve public safety
  - Create deterrent

- Oral fluid collection (and analysis?)
- Roadside test .v. Evidentiary specimen collection (Laboratory based analysis)

Oral Fluid Advantages

BLOOD

- Considered the "gold standard" for assessing driving under the influence of drugs (DUID) cases
- Disadvantage is the time it takes between traffic stop and sample collection
- Average time is 1.5–2 hours to collect a sample after a stop
- Drug concentrations will be declining as medical personnel/warrant are acquired
- THC (active component of marijuana) decreases rapidly in the blood

ORAL FLUID

- Reflection of free drug circulating in the blood:
  - Similar information regarding drug presence
- Easy, rapid, non-invasive, observed collection
- Can be taken proximate to the traffic stop
- No medical personnel required for collection
- Parent drug detection shows recent intake
- Roadside test devices commercially available

Roadside Oral Fluid Tests (POC)

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Many countries have implemented roadside oral fluid testing

- Argentina, Australia, Austria, Belgium, Brazil
- Canada, Chile, Columbia, France, Germany
- Ireland, Italy, Netherlands, New Zealand
- Poland, Portugal, South Africa, South Korea
- Spain, Sweden, Turkey, UAE
- United Kingdom (arrests up 600% since implementation in 2015)
- Vietnam

Roadside Test .v. Evidentiary Specimen Analysis

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- Roadside devices provide an initial drug test result
  - Presumptive result only
  - Limited panel of drugs (6 or 7 classes)
  - No standardized test cut-offs or drug panel

- Result may provide reasonable cause to collect a subsequent evidentiary specimen for laboratory testing
- Blood or oral fluid samples may be collected for this purpose
- Advantage of collection time maintained if oral fluid collected at roadside

Many rapid test choices…

iScreen® - OFD

iScreen® Oral

Ora-Check

Oral Cube

SalivaConfirm
(replaces Oraline)

Oral AQ7

OrAlert®

More choices…

Oral fluid cassette

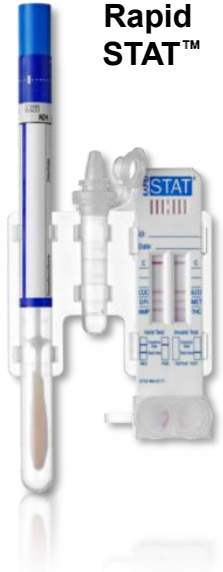
Oral-View®

DrugWipe®

6 panel saliva drug test

STAT SWAB®

Rapid STAT™



Rapid Detect SDS

US Pilot Studies

- Instrumented devices
- Print and retain results
- Published peer-reviewed studies with law enforcement input

NHTSA sponsored: Evaluation of 5 OFFS Devices

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Buzby D., et al. 2021 Evaluation of on-site oral fluid drug screening technology (DOT HS 812 854)

Overall Device Test Results									
Device	TP	FN	FP	TN	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)
DDT5000	**886**	**8**	**15**	**1766**	**99.1**	**99.2**	**99.1**	**98.3**	**99.5**
DDC3000 (Visual read or App)	589	17	0	929	97.2	100.0	98.9	100.0	98.2
Drug Wipe w/ Drug Read	289	213	3	489	57.6	99.4	78.3	99.0	69.7
Drug Wipe w/ Manual Evaluation	451	73	2	466	86.1	99.6	92.4	99.6	86.5
DDS2 (SoToxa)	**635**	**62**	**4**	**1306**	**91.1**	**99.7**	**96.7**	**99.4**	**95.5**
Aquilascan	161	581	5	988	21.7	99.5	66.2	97.0	63.0

US State Evaluations or Implementation

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- **Alabama: Program implemented (roadside and laboratory confirmation)**
- **Michigan: Second pilot study completed**
- **Indiana: Program implemented (roadside only)**
- Massachusetts: Report only
- Illinois
- Ohio
- Oklahoma (complete)
- Kansas (complete)
- North Dakota
- Wisconsin (first evaluation complete; second evaluation awaiting report)
- Mississippi
- Nevada

Alabama

- Alabama Department of Forensic Sciences (ADFS); Alabama Drug Recognition Expert (DRE) Program; Alabama Impaired Driving Prevention Council (AIDPC); Traffic Safety Resource Prosecutor (TSRP)
- Proof of principle study set forth to validate the use of oral fluid screening devices in the field by officers and oral fluid confirmation testing at ADFS

- 3 oral fluid screening devices
  - Draeger DT5000
  - Abbott SoToxa™
  - Randox Evidence MultiSTAT

- All three oral fluid screening instruments evaluated proved to be "fit for purpose" with comparable performance; approved devices
- Useful in rural areas lacking the presence of DREs
- AL code: blood, urine, or other bodily substance: no need to change state statute

Michigan

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- Phase I: Provided data on the overall performance and utility of the Roadside OF devices
- Data set not large enough to achieve a high confidence level, so Legislature approved Phase II (Oct 1st, 2019 – Sept 30th, 2020) which included 69 counties
- Report January 2021: "**Roadside oral fluid testing in the Phase II Pilot has been proven to be accurate to a certain degree**"
- Each of the six drug classes demonstrated varied percentages of accuracy when compared to the "gold standard" (blood test)
- "Oral fluid testing does not equal the "gold standard" but has been found to be accurate for purposes of preliminary roadside testing"
- "A roadside oral fluid test result regardless of positive or negative does not determine if a driver is impaired or not impaired"
- MI is not taking any steps forward with oral fluid confirmatory analysis until the legislature enacts something to indicate the matrix is approved for that testing

Indiana

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- Indiana's roadside drug testing program is the first established and funded by a state highway safety office
- Opted to establish a permanent program instead of a pilot
- Relied upon data from Michigan for approval
- Obtained buy-in from key stakeholders and agencies
  - ~ SoToxa™ device
- Indiana Criminal Justice Institute distributed devices across the state
- NHTSA covered the costs through federal funding

Disadvantages to OF program

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- Roadside devices are not standardized
  - Different cut-offs and drug test profiles
- Evidential collection devices not standardized
  - Differences in collection volume, drug recovery from pads etc.
- Not many laboratories currently able to carry out analysis
  - Lack of time, instrumentation, resources, staff, training etc.
- Benzodiazepines detection in roadside OFFS
  - Impairing drug class
  - Do not accumulate well into oral fluid
  - Test concentrations on devices generally too high to detect general use, but abuse likely will trigger a positive screen

Summary

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- Oral fluid testing is appropriate for DUID situations
- Provides similar information on recent drug intake to blood
- Roadside surveys have established the validity and viability of oral fluid testing to determine drug prevalence in drivers
- Data from roadside surveys and pilot projects are regularly published and presented
- THC accounts for approximately half the drug positives in all recent surveys
- Not just a cannabis issue: Amphetamines pose high risk of crash/arrest for DUID
- Drug combinations (medicines, illegal drugs, and alcohol) are the most likely to cause traffic problems
- Interest in using oral fluid roadside testing is growing, as marijuana legalization advances and concerns about drugged driving increase
- Need to educate public regarding new and emerging technologies
- Deterrence factor

Frequently Asked Questions

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- **Is oral fluid testing as accurate as blood testing ?**
  - Yes, the same scientific principles are used for screening and confirmation methods in the laboratory
- **How long are drugs detectable in oral fluid?**
  - After a single use, drugs are detectable at standard cut-offs for 1 – 2 days; the exception is active THC which is detectable for 8 – 12 hours
- **After an oral fluid roadside test, does a second evidential specimen need to be collected?**
  - Yes. Roadside testing devices are immunoassay based, and consequently for forensic purposes require an independent confirmatory test
- **Is the drug concentration in OF the same as in blood ?**
  - No. For some drugs it may be possible to determine an equivalent concentration (specific dosing), but for drugs which are smoked or inhaled this is difficult to calculate

Frequently Asked Questions

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- **Does a positive THC result mean the driver is impaired ?**
  - Not necessarily. There is no established correlation between THC concentration in blood or oral fluid and degree of impairment.
- **So, if the result doesn't prove impairment, why is this useful ?**
  - A positive result is an indication that the driver has ingested an impairing substance, but the result should be firstly used in conjunction with the officers' observations of the driver, and secondly confirmed in a laboratory
- **Can passive exposure to cannabis cause a positive result ?**
  - Yes, research has shown the presence of THC in the oral fluid of those passively exposed but at relatively low concentrations
- **Can substances such as food, beverages or mouthwash affect the test result?**
  - The effects of a variety of commonly ingested substances have been studied and found to have no effect on the outcome of the immunoassay result

Resources

- Committees and work groups formed in different organizations

- AAA: Use of Oral Fluid in Drugged Driving Investigations: A Toolkit (April 2022)
  - Part I: Background
  - Part II: The Tools for Oral Fluid Field Screening (OFFS)
  - Part III: Laboratory Oral Fluid Confirmation
  - Part IV: Oral Fluid in Court

- Audience:
  - Law Enforcement
  - Toxicologists
  - Prosecutors
  - Policy Makers

- This toolkit was designed with a collaborative approach in mind and provides guidance and key considerations to each of the primary stakeholder groups who must be consulted when exploring the possible initiation of an oral fluid program.

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