Dane County Oral Fluid Project

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blood poisons **Oral Fluid IOTENSIC** Investig **E toxicology** mpairment

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IMPAIRED DRIVING

Increasing awareness that drugs, as well as alcohol are responsible for, or at least a factor in traffic accidents

Understand the scope of the problem

Measurement of drug prevalence in driving population

Need for information related to traffic incidents

Improved procedures for detecting drugs in biological specimens and wider test panels

Rehabilitation of drivers using illegal drugs

Education of drivers using legal prescription drugs



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:

Drug	Crash Risk		
CANNABIS AND ILLICIT OPIATES	1-3 TIMES GREATER		
COCAINE	2-10 TIMES GREATER		
AMPHETAMINES (ALONE)	5-30 TIMES GREATER		

WHY ORAL FLUID ?



- Easy, rapid collection
- Minimally invasive
- Observed; gender neutral
- No need for medical personnel
- Can be taken proximate to the traffic stop
- Identification of active compound may provide information on recent drug intake
- Almost all recent roadside surveys have included collection of oral fluid (and sometimes blood)



WHY ORAL FLUID ?

- Drugs accumulate in saliva mainly by diffusion from the blood
- Reflection of drug circulating in the body
- Drug detection times similar to blood (except THC)
- Drug properties determine how much is deposited into oral fluid
 - Stimulants (amphetamines, cocaine)
 - higher concentration than in blood
 - Sedatives (benzodiazepines)
 - lower concentrations than in blood

DISPOSITION OF DRUGS IN ORAL FLUID

- Equilibrium between blood and oral fluid promotes accumulation of basic, free drugs into saliva (amphetamines; cocaine etc.)
- Acidic protein bound drugs do not incorporate easily into oral fluid (e.g. benzodiazepines)
- Pain medications (oxycodone, hydrocodone) accumulate very well into saliva



NORTH AMERICA: ROADSIDE SURVEYS



DRIVER SURVEYS

- NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION (NHTSA)
 CANADIAN GOVERNMENT
 - 2007: National Roadside Survey (Oral fluid & blood)
 - 2010, 2012: California Roadside Survey (Oral fluid)
 - 2010: Crash Risk Study* (Oral fluid and blood)
 - 2013-2014: National Roadside Survey (Oral fluid & blood)
 - 2014: Canadian Roadside Survey, Ontario (Oral fluid)
 - 2014: Washington State Initiative (Oral fluid & blood)
 - 2016: Canada Roadside Survey, Manitoba (Oral fluid)
 - 2017: Canada Roadside Survey, Ontario (Oral fluid)
 - 2018: Crash Risk Study* blood only
 - 2018: Canada Roadside Survey, British Columbia & Yukon (Oral fluid)



SAMPLE COLLECTION

BLOOD

- Gray-topped tube
- Samples shipped overnight to the laboratory for analysis
- Laboratory received blood and oral fluid samples separately
- Blinded to paired specimens

ORAL FLUID

- Quantisal[®] collection device
 - 1 mL of oral fluid collected (+-10%)
 - 3 mL stabilization buffer



2007 RESULTS

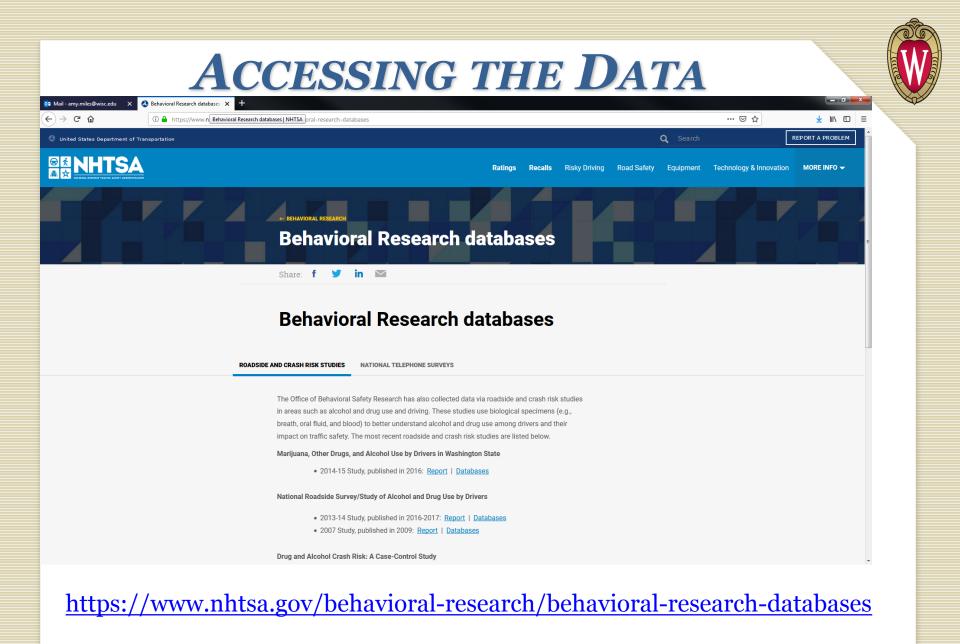
16.3% of drivers positive for drugs

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• Half of those positives were THC

326 pairs: positive 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
- Data supports utility of oral fluid as a viable alternative to blood, providing similar information on drug intake





DATA SOURCE

The most recent roadside and crash risk studies are listed below:

Marijuana, Other Drugs, and Alcohol Use by Drivers in Washington State 2014-15 Study, published in 2016: <u>Report</u> | <u>Databases</u>

National Roadside Survey/Study of Alcohol and Drug Use by Drivers 2013-14 Study, published in 2016-2017: <u>Report</u> | <u>Databases</u> 2007 Study, published in 2009: <u>Report</u> | <u>Databases</u>

Drug and Alcohol Crash Risk: A Case-Control Study 2013-14 Study, published in 2016: <u>Report</u> | <u>Databases</u>

DATABASE INCLUSIONS: GENERAL

- Region
- Date / Time
- Age
- Race
- Gender
- Spanish speaking
- Vehicle Type
- # of passengers
- Passengers under age 15

- Wearing a seatbelt
- Type of seatbelt
- Annual mileage
- % of day spent driving
- Coming from where ?
- Going where ?
- Miles traveled today
- Employed: Full time/ Part-time
- Student
- Income level



DATABASE INCLUSIONS: DRUG AND ALCOHOL USE

• PBT

- Alcohol use:
- Today
 - Weekly
- Binge drinker ?
- DUI ? How many times in last year ?
- Drug use? How often ?
- Specific drugs driver use(s)/ has used

- Tobacco
- Drugs:
- Marijuana
- Cocaine
- Heroin
- LSD
- MDMA / Methamphetamine
- GHB
- PCP
- Rohypnol
- Ketamine

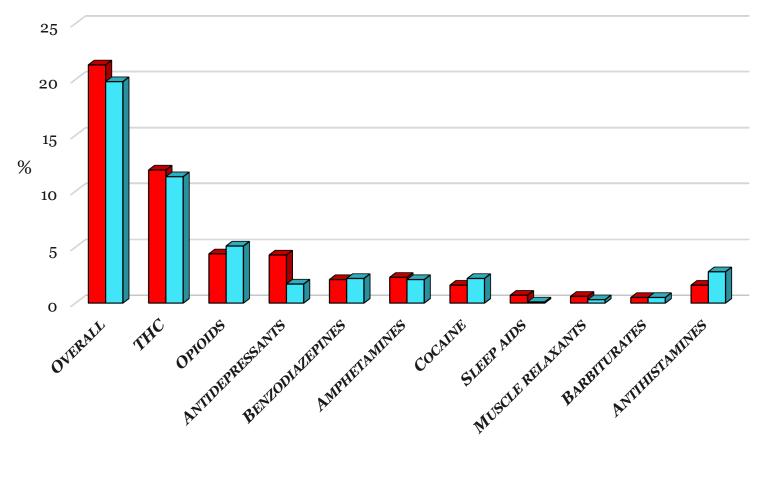
2013-2014 DRUG TEST PANEL



- Cocaine
- Marijuana
- Opiates
- Amphetamines
- Benzodiazepines (15)
- Tramadol
- Methadone
- Fluoxetine
- Sertraline
- Phencyclidine
- Barbiturates
- Antidepressants (16)

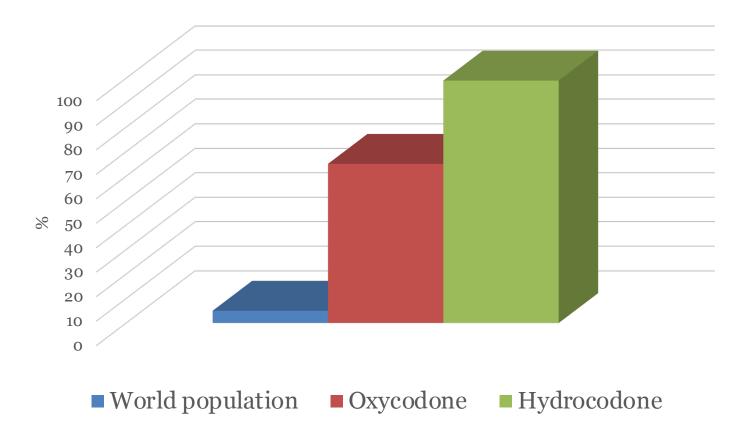
- Zolpidem
- Carisoprodol
- Methylphenidate
- Oxycodone /Oxymorphone
- Meperidine
- Propoxyphene
- Dextromethorphan
- Ketamine
- Diphenhydramine
- Chlorpheniramine
- Doxylamine
- Fentanyl
- Buprenorphine

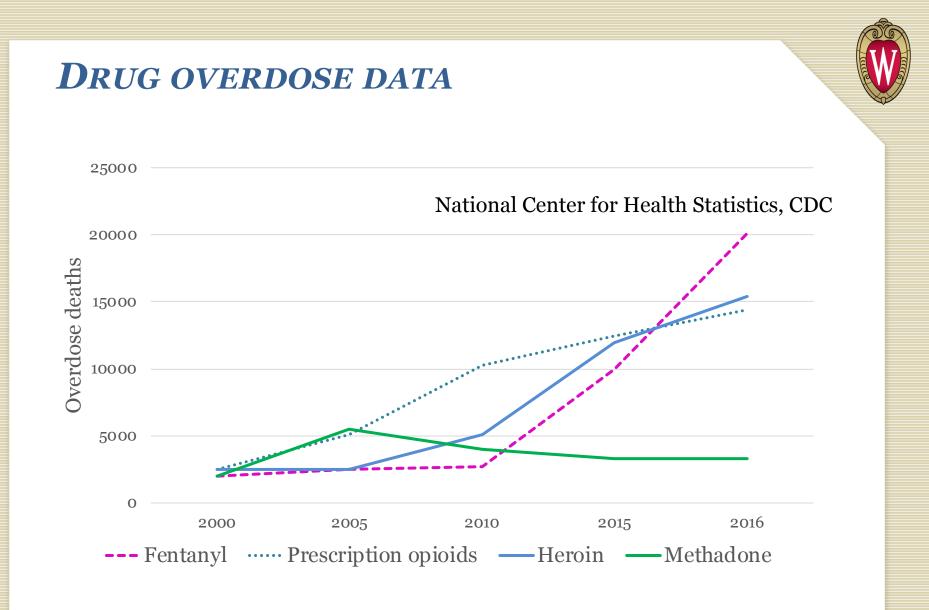
2013 – 2014 NRS Drug positives: Blood and Oral Fluid





PAIN MEDICATIONS







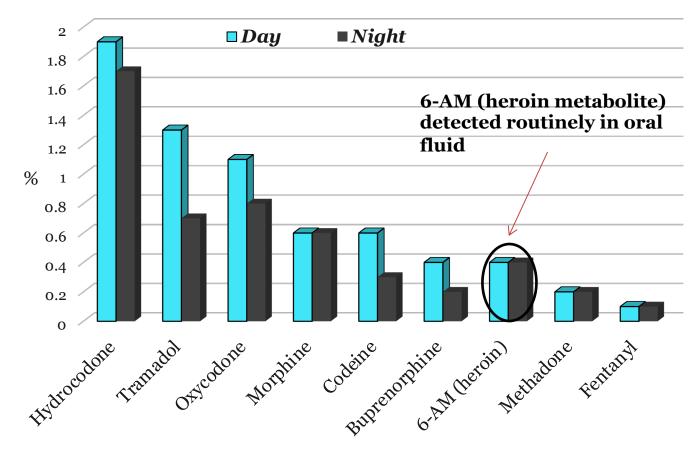
EXTENT OF FENTANYL PROBLEM

New York Times 9-2-2017

- > 2016: 64,000 people died because of a drug overdose
- > Drug overdoses are primary cause of death in those under 50
- > Fentanyl deaths up 540% in three years
- Drug deaths from fentanyl almost doubled from 2015 - 2016



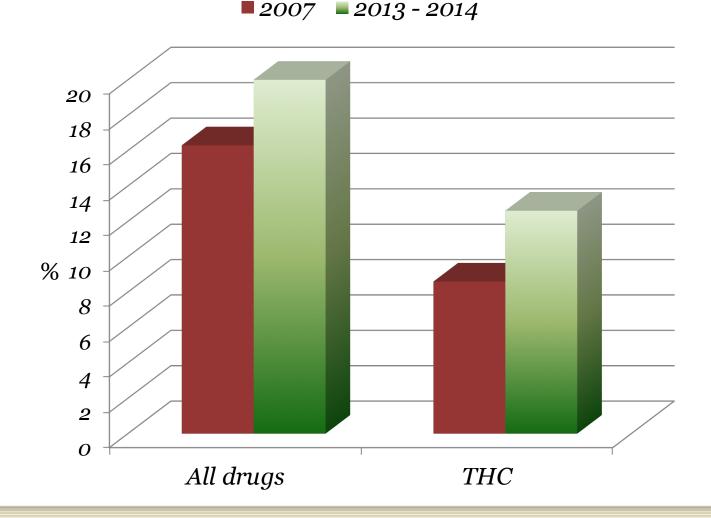
ORAL FLUID: OPIOID BREAKDOWN

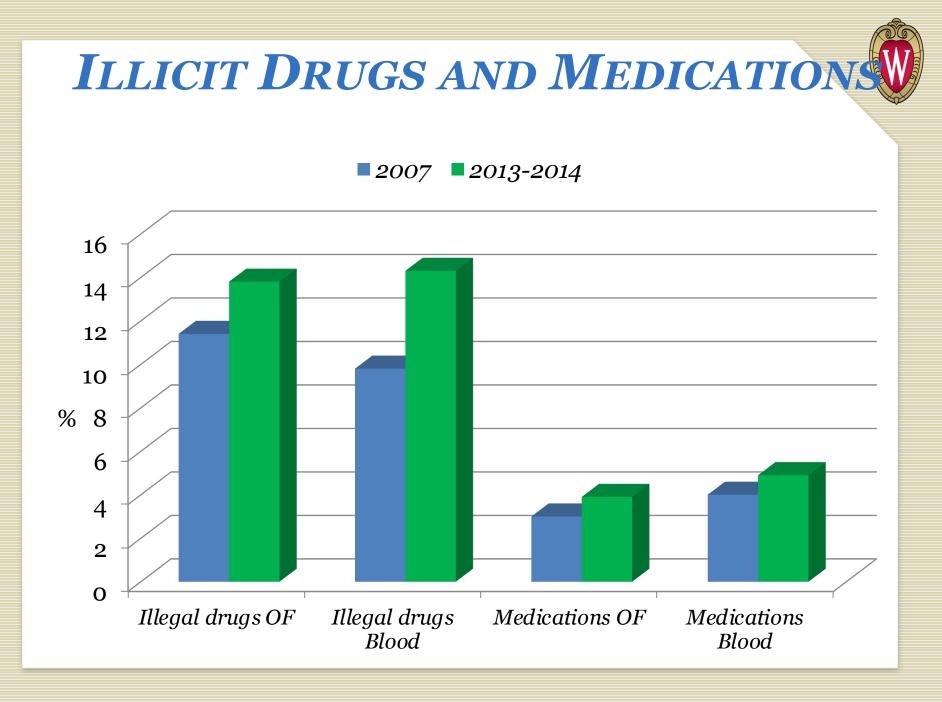


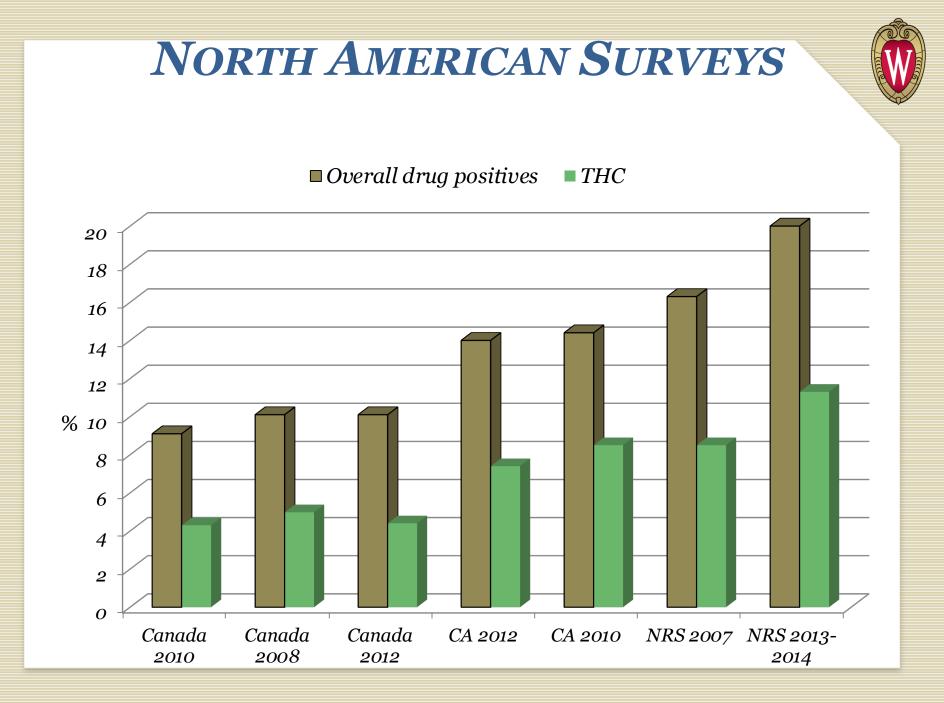




DRIVERS







SUMMARY



- While overall drug positives in drivers were lower in Canada than the USA, the percentage of THC positives remains approximately 50% in all major studies
- Drug positives for both medications and illegal drugs in US drivers has increased since 2007
- Overall drug prevalence (night-time drivers):
 - 2007: **16.3%**
 - 2013-14: **22%**
- The drug with the largest increase in weekend night time prevalence was THC
 - 2007: **8.6%**
 - 2013-14: **12.6%**





Established that oral fluid is a valid sample for testing drugs in drivers

Options:

- 1. Roadside collection, sent to laboratory for analysis
- 2. Roadside test followed by second collection for laboratory confirmation





LABORATORY BASED ANALYSIS

- Roadside collection (not test)
- More time until results received
- Wide drug test panel
- Confirmed results (evidentiary)
- Some recommendations for target cut-off concentrations in laboratory based testing for DUID
- Not all state laboratories have capability for oral fluid analysis (yet !)



ROADSIDE TESTING

- Portable test devices
- Rapid results at roadside (within minutes)
- Limited drug test profile
- Presumptive results only
- No standardized test levels

DRES, DRIVERS & ORAL FLUID DRUG TEST RESULTS



Society of Forensic Toxicologists (SOFT)

- SOFT/AAFS Drugs and Driving Committee
- SOFT/AAFS Oral Fluid Committee
 - Oral fluid project guidelines
 - LE/DRE related presentations

http://www.soft-tox.org/ddc



WI Dane Co Project

Identified the need for DUID project

- Strong DRE program
- Under-reporting DUID cases
 - Laboratories do not perform drug testing if BAC > 0.10
- Bureau of Transportation Safety (BOTS) took interest and was willing to fund project
- Education of LE and stakeholders began in 2015

Traffic Safety Commission support



WI Dane Co Project Project plan

- Set up a small group to plan the project
 - Lead LE
 - Toxicology lab
 - Highway Safety
 - TSRP
- Requested demonstrations from two vendors
- Decision to use the Alere DDS2 device
 - Portability



DRUG DETECTION SYSTEM (DDS2)

Rapid screening

 Sample collection in ~ 1 min

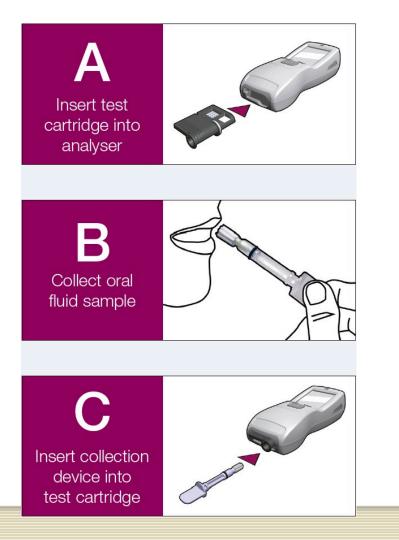
 Results in ~ 5 min
 Individual data can be stored in device
 Results can be printed



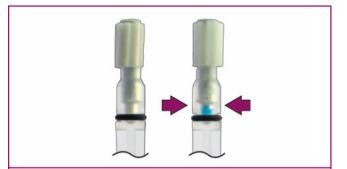


Drug Class
Amphetamine
Benzodiazepines
Cocaine
Methamphetamine
Opiates
THC

How does it work?



Lateral flow device



Continue swabbing until the sample presence indicator turns **completely blue**.

SOFTWARE FOR DDS2 SCREEN



TEST 10002369_(0000035
CNS STIM-COC	POSITIVI
NARC-OPI	NEGATIVE
CNS STIM-MAMP	NEGATIVE
CANNABIS	NEGATIVE
CNS DEPR-BZO	NEGATIVE
CNS STIM-AMP	NEGATIVE
	Exit
-	

WI Dane Co Project Outline

- Gather 100 samples beginning in March and running through May 2016
 - All subjects <u>must</u> volunteer or no sample is taken
 - Individuals stopped for suspicion of OWI, oral fluid test occurs *post arrest and post blood collection*
 - DDS2 devices stationed at hospitals
 - Oral fluid results and blood paired and then de-identified by the WSLH
 - Collected oral fluid samples even when alcohol considered impairing substance
 - WSLH performs testing on all samples collected during project



WI Dane Co Project

- 25 local LE in Dane Co plus State Patrol in Dane Co
 - Project presented to Chief's Association to ensure cooperation

48 of the officers involved in the project were ARIDE trained

Training on the DDS2 occurred during the ARIDE training

 150 additional officers trained on the DDS2 at the agencies during shift briefings

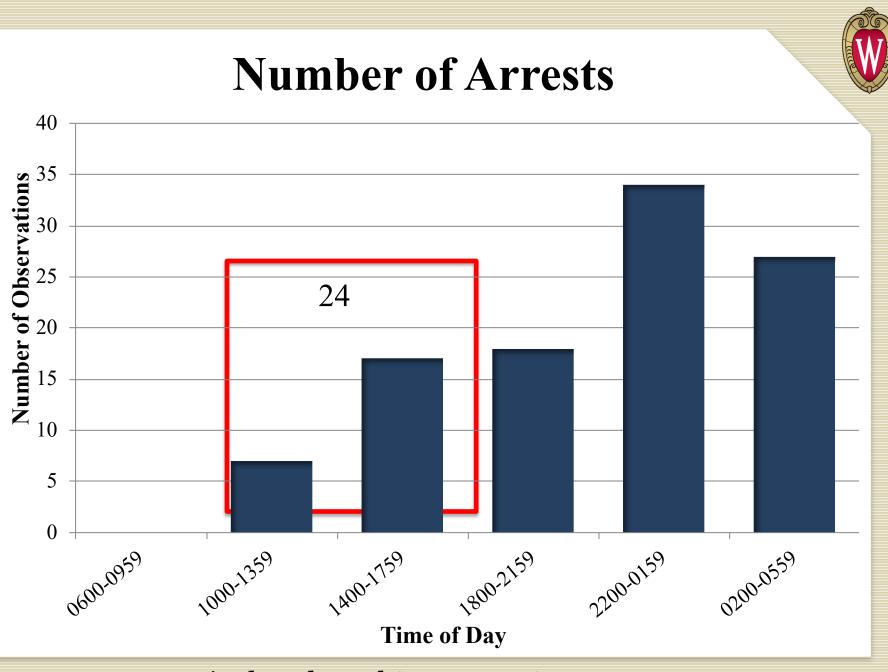
WI Dane Co Project

Successfully collected over 100 samples

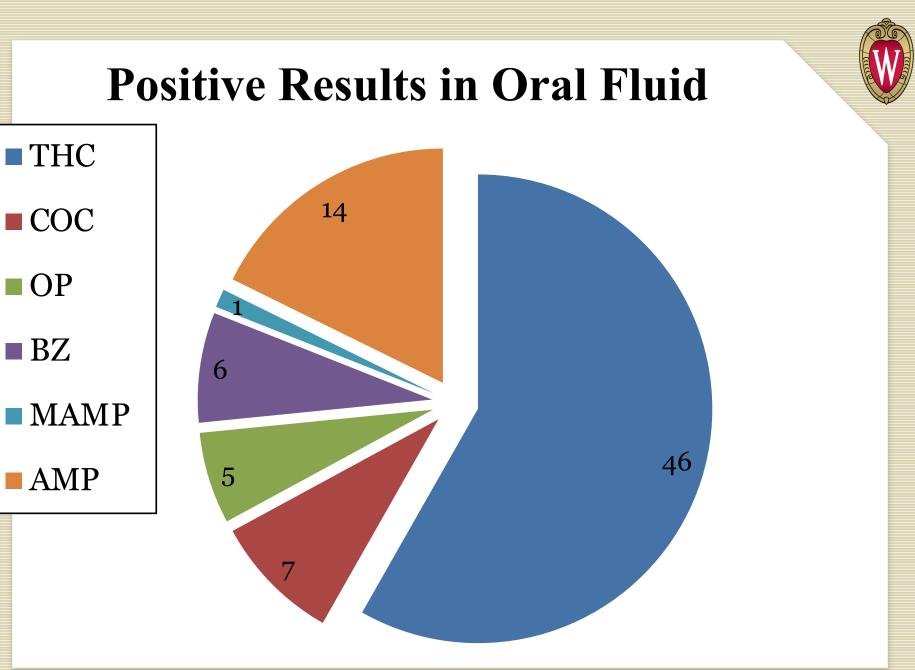
- Some samples excluded due to age (<18 yo)
- Invalid oral fluid results not included

WSLH contribution to the project

- Test the blood samples through routine OWI testing process
- De-identify blood samples in which drug testing was cancelled due to BAC and pursued drug testing
- Once all OF project samples complete, go back and test <u>all</u> OWI blood samples in Dane Co in which drug testing was cancelled due to BAC policy.



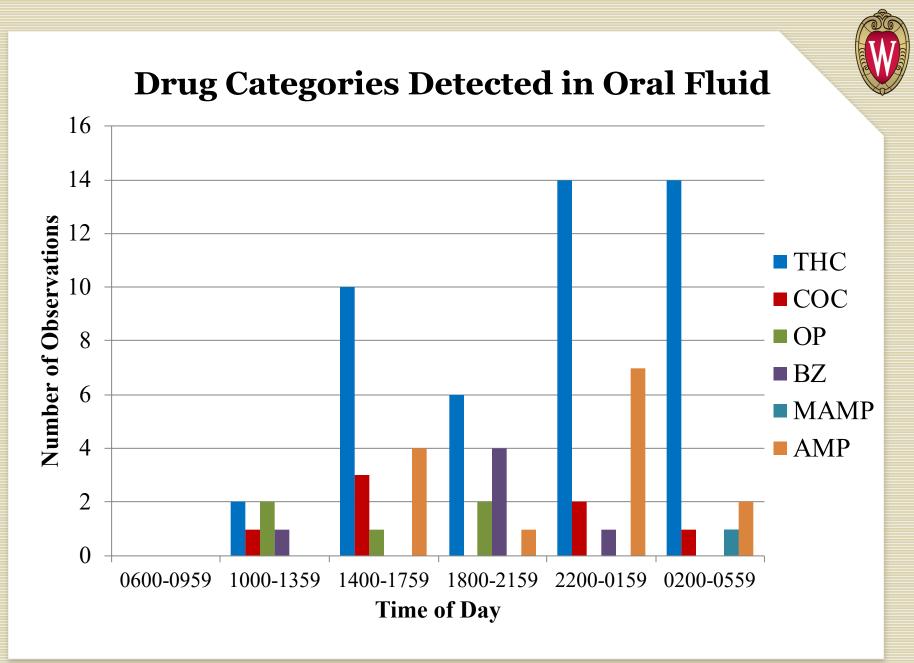
Lori Edwards, Ted Savage – WSLH 2017



Lori Edwards, Ted Savage – WSLH 2017

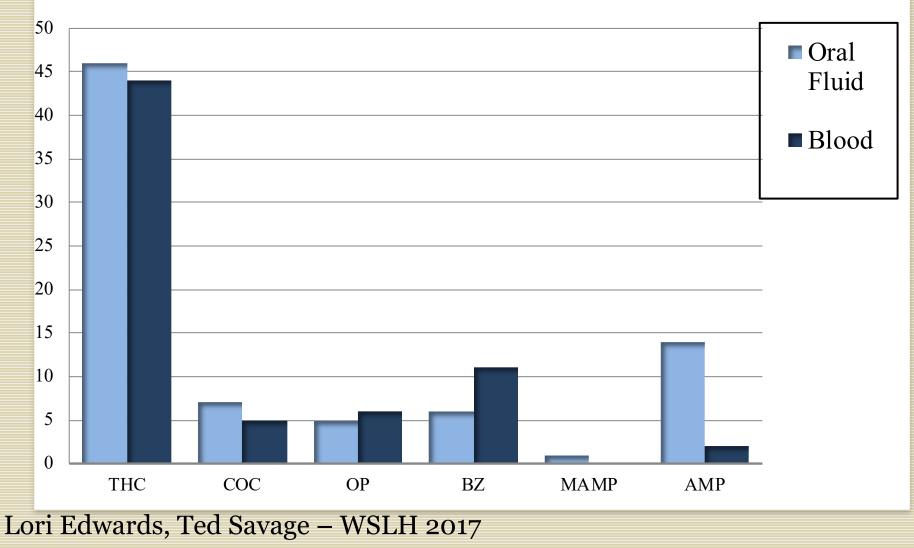
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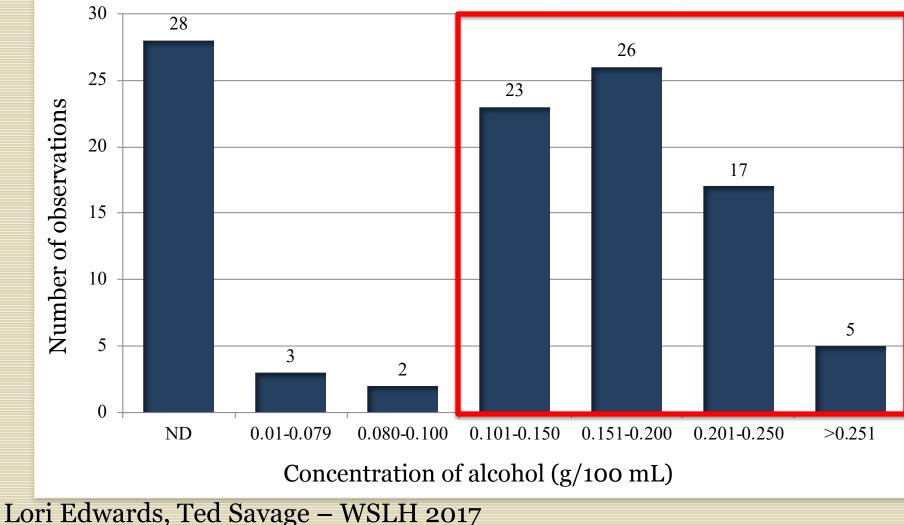


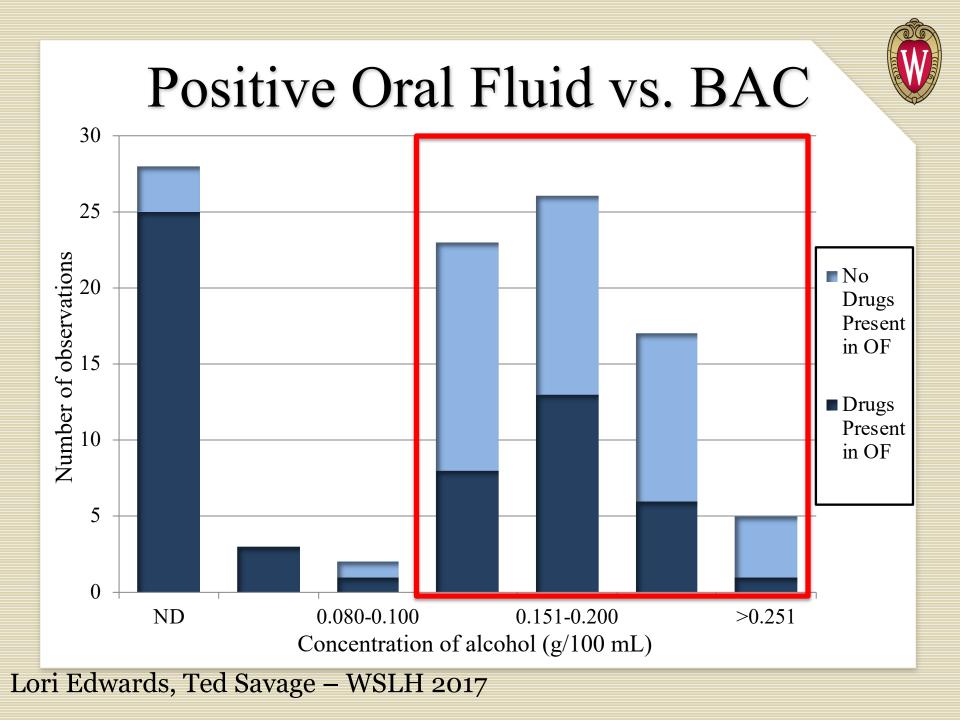
Lori Edwards, Ted Savage – WSLH 2017

Positive Drug Screening Results: Oral Fluid vs. Blood



Results: Blood Alcohol Concentration (BAC)







OF Compared to Blood

Analyte	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Accuracy
THC	88%	87%	83%	91%	88%
Cocaine	100%	99%	86%	100%	99%
Amphetamine	100%	88%	14%	100%	88%
Methamphetamine	N/A	99%	0%	100%	99%
Opiates	83%	99%	83%	99%	98%
Benzodiazepines	45%	99%	83%	94%	93%
All Drug Categories	82%	96%	70%	98%	94%

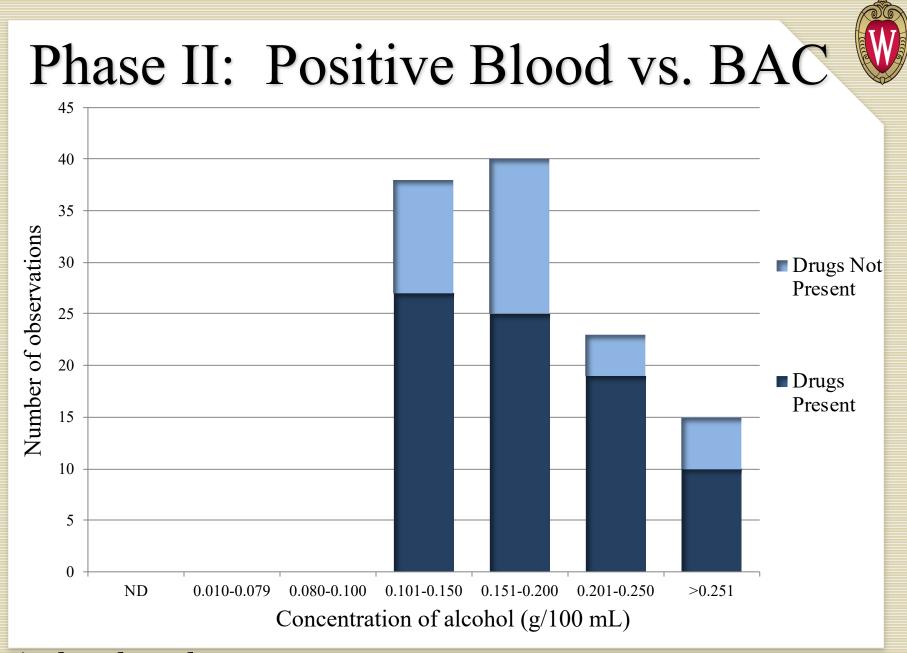
Lori Edwards, Ted Savage – WSLH 2017

Phase II

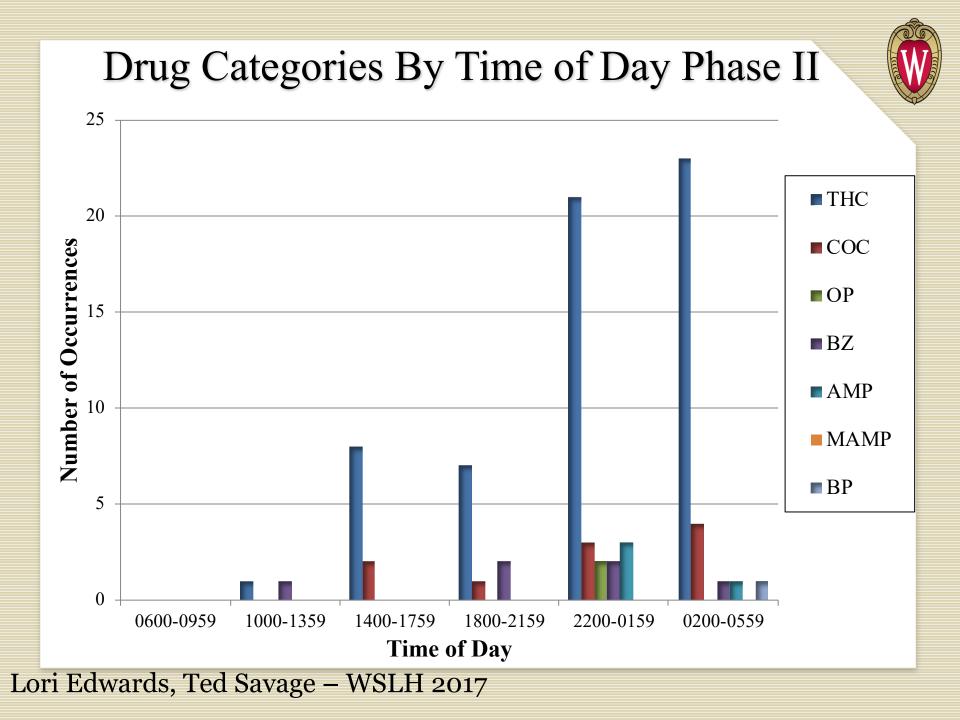


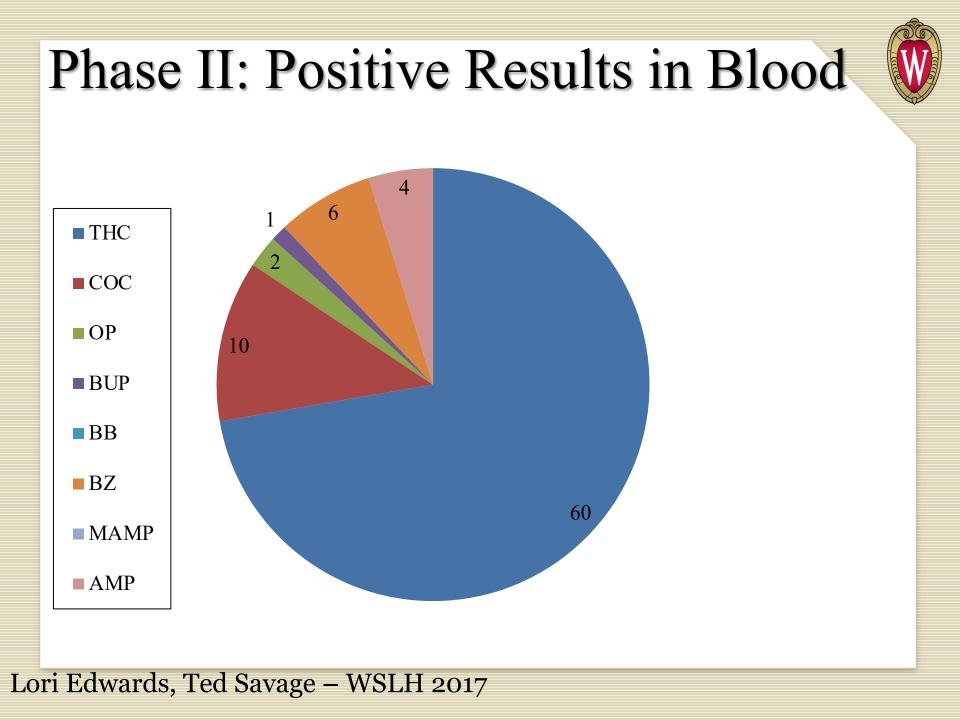
Interest in understanding the full DUID scope

- How does the lab's cancellation policy underreport DUID
- How many drivers have both EtOH and drugs on board
- Went back and performed drug testing on 116 specimen which were only tested for EtOH



Lori Edwards, Ted Savage – WSLH 2017





Phase II Results



- 116 specimens selected with BAC > 0.100g/100mL
 - 17 (15%) subjects between 10:00am-6:00pm
 - 83 (72%) subjects between 10:00pm-6:00am
- 81 (70%) subjects positive for 1 or more drug category
- 60 subjects (52%) positive for THC
- 10 subjects (9%) positive for cocaine



Summary Phase I and II 187 of 220 (85%) subjects with BACs >0.100g/100mL

141 (64%) subjects positive for 1 or more category

- 106 (57%) subjects > 0.100g/mL were positive for 1 or more drug category in blood
- Consistent correlation between OF and Blood results
- Arrests made in all time intervals



Take home message....

Phase II was an important part of the OF project

- Demonstrated the need to be looking at all drivers for drug use
- Emphasized the importance for LE to be trained to observe drug effects
- OF roadside device was helpful to LE to understand to look beyond alcohol



Analytical Toxicology

jat.oxfordjournals.org

Drugged Driving in Wisconsin: Oral Fluid Versus Blood

Lorrine D. Edwards Katherine L. Smith Theodore Savage J Anal Toxicol 1-7. Published: 14 July 2017

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ORAL FLUID ANALYSIS AT THE ROADSIDE

Guidelines available for starting a pilot project

- Intended for use in data collection projects regarding the utility of oral fluid in DUID situations
- Preliminary tests should not be considered as evidentiary
- Offered as a framework for the collection of information regarding drug use in drivers



Define Objectives (examples):

- To collect information on drug intake from stopped drivers
- To identify drivers under the influence of drugs in a more efficient and effective manner
- To use the information to potentially aid prosecution of DUID offenders, if allowable
- To provide data to assist in changing the law to include OF analysis as a viable specimen for DUID cases, or to provide data to implement the use of oral fluid
- To deter drug intake prior to driving by demonstrating reliable drug detection



Co-operation from key stakeholders, for example:

- Law Enforcement Agency Heads
- DRE /DUID officers, traffic safety officers
- District or City attorneys; TSRP's
- State Highway Safety Office
- Collection device and instrument providers
- State or local toxicology testing laboratory personnel
- Reference laboratory toxicologists
- Consultant toxicologists



Communication Complex – difficult to reach mid-level supervisors or line staff about the project

 Both ARIDE trainings in February were set up to train officers on DDS2 yet most officers didn't realize the ARIDE included oral fluid project training

- Involve traffic supervisors and line-level LE (2nd and 3rd shift) with proven records of arresting impaired drivers
- These groups proved to be the most helpful at disseminating information about the project
- Assisted in encouraging other officers to become trained in the DDS2 and project



Training

- Get the equipment in hand well before training
 - Jump through "red tape" in advance
- Train LE as close to launch date as possible

- Involve Highway Safety Offices and TSRPs immediately as well as those involved in LE budgeting
- Have the TSRP sit in on the training session, possibly provide a legal update at that time as well



Protocol for the project

- Collected information that may not have been needed or useful
- Redundancy regarding the OF test result
 - Recorded it on the form for LE, could have just printed out result from DDS2

- Keep questions to a minimum to ensure compliance
- Simple questions to include
 - PBT result?
 - Did you suspect drug impairment prior to making the arrest? Based on what articulable facts?



Invalid samples on the DDS2

- Received invalid results on a handful of test cartridges
- Likely the result of "lollipopping" the cartridge
- Actuator turned blue but fluid was drawn off the collection device

- Invalids were typically with officers that didn't attend the ARIDE training
- Make sure LE understands the proper way to collect the sample



Successes

- Placing devices at hospitals was key
- Hospitals cooperated in keeping the DDS2 devices charged
- No issues with weather when housed at hospitals
- LE did a great job of explaining project and getting consent from subjects
- Using the DDS2 at the end with no potential for recourse provided more compliance
- Did not dedicate certain LE for the oral fluid samples, tried to use any and all available and train them
- Used the DDS2 on all OWI arrests, not just those with high BAC

MANAGE PROJECT

Organize a meeting to cover project protocol:Oral fluid collection (screening and confirmation)

- On-site test training and operation of devices
 - · Instrumented devices will print and/or retain result
- Requisition forms and paperwork for confirmation tests
- Protocol for collection and submission of evidential specimen(s) to appropriate laboratory

MANAGE PROJECT

Ensure personnel understand legal aspects of the project and specimen collection

Have contact information readily available & identify individual in charge of collating results

Discuss and decide how results will be retained, analyzed, disseminated and utilized



Manage Project

Schedule a final meeting to discuss results with stakeholders

Decide whether the performance of oral fluid test devices warrants further expansion of the program, or whether the performance is not adequate for further evaluation



SUMMARY

- North American roadside surveys have established the validity and viability of oral fluid testing for in DUID
- Majority of drugs detected fall into 5 categories Recommended oral fluid drug concentrations for DUID are published
- Data from roadside/mobile oral fluid drug testing systems is increasingly published; preliminary results are encouraging

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- Guidelines for the implementation of data collection projects are available
- More and more states interested in oral fluid roadside testing in conjunction with DRE's as marijuana legalization advances and concerns about drugged driving increase

Oral Fluid and Courtroom Testimony

WISCONSIN STATE LABORATORY OF HYGIENE - UNIVERSITY OF WISCONSIN



The Role of Toxicology in the Courtroom

The Role of Toxicology

- Receive samples at the lab
- Provide ethanol and/or drug testing
 - Attend training to further develop testing abilities and interpretation skills
- Review data prior to sample reporting
- Provide reports to law enforcement and subject
- Testify at pre-trial motions and a trial



The Role of Toxicology in the Courtroom

- Blood vs urine
 - Understand matrices differences
 - Ability to testify regarding testing results
 - Know the difference between the two
 - Urine = Evidence of use
 - Blood = Recent use



The Role of Toxicology in the Courtroom

- Oral Fluid
 - Similar to blood, less like urine to indicate real time use, not historical
 - Variety of factors may effect results
 - Last time liquid consumed
 - Collection device?
 - Type of drug consumed
 - Amphetamines, benzos, etc
 - Roadside vs evidential
 - Passive exposure

Most commonly encountered drug: THC

WISCONSIN STATE LABORATORY OF HYGIENE - UNIVERSITY OF WISCONSIN



MOST FREQUENTLY ASKED QUESTIONS..

1. WHAT CONCENTRATION OF THC IN ORAL FLUID IS EQUIVALENT TO THC IN BLOOD ?

2. WHAT CONCENTRATION OF THC IN ORAL FLUID CORRELATES WITH IMPAIRMENT ?

3. IS PASSIVE EXPOSURE TO THC AN ISSUE ?

MOST FREQUENTLY ASKED QUESTIONS..

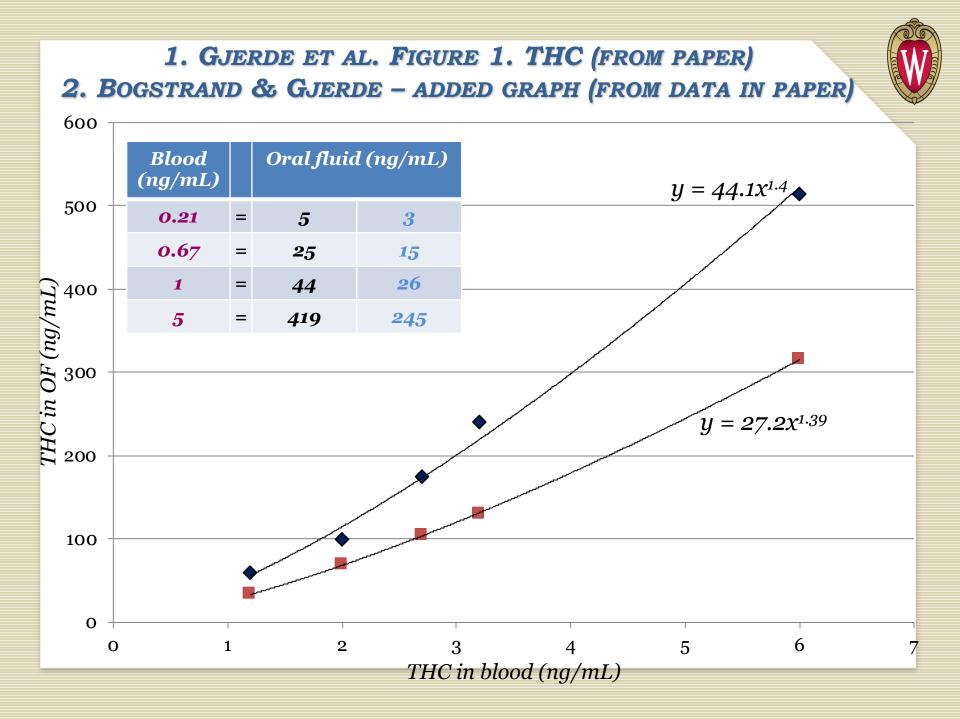


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GJERDE ET AL. Estimation of equivalent cutoff thresholds in $\Im_{\mathbb{C}}$				
blood and oral fluid for drug prevalence studies. J. ANAL. TOXICOL. 2014; 38(2): 92 – 98 (TABLE II)				
Substance	Cut-off in blood (ng/mL)	Cut-off in OF (ng/mL) 95%CI	Correlation R ²	n
Alprazolam	10	2.8 (1.8 – 4.2)	0.998	106
AMP	20	290 (84 – 680)	0.993	86
Clonazepam	10	1.2(0.2-2)	0.962	57
Cocaine	10	190 (26 – 350)	0.932	112
Codeine	10	83 (50 - 130)	0.999	92
Diazepam	50	1.1 (0.3 – 3.6)	0.930	94
METH	20	630 (120 – 1800)	0.993	55
Morphine	10	100 (37 – 180)	0.902	76
Nordiazepam	50	2.2 (1.2 - 4.5)	0.997	130
Oxazepam	50	12 (4.4 – 34)	0.962	55
THC	1	44 (27 – 90)	0.991	182
Tramadol	50	490 (85 – 1500)	0.966	51





MOST FREQUENTLY ASKED QUESTIONS..

I. WHAT CONCENTRATION OF THC IN ORAL FLUID IS EQUIVALENT TO THC IN BLOOD ?

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IS PASSIVE EXPOSURE TO THC AN ISSUE?

THC CONCENTRATION IN ORAL FLUID & SIGNS OF IMPAIRMENT

- Fierro et al. The relationship between observed signs of impairment and THC concentration in oral fluid. Drug Alcohol Depend 2014; 144: 231- 238
- Spanish researchers investigated whether the judgment of a police officer regarding signs of impairment was related to the concentration of THC in oral fluid
- 2632 drivers were investigated;
 - 253 were positive in oral fluid for THC only
- Recorded 31 signs of impairment in 6 categories

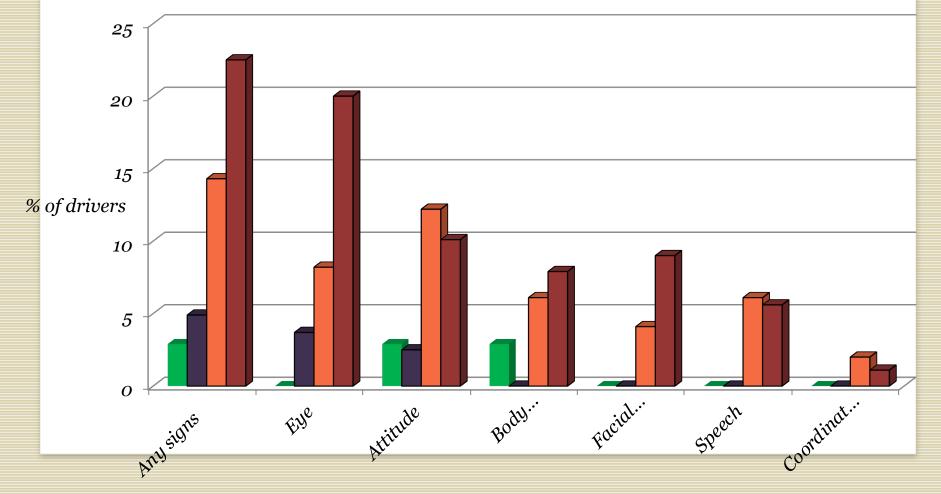


2014: FIERRO ET AL.

- 1. Eye signs: Red eyes; Brusque movement; Nystagmus; Pupil dilation or constriction; Slow pupil reaction
- **2. Attitude:** Nervous; Euphoric; Provocative; Tearful; Sleepy; Scratching; No comprehension
- 3. Body appearance: Trembling; Perspiration; Restlessness; Superficial breathing
- 4. Facial expressions: Blinking; Red nose; Sniffing; Swallowing; Cannabis smell
- **5. Speech:** Talkative; Difficulty speaking; Low tone
- 6. Co-ordination: Staggering; No co-ordinated movements; Legs trembling

RESULTS

THC < 3ng/mL (n = 34)
THC 3 - 25ng/mL (n = 81)
THC 25 - 100ng/mL (n = 49)
THC > 100ng/mL (n = 89)







- A relationship was found between THC concentration in OF and some observed signs of impairment
- Eye signs were noticeable at OF THC >3ng/ml
- OF THC >25ng/ml was related to behavior, facial expression, and speech signs of impairment

Summary

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- Alcohol and THC contributed to impairment
 independently and, when taken simultaneously,
 effects were comparable to the sum of the
 effects when consumed separately
- The observation of signs of impairment due to cannabis occurred in an OF concentration-related manner
 - As a **clinical test**, OF had low sensitivity and specificity in a random roadside survey



FREQUENTLY ASKED QUESTIONS..

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2. WHAT CONCENTRATION OF THC IN ORAL FLUID CORRELATES WITH IMPAIRMENT?

3. IS PASSIVE EXPOSURE TO THC AN ISSUE ?



PASSIVE EXPOSURE

>Could occur with any drug, but marijuana is most likely

Two publications:

1. Moore C. et al. Cannabinoids in oral fluid following passive exposure to marijuana smoke. Forensic Sci. Int. 2011; 212: 227 - 230

2. Cone E. et al. Nonsmoker exposure to secondhand cannabis smoke: III. Oral fluid and blood drug concentrations and corresponding subjective effects. J. Anal. Toxicol. 2015; doi: 10.1093/jat/bkv070



MOORE ET AL - SUMMARY

- Extent of marijuana use around subjects was not controlled
- THC was absorbed by drug-free individuals under realistic conditions when exposed to marijuana
- THC was detected in all subjects
- In close proximity to smokers, THC levels were up to 17ng/mL after 3 hours
- No samples were positive for the metabolite THC-COOH
- Passive exposure defense could be used especially if testing at low concentrations



PASSIVE *EXPOSURE*

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SUMMARY – CONE ET AL.



Extreme exposure to marijuana results in THC deposition in oral fluid

The metabolite, THC-COOH was not detected in any oral fluid specimens

SUMMARY – CONE ET AL.

- Only one non-smoker was positive by THC ELISA (4ng/mL) 3 hours after exposure
- Most non-smokers tested positively for less than 3 hours
- In the ventilated room the number of positive tests was much lower

SUMMARY – CONE ET AL.



"Extreme exposure of non-smokers could lead to positive drug tests and drug-induced behavioral changes not unlike those produced by active cannabis smoking"

> "It seems likely that exposure under less extreme conditions, such as casual encounters with cannabis smoke and in situations where an individual was not aware of smoke exposure, would be very unlikely to result in positive tests and behavioral changes"



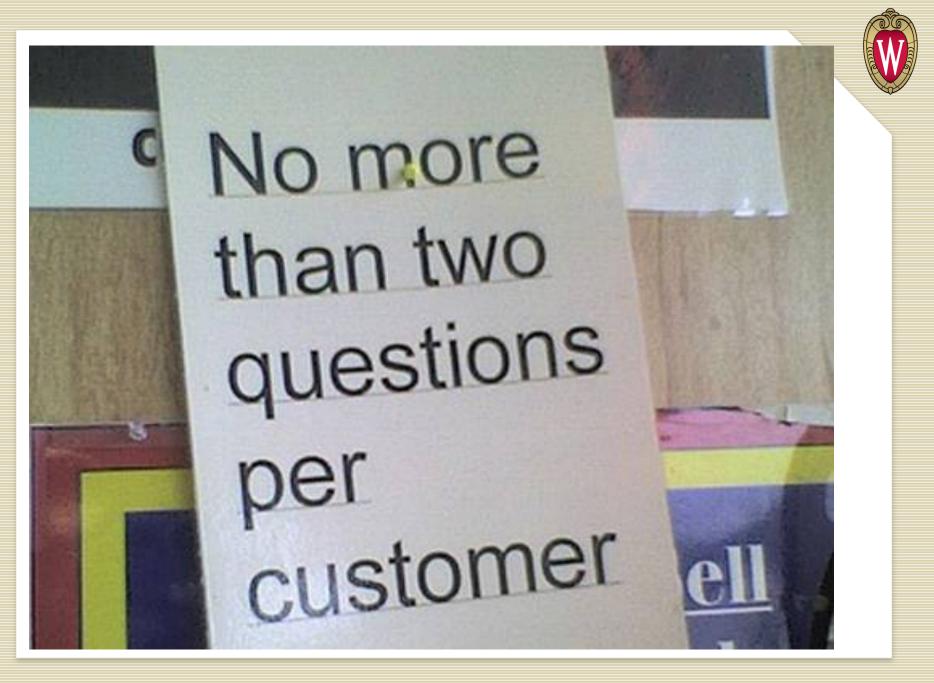
How does this all apply to the courtroom?

- Understand laws in your state regarding OF
 - Ok to collect?
 - Limitations in the statutes
- Know the difference between non-evidential and evidential tests
 - Roadside
 - Forensic
- Are the devices reliable and "approved"



OF in the courtroom

- Read the literature
- Use your colleague's knowledge and experience
- Read the literature
- Keep up on what other states are doing
 - Pilot projects, use in arrests, etc
- Read the literature
- SOFT/AAFS Drugs and Driving Committee
 - Oral Fluid Subcommittee



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