OVERVIEW

1. Impaired driving and utility of oral fluid
2. North American roadside surveys
3. California initiative
4. Oral fluid in DRE training sessions
5. DRE, drivers and drug test results (Oklahoma)
6. Ongoing projects

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 in the wrong way
**WHY ORAL FLUID?**

- Drugs accumulate in saliva by diffusion from the blood
- Drug properties determine how much is deposited into oral fluid
- Easy, rapid collection
- Can be taken proximate to the traffic stop
- Non-invasive & observed
- Identification of active compound may provide information on recent drug intake
- 2007, 2013 large scale NHTSA Studies included collection of oral fluid and blood in Roadside Surveys

**NORTH AMERICA: ROADSIDE SURVEYS**

- 2010, 2012: California Roadside Survey (Oral fluid)
- 2013, 2014: National Roadside Survey (Blood & oral fluid)
- 2014: Canadian Roadside Survey, Ontario (Oral fluid)
- 2014: Washington State Initiative (Blood & oral fluid)

**MEASURING THE PROBLEM**

- 2007: National Roadside Survey
- Blood & oral fluid
- 2010, 2012: California Roadside Survey (Oral fluid)
- 2013, 2014: National Roadside Survey (Blood & oral fluid)
- 2014: Canadian Roadside Survey, Ontario; (Oral fluid)
- 2014: Washington State Initiative (Blood & oral fluid)
**Sample Collection**

**Blood**
- Gray-topped tube
- 3,276 samples
- 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
- 7,539 samples

**2007 Results**
- 16.3% of drivers positive for drugs
- Almost 50% for 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

**2007 Drug Test Panel**
- Cocaine
- Marijuana
- Opiates
- Amphetamines
- Benzodiazepines (8)
- Tramadol
- Methadone
- Fluoxetine
- Sertraline
- Phencyclidine
- Barbiturates
- TCA's (4)
- Zolpidem
- Carisoprodol
- Methyldone
- Oxycodone/Oxymorphone
- Meperidine
- Propoxyphene
- Dextromorphan
- Ketamine
Five Classes cover >90% of positives

Table showing % of oral fluid positives across different classes.

Measuring the Problem

- 2007: National Roadside Survey (Blood & oral fluid)
- 2010, 2012: California Roadside Surveys
  - Oral fluid
- 2013: National Roadside Survey (Blood & oral fluid)
- 2014: Canadian Roadside Survey, Ontario; (Oral fluid)
- 2014: Washington State Initiative (Blood & oral fluid)

California Surveys

Oral fluid:
- 2010:
  - 14.4% of all drivers positive for drugs
  - 8.5% of all drivers positive for THC
- 2012:
  - 14% positive for drugs
  - 7.4% positive for THC
**Measuring the Problem**

- 2007: National Roadside Survey (Blood & oral fluid)
- 2010, 2012: California Roadside Surveys
  - Oral fluid
- 2013, 2014: National Roadside Survey (Blood & oral fluid)
- 2014: Canadian Roadside Survey, Ontario; (Oral fluid)
- 2014: Washington State Initiative (Blood & oral fluid)

**Sample Collection**

**Blood**
- Gray-topped tube
- 4,686 samples
- 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
- 7,881 samples
**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

**Positivity Rate: Night-time Drivers**

- 2007
- 2013-2014

**Results**

- 2007
- 2013-2014
**Summary**

- While overall drug positives in drivers were lower in Canada than the USA, the percentage of THC positives remains approximately 50%.
- 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: 20%
- The drug with the largest increase in weekend night time prevalence was THC:
  - 2007: 8.6%
  - 2013-14: 12.6%
CA Office of Traffic Safety Initiative

- Followed 2010 and 2012 CA studies where drugs were detected in the oral fluid of 1 out of 7 drivers
- **Objective:**
  - To reduce the incidence of DUID through increased enforcement
  - LA City Attorneys obtained funding to begin OF testing of drivers
- Suspect / driver underwent DRE exam and blood collection
- Then, voluntary rapid OF test using either DDS2 or Drug Test 5000 performed by officer
- Quantiscal™ specimens obtained for confirmation

CA-OTS Initiative

- CA does not specifically allow oral fluid analysis for DUID offenses
- Under this research project, drivers tested voluntarily
- 2 year project, which ended September 2014
- Many choices for oral fluid roadside testing….

- So which oral fluid test devices were chosen for the project, and why?

Important Features

- Easy, rapid collection at time of traffic incident
- Fast results (all devices run within 10 minutes)
- Instrumented testing device preferred
- Printed or stored test result

- Outcome assists law enforcement in decision making regarding the driver's competence
CA-OTS Initiative

- Alere DDS2 and Draeger Drug Test 5000 chosen

Printed or retained results
Published field studies
Law enforcement / DRE involvement

CA-OTS Sites

- Kern County PD, LA County PD (Draeger Drug Test 5000)
- Sacramento PD, Fullerton PD (Alere DDS2®)

Fullerton PD:
- 92 subjects with complete test results
  - DDS2® oral fluid screening
  - Quantisal™ oral fluid confirmation (NMS Labs)
  - Blood analysis (Orange County Crime Laboratory)

Sacramento PD:
- 34 drivers with complete test results
  - DDS2® oral fluid screening
  - Quantisal™ oral fluid confirmation (NMS Labs) and/or crime laboratory blood analysis
SUMMARY: FULLERTON PD

- 92 subjects completed OF rapid screening, OF confirmation, and blood analysis
- Excellent results
- DDS2:
  - 1 false positive METH - not confirmed in either matrix
  - 3 false negative benzo not confirmed in OF; alprazolam in blood
  - 3 false negative opiates not confirmed in OF; MOR in blood
  - 3 false negative THC not confirmed in OF; present in blood
  - Sensitivity decreased when the metabolite THC-COOH included in blood confirmation

SUMMARY: SACRAMENTO PD

- 34 drivers:
  - OF roadside screening, OF confirmation, and/or blood analysis
- DDS2:
  - THC and OPI: no false positives; no false negatives
  - COC: 1 false positive; no false negatives
  - AMP & METH: 3 false positives; no false negatives
  - Benzodiazepines: 3 false positives; 1 false negative

COMBINED DATA:

DDS2 v. QUANTISAL™ (n = 126)
FULLERTON AND SACRAMENTO PD
CA STUDY
LOS ANGELES AND KERN COUNTIES (n = 235)

<table>
<thead>
<tr>
<th>Drug</th>
<th>TP</th>
<th>FN</th>
<th>FP</th>
<th>TN</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Accuracy (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
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<tbody>
<tr>
<td>THC</td>
<td>82</td>
<td>3</td>
<td>13</td>
<td>150</td>
<td>98.8</td>
<td>98.7</td>
<td>98.7</td>
<td>97.6</td>
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<td>Cocaine</td>
<td>13</td>
<td>3</td>
<td>72</td>
<td>188</td>
<td>96.0</td>
<td>95.1</td>
<td>95.6</td>
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<td>97.5</td>
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<td>Amphetamine</td>
<td>75</td>
<td>2</td>
<td>74</td>
<td>184</td>
<td>85.7</td>
<td>98.9</td>
<td>98.9</td>
<td>96.2</td>
<td>95.5</td>
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<tr>
<td>Methamphetamine</td>
<td>97</td>
<td>0</td>
<td>97</td>
<td>184</td>
<td>100</td>
<td>98.9</td>
<td>98.9</td>
<td>100</td>
<td>100</td>
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<tr>
<td>THC</td>
<td>10</td>
<td>3</td>
<td>19</td>
<td>184</td>
<td>96.0</td>
<td>98.9</td>
<td>98.9</td>
<td>96.2</td>
<td>95.5</td>
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<tr>
<td>Opiates</td>
<td>19</td>
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<td>0</td>
<td>216</td>
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<td>100</td>
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<td>100</td>
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<tr>
<td>Methadone</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>233</td>
<td>100</td>
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<td>Overall</td>
<td>125</td>
<td>10</td>
<td>8</td>
<td>1416</td>
<td>95.5</td>
<td>99.4</td>
<td>98.9</td>
<td>96.3</td>
<td>99.3</td>
</tr>
</tbody>
</table>

*M. Mohr, NMS Labs, 2014 SOFT presentation

CONCLUSIONS

- Two mobile systems for drug detection in oral fluid were tested under realistic conditions in California Police Departments during 2014
- Overall device performance was excellent when compared to either oral fluid or blood as the “gold standard”
- In Fullerton and Sacramento - 756 tests:
  - 1% false positive results
  - 0.67% false negative results
- Accuracy in Kern and LA Counties: 98.9%

Acknowledgements

- California Office of Traffic Safety: Julie Schilling
- LA City Attorneys: Janette Flintoft
- Kern County DA’s office: Michael Traceburn
- DRE Officers and Police Personnel
  - Sgt. Timothy Petropoulos, Capt. George Crum (Fullerton PD)
  - Sgt. Christian Prince (Sacramento PD)
  - Sgt. Bill Ware (Bakersfield PD)
- NMS Laboratory Staff: Orange County Crime Lab Staff:
  - Dr. Barry Logan
  - Jennifer Harmon
  - Amanda Mohr
  - Dana Mati
DRE’S, DRIVERS & ORAL FLUID
DRUG TEST RESULTS

TULSA PD: DRUGGED DRIVING

- Can a roadside oral testing device serve as a preliminary screen to aid police officers in DUID detection?
- Is oral fluid a reliable specimen for collection and roadside testing?
  - Drivers stopped
  - DRE evaluation (includes SFST’s)
  - DDS2 oral fluid test:
    - non-evidentiary
  - Blood and/or urine collected as per Tulsa protocol:
    - for evidential purposes

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

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Amphetamines</th>
<th>Benzodiazepines</th>
<th>Cocaine</th>
<th>Marijuana metabolites</th>
<th>Opium</th>
<th>THC</th>
</tr>
</thead>
</table>
**HOW DOES IT WORK?**

- Lateral flow device

2013: **TULSA POLICE DEPARTMENT**

- Study designed with Drug Recognition Experts (DRE)
- DRE Training involves recognition of signs and symptoms caused by drugs falling into seven categories:
  - Cannabis
  - Narcotic analgesics (e.g. heroin, oxycodone)
  - CNS Stimulants (e.g. amphetamines, cocaine)
  - CNS depressants (e.g. benzodiazepines)
  - Hallucinogens (e.g. LSD)
  - Dissociative Anesthetics (e.g. PCP)
  - Inhalants (paint, gasoline)

**SOFTWARE FOR DDS2 SCREEN**
### RESULTS

<table>
<thead>
<tr>
<th>Subject</th>
<th>DRE observations</th>
<th>Intoxilyzer</th>
<th>DDS2 QuantiChrom™ (ng/mL)</th>
<th>Blood /Urine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Odor of burnt marijuana; Elevated blood pressure; Error code THC: 396</td>
<td>THC 44</td>
<td>THC-COOH positive</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>No drivers license</td>
<td>THC</td>
<td>ETH: 7299</td>
<td>AMP: 864</td>
</tr>
<tr>
<td>3</td>
<td>Parked vehicle, engine running</td>
<td>THC</td>
<td>THC: 44</td>
<td>THC: 99</td>
</tr>
</tbody>
</table>

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<tr>
<td>4</td>
<td>Driving erratically; HGN: no clues; Officer opinion: not impaired</td>
<td>COC</td>
<td>COC: 0.00%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
<td>THC</td>
<td>THC: 144</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Passed out at light, vehicle running, feet on brake; Stated taking one Xanax and smoking just 2-3 hours prior to stop</td>
<td>THC</td>
<td>THC: 99</td>
<td></td>
</tr>
</tbody>
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### COMBINED RESULTS

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<tr>
<td>7</td>
<td>Subject passed out in driver's seat with vehicle running; slurred speech; staggered gait; droopy eyes; used vehicle to balance</td>
<td>THC</td>
<td>THC: 44</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Subject speeding; ETH: odor; bloodshot eyes, slurred speech</td>
<td>THC</td>
<td>THC: 144</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Failed to maintain traffic lane; ETH: odor; Stated: beer 4 hours ago; Xanax night before; Refused collection</td>
<td>THC</td>
<td>THC: 99</td>
<td></td>
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<td>11</td>
<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
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<td>12</td>
<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
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<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
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<tr>
<td>21</td>
<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
<td>THC</td>
<td>THC: 144</td>
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<tr>
<td>25</td>
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<tbody>
<tr>
<td>26</td>
<td>Subject stated taking Larmat (Hyc), Xanax (alprazolam), marijuana, and cocaine</td>
<td>THC</td>
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<tr>
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OUTCOME

• DDS2 results correlated with laboratory screening and LC-MS/MS confirmatory tests
• Yes, a roadside test can serve as a preliminary screen to aid police officers in DUID evaluation
• Oral fluid analysis provided reliable results, consistent between laboratories
• Yes, oral fluid is a reliable specimen for collection and roadside testing
• Results very encouraging
• 2015: Project is on-going

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?
**GJERDE ET AL.** Estimation of equivalent cutoff thresholds in blood and oral fluid for drug prevalence studies. J. ANAL. TOXICOL. 2014; 38(2): 92 – 98 (TABLE II)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cut-off in blood (ng/mL)</th>
<th>Cut-off in OF (ng/mL)</th>
<th>95%CI</th>
<th>Correlation R²</th>
<th>n</th>
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<tbody>
<tr>
<td>Alprazolam</td>
<td>10</td>
<td>2.8 (1.8 – 4.2)</td>
<td>0.995</td>
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<tr>
<td>AMP</td>
<td>20</td>
<td>290 (84 – 680)</td>
<td>0.992</td>
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<tr>
<td>Clonazepam</td>
<td>10</td>
<td>1.2 (0.3 – 2)</td>
<td>0.942</td>
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<tr>
<td>Cocaine</td>
<td>10</td>
<td>790 (26 – 150)</td>
<td>0.932</td>
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<td>Codeine</td>
<td>10</td>
<td>88 (28 – 199)</td>
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<td>Diazepam</td>
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<td>1.1 (0.3 – 3.6)</td>
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<td>Meth</td>
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<td>490 (29 – 850)</td>
<td>0.993</td>
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<td>Methadone</td>
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<td>100 (20 – 180)</td>
<td>0.992</td>
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<tr>
<td>Methadone</td>
<td>50</td>
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<td>76</td>
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<tr>
<td>THC</td>
<td>1</td>
<td>44 (27 – 90)</td>
<td>0.991</td>
<td>182</td>
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<tr>
<td>Tramadol</td>
<td>50</td>
<td>490 (85 – 1508)</td>
<td>0.966</td>
<td>51</td>
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</tr>
</tbody>
</table>


**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?**
THC CONCENTRATION IN SALIVA & 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)
SUMMARY

- 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
- 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

PLANNING A PROJECT

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
**PLANNING A PROJECT**

- 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

**PLANNING A PROJECT**

- 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

**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
- 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 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
- 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