# ORAL FLUID
# IMPACT IN DUID INVESTIGATIONS

## AN AUSTRALIAN EXPERIENCE, 2004 –

## MOVING FORWARD IN CALIFORNIA, 2018 –

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*California Impaired Driving Task Force – September 27, 2018*

# Official Disclaimer

The opinions expressed here are the opinions of the speaker and do not reflect any view, position or opinion of the San Francisco Office of the Chief Medical Examiner

# Victoria, Australia


# Victorian Institute of Forensic Medicine (VIFM)

- Population > 6.4 million (CA ~40 million)


- 6000 coroners cases
- Forensic Pathology/Autopsy
- Forensic Odontology, Anthropology etc…
- Histopathology
- Molecular Biology/DNA
- National Coroners information System
- Clinical Forensic Medicine
- Department of Forensic Medicine (Monash University)

- Forensic toxicology (total 20,000+ cases)
  - 4,500 PM comprehensive testing
  - 400 DFSA
  - 100+ Hair
  - Private Casework
  - 6,000 Injured Drivers, passengers or pedestrians (Blood collected from hospital)
  - **10,000 + Oral Fluid**

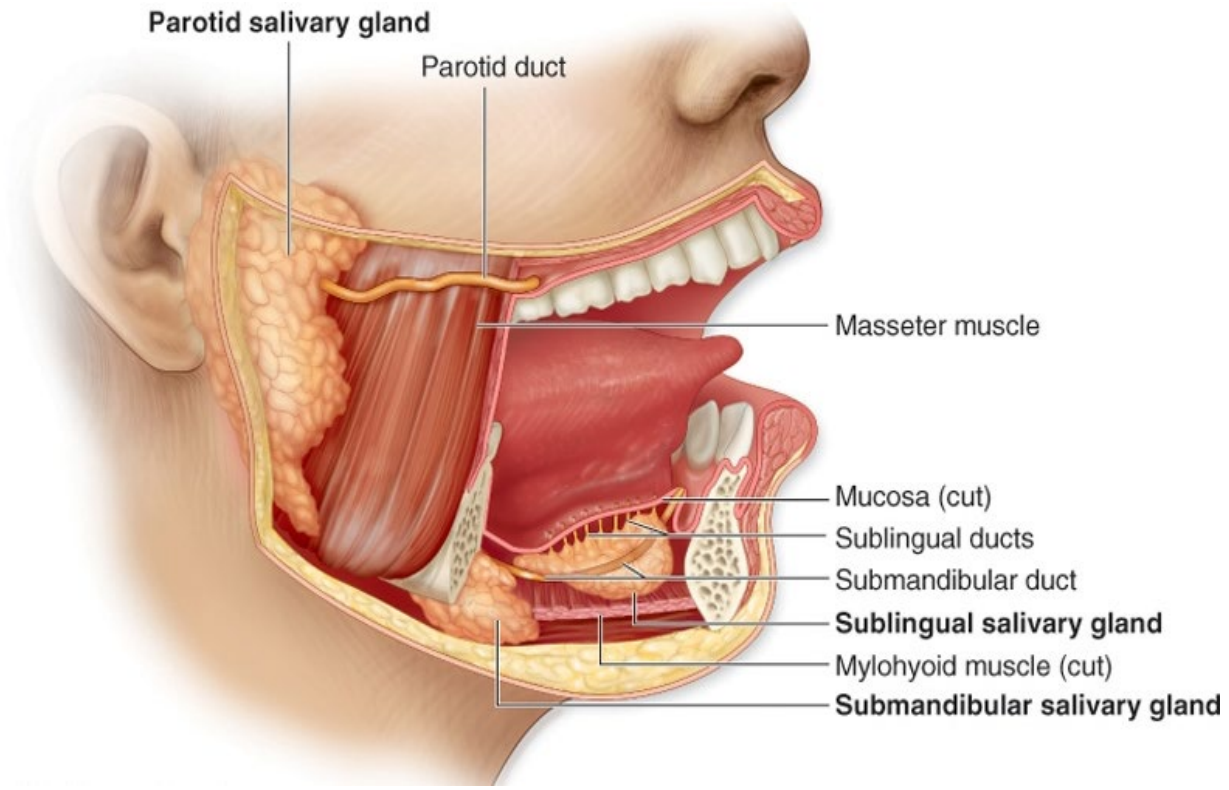
- Early acknowledgement - Prof. Olaf Drummer & Dr. Dimitri Gerostamoulos

# ORAL FLUID & DUID

Research to Implementation

# Oral Fluid

- OF is a mixture of fluids excreted Parotid, Sublingual & Submandibular glands
- It is a plasma ultra-filtrate
- Drugs partitioned from blood to OF by extraction & diffusion
- OF offers some advantages over other typ specimens
  - readily accessible
  - less susceptible to adulteration or substitution by the donor
  - Drugs can be detected in oral fluids rapidly



# Oral Fluid Drug Concentrations & Pharmacokinetics studies

| Drug | Dose (mg) | Peak concentration (ng/mL) |
|---|---|---|
| Methamphetamine | 9-18 (SM IV)<br>10 & 20 (PO ss) | Highest ≤1000, median ~ 250<br>100 & 200 |
| MDMA | 100<br>75 | 3400<br>1200 |
| Codeine | 30 (PO)<br>60 & 120 (PO)<br>60 & 120 (PO) | 3500<br>600 & 1600<br>≤4000 |
| THC | 2-25 (SM), 20-25 (PO)<br>16 & 34 (SM)<br>16 (SM) | 70 (SM), 4.0 (PO)<br>900 & 4200<br>150 - 390 |
| Cocaine | ~40 (IV, SM) | 400-1900 |
| Heroin | 12 (IN)<br>2.6-20 (IV, SM) | 300<br>>3000 |

IN = intra-nasal, IV = intravenous, PO = oral, SM = smoking, ss = sustained release

*Drummer, Forensic Science International : 2005;150:133-42*

# Window of Detection

- How long after consuming illicit drugs can they be detected?

- THC for several hours after use, depends on:
  - Strength and type of cannabis product
  - Individual pharmacokinetics
  - THC metabolites from previous use increase detection window
  - Prof. Huestis/NIDA

- Methamphet & MDMA may be detected for ~ 1 day or more, depends on:
  - Large doses, other drugs taken at the same time
  - Individual pharmacokinetics
  - May affect the duration of the effects of these drugs

# Background (DUID Research)

- Research started in 1990s in detection of drugs in OF. Some larger studies:
- Roadside Testing Assessment (ROSITA) study – 1999-2000 (Alain Verstraete)
  - 8 European countries evaluated technologies to detect drugs at roadside
- Roadside Testing Assessment (ROSITA) study – 2003-2005/6 (Alain Verstraete)
  - 6 EU and 4 states in US (funded by NIDA & NHTSA)
- Driving under the Influence of Drugs, Alcohol & Meds (DRUID) study – 2006-2011
  - > 20 European countries
  - New insights to the real degree of drug impairment and their actual impact on road safety
- Need: toxicology in DUID; OF; cut-offs/per se; impairment/DRE; rehabilitation
- Australian studies

# Background (DUID Research - Australia)

- The Parliamentary Road Safety Committee examined the issues of drugs other than alcohol in their enquiry in 1994-1996
  - 41 recommendations

- Other committees formed b/w DOJ, VIFM, VicRoads (DMV) & Victoria Police (CHP, DEA, SFPD, LAPD, etc. we have 1)
  - Led to enactment of legislation to detect impaired drivers – December 2000
  - For more effective deterrence Government enact random drug testing legislation – 2003

# Background (DUID Research - Australia)

- The Parliamentary Road Safety Committee examined the issues of drugs other
  - 41
- Othe ice (CHF
  - Lec
  - For 3

PERGAMON

Accident Analysis and Prevention 943 (2003) 1–10

ACCIDENT ANALYSIS & PREVENTION

www.elsevier.com/locate/aap

## The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes

Olaf H. Drummer [a,*], Jim Gerostamoulos [a], Helen Batziris [a], Mark Chu [a], John Caplehorn [b], Michael D. Robertson [c], Philip Swann [d]

[a] *Department of Forensic Medicine, Victorian Institute of Forensic Medicine, Monash University, 57-83 Kavanagh Street, Southbank, Vic. 3006, Australia*
[b] *School of Public Health, University of Sydney, Sydney, Australia*
[c] *Formerly of Department of Forensic Medicine, Monash University, Melbourne, Australia*
[d] *Road Safety Section, VicRoads, Denmark St, Kew 3101, Australia*

Received 29 May 2002; received in revised form 28 October 2002; accepted 25 November 2002

# Commissioned Research Studies OF/DUID (Australia)

- A number of studies to support the proposal & to validate road testing devices
  - Early 2000s
- Swinburne University volunteers studies
  - Several for methamphetamine and cannabis
  - Devices tested
  - Blood and oral fluid concentrations
  - Impaired and performance on driving simulator
- Field Studies by Police
  - To determine false positive rate
- VIFM evaluations
  - Cross-reactivity
  - False positive rate on control samples
  - Sensitivity and reproducibility

# Outcomes

- Standard doses of cannabis & methamphetamine could be detected in OF
  - Using roadside & standard laboratory techniques
- Selected devices could detect drug for a period after dosing
  - Very low false positive rate
  - Sensitivity was conservative
- Two devices chosen based on police operational requirements & performance
  - DrugWipe II
  - Rapiscan using Cozart collector (3 fold dilution in buffer)
- Laboratory Confirmation required
  - GC/MS & LC-MS/MS

# Drug Bus – started in Dec 2004 in Vic



- Meth, MDMA & THC
  - *Road Safety Act 2003*
    - Amended the *Road Safety Act 1986*
- Rationale, drugs selected because:
  - Impairing substances with the highest incidence in the blood of drivers
  - Clear evidence that drivers using these drugs are at increased risk of causing crashes
  - Not found in any prescription medicine (in Aus!)
  - Reliably detected in OF of drivers at the time of adversely affecting to drive safely

# Victoria Police Testing Protocol – Random Testing

1. Drivers stopped at road-block **randomly**
   - Breath alcohol test (if positive no drug test conducted)
2. If BrAC negative, drug test conducted
   - DrugWipe II test – swipe of top of tongue
   - ~ 5 min incubation time
3. If OF drug negative, driver can proceed;
   - if positive driver is escorted to “drug bus”
   - Cozart Rapiscan OF tests for drugs again
   - ~ 10-15 min incubation time
4. If OF drug negative, driver can proceed;
   - <u>if positive, 1 month suspended license</u>
5. <u>OF analyzed & confirmed by LC-MS/MS in lab</u>
   - If confirmed positive, driver will be prosecuted

# Victoria Police Testing Protocol – Observed impairment

1. Drivers stopped once **impairment is observed**
   - Breath alcohol test (if positive no drug test conducted)

2. Can test both Breath alcohol and/or drug testing
   - Alcohol – BrAC (if positive, driver will be prosecuted)
   - Drug – Blood to lab

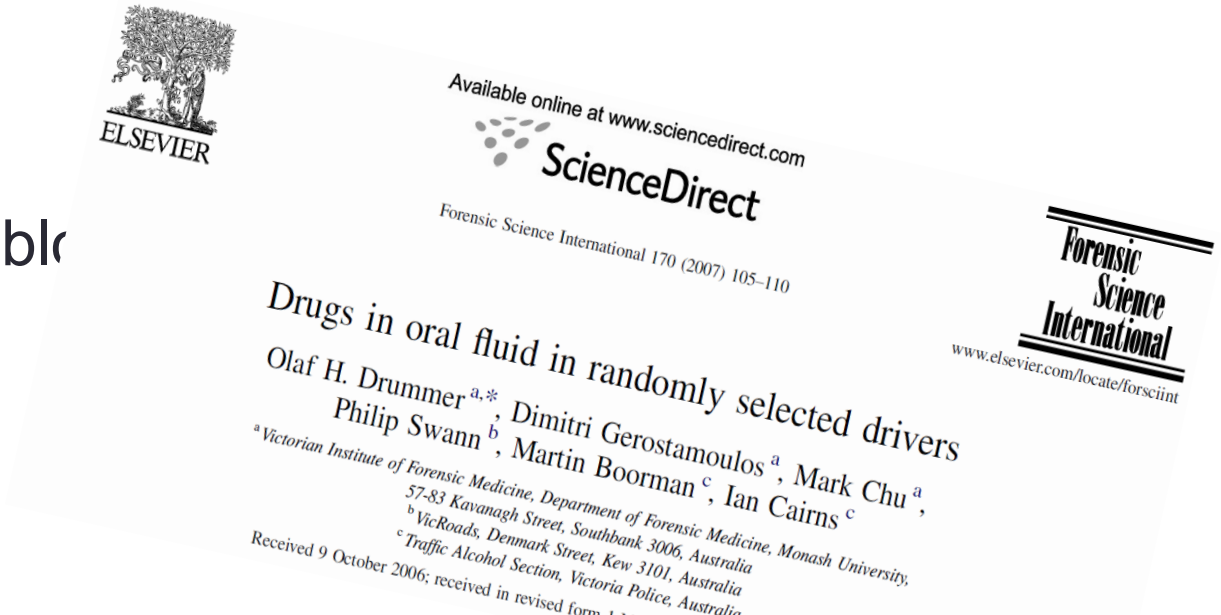
1. <u>Blood analyzed for (any) drugs by LC-MS/MS in lab</u>
   - if positive, driver will be prosecuted

# False positive rate

- Drug wipe
  - Very few in early pre-trial tests
  - None in 220 measurements using drug-free oral fluid
- Cozart Rapiscan
  - Very few in early pre-trial tests
  - One in 400 measurements
  - FP was negative on re-test.
- Cut-offs were high to avoid false positives
- Of course improved since 15 years ago…

# 2004 to 2005 - Device Performances

- 750 cases submitted to laboratory for analyses
- 38 cases with inconsistent readings
  - 0.01% of screened drivers
  - Cases dropped at roadside
- 9 cases both devices positive & drugs not confirmed
  - 8 to MA, 1 to THC
  - 99% cases confirmed positive
- 12 % (n=86) of cases req collection of blo
  - no OF
  - 83 confirmed positive to drugs (98%)
  - 2 cases not confirmed positive (2%)


ELSEVIER

Available online at www.sciencedirect.com

ScienceDirect

Forensic Science International 170 (2007) 105–110

Forensic Science International

www.elsevier.com/locate/forsciint

Drugs in oral fluid in randomly selected drivers

Olaf H. Drummer [a,*], Dimitri Gerostamoulos [a], Mark Chu [a], Philip Swann [b], Martin Boorman [c], Ian Cairns [c]

[a] Victorian Institute of Forensic Medicine, Department of Forensic Medicine, Monash University, 57-83 Kavanagh Street, Southbank 3006, Australia

[b] VicRoads, Denmark Street, Kew 3101, Australia

[c] Traffic Alcohol Section, Victoria Police, Australia

Received 9 October 2006; received in revised form

# 2004 to 2005 - Summary

- Victorian random drug testing program for 3 drugs
  - Unique approach in using 2 screening devices in series
  - Over 30,000 screened drivers
- Over 700 confirmed positive cases
  - Mainly younger male drivers
  - MDMA often associated with MA (75%)
- Prevalence of drugs 2.4%
  - MA 2.0%, MDMA 1.1%, THC 0.7%
- Program expanded to NSW, South Australia & Tasmania
  - (all states followed in subsequent years)

# DRUGS IN ORAL FLUID AS4760

Standards Australia

# AS 4760:2006


Australian Standard®

**Procedures for specimen collection and the detection and quantitation of drugs in oral fluid**

First published as AS 4760—2006.

# Applications of Oral Fluid testing

- All Australian states screen OF at roadside for methamphet, MDMA & THC
  - Over 100,000 tests per year
  - Positive rate 2-4% drugs and 1% alcohol
  - However, not just in DUID…
- Also in other industries
  - Australia saw a huge increase in the use of OF for drug detection for illicit drugs
  - In workplaces (e.g. aviation, mining, petrochemical and trucking industries)
  - Unions prefer OF to urine testing
  - Focus on safety rather than private time drug use

# Need for Oral Fluid Standard

- The increasing awareness and use of oral fluid for drug detection led to the initiation of a committee to produce an Australian Standard in 2005
  - “procedures for the collection, detection and quantitation of drugs in oral fluid”

- Recognition that OF drug testing would not replace urine testing (AS4308), rather
  - Enable detection of drugs used more recently
  - Better to show impairment at a workplace or driving a motorized vehicle

- **AS 4760:2006**

# LAB CONFIRMATION ANALYSIS

Victoria / VIFM

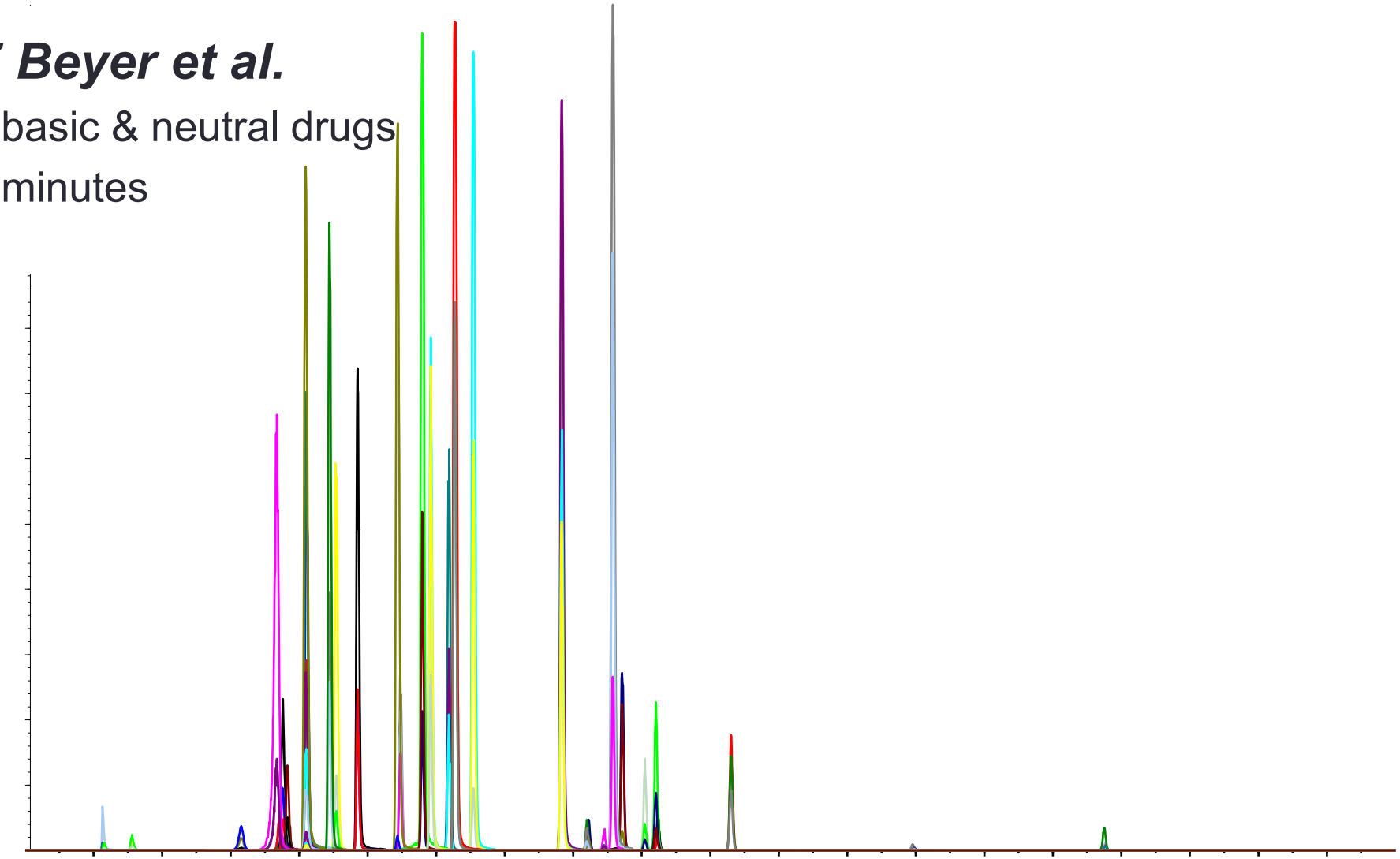
# Oral Fluid Collection (Victoria)

- **Dec 2004 – Begin OF testing**
  - Methamphetamine/THC/MDMA
  - ~3,000 roadside screens / 200 lab confirmations
    - 2 x GC-MS methods

- **2007**
  - ~ 26,000 roadside screens / 400 lab confirmations
    - 1 x LC-MS/MS method

## *2007 Beyer et al.*

- 32 basic & neutral drugs
- 20 minutes



# We were happy…

***2007 Beyer et al.***

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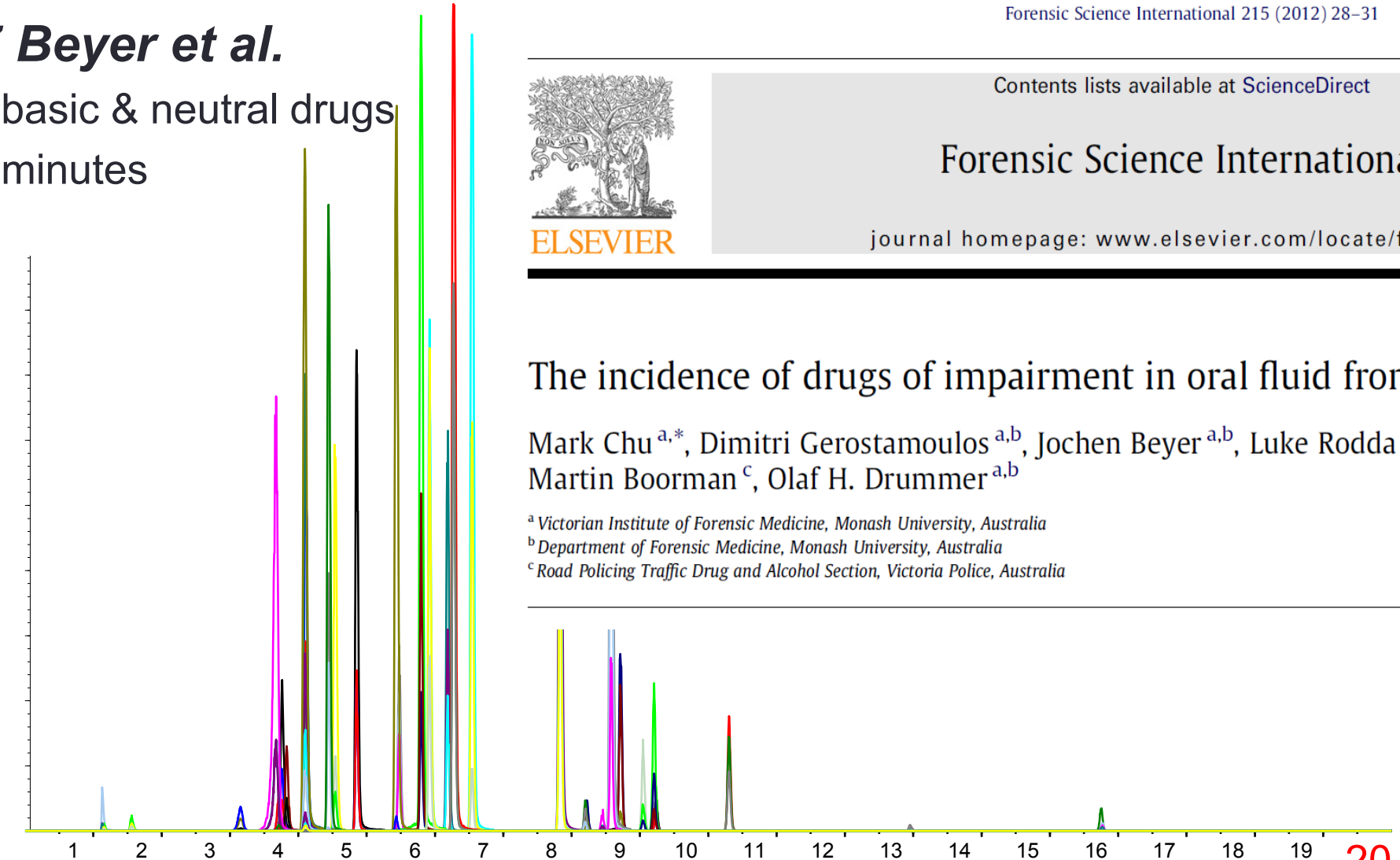
- 20 minutes

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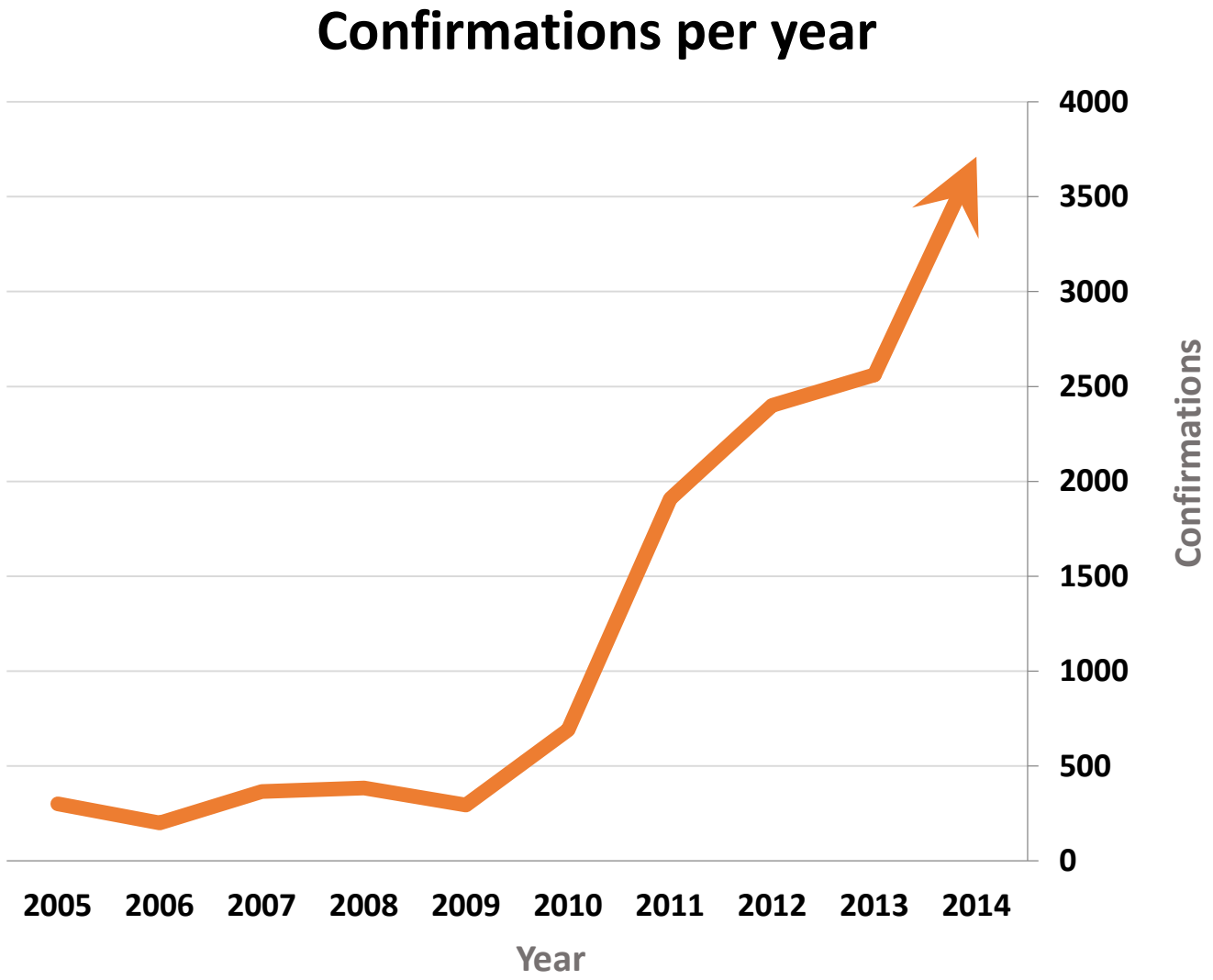
## The incidence of drugs of impairment in oral fluid from random roadside testing

Mark Chu [a,*], Dimitri Gerostamoulos [a,b], Jochen Beyer [a,b], Luke Rodda [a,b], Martin Boorman [c], Olaf H. Drummer [a,b]

[a] *Victorian Institute of Forensic Medicine, Monash University, Australia*
[b] *Department of Forensic Medicine, Monash University, Australia*
[c] *Road Policing Traffic Drug and Alcohol Section, Victoria Police, Australia*

# However - More and More…




- 20% increase each year
- 2014 ~4,000 confirmations
- MAX ~80 confirmations/week with **LC-MS/MS**

# 2015…

NEWS

## Police to double roadside drug testing in Victoria as state road toll increases

Updated 1 Jan 2015, 3:26pm

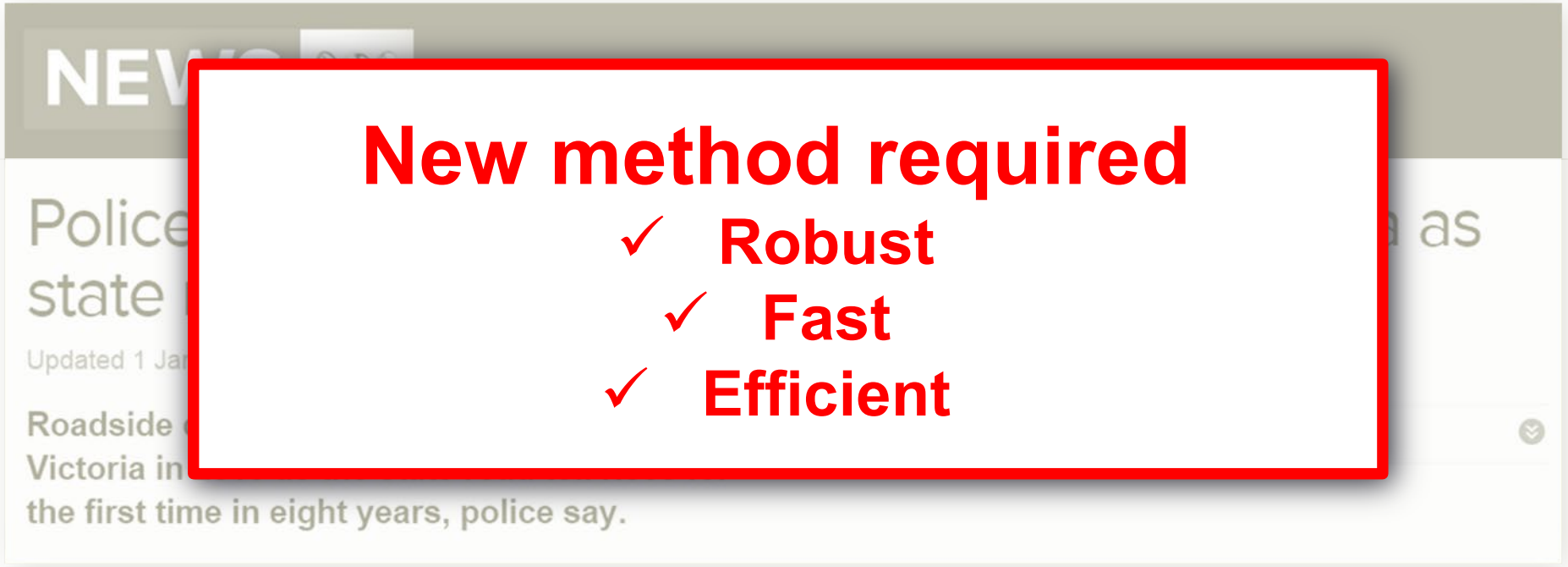
**Roadside drug testing will more than double in Victoria in 2015 as the state road toll rises for the first time in eight years, police say.**

MAP: VIC

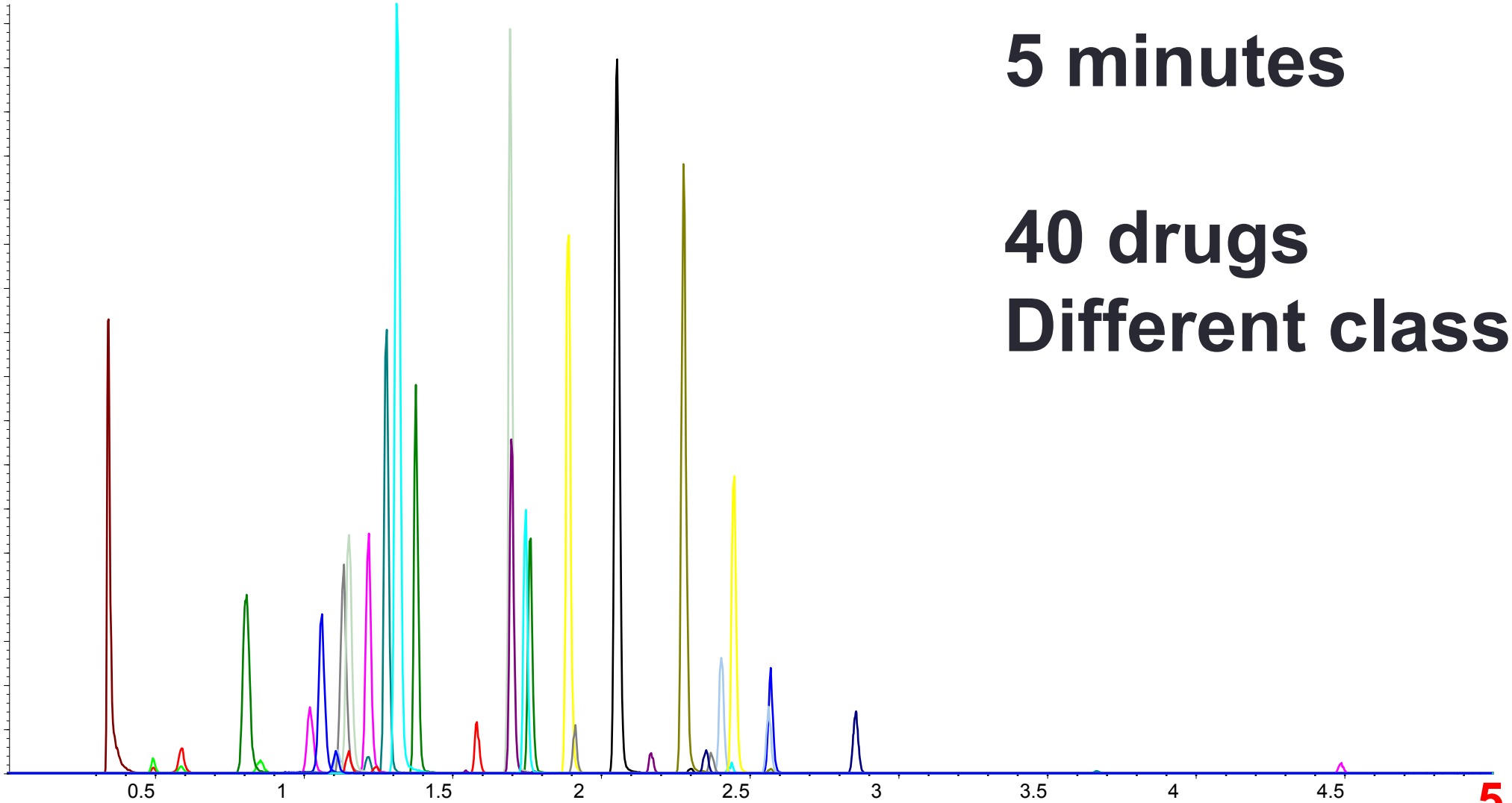
# 2015…


Police
state
as
Updated 1 Jan
Roadside
Victoria in
the first time in eight years, police say.
60% increase
~7,000 samples
~135 samples/week

# 2015…

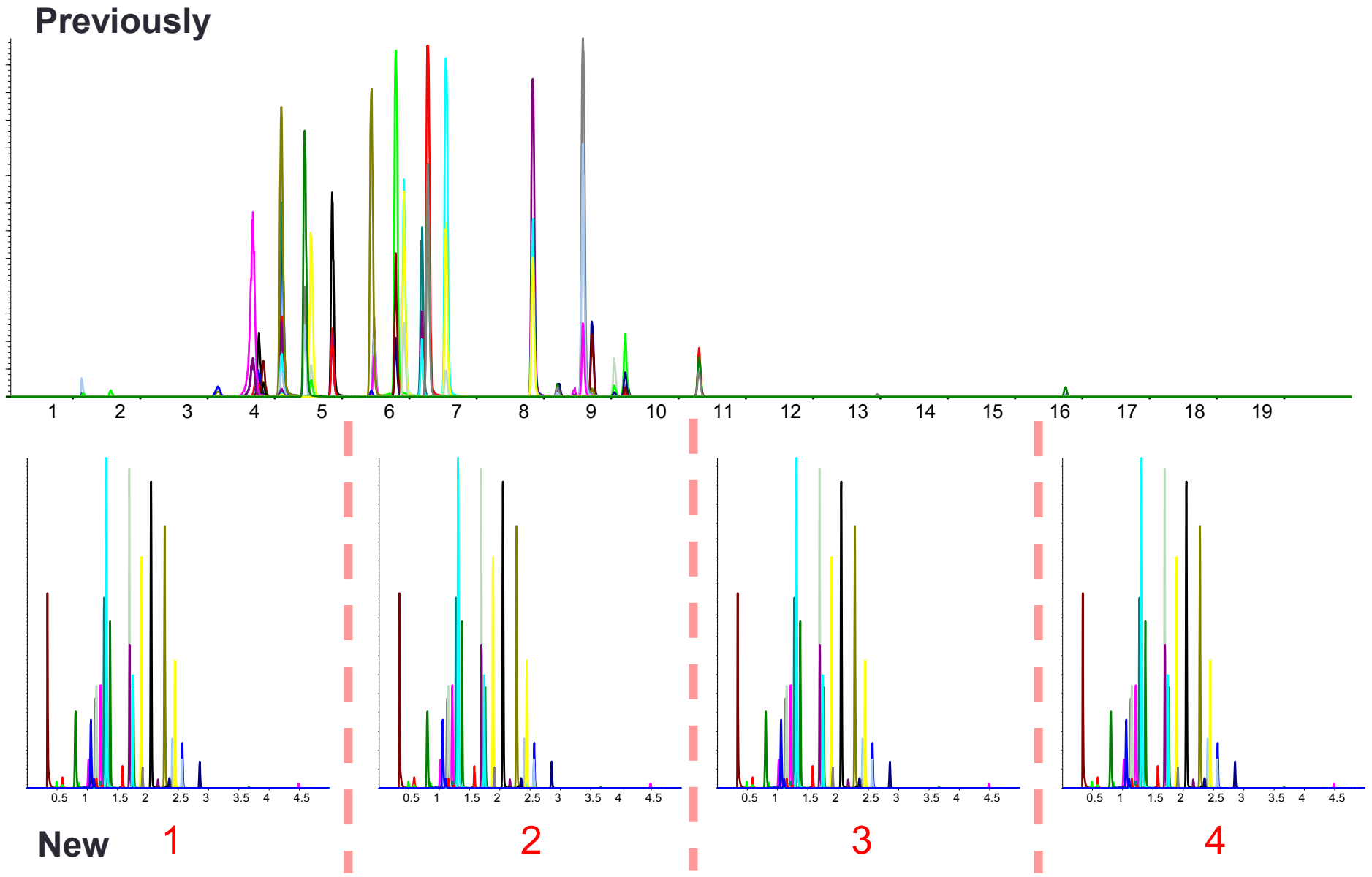

New method required
✓ Robust
✓ Fast
✓ Efficient
Police
state
as
Updated 1 Jan
Roadside
Victoria in
the first time in eight years, police say.

# UHPLC




**5 minutes**

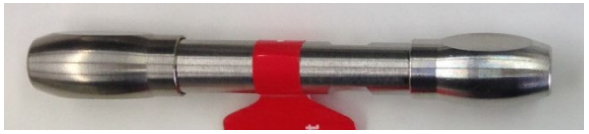
**40 drugs**
**Different classes**


Previously
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
0.5 1 1.5 2 2.5 3 3.5 4 4.5
New
1
2
3
4

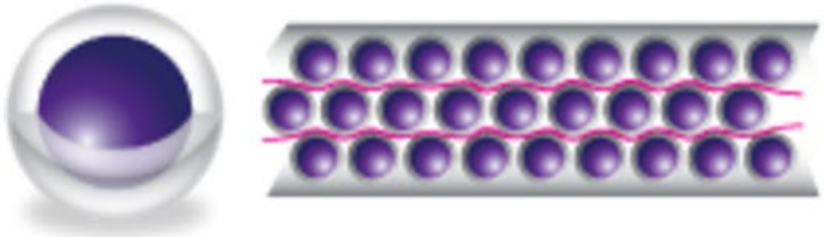
# Column Technology Advancements

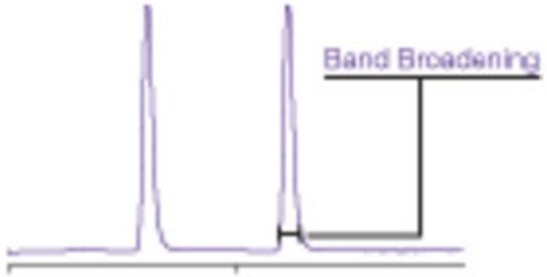
**New**

**50mm / 2.6µm**



Kinetex Core-Shell



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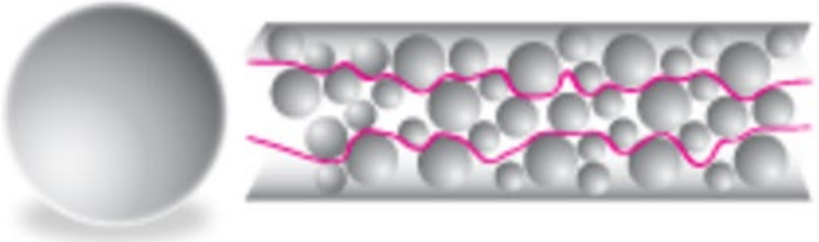
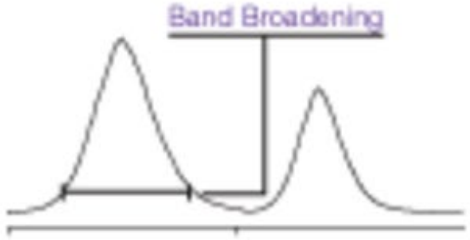
**Old**

**150mm / 5µm**

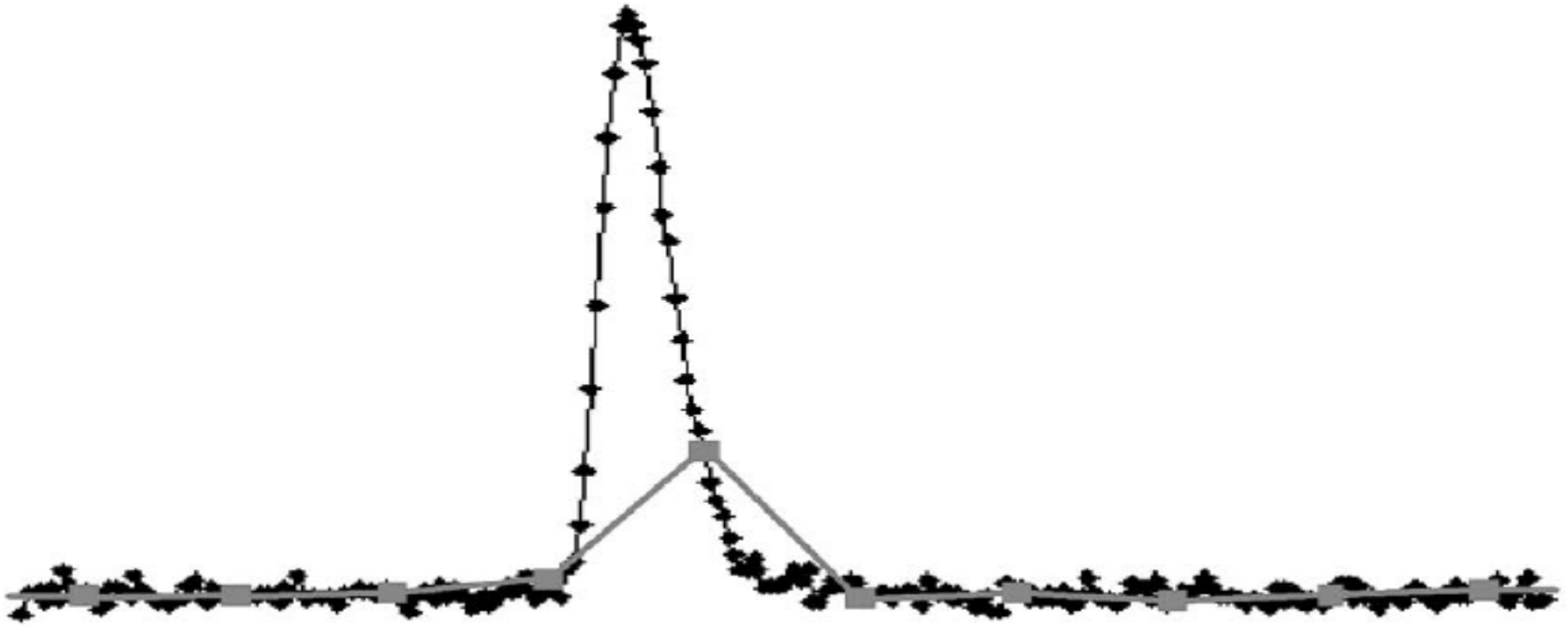
Fully Porous






# MS speed

- Aim ≥ 12 data points above half peak height

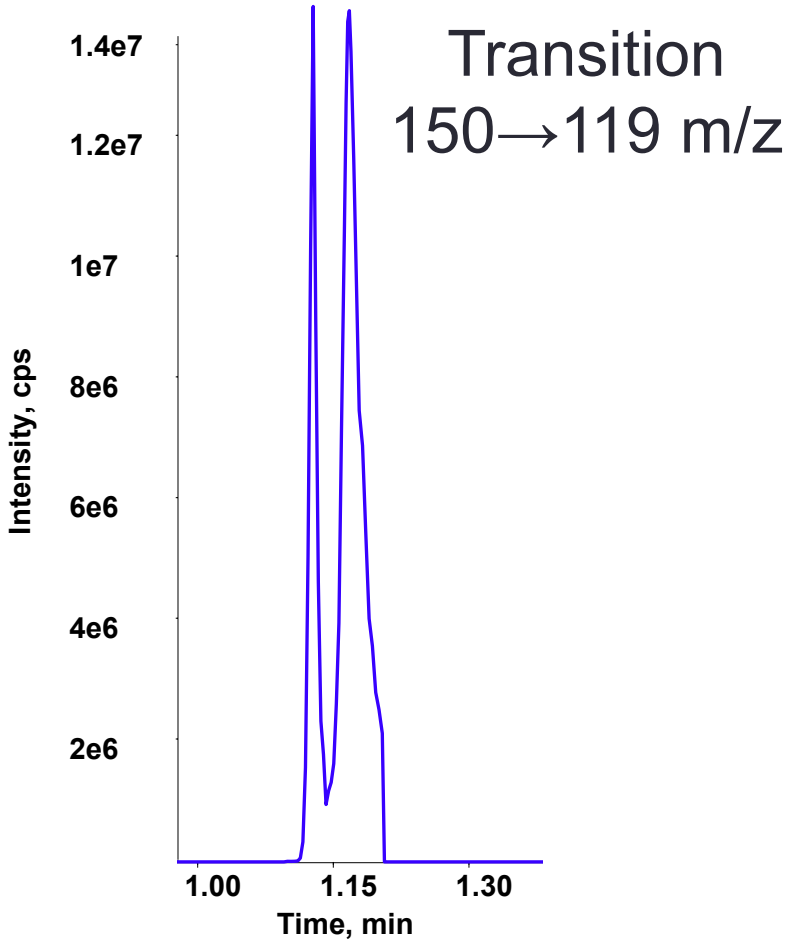


# Scope

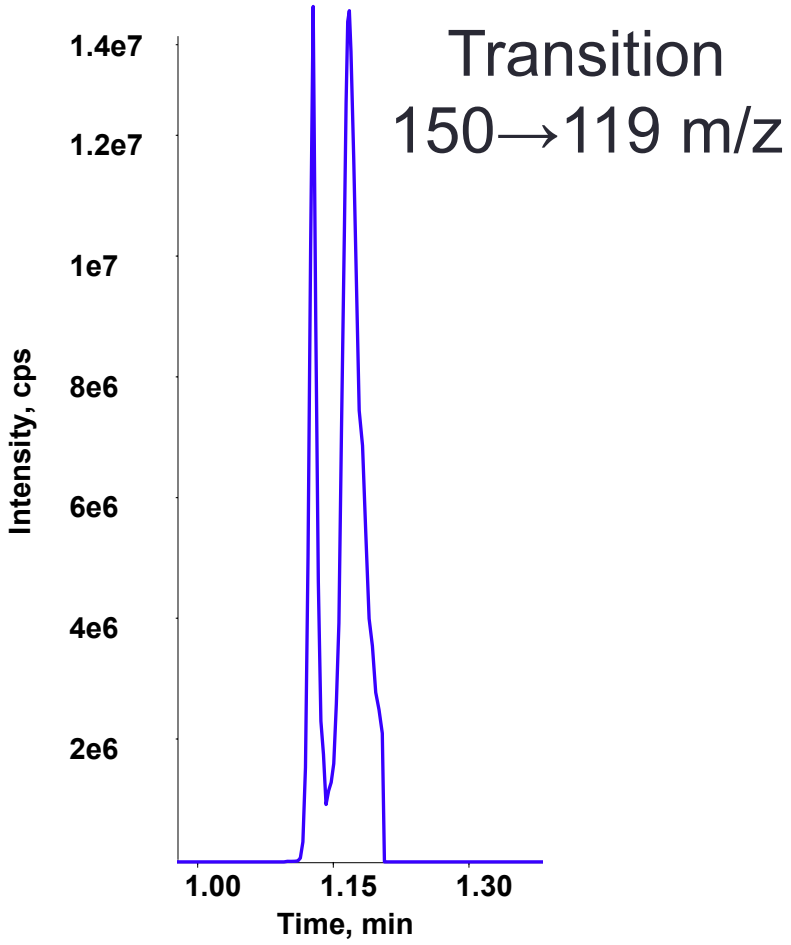
6-monoacetylmorphine
7-aminoclonazepam
7-aminoflunitrazepam
7-aminonitrazepam
Alprazolam
Amphetamine
Benzoylecgonine
Buprenorphine
Clonazepam
Cocaethylene
Cocaine
Codeine
Diazepam
Ecgonine Methyl Ester
EDDP
Fentanyl
Flunitrazepam
Hydromorphone
Ketamine
Lorazepam
MDA
MDMA
$C^{13}$-MDMA
MDPV
Mephedrone
Methadone
Methamphetamine
$C^{13}$-Methamphetamine
Morphine
Nitrazepam
Norbuprenorphine
Nordiazepam
Oxazepam
Oxycodone
Phentermine
Pseudoephedrine
Pyrovalerone
Temazepam
Tetrahydrocannabinol
THC-COOH
Tramadol
Zolpidem


LC/MS 11
QTRAP 4500
PEAK

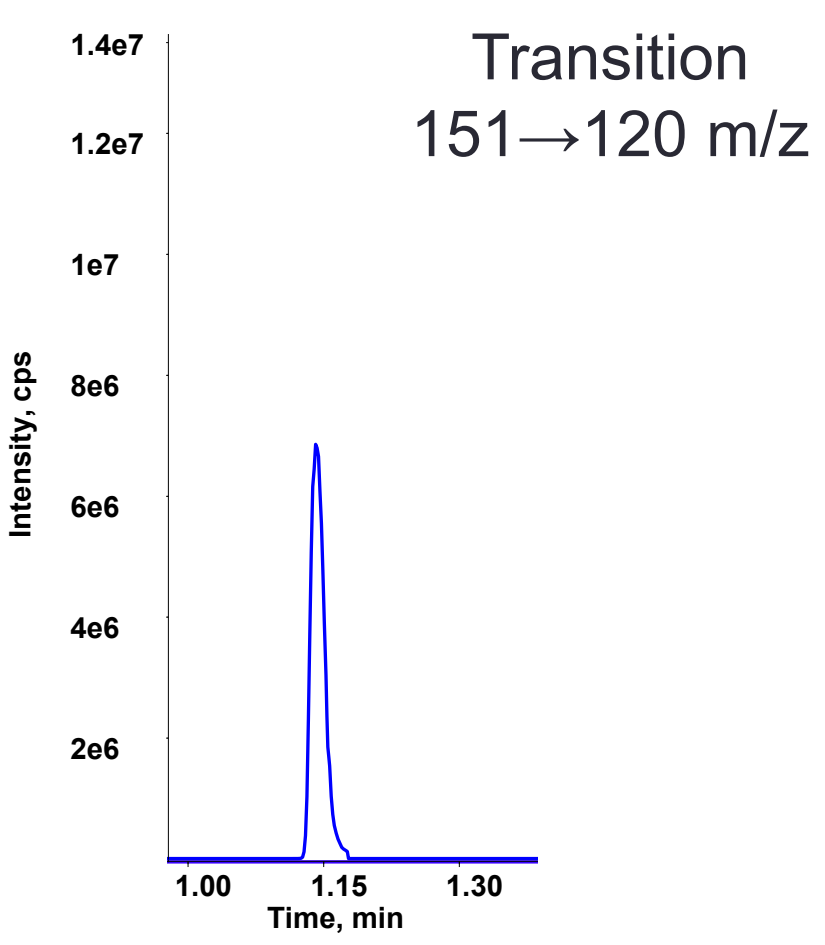
# Methamphetamine



## Methamphetamine




## $C^{13}$ Methamphetamine



# Validation Parameters (Peters et al. ABC 2007)

- **Selectivity**
  - 20 OFs, ~300+ drugs from other methods (+ synthetic oral fluid)
- **Matrix Effects/Ion Suppression & Enhancement**
- **Processed Sample Stability**
  - 24 hours and 7 days
- **Linearity**
- **Carryover**
- **Freeze/Thaw Stability**
  - 8 cycles
- **Accuracy and Precision**
  - 8 consecutive assays
- **Long Term Stability**
  - 12 weeks at -60ºC, -20ºC, +4ºC, RT

# Method results (4497 cases - 9 month period in 2015)

| Drug | Number | % |
|---|---|---|
| Methamphetamine | 3304 | 73.5% |
| Amphetamine | 3195 | 71.0% |
| Tetrahydrocannabinol | 2422 | 53.9% |
| Pseudoephedrine | 1185 | 26.4% |
| MDMA | 462 | 10.3% |
| MDA | 371 | 8.2% |
| Codeine | 347 | 7.7% |
| Morphine | 263 | 5.8% |
| Nordiazepam | 260 | 5.8% |
| Cocaine | 219 | 4.9% |
| Diazepam | 203 | 4.5% |
| 6-monoacetylmorphine | 192 | 4.3% |
| Methadone | 154 | 3.4% |
| Benzoylecgonine | 150 | 3.3% |
| EDDP | 125 | 2.8% |
| Tramadol | 118 | 2.6% |
| Oxycodone | 92 | 2.0% |
| Ecgonine methyl ester | 90 | 2.0% |
| Buprenorphine | 71 | 1.6% |
| Ketamine | 68 | 1.5% |

| Drug | Number | % |
|---|---|---|
| Oxazepam | 63 | 1.4% |
| Alprazolam | 59 | 1.3% |
| Norbuprenorphine | 43 | 1.0% |
| THC-COOH | 38 | 0.8% |
| Hydromorphone | 21 | 0.5% |
| Temazepam | 21 | 0.5% |
| Cocaethylene | 13 | 0.3% |
| Phentermine | 12 | 0.3% |
| Fentanyl | 10 | 0.2% |
| Clonazepam | 10 | 0.2% |
| 7-aminoclonazepam | 9 | 0.2% |
| Nitrazepam | 6 | 0.1% |
| Mephedrone | 6 | 0.1% |
| 7-aminonitrazepam | 4 | 0.1% |
| Lorazepam | 2 | 0.04% |
| Zolpidem | 1 | 0.02% |
| Pyrovalerone | 0 | 0% |
| MDPV | 0 | 0% |
| Flunitrazepam | 0 | 0% |
| 7-aminoflunitrazepam | 0 | 0% |

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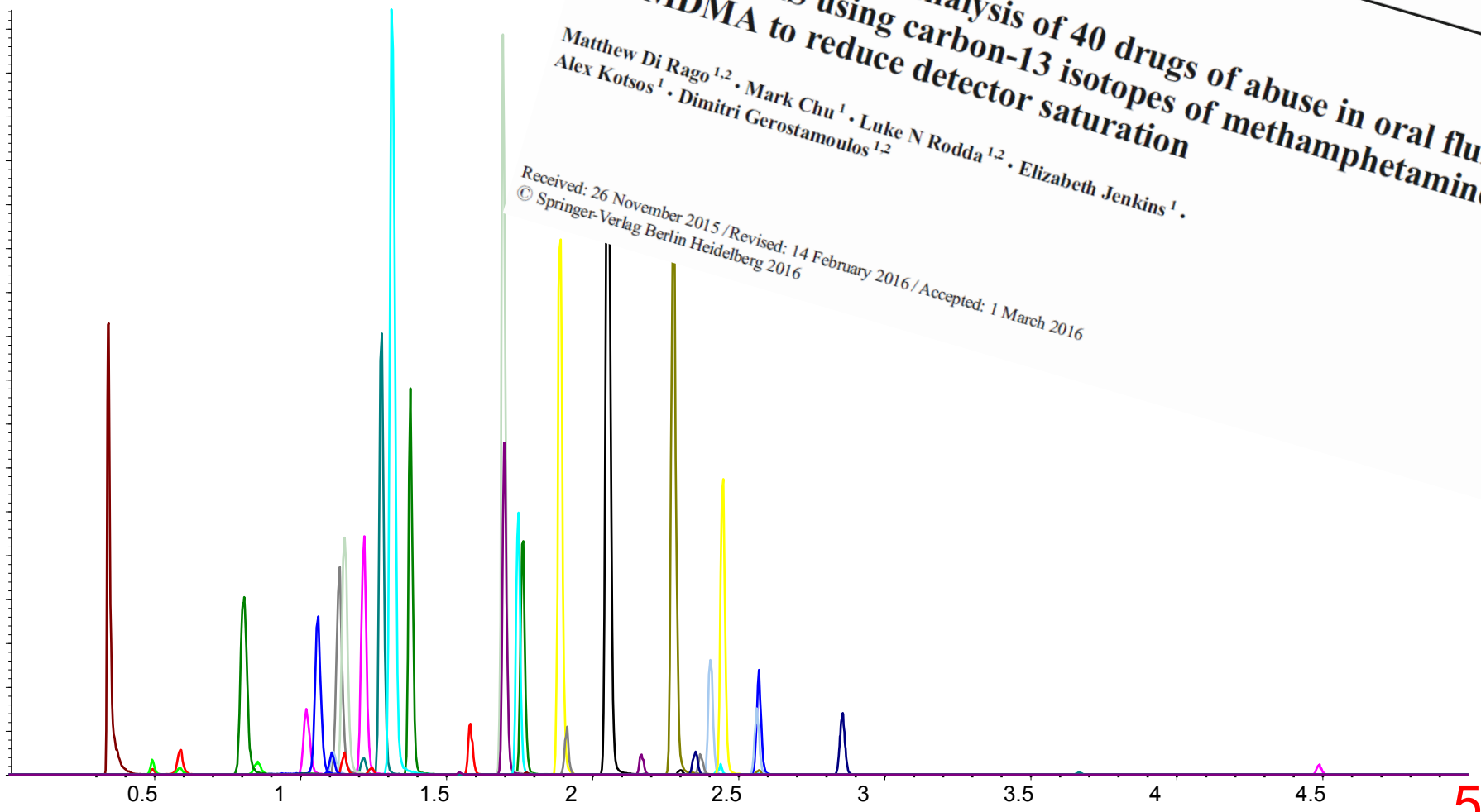
| Oxycodone | 92 | 2.0% |
| Ecgonine methyl ester | 90 | 2.0% |
| Buprenorphine | 71 | 1.6% |
| **Ketamine** | **68** | **1.5%** |

| Drug | Number | % |
|---|---|---|
| Oxazepam | 63 | 1.4% |
| Alprazolam | 59 | 1.3% |
| Norbuprenorphine | 43 | 1.0% |
| THC-COOH | 38 | 0.8% |
| Hydromorphone | 21 | 0.5% |
| Temazepam | 21 | 0.5% |
| Cocaethylene | 13 | 0.3% |
| Phentermine | 12 | 0.3% |
| Fentanyl | 10 | 0.2% |
| Clonazepam | 10 | 0.2% |
| 7-aminoclonazepam | 9 | 0.2% |
| Nitrazepam | 6 | 0.1% |
| **Mephedrone** | **6** | **0.1%** |
| 7-aminonitrazepam | 4 | 0.1% |
| Lorazepam | 2 | 0.04% |
| Zolpidem | 1 | 0.02% |
| Pyrovalerone | 0 | 0% |
| MDPV | 0 | 0% |
| Flunitrazepam | 0 | 0% |
| 7-aminoflunitrazepam | 0 | 0% |




Anal Bioanal Chem
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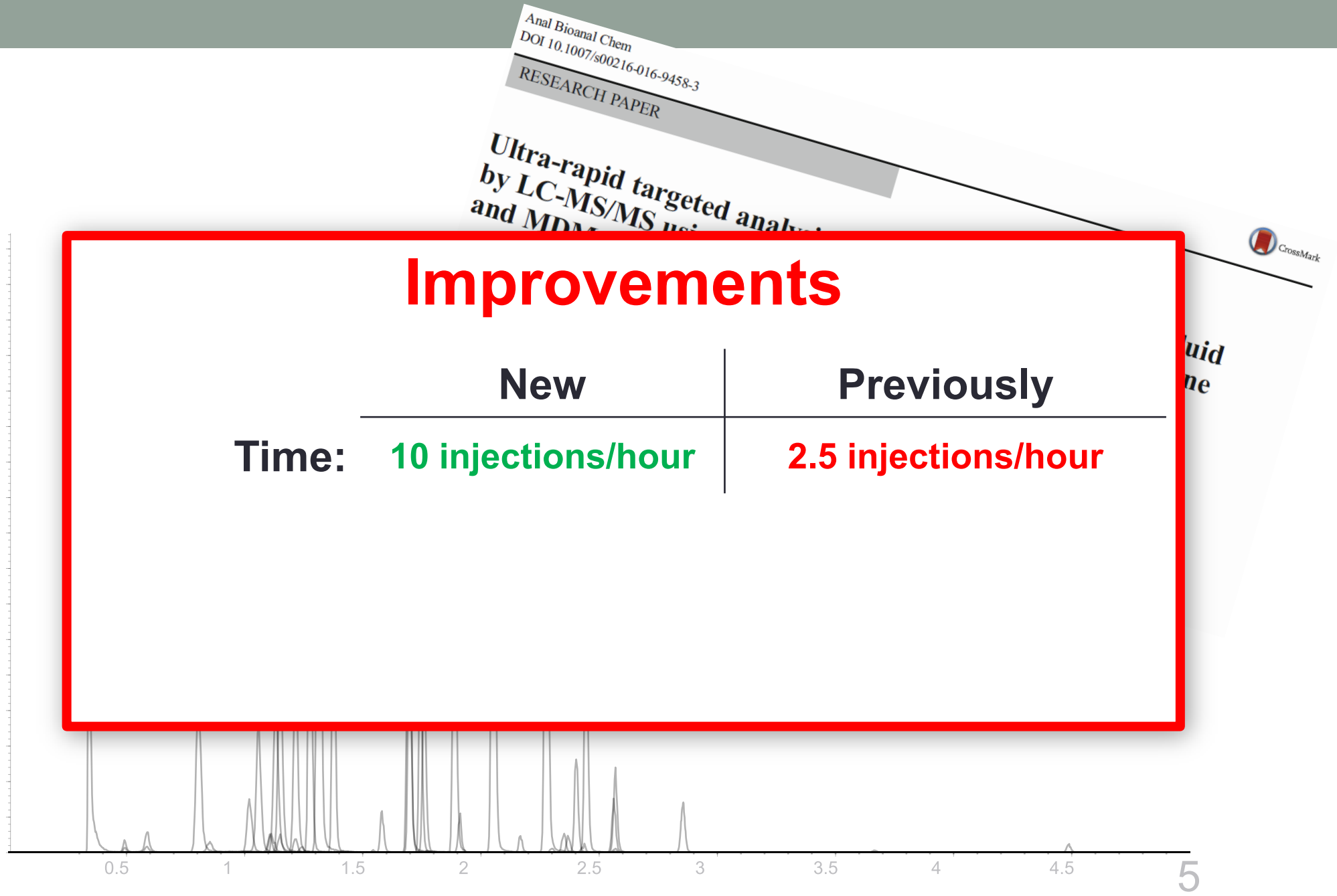
RESEARCH PAPER

# Ultra-rapid targeted analysis of 40 drugs of abuse in oral fluid by LC-MS/MS using carbon-13 isotopes of methamphetamine and MDMA to reduce detector saturation

Matthew Di Rago [1,2] · Mark Chu [1] · Luke N Rodda [1,2] · Elizabeth Jenkins [1] · Alex Kotsos [1] · Dimitri Gerostamoulos [1,2]

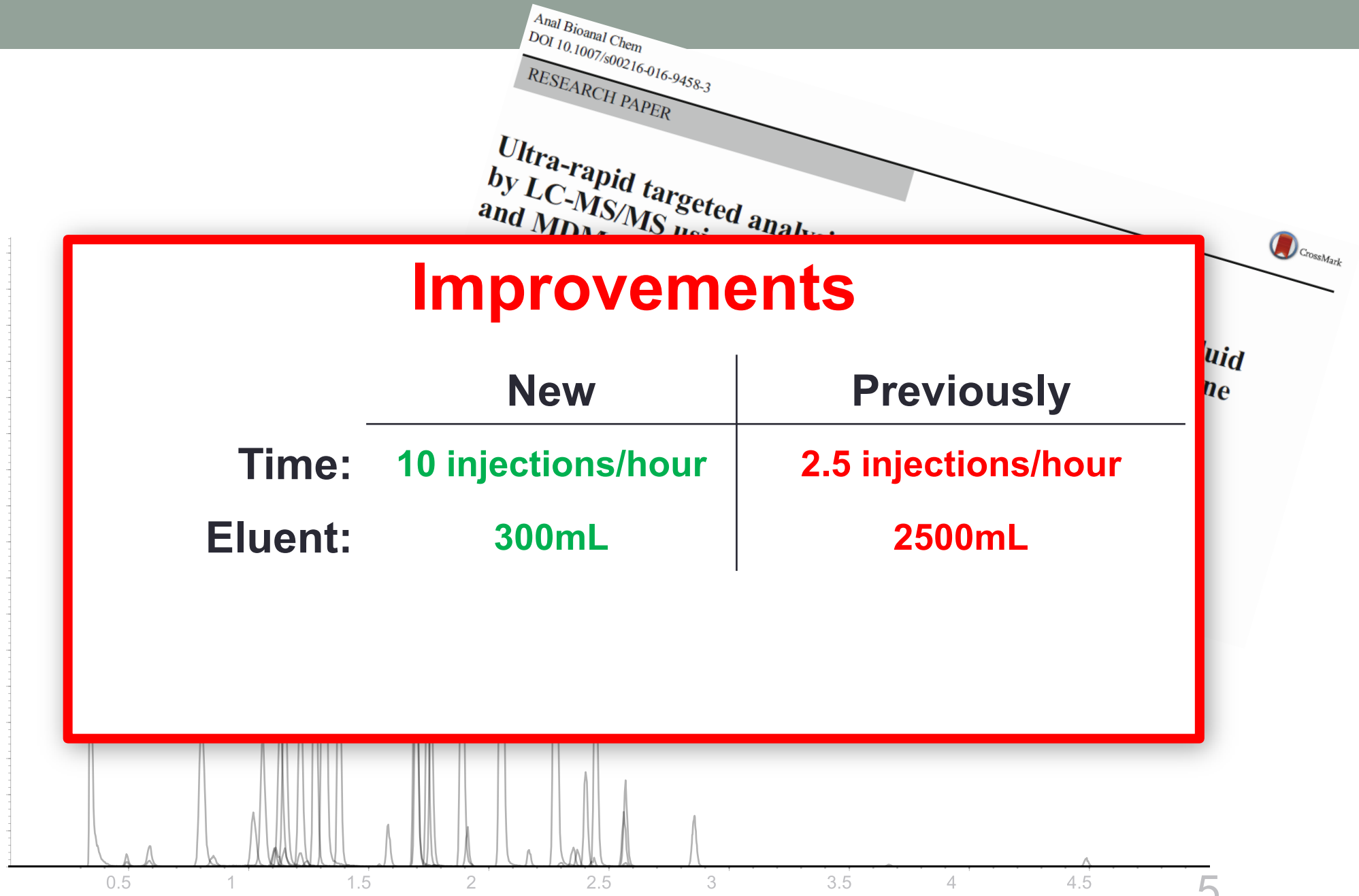
Received: 26 November 2015 / Revised: 14 February 2016 / Accepted: 1 March 2016


# Improvements



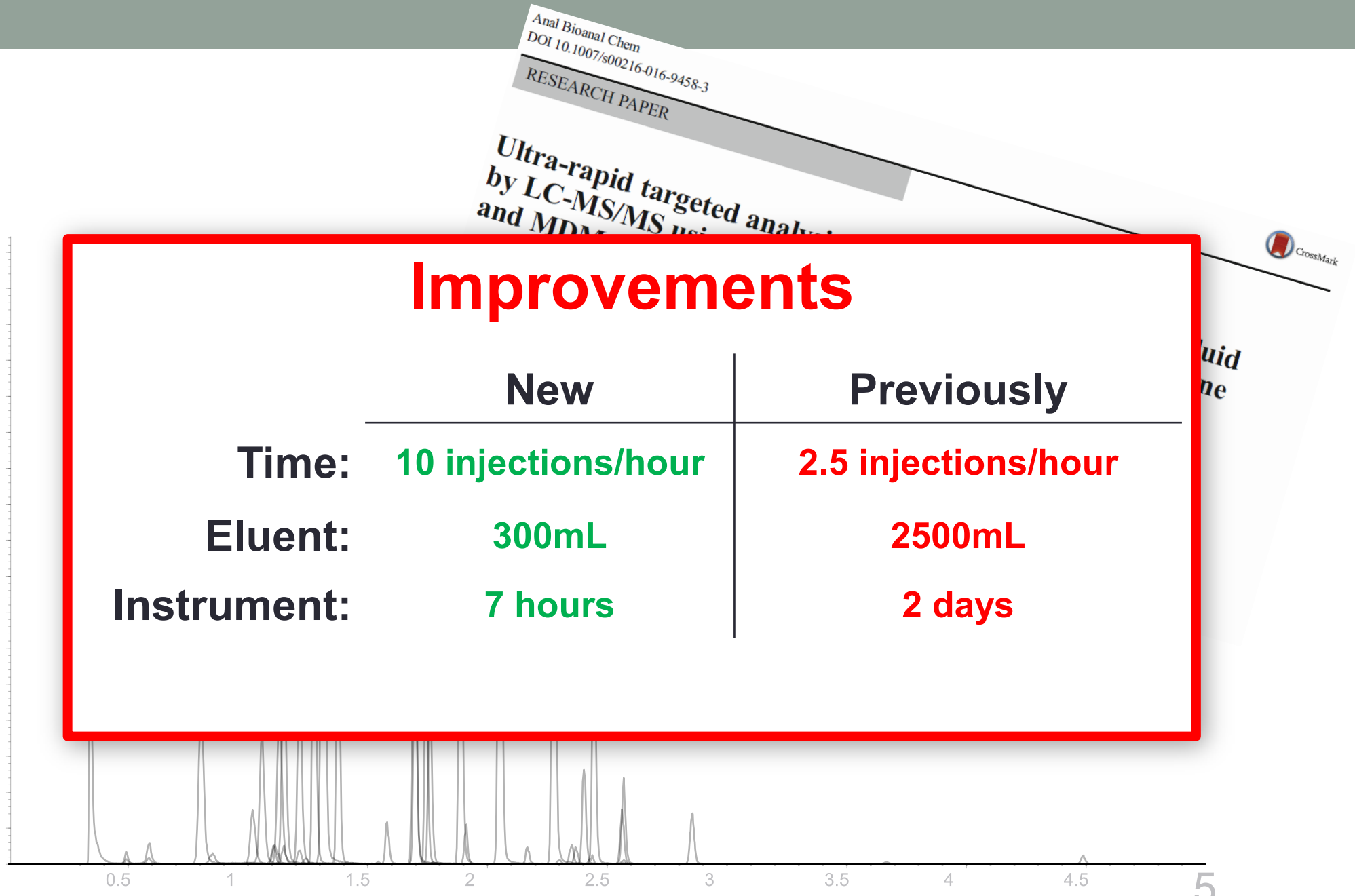

# Improvements

| | New | Previously |
|---|---|---|
| Time: | 10 injections/hour | 2.5 injections/hour |



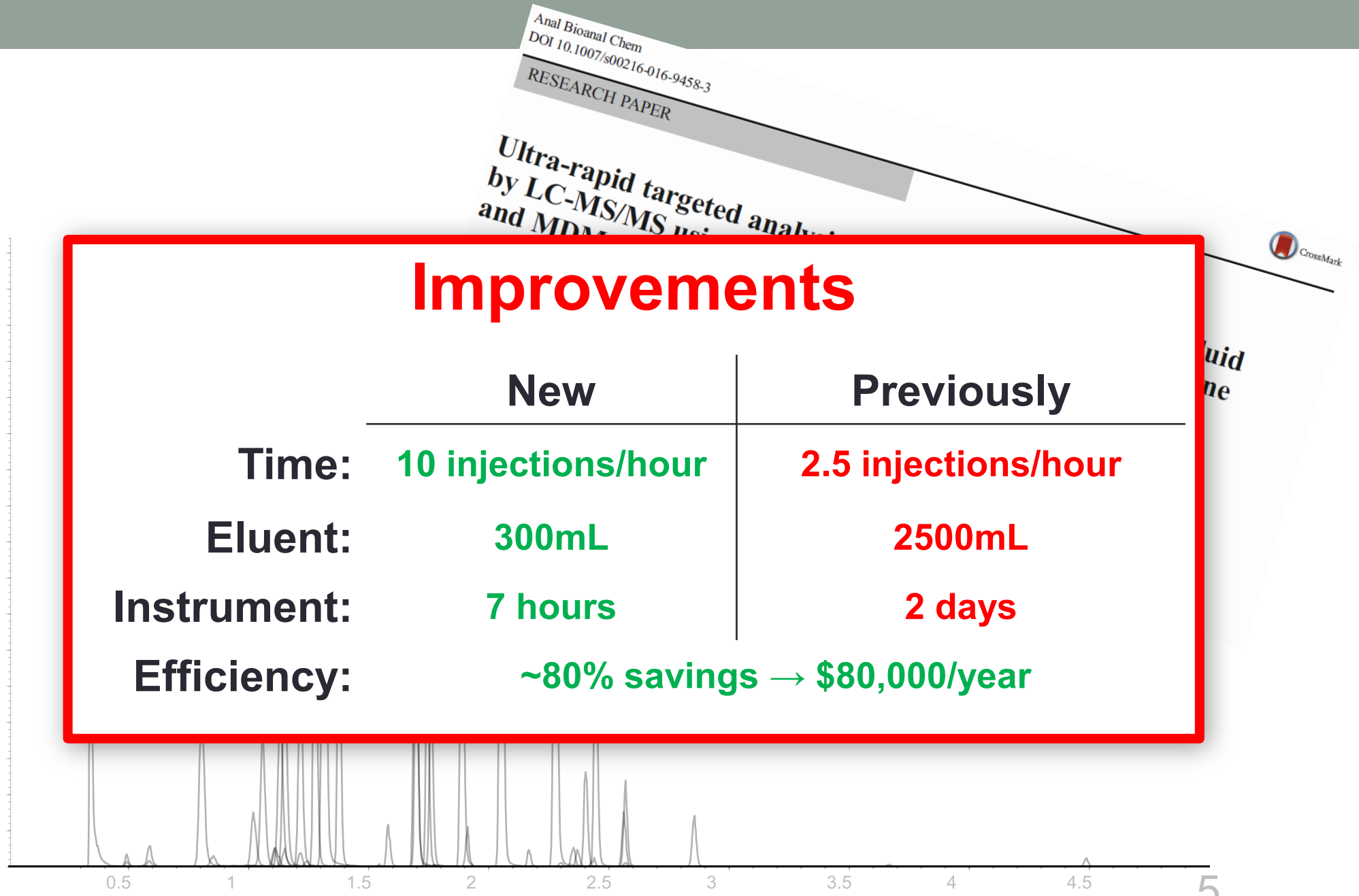

# Improvements

| | New | Previously |
|---|---|---|
| Time: | 10 injections/hour | 2.5 injections/hour |
| Eluent: | 300mL | 2500mL |




# Improvements

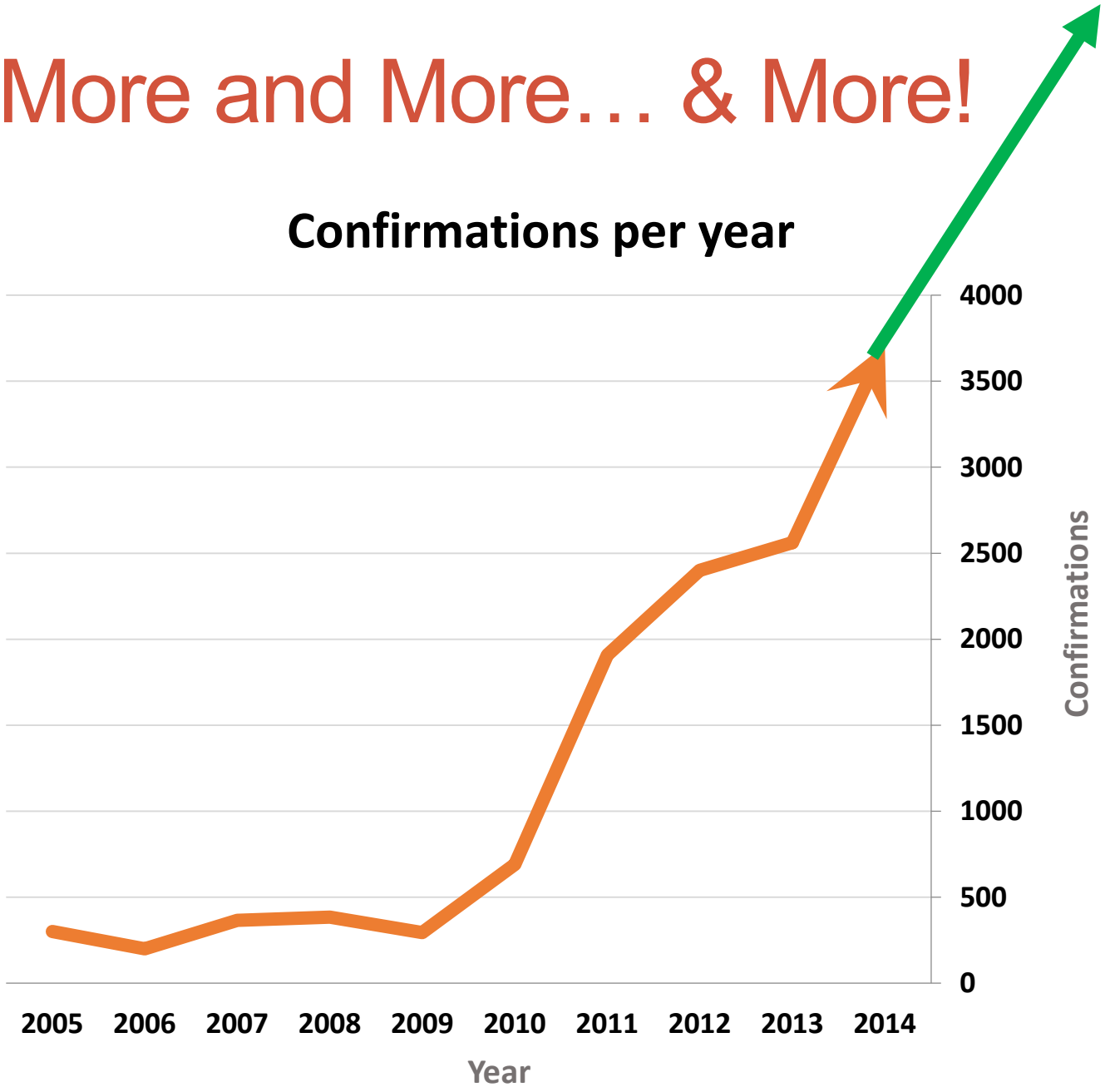
| | New | Previously |
|---|---|---|
| Time: | 10 injections/hour | 2.5 injections/hour |
| Eluent: | 300mL | 2500mL |
| Instrument: | 7 hours | 2 days |




# Improvements

| | New | Previously |
|---|---|---|
| Time: | 10 injections/hour | 2.5 injections/hour |
| Eluent: | 300mL | 2500mL |
| Instrument: | 7 hours | 2 days |
| Efficiency: | ~80% savings → $80,000/year | |

# More and More… & More!




- 2012 = ~2,000 confirmations
- 2014 = ~4,000 confirmations
- **2017 = >10,000 confirmations**

# AND - other MVA (VIFM)

- Injured Drivers, Passengers, Pedestrians, Cyclists etc.
  - In 2010 stared performing full toxicology on injured drivers.
  - If hospitalized, blood mandatory collected
  - 6,000 cases per year

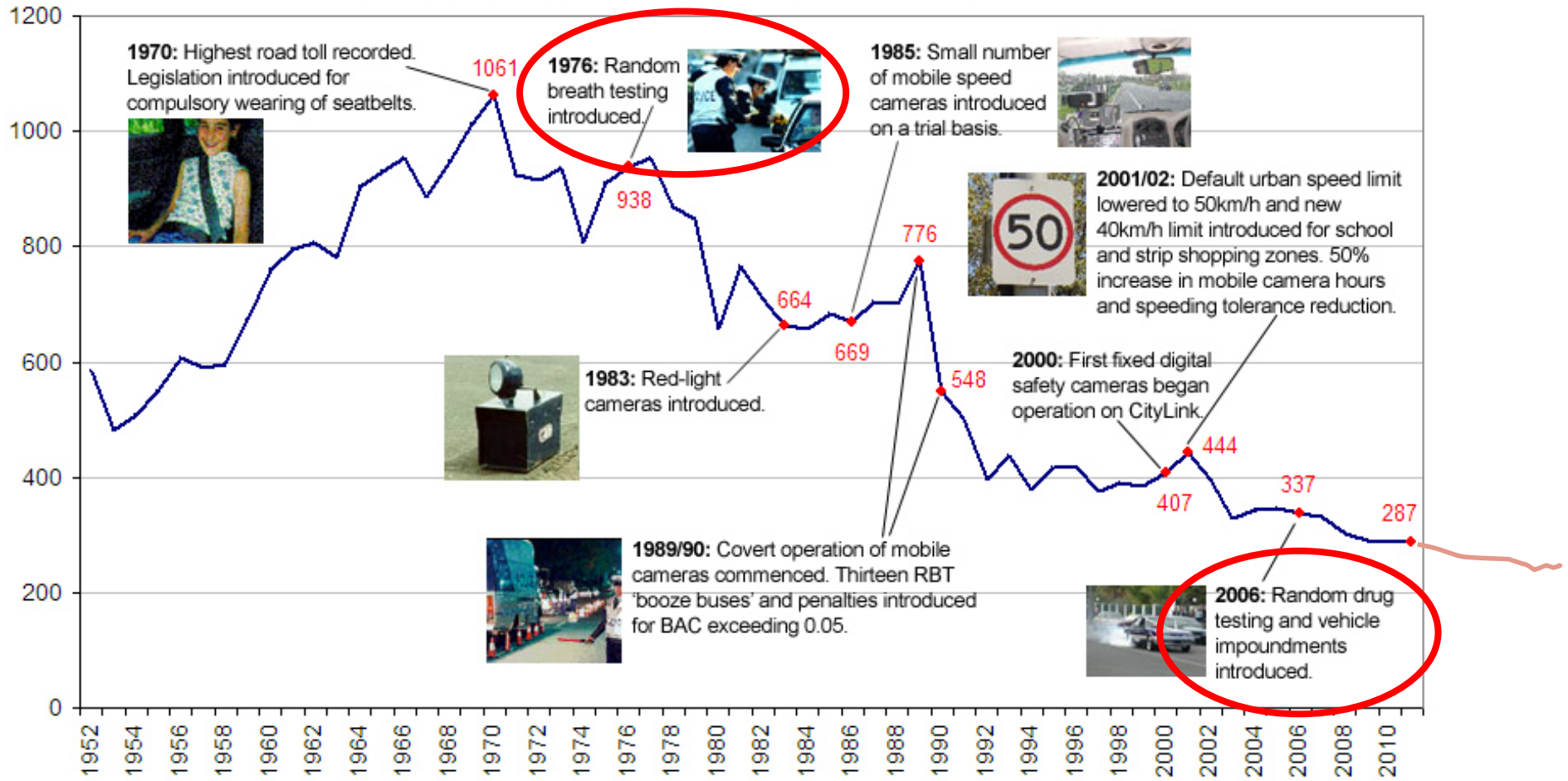
- Deceased Drivers, Passengers, Pedestrians, Cyclists etc.
  - Postmortem toxicology on Coroners cases
  - 200 cases per year

- Provide comprehensive testing for all MVA in the state
  - Show prevalence of drugs in driving studies
  - Demonstrate cost-effective measures
    - i.e. decrease in hospital admission and deaths

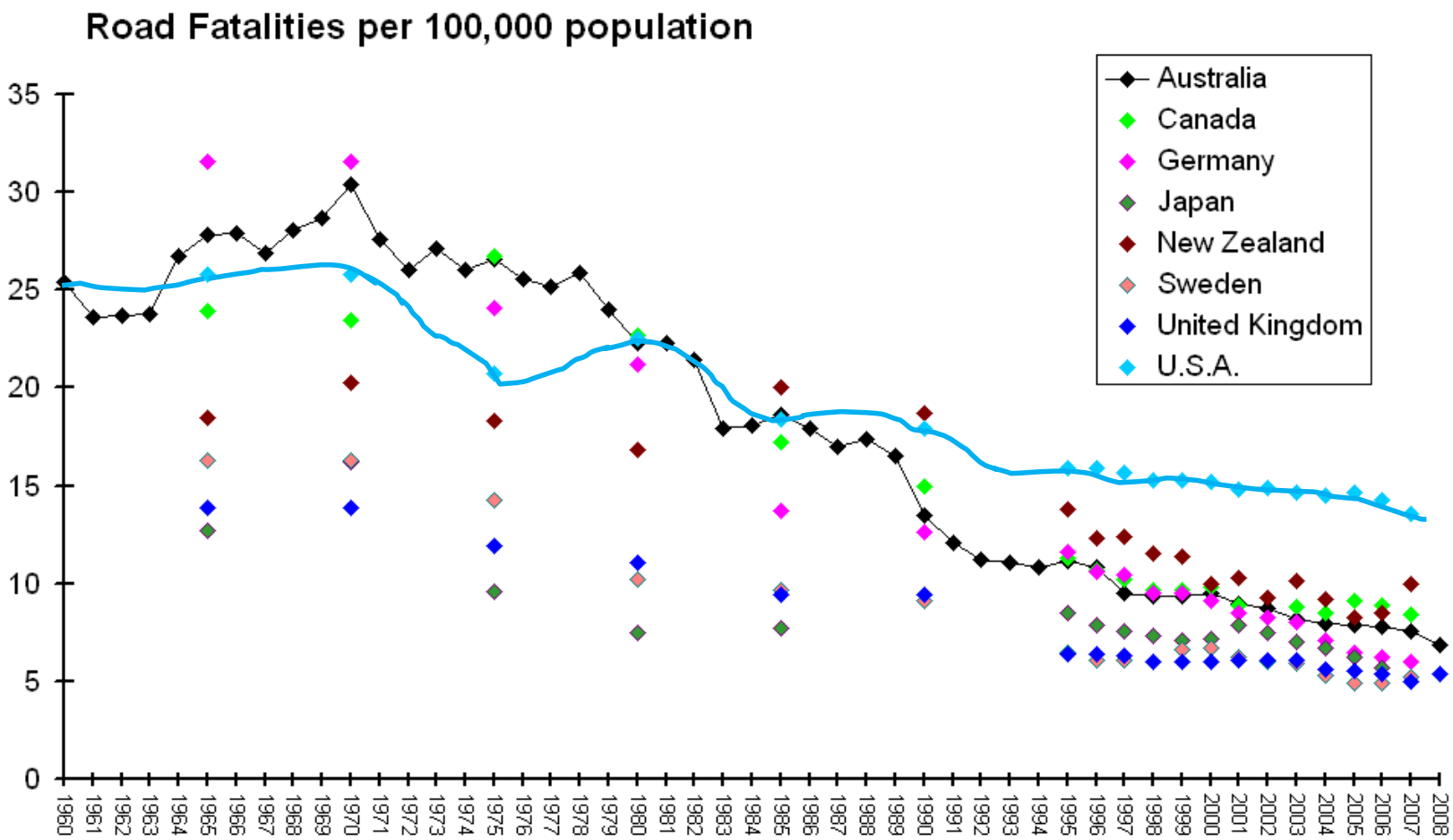
# ROAD FATALITIES

Why target DUID

# Victorian Road Deaths & Road Safety Initiatives

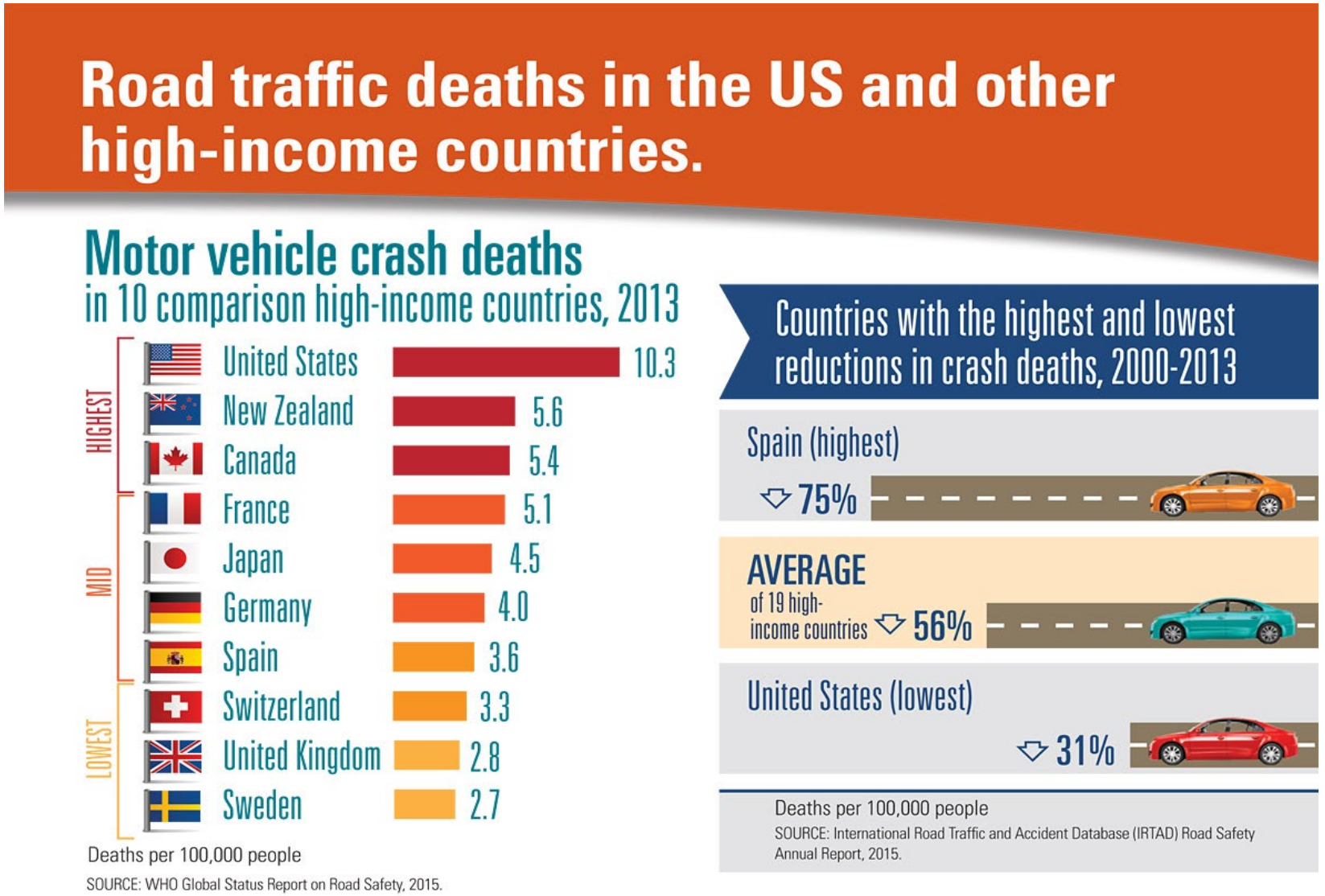


# Road Deaths – Country Comparison 1960-2008




1960 2008

# Road Deaths – Country Comparison 2013

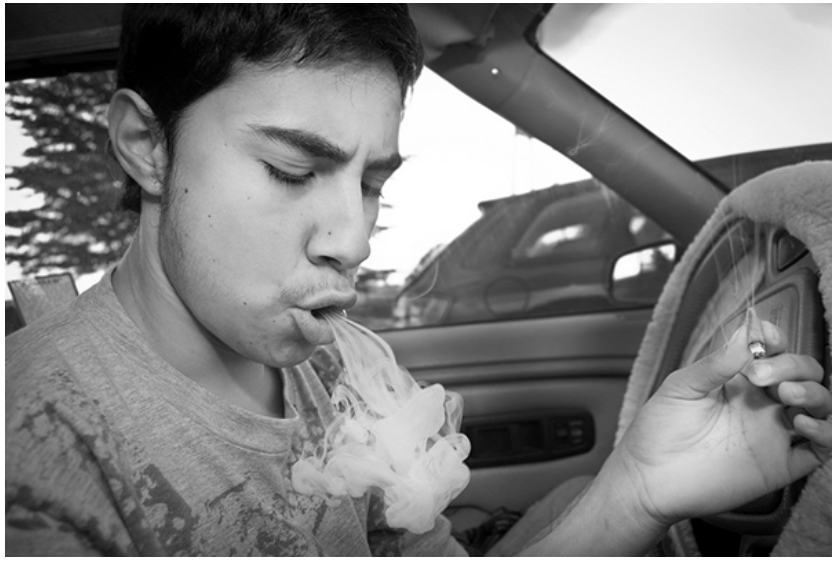


# CALIFORNIA

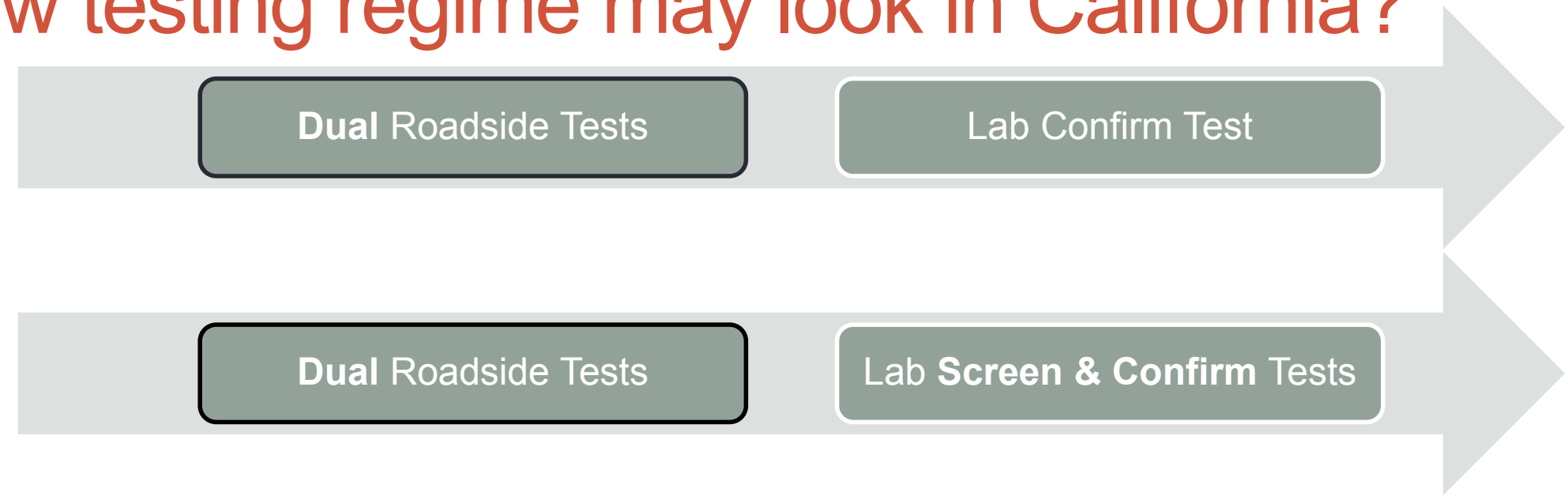
Future?

# Why?

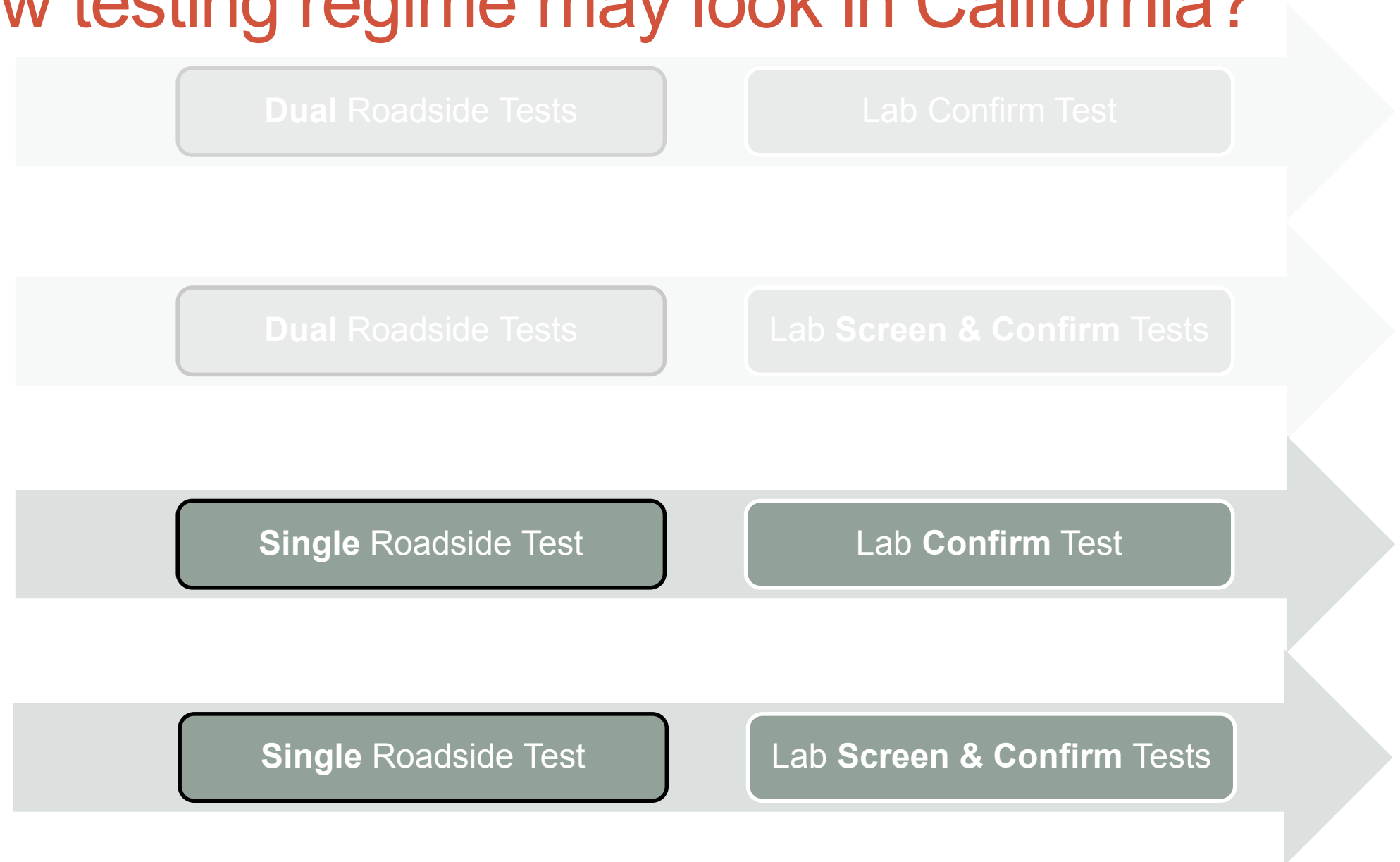
- Shorten times for blood collections?
- Lead to finding more drugs on board?
- Random roadside testing?
  - Or at least easier warrant for biological sample
- Decrease overall DUID impact on roads
  - Decrease MVA associated costs
  - Decrease injury
  - Decrease deaths



# How testing regime may look in California?



# How testing regime may look in California?



# How testing regime may look in California?

**Balance of risk**

With no immediate suspension of license, the low likelihood of initial false positive might be okay for Single Roadside Test.

**Single** Roadside Test → Lab **Confirm** Test

**Single** Roadside Test → Lab **Screen & Confirm** Tests

# Oral Fluid Roadside Device Options (not exhaustive)

**Cutoff values (ng/mL) for selected devices & for typical laboratory**

| | THC | Cocaine | Amphet | MAMPH | Opioids | Benzo |
|---|---|---|---|---|---|---|
| Alere DDS 2 | 25 | 30* | 50 | 33 | 30 | 20 |
| Dräger Drugtest 5000 | 5 | 20 | 50 | 33 | 20 | 15 |
| Securetec DrugWipe 6S | 10 | 10 | 60 | 60 | none | none |
| Laboratory | 0.5 | 2.5 | 2.5 | 2.5 | 2 | 1.5 |

*Douglas J. Beirness & D'Arcy R. Smith (2017) An assessment of oral fluid drug screening devices, Canadian Society of Forensic Science Journal, 50:2, 55-63,*



# Oral Fluid testing in CA

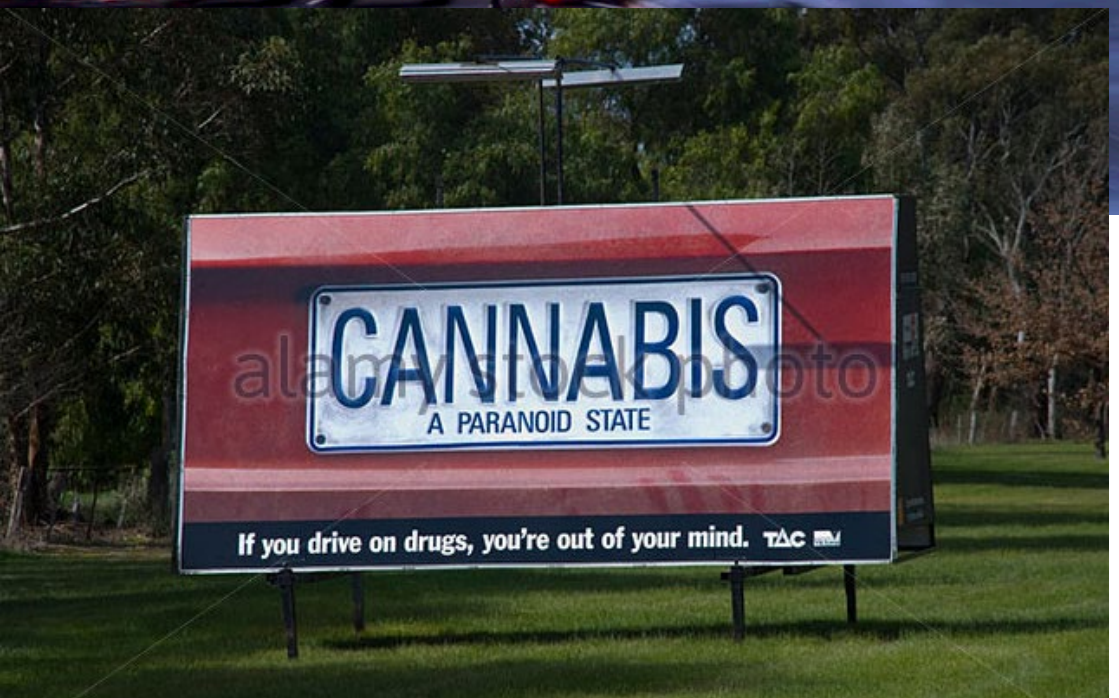
- Collaborate between CA & decide (i.e. Impaired Driving Task Force)
  - Share knowledge
  - Develop and agree on a CA Oral Fluid DUID **model** and possibly **standard**
    - Start small and target certain drugs?

- Pilot programs
  - Show prevalence/problem (what are we missing? Prop 64/THC?!)
  - Show procedures (DRE, dual roadside, lab confirm?)
  - Deterrent or prosecution?
  - Show cost effective – reduction in MVA mortality & morbidity
  - Publish studies!

- Involvement between stakeholders
  - Laboratories
  - Law Enforcement Agencies
  - District Attorneys, Defenders & Courts
  - Political support
  - Society

- *It is not about 'if' OF testing works, it is how it will work in each jurisdiction*


*Driving is a Privilege, Not a Right*




# Acknowledgements & RoundTable Discussion

San Francisco Office of the Chief Medical Examiner

Victorian Institute of Forensic Medicine (Matthew Di Rago)