Impairment and Driving Assessments of Drivers Given Amphetamines, Cannabis and Benzodiazepines and Oral Fluid Testing Results.

PD Swann  
MC Boorman  
K Papafotiou

Drugs and Driving Research Unit, School of Biophysical Sciences Engineering, Swinburne University, Hawthorn Victoria 3122 Australia

Background
Details of the impairment and driving assessments of drivers given amphetamines, cannabis and benzodiazepines have been submitted for presentation at this conference by co-author Dr K Papafotiou and this paper presents the results of the Oral Fluid Testing and the relationship of the testing program to the new Government legislation and Guidelines for the Performance of Oral Fluid Testing Devices.

In the state of Victoria in Australia, the development of effective alcohol and driving legislation and drug and driving legislation has been very similar. Early alcohol legislation in Victoria was based on the philosophy of individual driver impairment. This applied the principle of “specific deterrence” and was relatively unsuccessful in reducing road trauma. However, in 1976 the Victorian Government introduced “per se” Random Breath Test legislation, which was based on statistically determined average accident risk, rather than on individual driver impairment. This legislation introduced highly visible “booze buses” and applied the “general deterrence” principle. It has been successful in reducing alcohol related crashes particularly with recreational drinkers and those drivers who do not have a medical problem with alcohol. Currently Victoria Police undertake approximately 3.3 million alcohol breath tests per year. There are approximately 3 million licensed drivers within Victoria.

The development of drug driving legislation in recent years has followed a similar progression starting with impairment based enforcement to the recent introduction of random roadside screening of drivers for the presence of THC and methamphetamine. Details of the history of development of legislatively-based drug-driving countermeasures, and the operation of newly introduced roadside drug screening procedures have been submitted for presentation at this conference.

Incidence and Accident Risk of Drug Impaired Driving.
In Victoria, 16.2% of drivers killed in the year 2002 tested positive to the active substance in cannabis, D9- tetrahydrocannabinol, 4.2% tested positive to stimulants and 4.6% to benzodiazepines. The VIFM Australian Fatality study shows that 4.1% of drivers killed over a 10-year period, tested positive to stimulants. However, 23% of truck drivers tested positive and these drivers were at a very high accident risk, similar to car drivers with a blood alcohol level of 0.1 to 0.15 BAC. Since deaths associated with heavy vehicles make up 20% of the road toll this is a major public safety issue, and in the year 2002, 80% of stimulant associated driver deaths were positive for methylamphetamine.

In 2001, 29.2% of blood tests of killed drivers tested positive to drugs other than alcohol, and in comparison, 22.3% of drivers had a BAC of 0.05 or more. Figures in 2002 were 27% for drugs and 29% for alcohol.
The majority of these drug positive drivers fatalities were using illicit drugs. In 2001, 16.5% of driver fatalities had used THC or stimulant/amphetamine type drugs, whilst in 2002 this figure had risen to 20.4% of driver fatalities.

Studies of Australian Drivers killed in crashes\(^3\) showed that these illicit drugs produce a greatly increased risk of being responsible for a fatal crash.

In response to the above, in December 2003 the Victorian Government passed amendments to the Road Safety Act to give police greater powers to randomly test drivers using oral fluid testing devices. This random roadside saliva based testing is for the two illicit drugs, Delta 9 THC and methylamphetamine. THC is the most widely detected impairing substance, after alcohol, in Victorian driver fatalities, and methylamphetamine, is the most widely detected impairing substance in Victorian heavy vehicle driver fatalities.

**Road Safety (Drug Driving) Bill 2003 – Roadside Saliva Screening for Illicit Drugs.**

**Performance of Oral Fluid Testing Devices**

Oral Fluid Testing Devices have many features that make them attractive for drug testing programs in the workplace, in treatment programs and in schools. They are also attractive to the smaller market of road safety drug enforcement programs. Saliva collection is relatively simple and non-invasive and the sample can be collected by the donor under observation. Walsh\(^4\) details some important review articles and publications on saliva/oral fluid as a matrix for detecting drugs of abuse. It is noted that detection times for drugs in oral fluids are roughly similar to that in blood, that oral fluid normally contains parent drug rather than drug metabolites and oral fluid could be an excellent matrix to relate drug use with behavioural impairment.

However the performance requirements of the Oral Fluid Testing Devices for each of the potential markets in the workplace, in treatment programs or in schools or in enforcement programs may be very different.

Even in the specific market of road safety drug enforcement programs, the performance requirements for an Oral Fluid Testing Device for a “per se” general deterrence program may be significantly different than that for a specific deterrence program based on individual driver impairment. In a specific deterrence program it would be desirable to use a more sensitive test, whilst in a random roadside general deterrence program, where the bulk of drivers tested will be negative, it would be desirable to use a very specific test.

A call for Expressions of Interest to supply Oral Fluid Devices was advertised in February 2004 and several manufacturers have responded. Currently these devices are being assessed for their suitability for use in the program.

The assessment process involves laboratory analysis of simulated saliva samples, which have been spiked, with known levels of the target drugs, human controlled dose testing and larger scale human volunteer testing in the workplace.

The first type of assessment, involved selected accredited laboratories examining the performance of the oral fluid screening devices, using simulated saliva and spiked levels of the target drugs. Concentrations above and below the manufacturers cut off were used to assess the accuracy, specificity and sensitivity of the devices, and compliance with the Performance Guidelines\(^1\).
The second type of assessment, involved controlled dose administration of the target drugs to healthy male and female volunteers. These studies used a randomised, repeated measures, double blind, experimental design. Samples of saliva and blood were taken at set time intervals after either drug or placebo administration. For the amphetamines a single concentration of the drugs were given and for THC two doses were administered. The oral fluid screening devices were used at each saliva sampling interval and all saliva and blood concentrations were quantified using GCMS.

In the third level of assessment, each device is tested with several hundred volunteers in a controlled workplace environment. The selection process to choose the volunteers is designed to maximize the probability that those individuals who volunteer to test the devices were free of the target drugs, methamphetamine and THC. This has allowed a comparative assessment of the acceptability of devices in large numbers of volunteers. These larger scale assessments are necessary as the bulk of drivers tested in a Victorian random roadside saliva testing program could be negative to the target drugs. Accordingly, the oral fluid testing devices used need to have a very high specificity, so that the majority of drivers are not inconvenienced by false positive results. These larger scale studies use an estimate of true positives to indicate if a significant number of “false positives” could be present. The estimated rate of true positives is less than 1%.

This estimate of true positives for illicit drugs is based on the relative numbers of drivers estimated to test positive to illicit drugs, relative to the known number of drivers who test positive to illegal alcohol. The actual positives obtained for random roadside testing for illegal alcohol in Victoria is 1 in 200 for the 3.3 million tests done per year. It can be estimated from Insurance Company National Surveys⁵ that the incidence of driving after consuming illicit drugs will be less than approximately one third of the incidence of driving with illegal alcohol levels. National alcohol and drug use data⁶ also indicate that illicit drug use is less than one third of alcohol use.

**Victorian Performance Guidelines for Oral Fluid Testing Devices¹**

These Guidelines state that

> “Whilst it is desirable to maximise the sensitivity of the oral fluid devices being used at the roadside it is essential that False Positives be minimised, and accordingly the “cut-off” nominated by the manufacturer must allow the device to perform at the roadside with
> A demonstrated Accuracy of equal to or better than 95%
> A demonstrated Sensitivity of equal to or better than 90%
> A demonstrated Specificity of equal to or better than 90%

> These criteria were recommended in the ROSITA studies⁷.”

It is anticipated that by the date of the conference in August 2004, the results of all of the Controlled Dose Testing and the Workplace Volunteer Testing will be able to be presented. The results of the Controlled Dose Testing for one of the devices for one stimulant are presented as follows.

The aim of the study was to evaluate the performance accuracy of a Saliva Drug-Screening Device, specifically, the Cozart Rapiscan saliva collection kits, to detect dexamphetamine.
The study involved a counter-balanced, repeated measures, double blind, placebo controlled design. Twenty healthy volunteers (10 female; 10 male) aged between 21 and 32 years completed two treatment conditions:

i) 0.42mg/kg placebo Dexamphetamine Tablet, and
ii) 0.42mg/kg Dexamphetamine Tablet.

Dexamphetamine has a peak blood concentration between 120 and 180 minutes; therefore, testing was conducted after 120 minutes had elapsed from administration of the treatment. A blood and saliva sample was obtained prior to the performance tasks (120 min), and immediately after task completion, at 170 min and 240 min post drug administration.

The performance of the Cozart Rapiscan Oral Fluid Screening Device, when measured against the reference GSMS limit of Quantification for dexamphetamine of 20ng/ml, is compared to the VicRoads Performance Guidelines in the following table.

<table>
<thead>
<tr>
<th>Cozart Rapiscan %</th>
<th>Performance Guideline %</th>
</tr>
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<tbody>
<tr>
<td>Accuracy</td>
<td>88.1</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>75.9</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.4</td>
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</tbody>
</table>

The Guidelines state that a key factor in the assessment of Oral Fluid Devices is the number of false positives produced by a specific device. Surveys indicate that 99% of drivers in the overall driving population, will be free of illicit drugs and it is important that these drug free drivers are not inconvenienced by random roadside testing. Accordingly, the devices to be used by the Victorian Police should produce minimal false positives. Thus, it is important that the Oral Fluid Devices being considered for use in Random Drug Testing Operations have a very high Specificity (the ability of the test to detect the absence of a drug). VicRoads have set a guideline specificity of 90% for this issue and the Cozart Rapiscan device has recorded a 98.4% Specificity in this assessment.

The Performance Guidelines list a comprehensive range of Performance Criteria and other important criteria are the “Operating Characteristics” because the devices have to be acceptable to the Police and must be able to perform in Police Operations at the roadside.

The relevance of the results of the above study to actual on road fatalities can be commented upon by considering the levels of stimulants found in drivers killed. An investigation showed that in terms of accident risk, 90.6% of driver fatalities that tested positive to stimulants were judged to be fully or partly responsible for their death. The Therapeutic and Toxic Drug Concentrations guidelines show that 41% of these drivers had amphetamine stimulant drug levels, which could be considered toxic. Thus the majority of drivers had non-toxic levels and in these cases it is speculated that "sleep rebound fatigue" impairment was intensified by the use of the stimulant drugs.

The levels used in the Oral Fluid Testing were non toxic and could be relevant to those drivers who use drugs to combat fatigue.
Conclusions
The assessment of the Oral Fluid Testing Devices to be used by the Police for roadside saliva testing, involves
i) selected accredited laboratories examining the performance of the oral fluid screening devices, using simulated saliva containing spiked levels of the target drugs.
ii) testing using controlled dose administration of the target drugs to healthy male and female volunteers using a randomised, repeated measures, double blind, and experimental design.
iii) large scale testing in a workplace environment. This has allowed a comparative assessment of the acceptability of devices and uses an estimate of true positives to indicate if a significant number of “false positives” could be present.

The guidelines for the assessment specify an accuracy of 95%, a sensitivity of 90% and a specificity of 90%. The performance of the Cozart Rapiscan Oral Fluid Screening Device, when measured against the reference GSMS limit of quantification for dexamphetamine, was an accuracy of 88.1%, a sensitivity of 75.9% and a specificity of 98.4%.

References