Medical Bureau of Road Safety
An Lia-Bhiúró um Shábháilteacht ar Bhóithre

Report on Roadside Drug Testing and Equipment and Related Matters

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Terms of Reference

The Department of Transport, Tourism and Sport (DTTAS), on behalf of the Minister, wrote to the Medial Bureau of Road Safety (MBRS), in January 2012, stating that the "DTTAS wanted to gain a greater knowledge of the present thinking and developments in the area of detection of drug driving". The DTTAS requested that the MBRS "undertake a considered study on all aspects of roadside drug testing, including reference to and analysis of any equipment currently in use or anticipated to be introduced for carrying out such tests and indication of the likely timescale involved in reaching an acceptable solution to the problem". This report is the response to the DTTAS' request.

Summary

This report is a study on all aspects of roadside drug testing, including reference to and analysis of any equipment currently in use or anticipated to be used to carry out such tests. The report considers the current definition of a "drug" and current drug analysis procedure under the Road Traffic Acts. As part of the evidence base for driving under the influence of drugs (DUID) the prevalence of drug taking in the general population, in the driver population, in suspected drugs driving population and the toxicology data for drivers in fatal crashes are presented and reviewed. International data and reports are also considered to inform the relevant bodies as to drugs that could and should be targeted for testing into the future. The studies indicate that cannabis and benzodiazepines are currently the most prevalent drugs in driving under the influence of drugs cases followed by the opiates, methadone and cocaine.

The effects of individual drugs on driving and the relationship between impairment and measurement of those drugs in the human body are examined. The methods of detection of DUID by means of roadside impairment testing and with particular emphasis on roadside drug testing in oral fluid are reviewed to include medical, practical and scientific considerations. The consequential confirmatory laboratory testing for drug detection in body fluids including oral fluid in the future is explored.

Previous international studies and the current status of roadside drug testing in the international literature by way of extended studies are presented and support the introduction of roadside chemical drug testing devices but also acknowledge certain limitations. The introduction of roadside drug testing devices is a far more complex and complicated initiative than was the case for roadside breath alcohol testing.

Four currently available roadside drug testing devices were considered and reviewed to inform this report regarding the operation of such devices, their storage and operation conditions, the scientific criteria on which they are based and also the countries which are currently using the devices or propose to use them in the near future.

The practices for DUID roadside testing in 13 other countries were surveyed and are reviewed and presented with 8 of these countries or jurisdictions already having in place provision for the use of such devices and the remaining 5 countries purposely relying on roadside impairment testing rather than devices.

The report sets out the considerations and options for the introduction of roadside drug testing devices in Ireland. The considerations are under four main headings - legal, operational, scientific and medical. A number of options are outlined with the considered recommendation being the combination of roadside traffic impairment testing and roadside chemical drug testing. An implementation plan for the introduction of the recommended option is set out including a timeframe for implementation of the roadside drug testing recommendation, if so approved.

Chapter 1

Introduction

Chapter 1: Introduction

1.1: Introduction

Driving under the influence of drugs (DUID) has been a statutory offence in Ireland since the Road Traffic Act 1961. The Medical Bureau of Road Safety (MBRS) is the independent forensic body responsible for chemical testing of intoxicants under the Road Traffic Acts and also for the approval, supply and testing of apparatus for determining the presence or concentration of such intoxicants. The current statutory provisions for intoxicated driving offences are set out in Chapter 2 of the Road Traffic Act 2010.

Section 4 (1) of the 2010 Act states that "a person shall not drive or attempt to drive a mechanically propelled vehicle in a public place while he or she is under the influence of an intoxicant to such an extent as to be incapable of having proper control of the vehicle." The law sets out specified concentrations of alcohol in the blood, urine and breath (*per se* levels) which if exceeded constitute an offence. Such levels are not set out for drug intoxicants and the current offence requires that there be proven impairment or incapacity together with the confirmed presence of the drug or drugs other than alcohol.

With the introduction of the Road Traffic Act 1961, which removed the word "drunk" there was still no provision for alcohol limits and there was no standard test for determining the level of incapacity of the driver and doctors relied on clinical examination containing some sobriety tests. In 1968 a *per se* limit for alcohol was introduced and the limit was set at 125mg/100ml in blood. Since then with improvements in analytical technology and research into road trauma the alcohol limit has been reduced to 50 mg/100ml in blood.

Mandatory alcohol testing at the roadside was also accommodated by the improvements in detection technology and a fast and effective method of breath testing is achievable and in use in most jurisdictions worldwide, including Ireland.

However, in the case of drugs and driving, while it is mentioned in the 1961 RTA, roadside detection of drugs has not progressed scientifically and technologically to the same extent as with alcohol. The detection of drugs is complicated by the fact that generally they are consumed in lower quantities than alcohol and are therefore detectable at lower concentrations. This presents an analytical challenge. When testing for alcohol it is the only compound that is targeted, drug detection involves testing for multiple compounds. Alcohol is a volatile compound and so it can be detected in breath and also can be easily liberated from blood and urine for laboratory analysis. This is not the case with drugs and this complicates their analysis. Drug use patterns change over time and so the drugs that should be targeted require constant review. Because it is not possible to detect drugs in breath at present, alternative matrices had to be found. This report will outline some of the major research that has been carried out worldwide and also outlines what measures other jurisdictions use in relation to roadside drug testing. There is continued research into road trauma and drugs and continued improvements being made in the detection technology, however drugs are more problematic due to their diversity and complexity and

the solutions being adopted are not as cheap or as quick and simple to operate as roadside alcohol testing.

1.2: Definition of a "Drug"

The term "intoxicant" is defined in the Road Traffic Act 2010 as including "alcohol and drugs and any combination of drugs and alcohol". However, there is no definition of "drug" in the statute and therefore the term is a wide definition to include any substances recognised as drugs, be they controlled drugs, prescription drugs and medicines or over the counter drugs and medicines. Road Traffic legislation does not distinguish between so called illicit drugs and licit drugs. The consideration of driving capacity or safety is the core element rather than the legal status of the drug.

The relevant legislation relating to licit products for human use in Ireland derives from the EU Directive 2004/27/EC which considered medicinal products in the context of their presentation and the purpose for which they are administered. Article 1 of that Directive defines a medicinal product as "any substance or combination of substances presented as having properties treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis". The most recent comprehensive statutory instrument dealing with medicinal products was the Statutory Instrument 540/2003 Medicinal Products (Prescription and Control of Supply) Regulations 2003.

Drugs such as cannabis, cocaine and ecstasy fall within the category of controlled or illicit drugs and they are subject to the provisions of the Misuse of Drugs Act 1997-1984 (as amended) and the regulations made under those parent Acts. These regulations are updated as required and recent updates occurred in a number of Orders in 2010 to deal with the emergence of so called "head shop drugs". The Oireachtas has also enacted the Criminal Justice (Psychoactive Substances) Act 2010.

1.3: Targeted Outcome of Review

The problem of drug driving is under detected when compared to the detection of drink driving. Within a framework of improved detection and analysis, with particular emphasis on what happens at roadside checkpoints this initiative has a clear aim, in the context of the road safety strategy, of improving road safety with a decrease in drug related fatalities, road traffic injuries and collisions.

Similar to the mandatory breath testing program currently in place, the objectives of mandatory drug testing would be to:

- Increase detection of DUID
- Educate drivers and increase awareness of the dangers of DUID
- Change driver behaviour by deterring them from DUID
- Reduce road traffic accidents, injuries and fatalities

In considering all aspects of driving under the influence of drugs there are four distinct and overlapping areas:

- The *legislative framework* will determine what can be done and the effectiveness of enforcement.
- The *operational requirements* of An Garda Síochána and the MBRS in terms of the practicalities of devices including their scientific basis, the training requirements for their use, the testing of devices and the cost, which will all impact on the timescale for the introduction of suitable devices at the roadside.
- The *scientific requirements* for specificity and sensitivity having regard to levels of detection and cut-offs.
- The overlap with the *medical aspects of fitness to drive* currently being reviewed by the Royal College of Physicians of Ireland and the Road Safety Authority which must be integrated with the other necessary aspects.

The MBRS has kept a abreast of developments in oral fluid testing both in the laboratory and at the roadside. The MBRS has not yet entered into any scientific or technical evaluation of any devices or system of oral fluid testing. The MBRS therefore has not approved any device for the purposes of oral fluid testing at the roadside.

In this review we give consideration to:

- Prevalence
- Effects of drugs on driving and relationship between impairment and bodily fluid
- Detection of driving under the influence of drugs
- Previous studies and current status of roadside testing
- Review of selected current roadside chemical testing devices
- Practice in other countries
- Considerations and options for roadside drug testing
- Implementation of the recommended programme for roadside drug testing

1.4: Current Drug Detection and Analysis Procedure Under the Road Traffic Act

When a driver is arrested under the Road Traffic Act 2010, on suspicion of driving under the influence of an intoxicant an evidential sample of blood, urine or breath is taken. A driver is arrested on such suspicion following observed impaired driving, from which a Garda forms the opinion that the person is intoxicated, or arising from a mandatory alcohol testing (MAT) checkpoint following a fail result in the roadside breath alcohol test or observation by a Garda who forms the relevant opinion as to intoxication. There is currently no provision in the law for mandatory intoxicant testing (MIT). There is a

provision for road traffic impairment testing (RTIT) which has not been enacted to date (See chapter 4, roadside impairment testing).

When a specimen of blood or urine is forwarded under the Road Traffic Act 2010 to the MBRS, it is analysed in the first instance for the concentration of alcohol. If the blood alcohol concentration is 80mg/100mL or less or the urine alcohol concentration is 107mg/100mL or less, the specimen is then analysed for the presence of seven drugs or classes of drugs by means of a two stage analytical process. The Bureau analyses for cannabinoids, benzodiazepine class, amphetamines class, methamphetamine class, cocaine, methadone and opiate class drugs. The Bureau issues a statutory certificate indicating the presence of a drug or none detected to the driver and the Gardaí. This certificate along with the Garda evidence of impairment is required for prosecution purposes. A Garda can still request drug analyses if the alcohol level is greater than the legal limits or if an evidential breath alcohol test has been carried out and found to be below the legal limit. The classes of drug or drugs which the MBRS test for are kept under review. Prevalence and trends of drug use are very important factors which require consideration in the detection of drugs in drivers.

Chapter 2

Prevalence

Chapter 2: Prevalence

2.1: Introduction

A review of available Irish and International data was conducted in order to establish the prevalence of drugs used both in the driving population and the wider population. In terms of Irish data the following were considered:

- The nationwide survey conducted by the MBRS in 2000-2001
- MBRS Specimen Analysis Data 2007-2011
- The NACD drug prevalence survey from 2010/2011
- Fatal Crash Toxicology data from the National Drug-Related Death Index (NDRDI) and the Kildare County Coroner
- The RSA 'Driving Under the Influence of Drugs' report
- Garda DUI crime statistics.

In the case of International prevalence data from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the DRUID project and the North Report were taken into consideration. The objective of this review was to identify the most prevalent drugs, so that this would inform any road side testing strategy that may be introduced.

2.2: Ireland

2.2.1: Nationwide Survey: Medical Bureau of Road Safety and University College Dublin 2000-2001

The MBRS was commissioned by the then Department of Environment and Local Government to carry out a nationwide survey during 2000 and 2001 on blood and urine specimens from drivers suspected of intoxicated driving, in order to determine the trends in DUID in Ireland and to establish an 'evidence based' model to inform future Road Safety Strategies and a review of the legislation at that time. 2,000 specimens were selected for drug analysis, 1,000 with results under the limit for alcohol and 1,000 over the limit of 80mg/100mL in blood or 107mg/100mL in urine. [1, 2]

The drugs tested for were:

- Amphetamine Class
- Methamphetamine Class
- Opiate Class
- Cannabinoids Class
- Methadone
- Cocaine
- Benzodiazepine Class

231 (33.1%) of the drivers under the legal limit for alcohol tested positive for one or more of the relevant drugs, and the corresponding figures for drivers over the limit was 142 (14.2%). Using weighted analysis this corresponded to 15.7% of all tested drivers (15.8% in men and 14.5% in women).

Of drivers who had minimal blood alcohol levels (<10mg/100mL), 67.9% were taking at least one type of drug. The prevalence of taking drugs reduced steadily as alcohol concentration increased, but still remained as high as 11.1% for drivers with blood alcohol concentrations greater than 200mg/100mL. Being under the limit for alcohol, being stopped in a city area, being stopped between 6am and 4pm, or 4pm and 9pm, and being of the younger age group were each independently associated with drug positivity.

This study also showed that the impairing drugs being used by drivers were both licit and illicit in nature. The most prevalent drug by far was Cannabis followed by Benzodiazepines.

2.2.2: Medical Bureau of Road Safety Specimen Analysis Data 2007-2011

Testing for drugs has continued as part of the enforcement of the Road Traffic Act and drug test results for 7,776 specimens of blood and urine tested between the years 2007-2011 were reviewed. Cannabis followed by benzodiazepines continued to be the most prevalent drugs detected. Cocaine, opiates and methadone are the next most prevalent and have increased in prevalence when compared with the 2000-2001 study. Amphetamine and methamphetamine type compounds are less prevalent recently than previously reported in that study. The data from the 2000-2001 study and the review of the data between 2007 and 2011 have been tabulated (See Table 2.1) and charted (Figure 2.1). The total number of specimens analysed and the number subsequently certified for the presence of a drug or drugs is set out for 2007-2011 (Table 2.2).

Drug Class	Prevalence (% of all Under the Alcohol Limit Tested Drivers Positive for drugs)					
	2000/1	2007	2008	2009	2010	2011
Cannabis	63.1	54.3	63.1	57.7	48.9	52.2
Amphetamines (Incl. MDA)	25.4	11.9	4.7	2.6	5.2	5.3
Methamphetamines (Incl. MDMA)	27.2	13.0	8.2	1.5	3.3	3.7
Opiates	20.8	39.1	33.7	12.4	24.9	15.9
Cocaine	8.5	17.2	15.9	23.8	9.5	10.2
Methadone	7.5	17.8	15.9	8.8	10.8	7.2
Benzodiazepines	27.1	45.5	44.4	44.2	46.7	40.5

Table 2.1: Prevalence for the 7 classes of drugs tested for by the MBRS from the study conducted in 2000-2001 and also for the years 2007-2011.

	2007	2008	2009	2010	2011
Total Number of Specimens Analysed	1,154	1,867	1,980	1,554	1,221
Total Number of Specimens Certified	952	1,411	1,444	1,163	865

Table 2.2: The total number of specimens analysed and the number subsequently certified for the confirmed presence of a drug or drugs for the years 2007-2011.

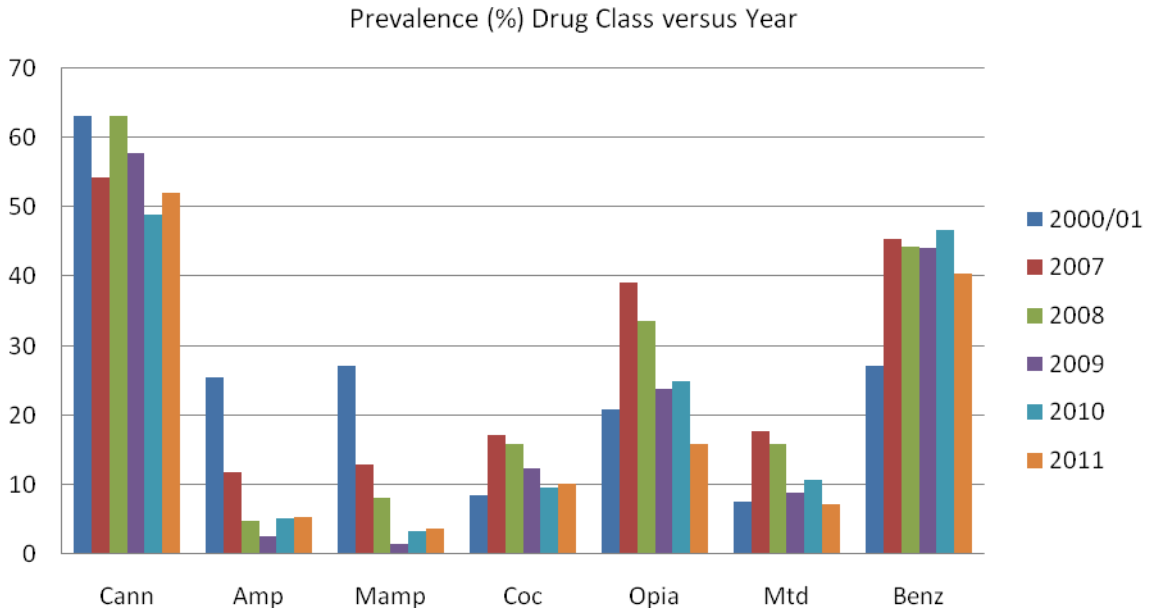


Figure 2.1: Prevalence for the 7 classes of drugs tested for by the MBRS from the study conducted in 2000-2001 and also for the years 2007-2011.

Figure 2.2 below gives a percentage breakdown of the number of classes of drug that specimens tested are found to contain for the years 2008-2011. This shows that poly-drug use, as reported in 2000-2001 study, is still being observed to the end of 2011 [1]. As can be seen 23.5% are positive for no drugs and 30.7% are positive for one drug. The remaining 45.8% are positive for two or more drugs.

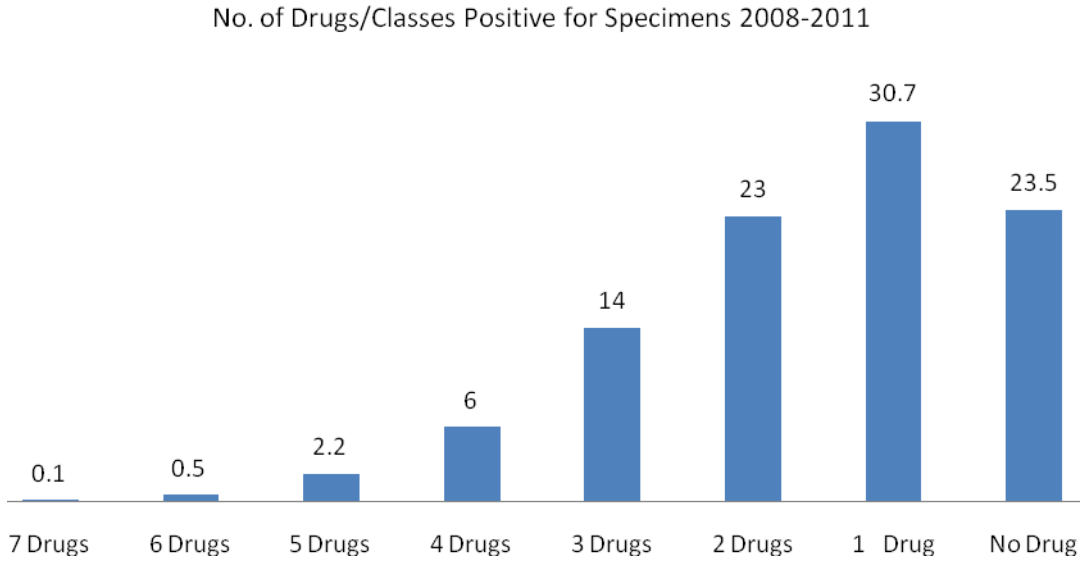


Figure 2.2: Percentage breakdown of the number of classes of drug, that specimens tested, are found to contain between 2008 and 2011

2.2.3: National Advisory Committee on Drugs: Drug Prevalence Survey 2010/2011

Data published by the National Advisory Committee on Drugs (NACD) on surveys of drugs trends is available. In 2012 the NACD and the Public Health Information and Research Branch (PHIRB) in Northern Ireland published data from a household survey conducted in 2010/2011 [3]. The results of the survey showed that cannabis was the most commonly used illegal drug with a lifetime prevalence of 25% in the Republic of Ireland and 24% in Northern Ireland. Cannabis use was more prevalent in the younger age groups. Another finding was that women and older adults continue to report higher levels of use of sedatives, tranquiliser and anti-depressants. This shows that in terms of the use of cannabis and benzodiazepines the most up to date data points to the fact the cannabis and drugs such as benzodiazepines are the most relevant in the driving population as was borne out in the MBRS survey in 2000/2001 and MBRS data from 2007-2011.

It is important to address the numerous new psychoactive substances which have been available on the Irish market in the last number of years. From the study conducted by the Dublin Institute of Technology (DIT) it would appear that there are a significant number of different drugs sold as intoxicating alternatives to illegal drugs [4]. Examples are drugs such as benzylpiperizine and mephedrone. These substances have received a significant deal of media attention in the last few years. These drugs are sold over the internet and through 'Head Shops'. The difficulty with these is that suppliers offer drugs for sale which are not currently controlled by any relevant legislation. If the drug is considered to be a danger to public health and are subsequently brought under control an alternative is very rapidly available. This presents a new challenge for policymakers, legislators and scientists. A new consideration in the NACD/PHIRB 2010/2011 survey was that new psychoactive drugs were included [3]. It showed that last year prevalence was 9.7% in the 15-24 year age group and 4.6% in the 25-34 year age group highlighting the significance of this new trend. The MBRS does not currently test for these new psychoactive substances, however the classes of drugs for testing is under continual review.

2.2.4: Fatal Crash Toxicology Data – National and County Kildare Studies

The National Drug-Related Death Index (NDRDI) was established in September 2005 to comply with Action 67 of the 2001–2008 National Drugs Strategy. [5]

Road Traffic Collisions (RTC) deaths in vehicle drivers with a positive toxicology for an illicit drug(s), recorded by the NDRDI 2004 to 2009 in Coroner's Districts Nationally

A review was undertaken by the NDRDI of drug toxicology from Coroners' nationwide data on driver fatalities between 2001 and 2009. The following analysis presents the NDRDI data on road traffic collisions (RTC) deaths among vehicle drivers in Ireland, for the period 2004 to 2009, where the individual had a positive toxicology finding for an illicit drug(s) at the time of death. In this six year period there were 93 of these deaths recorded by the NDRDI. Cannabis (38.7%) was the most common illicit drug found in the toxicology of these 93 individuals, followed by cocaine (23.7%) and MDMA (18.3%) (Figure 2.3). A more in-depth description of the NDRDI methodology is set out on pages 6-8 of the HRB Trend Series 8. [6]

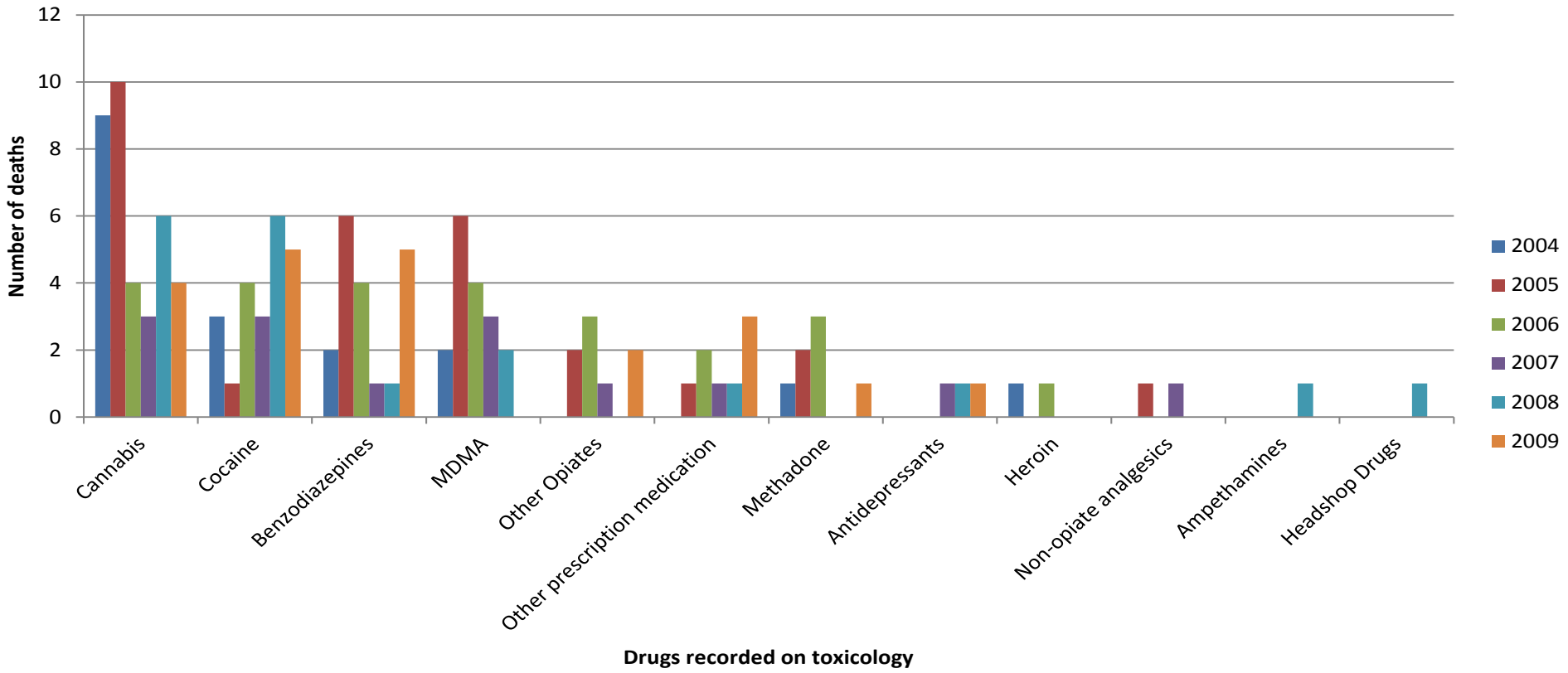


Figure 2.3 Positive toxicology for an illicit drug(s), vehicle drivers, NDRDI 2004-2009 n=93

RTC deaths in drivers of a vehicle (car, van or motorcycle) reported to the Coroner's District of Kildare 1998 to 2009

A review of road traffic collisions and drug and alcohol toxicology analyses from the Coroners District in Kildare during the period of 1998 – 2009 was also carried out. This was undertaken jointly by the NDRDI and the Kildare Coroner. The focus of the analysis was on deaths where a positive toxicology finding was recorded. In the eleven year period a total of 164 deaths due to road traffic collisions were reported in the district of Kildare. The majority of the deaths were males (81.7%) and between the ages of 15-34 years (61%). The median age was 29.5 years.

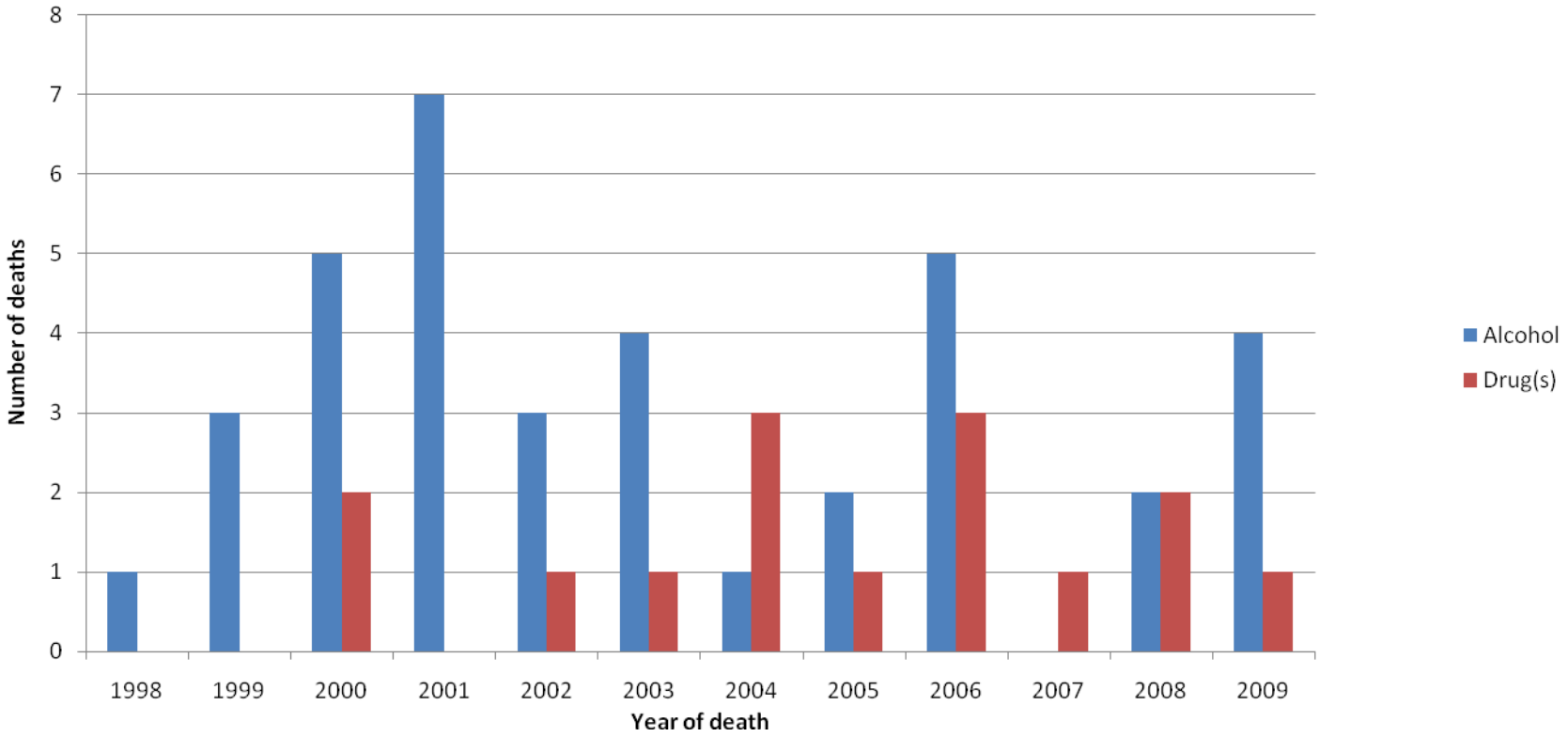
Of the 164 deaths during the reporting period 1998 to 2009, 92 (56.1%) were the driver of a vehicle (car, van or motorcycle). Of these 92 deaths, 46 (50%) had a recorded positive toxicology. Of the 92 driver deaths:

- 31 (33.7%) had a positive toxicology for BAC ≥80mg/100mls.
- 6 (6.5%) had a positive toxicology for a BAC≥80mg/100mls and a drug(s).
- 9 (9.8%) had a positive toxicology for a drug(s).
- A further 6 drivers (6.5%) had a positive toxicology for BAC ≥20mg/100mls.

These data are set out in Table 2.3 and charted in Figure 2.4.

Year	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09
Total deaths BAC≥80mg/100mls and/or drugs	1	3	6	7	4	5	3	2	7	1	3	4
Alcohol only	1	3	4	7	3	4	0	1	4	0	1	3
Alcohol and drug(s)	0	0	1	0	0	0	1	1	1	0	1	1
Drug(s) only	0	0	1	0	1	1	2	0	2	1	1	0

Table 2.3 RTC deaths among vehicle drivers, reported to the Coroner's District of Kildare, BAC≥80mg/100mls and/or drug(s), 1998 to 2009, n=46



* This is a multiresponse graph taking into account individual incidences of alcohol and drugs present on the toxicology report. Therefore, totals exceed the 46 deaths.

Figure 2.4 RTC deaths among vehicle drivers, repo rted to the Coroner's District of Kildare, alcohol or drug(s) present in toxicology, 1998 to 2009 n=46

2.2.5: Road Safety Authority DUID Report 2010

The RSA published a report in 2010 entitled 'Driving Under the Influence of Drugs: A review of the Evidence and Legislation' [7]. This report reviewed DUID in the context of:

- Prevalence
- Characteristics and perception of risks of DUID drivers
- DUID legislation and policy and procedures
- Detection of drugs in drivers

The report also made a number of recommendations and concluded that:

- DUID is significant problem worldwide
- There was a general lack of knowledge around the effects of drugs on driving
- The main drugs of concern were cannabis and benzodiazepines and also drugs in combination with alcohol.

Chapter 5 of the report dealt specifically with the detection of drugs in drivers. From an enforcement and legislative perspective the report concluded *per se* DUID laws can assist in the prosecution of DUID.

2.2.6: Garda DUI Recorded Crime Statistics 2004-2011

The incidence of Garda recorded crime statistics 2004-2011 [8] for driving or being in charge of a vehicle while over the alcohol limit or under the influence of a drug are reproduced below (Table 2.4).

Year	'04	'05	'06	'07	'08	'09	'10	'11
Driving/In charge of a vehicle while over legal alcohol limit	12,168	14,075	18,598	19,822	17,940	13,771	10,682	9,013
Driving/In charge of a vehicle while under the influence of a drug	77	106	117	270	728	891	602	421

Table 2.4: Recorded Crime Offences (Number) for Driving/In charge of a vehicle while over legal alcohol limit and Driving/In charge of a vehicle while under the influence of drug 2004-2011

There has been a decrease in the number of DUID incidents detected by An Garda Síochána since 2009 and there has always been a difference between the number of samples submitted to the MBRS which on analysis were found to be confirmed positive for drugs other than alcohol (Table 2.2) and the corresponding numbers recorded in crime statistics (Table 2.4) and subsequently prosecuted in the courts for DUID. These differences have never been satisfactorily explained but may be due to legal difficulties encountered in evidential proofs of impaired driving whilst under the influence of drugs other than alcohol.

2.3: International

2.3.1: European Monitoring Centre for Drugs and Drug Addiction 2011

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) provide data in a European context. The EMCDDA reported in its 2011 annual report that the last year prevalence for cannabis in 15-64 year olds was 6.7% and the last month prevalence for cannabis in the same group was 3.6% [9]. In the 15-34 year old age group the last year prevalence for Cannabis was 12% and the last month

prevalence for cannabis was 6.6%. The youngest age group was the 15-24 year old age group which showed the highest prevalence with last year prevalence for cannabis being 15.2% and the last month prevalence for Cannabis being 8.0%. When compared with prevalence data from Canada and the U.S.A. last year prevalence for Cannabis was 21.6% and 24.1% respectively in the young adult age group (ca. 15-34 years) [9]. The EMCDDA reports that last year prevalence for amphetamine and ecstasy is ca. 0.5% in the 15-64 age group and ca. 1-2% in the 15-34 age group. Last year cocaine prevalence in Europe is 1.2% in the 15-64 age group and 2.1 in the 15-34 age groups. Again as with cannabis prevalence the European averages are lower than Northern America. While the EMCDDA do not provide details of opioids prevalence it does take into consideration opioids other than the most common methadone, morphine and codeine and cites emerging trends in the misuse of opioids such as fentanyl, oxycodone, hydrocodone and buprenorphine.

The 2011 EMCDDA annual report highlighted the problem presented by new psychoactive substances [9]. Between the establishment of the EMCDDA in 1997 and 2010 the EMCDDA has included 150 drugs into its monitoring programme, 65 of these were added in 2009 and 2010. A further 70 were added in 2012. This clearly demonstrates that the illicit drug problem is 'increasingly dynamic and fast moving in nature' as suggested in the report.

2.3.2: DRUID (Driving Under the Influence of Drugs) 2006 - 2011

Various studies have been carried out worldwide, at European level and in Ireland to ascertain the prevalence of drugs driving. However, prevalence data from different countries have not been readily comparable owing to differences in study designs. One of the most significant projects to conduct research into drugs, alcohol and medicines in the context of EU Transport Policy and Road Safety was the DRUID (Driving Under the Influence of Drugs) project which was funded by the European Union. The research consortium participants were 37 institutions from 19 countries. DRUID's scientific structure consisted of 7 different "work packages" on:

- Methodology and Research (observational, experimental, accident databases);
- Epidemiology (prevalence and risks of psychoactive substances in driving);
- Enforcement (on site detection of impairing substances);
- Classification and Categorisation (of medicines in driving);
- Rehabilitation (behavioural change programmes);
- Withdrawal (of driving licence);
- Dissemination (information campaigns for general public and healthcare professionals)

The project commenced in 2006 and the final conference took place in September 2011 at which the outcome of the completed research was presented [10]. The epidemiology (with methodology and research) of drug and alcohol consumption in the driving population, in drivers killed or injured in crashes and in drivers involved in fatal crashes was presented. The participating countries, in which these studies were conducted in, show prevalence in the general driving population of up to 10% for alcohol; up to 2% for drugs in combination with alcohol; up to 5% for illicit drugs; and up to 3% for medicines. There were limitations on some of the countries studies, e.g. small sample size for some of

the studies involving injured drivers. The findings of the DRUID project with respect to roadside chemical testing are discussed in chapter 5.

2.3.4: UK: The North Report 2010

The North Report, published in 2010, was a 'Review of Evidence Related to Drug Driving in the UK' which was overseen by Sir Peter North and his team for the UK Government [11]. The first part of this report dealt with prevalence and it noted that there was a lack of recent UK data on the impact of drug driving on casualty rates. The review recommended the use of Coroner data and data from toxicology laboratories as potential sources of data and acknowledged that this would require co-ordination among the stakeholders if it was to be realised as a potential source of data. Analysis of the available data sources found that cannabis was the most prevalent drug across all surveys and data sources, but that since the mid 1990s there had been an increase in cocaine use in the general population, the DUID population and other road users. It cited regional variations such as in Scotland where benzodiazepines were the most prevalent, with more that 80% of DUID cases being down to this drug class. In addition the review stated that there has been a considerable increase in polydrug use. As the review was published in 2010 it refers to anecdotal evidence of a 'surge in legal highs'.

2.4: Drugs that should be Targeted for Testing: Current and Future

Taking into consideration the prevalence evidence discussed above it is clear that cannabis and benzodiazepines are the most prevalent drugs used both nationally and internationally. It is also clear that the pattern of drugs which are used or abused changes. The importance of monitoring these changing trends cannot be understated. Sometimes these changes are short-lived and at other times they are more permanent changes. Some considerations leading from this are:

- The authorised and legal medicinal use of cannabinoids (e.g. Sativex®) is permitted in other countries within the EU. In the event that cannabinoids become legally available in the Republic of Ireland for medicinal use, this would need to be considered in the framing of any legislation.
- New prescription medications which have new drug components which cause impairment need to be monitored and included in drug testing strategies. Examples of these would be the introduction of new opioid drugs such as buprenorphine in the last number of years.
- There are many drugs which are not currently targeted by the MBRS and these include anti-histamines, antipsychotics and antidepressants all of which can have impairing effects. Analysis of these drugs will form part of the continuing development of the drug testing programme at the MBRS.
- New psychoactive substances legislation describes psychoactive substance as a substance that is 'not specifically controlled under existing legislation, that have the capacity to stimulate or depress the central nervous system resulting in hallucinations, dependence or significant changes to motor function, thinking or behaviour'. The risk is that while a substance may fit the description above an absence of evidence in the literature may undermine their categorisation as an intoxicant. Careful consideration will need to be given to this issue in road traffic legislation.

2.5: Conclusion

Based on the drug testing conducted by the MBRS, national and international drug testing trends, the cannabinoids and the benzodiazepines are the most prevalent drugs used, followed to a lesser extent by the opiates, methadone and cocaine. The amphetamine and methamphetamine class drugs are least prevalent. These trends and the emergence of new drugs need to be considered when selecting drug targets for roadside drug testing.

Chapter 3

Effects of Drugs on Driving and the Relationship Between Impairment and Bodily Fluids

Chapter 3: The Effects of Drugs and Driving and the Relationship Between Impairment and Body Fluids

3.1: Introduction

The purpose of this chapter is to provide background on the effects that different drugs have on driving and the relationship between impairment and a measured drug level in specific biological specimen types is discussed.

3.2: Drugs and their Effects by Class

There are many useful resources which deal with the effects of drugs and driving and some of these are referenced here [12, 13].

3.2.1: Cannabinoids

The chemical compounds unique to the cannabis plant are known as the cannabinoids. The main pharmacologically active constituent of cannabis is Δ^9-tetrahydrocannabinol (THC). This is a central nervous system depressant that may cause ataxia, confusion, dizziness, somnolence, euphoria, hallucinations, speech difficulties, weakness, malaise and vision difficulties. Single doses of THC, via smoking or oral ingestion, are capable of producing significant psychomotor performance decrements in healthy volunteers for up to 24 hours in laboratory studies and up to 3 hours under actual driving conditions. The deleterious effects of THC appear to be additive to or possibly synergistic with those of alcohol, and the combination of the two agents results in the prolongation as well as enhancement of their effects [12, 13].

3.2.2: Benzodiazepines

Examples of benzodiazepines are drugs such as diazepam and alprazolam. Many benzodiazepines are available on prescription. Such drugs are central nervous system depressants that may cause drowsiness, lethargy, dizziness and confusion. Manufacturers state that patients taking these drugs should be warned against engaging in potentially hazardous activities requiring mental alertness and that they should be advised against the simultaneous use of alcohol and other central nervous system (CNS) depressants. Simulator and driving studies have shown that such drugs produce significant driving impairment. Single doses of diazepam can increase lateral deviation of lane control, reduce reaction times, reduce ability to perform multiple tasks, decrease attention, adversely affect memory and cognition and increase the effects of fatigue. Significant impairment is further increased if diazepam is combined with low concentrations of alcohol [12, 13].

3.2.3: Opiates

Drugs in the opiates class include morphine, codeine and heroin. Many opiates are available on prescription. These drugs are central nervous system depressants that can cause drowsiness and dizziness, lethargy, ataxia, visual disturbances, weakness and confusion. Some of the drugs are used medicinally and manufacturers warn that the drug can impair mental and/or physical abilities required for the performance of potentially hazardous tasks and additive depressant effects may be produced by the concomitant administration of other CNS depressants, including alcohol. Single or repeated

intravenous intramuscular or oral morphine doses given to healthy volunteers as well as former opiate addicts, have been shown to be capable of causing subjective sedation and significant psychomotor impairment for up to 4 hours after a single dose and for up to 36 hours after a repeated doses in laboratory studies [12, 13].

3.2.4: Methadone

Methadone is a central nervous system depressant that can cause drowsiness, dizziness, weakness, disorientation, lightheadedness and visual disturbances. Prescription users are advised that methadone may impair their mental and/or physical abilities required for the performance of potentially hazardous tasks, and that the sedative effects of the drug may be enhanced by the concurrent use of other CNS depressants such as alcohol. In healthy, non-methadone using volunteers, single doses of methadone will impair driving ability [12, 13]. Studies of long-term methadone maintenance patients have shown appropriately administered methadone doses do not cause significant psychomotor or cognitive impairment when administered regularly and when the subject abstains from all other drugs [14].

3.2.5: Cocaine

Cocaine is a central nervous system stimulant that may cause restlessness, euphoria, dizziness, dyskinesia, tremors, dysphoria and insomnia. Chronic usage may lead to personality changes, irritability, hyperactivity and psychosis. Observed signs of impairment and driving performance have included subjects speeding, losing control of the vehicle, causing collisions, turning in front of other vehicles, high risk behavior, inattentive driving and poor impulse control. As the effects of cocaine wear off subjects may suffer from fatigue and depression, sleepiness and inattention [12, 13].

3.2.6: Amphetamines, Methamphetamines and Ecstasy (MDMA)

Amphetamine and methamphetamine are central nervous system stimulants that may cause restlessness, euphoria, dizziness, dyskinesia, tremor, dysphoria and insomnia. Chronic use may lead to personality changes, irritability, hyperactivity and psychosis. Driving and driving behaviours included; speeding, erratic driving and accidents. Other notable effects included nervousness, rapid and non-stop speech, un-intelligible speech, disorientation, agitation, staggering and awkward movements, irrational violent behavior and unconsciousness. Impairment is attributed to distraction, disorientation, over excitation, hyperactive reflexes, general cognitive impairment or withdrawal, fatigue and hypersomnolence [12, 13].

MDMA (ecstasy) is a weak central nervous system stimulant that may cause the sensory disturbances, nausea and dizziness, ataxia, muscular rigidity, diaphoresis, restlessness and tremor. In driving studies moderate effects on vehicle control, acceptance of higher levels of risk, acute changes in cognitive performance and impaired information-processing ability were observed [12, 13].

3.2.7: Prescribed Drugs

The accident risk is considered to be less for the therapeutic use of drugs because of tolerance development and the beneficial effect of treatment, than the risk associated with intermittent, illegal use or use outside of professional therapeutic advices. However with certain prescribed drugs used in certain situations impairment can occur and can contribute to accident risk [15]. A recent study

suggested that particular attention should be given to older drivers (45+) using two or more CNS-acting agents [16].

3.3: Impairment and Body Fluids

The two specimen matrices which have been most used in drug driving research and enforcement practice to date are blood and urine. Blood collection is the most invasive specimen collection procedure and requires transportation of the subject to a Garda station or hospital where a medical practitioner or nurse is required to obtain a specimen. In the collection of blood, valuable time is lost transiting the suspect and it is inevitable that the level of any impairing drug will decrease from the bloodstream during this period.

Blood gives the most information about the subjects state of intoxication because it correlates relatively well with impairment. The main challenge of identifying specific blood concentrations of drugs, other than alcohol, that correlate with specific levels of impairment is compounded by many factors such as:

- Inter-individual differences (metabolism and tolerance);
- Polypharmacy and drug interactions;
- Passage of time between driving and collection of a blood sample.

For this reason few countries have adopted the *per se* approach to DUID and many have instead adopted a zero tolerance approach for illegal drugs and/or an impairment approach with confirmed drug presence for medically prescribed drugs.

Urine is equally difficult to collect at the roadside. However, urine drug concentrations are not effective in establishing impairment, but can be used to establish previous use of a drug.

The relationship between the level of a drug in oral fluid and impairment has not yet been fully established. Some jurisdictions use oral fluid testing with cut-off concentration levels for oral fluid which are set administratively. These levels are not based on a relationship to impairment or on any correlation between oral fluid and blood levels.

Chapter 4

Detection of Driving Under the Influence of Drugs

Chapter 4: Detection of Driving Under the Influence of Drugs

4.1: Introduction

Currently detection of driving whilst under the influence of intoxicants, including drugs other than alcohol, is by means of observation of impaired driving or a combination of preliminary alcohol breathalyser testing and observation at mandatory alcohol testing (MAT) checkpoints. This chapter deals with the two main approaches, which are being adopted internationally, for detection of DUID. These two approaches are Roadside Impairment Testing and Roadside Chemical Testing.

4.2: Roadside Impairment Testing

In accordance with the Road Safety Strategy 2007 – 2012, the MBRS in partnership with the School of Medicine and Medical Science at University College Dublin and An Garda Síochána established a training programme for Garda Trainers in Road Traffic Impairment Testing (RTIT), also known as Field Impairment Testing or FIT. This was done in the context of the new Section 11 of the Road Traffic Act 2010 which provided for preliminary impairment testing. Some 80 Garda Trainers were trained and certified in a professional course as being proficient in Road Traffic Impairment Testing and are currently undertaking training of Garda members to carry out these tests at the roadside. More than 3,000 Garda members had been trained up to end of March 2012. The RTIT tests comprise of examination of the driver's pupil; a modified Romberg balance test (an indicator of the drivers ability to balance and internal clock); a walk and turn test (assessing walking, balancing and following of instructions); one leg stand (balance and counting out loud); and finger to nose test (test of balance and depth perception). The proscribed format in which the results are recorded by the Garda carrying out the tests is currently being reviewed in terms of possible legislative amendment and is anticipated to be included in road traffic legislation for 2012.

4.3: Roadside Chemical Testing

4.3.1: Specimen Types

There are three main specimens types that have been used in testing for drugs in drivers, namely blood (or a blood derived product such plasma or serum), urine and oral fluid. Each has advantages and disadvantages in the context of roadside testing and these are set out in the Table 4.1. Oral fluid is the specimen of choice for roadside drug tests and this is borne out in a survey conducted by the MBRS and also in the available literature [10, 17-19]. A key advantage of oral fluid is that it can be collected at the roadside and a preliminary chemical test can be conducted at the roadside. For these reasons oral fluid testing is the focus of this review.

4.3.2: Oral Fluid

Saliva is the secretion product of the saliva glands of the head and mouth. Human saliva glands produce between 0.5 and 1.5L of saliva daily. Saliva itself is composed of 99% water, 0.3% protein (mostly amylase) and 0.3% mucins. The term saliva is specific to the secretions which originate directly from the saliva glands. The fluids found in the oral cavity are a mixture of, predominantly saliva with smaller amounts of gingival crevicular fluid, cellular debris and blood. Oral fluid is the term used to describe the

fluid collected by placing absorbent pads in the oral fluid cavity or by expectoration (spitting) [20]. Oral fluid is predominately saliva. A full review of the anatomy and physiology of saliva is available in Clarke [20].

Parameter	Blood	Urine	Oral Fluid
Specimen collection	Impractical to collect at the roadside. Requires a Doctor or Forensic Nurse to collect in a Garda Station or Hospital.	Impractical to collect at the roadside. Requires a Doctor or Forensic Nurse to collect in a Garda Station or Hospital.	Can be collected non-invasively at the roadside by a trained law enforcement officer.
Collection time	Depends on the availability of a Doctor or Forensic Nurse. Legally must be collected within 3 hrs.	Depends on the availability of a Doctor or Forensic Nurse. Depends on ability of arrestee to provide a specimen. Legally must be collected within 3 hrs.	Could require an observed nil by mouth period at the roadside or station. Specimen can take up to 10 minutes to collect after this time.
Sample Integrity	Not easily adulterated	Not easily adulterated if collection is observed.	Not easily adulterated if collection is observed
Suitability in determining the presence of a drug or drugs	Suitable	Suitable	Suitable
Relationship between concentration and impairment	Relationship exists but requires careful and qualified interpretation by a Toxicologist	No reliable relationship as drug concentration in urine is subject to variation.	Evidence gathered to date that some relationship does exist however the evidence is still incomplete.

Table 4.1: Differences between blood, urine and oral fluid for a number of important parameters relating to roadside drug testing.

4.3.3: How Drugs Get Into Oral Fluid; Factors Effecting Drug Concentration and Oral Fluid Production

For drugs to enter the mouth via saliva, the drug molecules must be lipid (fat) soluble, non-ionised and unbound to proteins. For this reason, the concentrations of drugs in saliva represent their free non-ionised portion in the blood plasma [20].

The pH of saliva can have a significant effect on the level of drug found in saliva compared to the level of drug found in the blood at the same time. It has been demonstrated that saliva pH changes as the flow rate of saliva changes. It is possible to stimulate saliva production using citrate salts and an example of this is where an oral fluid collection device incorporates citrate salts in the absorbent pad. When the pad is placed into the mouth, oral fluid production increases due to the effect of the salts. At faster saliva flow rates the pH rises, so stimulated saliva would have higher pH and can be as high as pH 8. Unstimulated saliva has a low pH between pH 6 and 7 and is fairly constant. A good example of how the change in pH can affect the concentration of the drug found in saliva is for Cocaine, as the saliva pH changes from 5 to 7.8, the saliva to plasma ratio for Cocaine varies from 273 to 0.44. So at higher pH values there will be very little cocaine while at the lower pH values there will much greater levels of Cocaine. As this example shows that there is a poor relationship between oral fluid drug concentrations and blood drug concentrations for cocaine due to variations in saliva pH and this effect has to be considered for all drug targets [20].

Spiehler *et al*. have published the theoretical ranges of saliva to plasma ratios, ranging in pH from 6.4 to 7.6 for a number of drugs [21]. Due to the saliva to plasma ratio of basic drugs (drugs that are ionised at pH values greater than 7) such as opiates, amphetamines and cocaine drug concentrations in oral fluid

are easily measurable. In contrast the saliva to plasma ratio of benzodiazepines and cannabis are generally low [22].

Saliva production is controlled by the CNS. Because drugs also affect the CNS they can interfere with the production of saliva. This has implications for the ability to provide oral fluid specimens based on the drug the driver may be using. Drugs which effect the secretion of oral fluid include amphetamine and MDMA where typically oral fluid production is reduced. This can also be the case with cannabis, sedating antihistamines, antipsychotic drugs, ant-cholinergic drugs and a number of antidepressants [17].

In addition to the introduction of drugs via the saliva glands, it is also possible that drugs are present in the mouth due to smoking, oral consumption and snorting [23]. Because of this drugs may be detectable in the mouth due to direct contact and/or recent consumption.

4.3.4: Specimen Collection for Roadside Chemical Testing

Expectoration or spitting provides a neat oral fluid, but this is a very viscous fluid and it can be difficult to work with at the roadside. In addition it can be contaminated with food and other debris from the mouth such as cellular matter. Commercial oral fluid collection devices are available which get around the sample handling difficulties associated with the collection of a neat sample. These typically take the form of an absorbent material made from cotton or polyester, which is used to collect oral fluid. The pad can then be added to a diluent and the resultant fluid is used for testing. Other devices involve squeezing absorbed oral fluid from a foam pad onto the drug detection device. Collection times vary, however, they can be as short as a couple of seconds, and as long as 10 minutes. Collection volumes also vary where some devices collect only enough for the roadside test and others which collect sufficient for roadside testing and laboratory testing.

4.3.5: Onsite Oral Fluid Tests

There are numerous on-site testing systems for drugs in oral fluid. These tests can be described as immunochromatographic devices. They generally operate by lateral diffusion of the oral fluid sample mixed with labeled antibodies in a buffer across lines of immobilised drugs. The specimen is collected from the mouth of the donor and applied to the test strip. Figure 4.1 depicts an example which involves a specimen containing morphine. At the start end of the strip, where the sample is applied, a buffer containing antibodies for the drug is added. When drugs are present in the oral fluid, they bind to the antibodies in the buffer and travel down the strip. When drugs are absent the antibodies travel down the strip and are free to bind with the immobilised drug (hapten-protein conjugate) in the test region at the end of the strip. When drugs are present they will be bound to the antibodies in the buffer and pass by this immobilised drug (hapten-protein conjugate) in the test line. The operator can see the result because the antibodies are labeled with colloidal gold and will be visible as a red line, indicating that no drug was present. Figure 4.2 depicts the four possible outcomes of such a test for a single analyte. The test normally includes a control the purpose of which is to ensure that the test has worked correctly. If the control is not visible the test is invalid. The tests are single use only. This is the same type of technology that is used in point of care urine tests used in workplace drug testing and pregnancy testing.

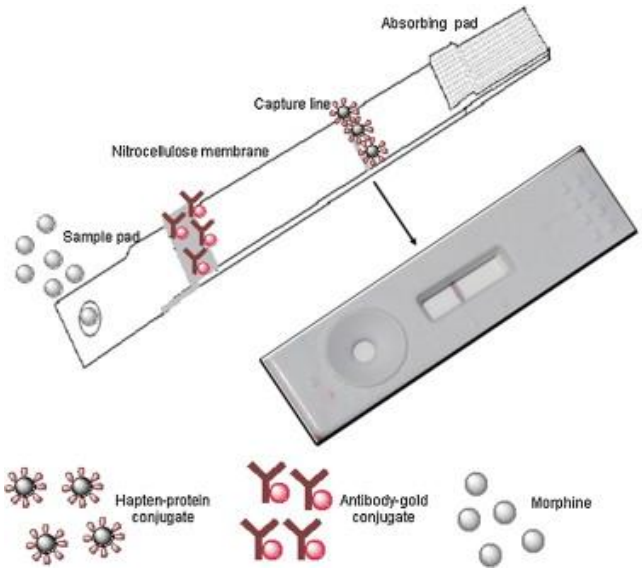


Figure 4.1: Diagram of an oral fluid test for opiates. The diagram shows the test strip in the upper left. The strip would normally be housed in the plastic cartridge shown on the lower right. The cartridge include the sample well and the test window. Reproduced from reference [24]

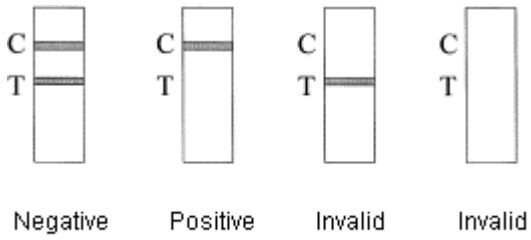


Figure 4.2: The four possible outcomes of a single analyte immunochromatographic test where C is the control line and T is the test line. Reproduced from reference [25]

It is worth noting that there can be a degree of subjectivity in interpreting positives and negatives. Figure 4.3 shows a specimen which has been tested for cannabis and was found to be negative using a test for oral fluid with a cut-off for THC at 25ng/ml (see section 4.4.1 for an explanation of cut-offs). As can be seen there is a visible line in the test region indicating that the specimen is negative. Figure 4.4 shows a specimen which has been tested in the same way and is positive. Figure 4.5 shows cannabis specimen which has been tested in the same way which contained 6ng/ml of THC. This specimen is negative however a faint line is visible. For this reason many of the manufacturers have developed electronic readers which use cameras to detect the lines and provide a more consistent interpretation of the result. These also have the benefit of being able to export data to a printer or other electronic media.

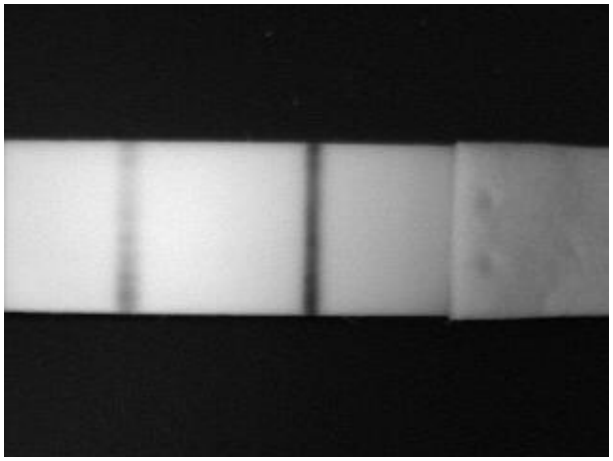


Figure 4.3: An oral fluid specimen tested for cannabis and found to be negative due to the strong test line on the left and strong control line on the right. Reproduced from reference [26]

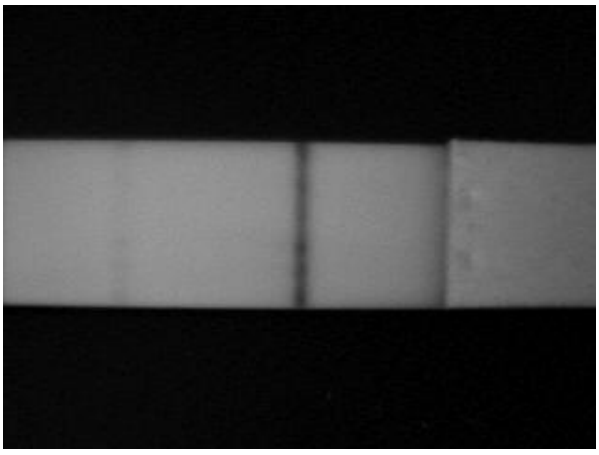


Figure 4.4: An oral fluid specimen tested for cannabis and found to be positive due to the absence of a test line on the left and strong control line on the right. Reproduced from reference [26]

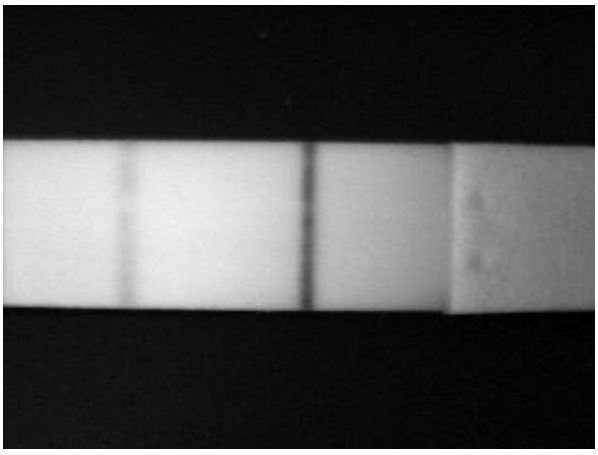


Figure 4.5: An oral fluid specimen tested for cannabis and found to be negative due to the weak test line on the left and strong control line on the right. Reproduced from reference [26]

4.3.6: Adulteration

The possibility of adulteration in the case of roadside collection would need to be considered in the selection of a device. Adulterants could be added to the mouth before a specimen is taken which could interfere with the ability of the test to give a reliable result. For this reason, a period of time should be allowed to elapse before a specimen is taken under supervision. Proper training and conduct of specimen collection should rule out the possibility of adulteration.

4.3.7: Interfering Substances

A British "Guide to Type" for preliminary drug testing recommended a number of potential interfering substances (and concentrations) that should be tested for when evaluating oral fluid testing devices, including cigarette smoke (unspecified volume), sodium bicarbonate (50 ng/ml), caffeine (50 ng/ml), menthol (50 ng/ml), vitamins C (50 ng/ml) and phenylalanine (50 ng/ml) [27]. Any other potential intereferents should also be considered.

4.3.8: Contamination

It has been reported that oral fluid testing devices and oral fluid collecting devices, which are not properly used can in themselves become contaminated with airborne drug from cannabis smoke [28]. Training of the Gardaí in the proper use of the oral fluid collection devices will avoid the possibility of airborne or surface contamination.

4.3.9: Environmental Considerations

The lighting conditions may have an impact on devices which are visually read or interpreted. Devices with readers would get around this if they were equipped with screens capable of reading in low light (e.g. backlit screens). All of the devices use liquid as part of the development of the test and so the operation of devices could be affected by cold weather (freezing) and also by hot weather (evaporation/humidity). Manufacturers normally advise on an optimum working temperature and humidity ranges for devices.

4.3.10: Health Risks Associated with Handling Oral Fluid Specimens.

Saliva is known to be a source of infectious microorganisms therefore, appropriate precautions need to be taken. Devices should be disposed of in accordance with proper waste disposal guidelines (e.g. Garda Health and Safety procedures).

4.4: Important Concepts for Evaluation of Roadside Chemical Testing Devices

4.4.1: Drug Cut-offs

In drug testing generally cut-off concentrations are applied. This means that when the drug level is below the cut-off concentration the result is negative and where the result is at or above the cut-off concentration the result is positive. Cut-offs are often set so that detection is possible within a reasonable timeframe, but that the window of detection does not persist for too long a period after abstinence from the drug under test. In oral fluid, drug cut-offs have been proposed by various institutions, projects and countries. The oral fluid cut-offs tend to be lower for drugs than the commonly applied screening cut-offs for DUID in urine and blood [29]. In addition it is not uncommon for the cut-offs for onsite testing and laboratory testing to be different. In some cases this is because the onsite test

is a broad spectrum test for a class of drugs, e.g. opiates, whereas the laboratory test is capable of detecting and quantifying the individual members of the opiate drug class, e.g. morphine, codeine.

4.4.2: Cross Reactivity

All of the available roadside tests are based on lateral flow immunoassay principles. The way immunoassay testing works is that an antibody is produced that has a high degree of binding to the chemical that is to be tested for and this is incorporated into the test device. This binding is based on the shape of the chemical and the impression in the antibody matching much like a key (drug) in a lock (antibody). Whilst this binding is highly specific it is always possible that other chemicals or parts of chemicals could also fit the impression in the antibody. For structurally related compounds in a class this is advantageous, as for example an opiate immunoassay test will detect morphine, codeine and related compounds. This concept is called cross reactivity and whilst in some instances it is advantageous it can result in false positives. This occurs where a structurally related chemical, but not one from the specific class, gives a positive result due to cross reactivity. Because of the possibility of cross reactivity and false positives, all specimens testing positive by immunoassay must be confirmed by a laboratory based confirmatory method (e.g. GC-MS or LC-MS) in order to produce a legally defensible result.

4.4.3: Accuracy, Sensitivity and Specificity

When evaluating onsite drug tests the terms specificity, sensitivity and accuracy are used to measure the capability of the test.

Specificity

The specificity of the test can be described as the ability of the test to return a negative test result (absence of the drug) when it should. The mathematical formula for this is as follows:

$$TN/TN+FP$$

Where TN is true negative and FP is false positive

A test with a specificity of 100% would be expected to give a negative result every time it is used to test a truly negative specimen. A test which has a specificity of 90% will give a false positive result 10% of the time and so on. However as all preliminary testing must be confirmed by a confirmatory technique which is 100% specific, such false positives will be detected by confirmatory laboratory testing.

Sensitivity

The sensitivity of the test can be described as the ability of the test to return a positive test result (presence of the drug) when it should. The mathematical formula for this is as follows:

$$TP/TP+FN$$

Where TP is true positive and FN is false negative

A test with a sensitivity of 100% will give a positive result every time it is used to test a truly positive sample. A test which has a sensitivity of 90% will give a false negative result 10% of the time and so on. This could result in failure to detect DUID by a chemical test. Impairment testing could be used in circumstances such as this.

Accuracy

Accuracy is a mathematical combination of specificity and sensitivity and is the measure of the tests ability to return the correct result whether it is positive or negative. The formula used for this calculation is as follows;

$$TP + TN / TP + TN + FP + FN$$

Where TP is true positive, TN is true negative, FP is false positive and FN is false negative

The ROSITA project (See Chapter 5) set the sensitivity and specificity requirements for onsite tests at greater than 90% and the accuracy at greater than 95%. The DRUID Project (See Chapter 1 and 5) set the criteria of greater than 80% for specificity, sensitivity and accuracy.

4.5: Drugs in Oral Fluid by Class

4.5.1: Cannabinoids

Cannabinoids in saliva often result from residual cannabinoids left in the mouth during smoking of Cannabis products. The presence of THC through passive exposure is possible and has been reported [28, 30]**.** The main component which is targeted is THC, however recent studies have shown the metabolite, THCA, is detectable in picogram quantities in oral fluid. Cone *et al.* found the saliva: plasma ratio of THC to be 10 after smoking [31]. The presence of THC in oral fluid is an indication of recent use. Oral fluid cut-offs for cannabinioids tend to be ca. 10-25ng/ml.

4.5.2: Benzodiazepines

The saliva: plasma ratio for the benzodiazepines is low (range 0.01 to 0.08). This is due to acidic pKa's and high protein binding (95-99%) [20]. As a result these compounds are difficult to detect in oral fluid and cut-offs need to be low e.g. 10-25ng/ml.

4.5.3: Opiates

The common opiates such as morphine and codeine are all detectable in oral fluid. Oral fluid is an excellent specimen for detecting heroin use as the metabolite 6-AM is readily detected. Reported saliva to plasma ratios for 6-AM, Morphine and Codeine were 0.12 to 7.2 [23], 0.1 to 1.82 [23] and ca. 3.0 [31] respectively . Oral fluid cut-offs for opiates tend to be ca. 10-40ng/ml.

4.5.4: Methadone

Methadone is detectable in oral fluid and as it is only available in linctus form it can be present in the oral cavity at the time of dosing. Saliva: plasma ratios of 0.6 to 7.2 have been reported for the pH range 5.0 to 7.0 [32]. Oral fluid cut-offs for opiates tend to be ca. 10-40ng/ml.

4.5.5: Cocaine

The parent drug is the major analyte in oral fluid. As noted earlier as the saliva pH changes from 5 to 7.8, the saliva to plasma ratio for Cocaine varies from 273 to 0.44 [21]. The DRUID study found that the sensitivity for cocaine was very low (average 36%) [10]. Oral fluid cut-offs for cocaine tends to be ca. 10-30ng/ml.

4.5.6: Amphetamines, Methamphetamines and Ecstasy (MDMA)

Typically the parent drug is found in oral fluid for these compounds and the saliva: plasma ratios are reasonably favourable, for drug detection in oral fluid, being reported at 2.76 for amphetamine, 3.98 for methamphetamine [33] and 18.1 for MDMA [34] . Oral fluid cut-offs for amphetamines tend to be ca. 25-50ng/ml.

4.6: Confirmatory Laboratory Testing for Drug Detection in Oral Fluid

The currently available roadside chemical tests are based on immunoassays and will give presumptive results and so the roadside result alone is not conclusive. The possibility that a false positive result will occur cannot not be ruled out when conducting roadside tests and where tests on devices have specificity levels of less than 100% this is inevitable. Because of this, there will always be a need to conduct a confirmatory drug analysis. Such tests can only be conducted in laboratory facilities by laboratories which are specialised in such testing.

4.6.1: Specimen Selection

The type of legislation has an impact on the specimen(s) chosen for confirmatory analysis. An example would be a *zero tolerance* type law. If the law requires that the presence of a drug or drugs be confirmed, an oral fluid specimen could be appropriate for confirmatory testing. While it may be more challenging for the laboratory due to the fact that drug concentrations are lower and therefore harder to detect in oral fluid than in urine or blood. Some jurisdictions have commenced using oral fluid as a confirmatory specimen. Urine and blood are also suitable specimen types for confirmatory analysis in a *zero tolerance* type law.

There is no consensus on appropriate *per se* levels for drugs in blood due to insufficient research in this area, although some jurisdictions have introduced levels [35]. However, if *per se* levels were included in legislation for a particular drug(s) they would need to be based on blood drug concentrations due to relationship between blood drug concentrations and impairment (See Chapter 3). Therefore it would not be appropriate to use oral fluid or urine for confirmatory analysis and instead a blood specimen would be required.

Requirements as currently exist for the collection of urine and blood in terms of chain of custody and sample integrity would also apply to oral fluid collection. In addition, sample stability would be a requirement and the addition of a suitable preservative will be necessary.

4.6.2: Blood and Urine Specimen Collection for Laboratory Testing

Well established procedures for the collection of blood and urine exist and so will not be dealt with here.

4.6.3: Oral Fluid Specimen Collection for Laboratory Testing

For the roadside chemical test the volume of oral fluid collected is small and can range from 5µL to ca. 500µL. The specimen collection is not intended for anything other than the performance of the roadside chemical test. The collection of an oral fluid specimen for confirmatory testing is a separate process. It will normally involve a separate collection device which has the ability to collect a larger volume of oral fluid (1ml). Some devices include an indicator of the volume. The specimen collection device will

normally consist of a dry absorbent pad which when placed in the mouth will soak up oral fluid. This pad is then transferred to a collection tube which contains a buffer and preservative. The collection tube will have screw/press-in cap which can be placed on top and secured. An integrity seal can be placed over the tube or alternatively the tube can be placed in another container which can be integrity sealed, the latter being the current practice under the RTA for blood and urine. Some devices stimulate saliva production in order to speed up specimen collection. This can be achieved by using citric acid, chewing gum and other agents. There has been a move away from this approach as there is no net gain in the concentration of drug in the fluid, instead only the specimen volume is higher, with a lower concentration of drug as the oral fluid has been unnaturally stimulated. It should be stated that to a certain extent oral fluid production will be stimulated by the placement of a collector in the mouth. Specimen collection volume in the case where oral fluid is used as the evidential sample is very important. The exact volume must be known or estimated accurately in order to provide a quantitative result. This is often achieved by weighing the specimen. Current law permits splitting of the blood/urine specimen so that one portion can be anlaysed by the MBRS and the other offered to the arrested person for separate analysis by their own arrangement. Similar consideration would have to be given to the option of a second specimen if oral fluid were to be used for confirmatory testing.

If it is collected as an alternative to urine or blood then it could be collected at the roadside by a Garda, sealed to ensure its integrity and sent under chain of custody for confirmatory testing. This could eliminate the need for blood or urine specimen collection by a Doctor or Nurse at a Garda station.

In the case of devices which are used for confirmatory testing in the laboratory, recovery of drugs is a consideration. Certain drugs such as THC, the active component of cannabis has been known to adhere to the collectors and therefore is not available for analysis and the end result is poor recovery [17]. Specimen collection device manufacturers have addressed the problem by reducing the binding of drugs onto the surface of collection devices by using liquid buffers. These buffers have the advantage of reducing the viscosity of the oral fluid making it easier to work with during subsequent processing. A disadvantage of this is that many of the buffers and surfactants used can interfere with the subsequent confirmatory analysis increasing phenomena such as matrix effects [36] . Device materials and buffers are proprietary and it is not possible to predict when recovery might be an issue.

4.6.4: Stability of Oral Fluid for Confirmatory Testing

As there may be a period of time between specimen collection and confirmatory testing in the laboratory the stability of drugs in oral fluid is extremely important. Also, samples may have to be stored for possible reanalysis at some later date. Stability and oral fluid is very much collection device dependent [37]. Drug instability can arise from spontaneous hydrolysis of drugs such as cocaine and heroin [38] and conversion of nitrobenzodiazepines to their seven amino metabolites [39]. In the collection of urine or blood in Ireland, sodium fluoride salt is added to specimen collection vessels in order to stabilise the specimen once collected. The addition of sodium fluoride to oral fluid helps to reduce the degradation of nitrobenzodiazepines. Other stability problems with oral fluid collection have been noted for THC [40] and the methadone metabolite EDDP [41].

4.6.5: Test Equipment

The equipment that is most suitable for laboratory based confirmatory testing is GC-MS(-MS) or LC-MS(-MS). This specialist equipment, which the MBRS has operating in its laboratory, is currently in use for confirmatory testing of drugs in blood and urine specimens take under the Road Traffic Act. Were oral fluid to be a specimen for confirmation the MBRS could adapt existing methods to detect drugs in oral fluid.

4.7: Conclusion

Whilst oral fluid is suitable for roadside chemical testing it is not recommended for confirmatory testing at this stage. In the future as technology and the understanding of the relationship between drugs and oral fluid advances it may become a suitable specimen type.

Chapter 5

Previous Studies and Current Status of Roadside Testing

Chapter 5: Previous Studies and the Current Status of Roadside Drug Testing

5.1: Introduction

The search for suitable roadside chemical testing devices has been continuing over the past two decades. There have been several international research projects conducted on various aspects of drugs and driving and the following projects have included evaluation work on the status of roadside drug testing devices. Each study has recognised the need for further improvements.

An outline of the findings of each of these studies is presented below.

5.2: ROSITA 1 (1999-2000)

ROSITA was an acronym for ROadSIde Testing Assessment. The ROSITA 1 project evaluated 19 roadside drug testing devices (15 onsite urine devices, 3 oral fluid and 1 sweat device) in 8 European countries [42]. The proposed analytical criteria was set at a sensitivity of greater than 90%, a specificity of greater than 90% and an accuracy of greater than 95%. Over 2,900 specimens were collected and tested in these trials. Oral fluid was the overall preferred specimen for roadside collection in 6 of the countries, with urine preferred in Italy and sweat preferred in Germany by the police operators.

The conclusion of ROSITA 1 was that the sensitivity, specificity and accuracy of the oral fluid devices did not meet the criteria as set out, criteria which is achievable with blood analysis by GC-MS in a laboratory.

5.3: IMMORTAL (2002-2005)

The IMMORTAL project was an acronym for Impaired Motorists, Method Of Roadside Testing and Assessment for Licensing [43]. It was established to:

1. Investigate the accident risk associated with different forms of driver impairment.
2. Investigate the influence of chronic and acute impairment in order to make a more accurate risk assessment.
3. Recommend criteria for high risk categories and to improve key information to support EU policy on licensing and roadside testing.

This study did not evaluate roadside chemical tests, however the study noted that roadside testing needed further improvement as both the drug recognition method (impairment testing) and the roadside testing devices still seemed to be 'error prone'.

5.4: ROSITA 2 (2003-2006)

The Rosita 2 project followed on from the ROSITA 1 project and was carried out to evaluate the available onsite devices for the detection of drugs in oral fluid [22]. The project was funded by the European Commission and was conducted by 6 European countries and 4 states in the USA. A total of 9 devices were evaluated in the ROSITA 2 project. The proposed analytical criteria set out in ROSITA 1 were applied to ROSITA 2 (sensitivity >90%, specificity >90% and accuracy >95%). An oral fluid sample was

taken for analysis using an on-site device and an additional oral fluid sample was taken with a collection device for confirmation analysis in a laboratory. At the same time a blood sample was also taken for confirmation analysis in a laboratory. The onsite test was conducted by a police officer. Subjects who the officer had a suspicion of driving under the influence of drugs were asked to participate in the study on a voluntary basis. In total 2,605 test evaluations were performed on the 9 devices. All of the devices evaluated were tested for the following drugs:

- Amphetamines
- Methamphetamines
- Cannabis
- Cocaine
- Opiates

Three of the devices were also tested for benzodiazepines.

The operational evaluation by the users varied with problems outlined such as:

- Procedure long and complicated
- Test must be read by an instrument
- Reading of test strips difficult
- Sample collection was too complicated
- Device could be out-smarted by the tested person
- Problems of use in cold and rainy weather

The analytical evaluation was conducted to measure sensitivity, specificity and accuracy of the devices.

The conclusion from ROSITA 2 was that no device met the criteria as set out in ROSITA 1 of sensitivity and specificity >90% and accuracy >95%. At the end of the study, no device was considered to be reliable enough in order to be recommended for roadside screening of drivers.

5.5: ESTHER (2006-2009)

ESTHER was an acronym for Evaluation of oral fluid Screening devices by TISPOL to Harmonise European Police Requirements [44]. The ESTHER project was part of the overall DRUID programme (See section 5.6). In all 13 devices were evaluated by police in 6 different countries and Ireland participated in this project. The devices were tested in two different phases and were tested for operational aspects such as:

- Specimen collection time
- Analysis time
- Hygiene
- User experience in terms of successful completion of the test
- User experience of the simplicity of the test
- The reliability of the test result indication (lines)

The devices were not evaluated for analytical specificity, sensitivity or accuracy. From phase 1, 5 devices were recommended for further 'analytical reliability' testing. This project also identified requirements for training of police officers on the use of oral fluid screening devices.

At the end of the project it was concluded that the Cozart DDS and Draeger Drug Test 5000 showed promise, from a practical perspective, for use during daily traffic law enforcement activities. Also, the Biosensor BIOSENS showed promise for use during very specific activities where large numbers of people require testing in a limited period of time e.g. raves and festivals.

5.6: DRUID (2006-2011)

The DRUID project was previously mentioned in Chapter 1. DRUID was an acronym for Driving Under the Influence of Drugs. The DRUID project was an international research project funded by the EU in which several different countries in Europe collaborated in 7 different work packages relating to aspects of drug and driving [10].

There was a scientific evaluation of the available screening devices carried out as part of the enforcement work package. For this scientific evaluation, 8 devices were evaluated in Belgium, Finland and the Netherlands for their reliability and accuracy. This work was carried out between October 2007 and December 2009. The performance of the tests was assessed based on sensitivity, specificity and accuracy for the individual drug tests of the devices. The criteria used in the ROSITA projects were eased and instead the DRUID project opted for sensitivity, specificity and accuracy of greater than 80%. The cut-offs were set to allow optimal detection of drug positive cases. The cut-offs are shown in table 5.1 below.

Drug	Cut-off (ng/mL)
Cannabis	1
Benzodiazepines	1-5
Opiates	20
Cocaine	10
Amphetamine	25
Methamphetamine	25

Table 5.1: DRUID project oral fluid testing device cut-offs

The on-site devices were evaluated by comparison of the oral fluid result of the device with the confirmation result of oral fluid collected at same time and sent to a confirmatory laboratory. All oral fluid samples analysed in the laboratory were stored at -20^{o}C until analysed. Analysis was carried out within one month of collection. Comparisons were made against blood specimens in some instances, such as the specimens from roadside police tests in Finland and in the Netherlands, however knowledge of oral fluid: blood ratios for drugs is still developing and the data available is limited. For some tests there were too few positive cases (methamphetamine/MDMA and PCP). There was also a lack of cocaine found in tests in Finland, benzodiazepines in the Netherlands and amphetamines/ methamphetamines in the Netherlands and Belgium. This demonstrated that the prevalence of drugs in individual countries is an important factor in deciding which drugs should be targeted for detection.

Several device failures were noted in the study with variety of reasons for the failures such as, incorrect operation of the device or only part of the device was successful. Some devices appeared to fail completely and some were stopped because it took too long to collect the sample at the roadside. It is worth noting that within a drug class (e.g. benzodiazepines) the on-site tests do not necessarily cover all the members of that drug class. A high degree of cross-reactivity for the different members of a drug class improves the detection capability of the device for that drug class. The manufacturers often test the cross-reactivity of many compounds within a drug class; however they may not always do so exhaustively. None of the devices reached the target of greater than 80% for sensitivity, specificity and accuracy for all drugs.

DRUID concluded that while the devices showed improvements in general from the devices tested in ROSITA 1 & 2 trials there was still room for improvement. The study also showed that the Draeger Drugtest 5000 system gave a sensitivity and specificity of greater than 80% for cannabis, meeting the DRUID criteria [45]. The suggestion was that the device intended for national use should consider the expected types of drugs and their prevalence in the DUID population and choose a device that has the best overall performance for those substances.

While these international trials were ongoing several countries commenced using the existing oral fluid devices knowing that the devices would be issuing a high number of false negatives and adopting the approach that using the technology which can give a number of false positives is better than identifying no drugs in drivers at all.

5.6.1: Developments Since Publication of the DRUID Findings

A Belgian study (2012) arising from their participation in DRUID reported on the analytical evaluation of 4 on-site oral fluid drug testing devices [46]. This study indicated that all tests showed good specificity but more improvement in the area of sensitivity is required.

5.7: Conclusion

A number of projects have been conducted in the EU and have improved the understanding of how oral fluid testing at the road side is operated and how the tests perform. ROSITA 1 and 2 were useful projects and most likely were of great benefit to device manufacturers who used the outcomes of these projects to develop and improve their products. These projects highlighted that at the time of completion a roadside test that could match a laboratory based test was not available in terms of specificity, sensitivity and accuracy criteria set by the projects. The DRUID project built on these studies and while there has been no breakthrough in terms of a device being specific, sensitive and accurate for all drugs the most recent drug study shows that there are roadside oral fluid chemical testing devices, that are capable of meeting the DRUID criteria for cannabis testing. Manufacturers are still involved in improving their devices. The ESTHER project is useful as it sets out the requirements of the training of operators of roadside oral fluid tests.

Chapter 6

Review of Selected Current Roadside Chemical Testing Devices

Chapter 6: Review of Selected Current Roadside Testing Devices

6.1: Introduction

As part of the request from the DTTAS the MBRS decided to review a number of representative roadside chemical testing systems. The objective of this review was not to perform a critical review of the devices but instead to:

- Gain a better understanding of the scientific basis of the tests
- Gain a better understanding of the format and operation of the systems
- Identify the cut-offs that the devices are able to operate to
- Identify costs of the systems
- Identify jurisdictions using the devices
- Identify challenges that may have been encountered with the particular devices
- Get the most up to date information available directly from the manufacturers, including any updates on developments since the completion of the DRUID project, where applicable

To date a complete type approval specification for these devices has not been drawn up by either the OIML (International Organization for Legal Metrology) or CEN (European Committee for Standardization).

Guide to type approval for preliminary drug testing devices was published by the Home Office in the UK [27]. This document is similar to the current guide type for the evidential breath testing systems; however the UK specification is concerned with a device or instrument for use in a police station and not for use at the roadside. To date, no oral fluid drug testing systems have been approved by the Home Office but this process is ongoing and it is noteworthy that the guide to type for preliminary drug testing devices specified the use of a reader.

The manufacturers and devices chosen for review were:

- Securetec Drugwipe
- Draeger Drugtest 5000
- Alere DDS2
- Mavand Rapid Stat

All of the manufacturers selected have devices which are currently used by police forces and they all use immunoassay technology which can simultaneously detect several different drugs from a single oral fluid specimen. They are all designed for single use in the form of a disposable cartridge with minimal steps required by the operator. The different test devices require different numbers of steps to be taken by the operator and some of which are timed steps with the exact time specified. The oral fluid is collected using a collector which can be combined with or used separately to the testing cartridge. The oral fluid is applied to the immunoassay strip which contains the actual test. In some cases the oral fluid is combined with a buffer solution before application onto the immunoassay strip, in other formats the oral fluid is applied to the strip and then the buffer is introduced upstream from the site of specimen

application. In some cases the tests are incubated at specific temperatures while others operate at ambient temperatures. The effect of temperature may also influence the ability of the test to operate successfully and can also influence the speed at which the test occurs.

The devices that the MBRS researched are in use for roadside testing by police forces in certain jurisdictions internationally. Each country set out the drugs targeted and the individual cut-offs for the targeted drugs. Some countries have specified a collection time for the oral fluid and others have specified a test time for the tester. Some have specified an electronic device and others have requested devices which can be read visually and that do not require an electronic device. These specifications are usually set out in the relevant tender documents. Such documents tend to apply specifications based on what is known to be currently achievable.

6.2: Securetec Drugwipe

Securetec are the manufacturer of the Drugwipe and they produce custom made disposable testers in the form of a cartridge for different police forces in different countries. The results from this device can be read visually or with the aid of an electronic analyser.

6.2.1: Operation of Device

The device consists of a test device, with a cover containing an integrated oral fluid collector, this can be removed, a specimen can be collected and the collector is returned to the test device. When oral fluid is collected, a colour indicator shows that the specimen has been collected successfully. Oral fluid collection takes ca. 5 seconds. There is buffer capsule which when broken releases buffer down the immunoassay strips and moves the specimen towards the test area. The operator is requested to keep the device vertical for 15 seconds after breaking the buffer capsule and then the operator must move a sliding cover, which is part of the device, over the test area. The device is then left flat on a horizontal surface. The test takes 8 minutes to develop before a result can be read. The results are then interpreted depending on the presence or absence of a series of red lines, with the absence of a line indicating that the drug is present; and the presence of the line indicating that the drug is absent.

6.2.2: Countries Which Use the Device

Securetec have also produced a tester for cannabis and cocaine for Spain, cannabis and methamphetamines for Australia and cannabis and amphetamines for East German states. In addition they have the Drugwipe5 which is a tester for cannabis, amphetamines, methamphetamines, opiates and cocaine which is used in France and Belgium. They have produced a Drugwipe6 for use in Finland. The additional drug class that is included in the latter tester is benzodiazepines.

6.2.3: Device Cut-offs

The cut-offs for all reviewed manufacturers tests are shown in Table 6.1. Since the DRUID evaluation Securetec have managed to reduce the cut-off for the cannabis test and they are claiming that they can achieve a cut-off of 10ng/ml. A French tender document specified a cut-off of 15ng/ml for their device. The manufacturer claims that the lower the cut-off required the longer the test time of the device. The Belgian device has a cannabis cut-off of 25ng/ml. The Drugwipe used in Australia has a cut-off of 30ng/ml for cannabis [47].

Drug	Securetec Drugwipe Cut-offs (ng/mL)	Draeger Drugtest 5000 Cut-offs (ng/mL)	Alere DDS 2 Cut-offs (ng/mL)	Mavand RapiSTAT Cut-offs (ng/mL)
Cannabis	10-30	5-10*/25	10*/25	15
Benzodiazepines	n/a	10	20	25
Opiates	n/a	40	40	10
Cocaine	30	30	30	10
Methadone	n/a	50	n/a	n/a
Amphetamines	40	40	50	25
Methamphetamines	40	40	50	25

*Table 6.1: Drug cut-offs by manufacturer and device in ng/mL. *Lower cut-offs require longer time.*

6.2.4: Electronic Reader/Analyser

The Drugwipe tester can also be read using a proprietary electronic reader called the DrugRead. This is a hand held (two hands) portable device. The DrugRead offers precise time keeping for the time controlled test and provides a clear result. In the case of the Drugwipe there are two steps which are time critical and the automatic reader controls these for the police officer. It also has the capacity to self test and to be calibrated. A wireless printer is also available.

6.2.5: Storage and Operation Conditions

Storage conditions and temperature range for use are important considerations. The recommended temperature range is 15°C to 35°C. The recommended shelf life depends on the storage conditions which is 6 hours at 0°C to 40°C, for 3 days is 5°C to 35°C and for 2 years is 5°C to 25°C.

6.3: Draeger DrugTest 5000 Analyser

Draeger are the manufacturers of the DrugTest 5000 analyser. This is a powered portable module intended for use in combination with the Drugtest 5000 test kits. It is not handheld but can be easily used from the boot of a car. A wireless printer is also available.

6.3.1: Operation of Device

The test kits are cassettes with a collector module and the immunoassay test strips. A separate buffer cartridge is also used in the analyser. For sampling, the operator instructs the donor to provide and oral fluid sample and after 1 minute the operator inspects the sample collector. If after this time the indicator has not turned blue then insufficient oral fluid has been collected and the donor is required to provide more. Sampling can continue for a further 3 minutes. The operator places the test cassette in the lower compartment of the analyser and the buffer cartridge in the upper compartment. Closing the door will then start the analysis automatically. The operator can see if the cassette is in date as this is read along with kit batch number and the number of drugs being tested. The results are issued as either named drug detected or not detected. Results are available within 8 minutes.

6.3.2: Countries Which Use the Device

It is approved for use in Portugal, Poland and Germany

6.3.3: Device Cut-offs

The cut-offs for all reviewed manufacturers tests are shown in Table 6.1. The cut-off for cannabis has also been reduced since DRUID evaluations. The production of a new antibody means that Draeger can offer a cut-off range between 5 and 25ng/ml, however the trade-off is again with the test time of the analyser, 5-15ng/ml takes less than 8 minutes, at 25ng/mL it takes less than 5 minutes.

6.3.4: Electronic Reader/Analyser

The proprietary electronic analyser is used to control temperature and timing of the test and also reads and provides the final result without subjectivity. Quality assurance and calibration checks are possible with this system. There is also a memory component and a wireless printer available. The expiry date of the cartridge is noted before the test is commenced.

6.3.5: Storage and Operation Conditions

The temperature range for the use of this device is not critical as the analyser controls the test temperature however, the rating indicates using the device between 5°C to 40°C. The recommended storage conditions for the test devices are 4°C to 30°C. Currently the shelf life of a cassette is 12 months.

6.4: Alere DDS2

Concateno, a subsidiary of Alere, manufacture the DDS2. It is a portable, handheld device intended for use with the Alere DDS 2 test cartridge. The test cartridge contains dried reagents, the buffer and the immunoassay test strips. The collection device is separate. The vendor is currently offering 2 different test cartridges, a 5 drug panel and a 6 drug panel. The 6 panel drug test includes amphetamine, benzodiazepine, THC, cocaine metabolite, methamphetamine and opiates.

6.4.1: Operation of Device

The test cartridge must first be inserted into the device and then the driver is asked to provide an oral fluid sample. The collection time is 1 minute. The sample collector is then inserted into the test cartridge within the analyser. Analysis takes approx 5 minutes depending on the cut-off chosen.

6.4.2: Countries Which Use the Device

Its predecessor was the Cozart DDS device which is currently being used in Australia, Spain, Italy and Croatia. The new generation DDS2 device is currently under evaluation in Australia, Spain and Italy.

6.4.3: Device Cut-offs

The cut-offs for all reviewed manufacturers tests are shown in Table 6.1. The THC cut-off is dependent on the amount of time given for the test to develop in the analyser. A cut-off for THC of 25ng/ml is possible with a 5 minute test time. A THC cut-off of 10ng/ml is possible with the longer test time of 9 minutes.

6.4.4: Electronic Reader/Analyser

The proprietary analyser controls the temperature and timings. It is possible to run QC cartridges to check that the analyser is performing correctly. It also can be used with a wireless printer.

6.4.5: Storage and Operation Conditions

The test cartridge can be stored at temperatures of 15-25°C. Stability studies are currently being carried out and it is anticipated that the expiry date will be at least 18 months.

6.5: Mavand Rapid STAT

Mavand manufacture the Rapid STAT which is a disposable unpowered system comprising of a sample collector, a buffer bottle and a test cassette combined in a 'One-Hand-Clip' System. The test cassette contains two reaction chambers and the test strips. The devices can be manufactured to test for between 2 to 7 drugs. The 7 possible drugs which can be tested for are amphetamines, benzodiazepines, cocaine, methadone, methamphetamine/MDMA, opiates and THC.

6.5.1: Operation of Device

Following collection of the oral fluid the sponge of the collector is washed out in the buffer bottle, this buffer-saliva solution is then introduced to the reaction chambers containing the antibodies and allowed to incubate for 4 minutes. This solution is then released onto the test strips and the results can be evaluated after 8 minutes. The results are then visually interpreted by checking for the presence or absence of lines on the strips opposite the name of the drug on the cartridge. The collector contains an unspecified compound which stimulates saliva production.

6.5.2: Countries Which Use the Device

This device is currently in use as a roadside chemical test by the North Rhine-Westphalia police in Germany and was used by French authorities from 2008 to 2011.

6.5.3: Device Cut-offs

The cut-offs for all reviewed manufacturers tests are shown in Table 6.1.

6.5.4: Electronic Reader/Analyser

Mavand produce a desktop reader requiring a PC, a mobile reader and a desktop reader with integrated PC. The desktop reader can have a computer keyboard and printer attached, while the mobile reader has an integrated 'touch sensitive' tablet PC and portable thermal printer. All the steps outlined above are still carried out away from the reader and the cassette is inserted into the reader which contains a camera with a sensor which measures the intensity of the colour lines and provides an objective result.

6.5.5: Storage Conditions

Use of this system should ideally be between 15°C to 35°C. The recommended storage temperature is between 2°C to 30°C. The shelf-life is set by the expiry on the packaging which normally extends to 1 year from purchase.

6.6: Costs of Tests and Analysers

The costs for the tests were provided by the manufacturers and these are summarised in Table 6.2. This table also includes the cost of the readers/analysers. It is important to point out that these are costs provided for estimate purposes only and are not to be construed as quoted prices. Until the numbers of readers and tests and indeed the format of the tests (1 drug or multiple drugs) are decided it is not possible to put a figure on the final cost of introducing any one of these systems. The cost will also depend on whether the cassette or test cartridge is custom made or is similar to other jurisdictions. In

some cases it may also be possible to offset the cost of the reader/analysers against the cost of the tests themselves and spread the cost over the lifetime of a contract arising from a successful tender bid.

Unit Cost	Devices
5-7 drug test cartridge	€10-€20
Reader/Analyser	€2000-€4000

Table 6.2: Unit Costs for Devices

If the disposable materials are taken into account alone the cost of a drug test at the roadside is significantly more expensive by a factor of 60 to 125 times the cost of a roadside alcohol breath test. This is based on the roadside breath alcohol test mouth piece costing approximately 16 cent and the roadside drug testing disposable cartridge cost of €10 to €20. However, if the overall costs are assessed (to include equipment purchase, depreciation, maintenance etc.) this differential is reduced to approximately 10 to 20 times more expensive than a roadside alcohol breath test, depending on whether or not the roadside drug test includes an electronic reader. The fact that the devices test for between 5-7 drugs rather than just a single drug as with alcohol should also be taken into account when considering costs.

6.7: Conclusion

The 4 devices were selected to demonstrate the variety of test devices available and their different operational requirements. They illustrate the complexity of drug testing compared to the simplicity of alcohol breath testing. They also highlight some of the considerations that will need to be addressed when setting out specifications in a tender and procurement process for the approval, supply and testing of devices by the MBRS for proposed use in this jurisdiction.

This review highlighted the importance of selecting devices that have a minimum number of steps and a short collection and test time. It also showed that devices capable of detecting the most prevalent drugs found in Irish road users, cannabis and benzodiazepines, are available and a number of these devices are currently in use for roadside drug testing in other jurisdictions. The drugs targeted are selected by the buyer and to date these have been the most prevalent drugs found to impair the driving internationally. It is not possible to target all impairing drugs with these devices.

Chapter 7

Practice in Other Countries

Chapter 7: Practices in Other Countries

7.1: Introduction

In order to gain the most up to date information on the practices adopted by other jurisdictions in the detection of drug drivers the MBRS conducted a survey of scientific colleagues working in the area of DUID in 13 countries. The questions posed in this survey covered legislative, practical and scientific matters relating to the introduction of roadside oral fluid testing. A copy of the survey questions and a summary of the responses can be found in Appendix 1. Information gathered from the survey is included here for the relevant jurisdictions.

In addition the MBRS reviewed the literature to ascertain the current practices in several countries in relation to detection of drug drivers at the roadside. The following countries/states are discussed below.

The following eight countries or jurisdictions either; use oral fluid devices, or are at the tender stage of procuring devices:

1. Australia/State of Victoria
2. Belgium
3. Finland
4. France
5. Germany
6. Norway
7. Denmark
8. Switzerland

The remaining five jurisdictions do not currently use roadside drug testing devices and have not indicated if they plan to introduce them in future.

9. Canada
10. New Zealand
11. Sweden
12. UK
13. USA

7.2: Australia: State of Victoria

The Australian state of Victoria was the first jurisdiction to introduce random roadside drug testing, beginning in 2004. This legislation includes offences based on observed impairment. The roadside chemical test element of the legislation started with only two drugs in the test kits, methamphetamine and THC. In 2006 they introduced MDMA (ecstasy) to this group [48].

The procedure at the road side involves an initial test using the Securetec, DrugWipe TWIN and if positive for one or both drug groups, another oral fluid test is conducted using a second immunoassay device, the 'Cozart Rapiscan' which was manufactured by a company now owned by Alere. This second

test is conducted in a custom-built vehicle at the roadside adjacent to the checkpoint (see cut-offs in table 7.1). If this device also reveals a positive result for either or both drug groups, then drivers are not permitted to continue driving their vehicles for a minimum period of 24 hours, and an oral fluid specimen is sent to the laboratory for confirmation. If another oral fluid specimen cannot be provided a blood specimen is taken for confirmation testing. The specimen forwarded to the laboratory is tested for the two drug groups and also for a further range of drugs. The presence of one or more of the proscribed drugs at any concentration is deemed an offence. The Australian states of New South Wales, Queensland, South Australia, Western Australia and Tasmania now conduct similar testing to Victoria.

Device	Target drug	Cut-off (ng/ml)
DrugWipe TWIN	Methamphetamine/MDMA	100
	THC	30
Rapiscan	Methamphetamine/MDMA	60
	THC	150

Table 7.1: The cut-offs used in the State of Victoria, Australia.

7.3: Belgium

The legislation permitting the use of oral fluid testing at the roadside was introduced in 2010. The arrest is based on suspicion and not random checks. The Securetec DrugWipe 5 was chosen as the device following a procurement exercise. Before the introduction of this, Belgium had a FIT test, followed then by a urine test, as the preliminary roadside test. If positive, there was an immediate administrative sanction of disqualification from driving for 6 hours. A blood specimen was also taken and the confirmatory results were used for the ultimate sanction [49].

Belgian police and scientists conducted an evaluation of on-site oral screening using 3 commercially available devices, with the findings of this study published in 2010 [49]. It concluded that the devices could detect approximately 70% of all cocaine and cannabis users. Amphetamines were detected more easily with a sensitivity of greater than 92%. In approximately 15% of the blood samples analysed, none of the analytes mentioned in the Belgian DUID law were detected at a concentration above the legal cut-off. While this is undesirable it may be justifiable as confirmatory analysis in a laboratory will ensure that no injustice occurs.

Belgium has decided that the sensitivity currently provided by the manufacturers is high enough for their goals, which are:

- To have a roadside drug test which will have a deterrent effect on drug drivers
- Decrease the accident risk for all drivers.

Law enforcement agencies also want to reduce the percentage false positives. The authorities have chosen an unpowered device, the police do not use a FIT test, they use a checklist with parameters such as emotional state (aggressive, stressed, sleepy etc.), visual signs (eyes, pallor etc.). Based on this checklist they quickly screen for possible drug driving suspects. Then the on-site test is performed. If the subject is negative for this test and also negative for alcohol, but the police officers' opinion is that the

driver is impaired he/she can still press charges via a special article in the law. This means that a blood sample can be drawn and that laboratory analysis can be performed, focusing on drugs or medications not tested for by roadside chemical testing such as benzodiazepines. The legislation requires the use of oral fluid for confirmation purposes; however it is the understanding of the MBRS that blood specimens are still taken and that oral fluid collection has not been finalised.

The legislation has indicated *per se* levels for use with blood or oral fluid specimens (table 7.2) and if the driver has a level above these he/she is sanctioned..

Specimen type	Drug group	Cut-off (ng/ml)
Oral fluid (Roadside)	Amphetamine	50
	Methamphetamine	50
	Opiates	10
	Cannabis	25
	Cocaine	20
Blood (CLT)	Amphetamine	25
	Methamphetamine	25
	Opiates	10
	Cannabis	1
	Cocaine	25
Oral Fluid (CLT)	Amphetamine	25
	Methamphetamine	25
	Opiates	5
	Cannabis	10
	Cocaine	10

Table 7.2: Belgian per-se levels in oral fluid and blood (CLT=Confirmatory Laboratory Test)

7.4: Finland

Zero tolerance legislation on illicit drugs and driving was introduced in Finland in 2003. All controlled substances, including medicinal drugs such as benzodiazepines, fall within the scope of zero tolerance drug laws, if used without a prescription. Drugs that have a potentially harmful effect on driving ability have warning labels on their package [19]. The police are authorised to conduct a breath alcohol test or an oral fluid drug test on-site even when no suspicion exists. The devices for onsite testing for alcohol and drugs have the same position under the national law. The main reasons for using roadside drug tests are random checks, impaired or dangerous driving, road traffic accidents or information from a bystander. Impairment law remains on the statute books and the police officer can provide evidence of impairment using a standardized field sobriety observation sheet. Any evidence/observations of drug use are also documented.

Finland also participated in the DRUID evaluation of oral fluid drug roadside drug testing devices [50]. Drugwipe devices have been in regular use by Finnish police for several years and the police officers have been satisfied with the operability of the device. Benzodiazepines and amphetamines have been identified as the most prevalent substances in suspected DUID cases in Finland for the period 1977-2007

(76% and 46% respectively). THC is also prevalent at 20%. Previously the Finnish traffic police have been using DrugWipe5 and DrugWipe5+ and using a separate Drugwipe single test device for benzodiazepine. Finnish police are currently using Drugwipe6 which includes a test strip for benzodiazepines. Confirmation of the drug is carried out in the laboratory and a blood specimen is used for this purpose.

7.5: France

France introduced roadside drug testing in 2001 using urine tests and in 2008 introduced oral fluid on-site drug testing. The minimum levels for detection in oral fluid and urine are set out by order and are outlined below (Table 7.3). Confirmation tests are carried out using blood specimens and the minimum levels of detection for the blood analysis are also set out by order and are also outlined below. The police officer can arrest a driver on the basis of suspicion and a test is also mandatory after a collision or if the driver is a traffic offender. The only drugs specified in legislation are illegal drugs. France awarded its first contract for oral fluid devices in August 2008 for a period of three years and in February 2011 issued a new tender. DrugWipe5 is the oral fluid device chosen from the latest tender.

Specimen type	Drug group	Cut-off (ng/ml)
Oral Fluid (roadside)	Amphetamine	50
	Methamphetamine	50
	Opiates (Morphine/6-AM)	10
	Cannabis (THC)	15
	Cocaine/Benzoylecgonine	10
Urine (roadside)	Amphetamine	1000
	Methamphetamine	1000
	Opiates (Morphine)	300
	Cannabis (THCA)	50
	Cocaine/Benzoylecgonine	300
Blood (CLT)	Amphetamine	50
	Methamphetamine	50
	Opiates (Morphine)	20
	Cannabis (THC)	1
	Cocaine	50

Table 7.3: French per-se levels in oral fluid and blood (CLT=Confirmatory Laboratory Test)

7.6: Germany

Germany, in 1998, was the first European country to introduce zero tolerance legislation prohibiting driving under the influence of the drugs cannabis, cocaine, heroin, morphine, amphetamine and the designer drugs MDMA and MDEA [50]. In most Federal States of Germany roadside drug tests have been introduced on a routine basis where there is a suspicion of drugs use, these can take the form of a urine, sweat or more recently oral fluid screening device. The police officer can arrest a driver on the basis of suspicion or conduct a test which is mandatory after a collision. A police officer can either carry out a roadside test or carry out a roadside assessment. The different police forces are using different devices. Of the 4 device manufacturers contacted, 3 were able to give an example of a German police force which uses their particular device. Zero tolerance is for illegal drugs only. Blood specimens are used for

confirmatory purposes and the analytical thresholds are set out in law for the specific drugs in blood (Table 7.4) [10, 44].

Specimen type	Drug group	Cut-off (ng/ml)
Blood (CLT)	Amphetamine	25
	Methamphetamine	25
	Opiates (Morphine)	10
	Cannabis (THC)	1
	Cocaine/Benzoylecgonine	10/75

Table 7.4: German per-se levels in blood (CLT=Confirmatory Laboratory Test)

7.7: Norway

In February 2012, Norway introduced *per se* limits into legislation for twenty illegal drugs and medicines with an abuse potential. Norway is the first country to define both impairment based legislative limits and limits for graded sanctions for drugs other than alcohol [35]. The impairment limits are specified for blood specimens. The police officer can stop a driver at random and conduct a roadside assessment. They perform legislation based specific performance impairment tests. Oral fluid roadside testing is permitted but has not been implemented as yet. Norway is conducting a procurement process at present.

The use of the limits does not apply to therapeutic use of medicines with an abuse potential prescribed by a doctor. In such cases the assessment is made on the basis of concentration of intoxicant found in the blood specimen and the results from the standard medical examination and any other relevant information including roadside assessment.

7.8: Switzerland

In January 2005 a two tier system based on impairment by any psychoactive substances which affect the capacity to drive safely and zero tolerance for certain illicit drugs was introduced [51]. A driver is sanctioned when THC, free morphine, cocaine, amphetamine, methamphetamine, MDMA or ecstasy and MDEA can be unequivocally detected by toxicological analysis in whole blood. The Federal Roads Office (FEDRO) is responsible for the definition of the punishable concentration limits for the controlled substances. At present these limits are 1.5ng/ml for THC and 15ng/ml for the other substances. For all other psychoactive substances, in particular medicinal drugs such as benzodiazepines, methadone and antidepressants, impairment must be proven. Evidence of impairment is based on police report, results of clinic examination by physician at the time of specimen collection and the results of the toxicological analyses of the biological samples. The police report includes observations of impairment and can also record results of a breath alcohol test and/or roadside drug test device. A blood specimen can be obtained without oral fluid testing on the basis of suspicion. A blood and/or urine specimen can be used for zero tolerance drug detection. Currently Switzerland uses Drugwipe5 for roadside drug testing.

7.9: Canada

Section 253 of the Criminal Code of Canada prohibits driving while impaired by alcohol or drugs. In 2008 the law gave increased powers to the police to test for drugs in drivers. If the police officer is suspicious of impaired driving due to the presence of a drug or drugs then he can examine the driver using a field impairment test at the roadside and by subsequent tests by drug recognition experts and bodily fluid tests provided in the police station. Blood, urine or saliva specimens can be provided in the police station or in a hospital. There is a *per se* limit for alcohol but not for drugs. The law does not specify any particular drug but instead includes all impairing drugs. There is no roadside testing device used by the police [52].

7.10: Denmark

Until July 2007 DUID legislation in Denmark was based on impairment evaluated on the basis of a clinical investigation performed by a physician and toxicological analyses. In July 2007, fixed concentration limits in blood for drugs of abuse were introduced into the Danish traffic legislation. The police can now stop drivers on suspicion and at random without suspicion. The police are permitted to take an oral fluid or sweat sample and to conduct an eye examination. At present oral fluid devices are not in use. The fixed concentration limits are based on low therapeutic blood concentrations and on blood concentrations expected a short time (hours) after the intake of illicit drugs and not on the analytical limits of quantitation based on the analytical equipment used in the laboratory. These limits apply to illicit drugs and psychotropic substances with abuse potential registered with the UN conventions. Evidence of impairment is still required for prescribed drug drivers and for drugs such as benzodiazepines, morphine and methadone which are used both after a prescription and as illicit drugs, the fixed concentrations are used for prosecution [53].

7.11: New Zealand

The Land Transport Amendment Act 2009 gave police greater powers to deal with the problem of driving under the influence of drugs. There are three steps which the police must follow before charging a driver with driving while impaired:

1. Good cause to suspect- i.e. evidence of erratic driving or drivers personal demeanour
2. Unsatisfactory completion of a compulsory impairment test (CIT) which consist of 3 behavioural tests that check whether a driver is impaired
3. Presence of a drug or drugs in a blood sample

There is no roadside testing device currently in use by the police in New Zealand. While random roadside drug testing is not permitted under this Act and the police do not use roadside drug testing devices, police can still require a driver to carry out a CIT if he/she has passed a roadside breath alcohol test and is behaving in an intoxicated manner.

The drugs targeted are opiates, amphetamines, cannabis, sedatives, antidepressants and methadone. The list is reviewed from time to time in light of research and changes in drug trends in New Zealand.

7.12: Sweden

The Swedish government introduced zero tolerance for driving with a measurable amount of a controlled substance in blood on July 1 1999. Sweden was the first country to include scheduled prescription drugs as part of this legislation. The zero-limit applies whenever a controlled substance is unequivocally identified in a specimen of blood and a prosecution is made regardless of whether the driver shows signs and symptoms of being under the influence of drugs. Currently the police do not use a roadside chemical test. They have powers to examine a suspect's eyes with the help of a small flashlight and a pupillometer. The police also note responses to questioning and any disturbance of speech or gait. The police require a reasonable suspicion to request a blood specimen for toxicological analysis. If a medication is used in accordance with a doctor's prescription the person is exempt from prosecution for DUID provided certain conditions are met. A successful DUID prosecution with only a prescription drug in the blood requires proof that the person was overdosing or abusing the medication in question and this requires expert testimony [54].

The limits of quantitation for the analytical method used serve as the *per se* threshold concentration limits in blood. Analytical results below these limits are reported as negative. Indeed these limits are not static and are therefore not written into law because they are likely to change depending on developments and improvements in analytical methodology.

With the introduction of zero limit law and the simple roadside tests of drug influence, there has been a tenfold increase in the number of cases being submitted for forensic analysis. The police in Sweden do not use roadside chemical test devices for drugs as they do not consider them to be effective and that the vast majority of specimens (approximately 85%) sent for toxicological analysis contained one or more scheduled drug when the zero tolerance limit was introduced.

7.13: UK

The UK has a provision in current legislation for onsite oral fluid roadside drug testing by police officers however to date it has not been legally implemented. The North Report has recommended that a device to be used in a police station should be approved within two years [11]. The Home office issued formal guidelines for type approval in January 2011 with the intention of completing the process in June 2011, however to date no device has been approved [27]. At present a police officer on the basis of suspicion can perform field impairment tests, which are outlined in the Code of Practice for Preliminary Impairment tests. There is no requirement by the police officer to administer the FIT test in order to assess impairment. The North Report recommends that it should be policy to carry out this test in all cases where impaired driving is suspected. The current legislation requires that a physician has to determine whether the drug driving suspect has a condition which might be due to a drug. The North Report recommendation is to allow nurses to also take on this role. The report has made several recommendations including the introduction of impairing levels for named drugs, zero tolerance for specified drugs and also to retain the current offence of driving while unfit due to a drug. North has also recommended that once preliminary drug screening devices are type approved for use in police stations that the type approval of roadside devices would commence. A bill which is currently going through due process in the UK includes specified limits for specified controlled drugs.

7.14: USA

In the USA the police officer can stop a driver on the basis of suspicion of driving under the influence of a drug. The officer can check for alcohol at random but not for a drug. There are no onsite drug screening devices approved in the USA. The US developed the Drug Recognition Expert (DRE) program however it is accepted that the DRE program "as is" is not scalable to the size of the drugged driving problem [55]. There are a total of 17 US states that have variations of zero tolerance type legislation with regard to DUID. In 7 States, it is illegal to have any amount of prohibited drug or its metabolite in the body while operating a motor vehicle. In North Carolina and South Dakota, the *per se* drugged driving laws pertain only to drivers less than 21 years. In 5 States it is illegal to have any amount of a prohibited drug in the body while operating a motor vehicle, in 3 States it is illegal to have specified amounts of specified prohibited drugs in the body while operating a motor vehicle. The *per se* drug law in Minnesota does not include cannabis. In 5 States it illegal for any drug addict or habitual use of drugs to drive a vehicle in their State [56].

A number of States use a separate statute for driving under the influence or with impaired driving or both. Evidence of impairment is required [57]. Only two States, Alabama and Alaska, have compulsory testing in certain circumstances in crashes involving serious injury or death. Different States stipulate the type of specimen that law enforcement officers are authorised to collect. In 34 States it is permitted to take blood/urine, 8 States permit only blood, 6 States permit saliva, 8 States permit other bodily substances and 3 States do not have a provision for collecting specimen to test for drugs. From this limited review there is a lack of uniformity or consistency in the way individual States approach drugged drivers. One report recommended the standardisation of drugged driving testing in the USA [55].

7.15: Conclusion

The Bureau has reviewed the practices in 13 different countries and from this snapshot of countries worldwide there is a divergent approach taken to roadside drug testing both in the legislative approach and the detection approach by the police officer. The manner and type of device and the number of drugs targeted when using oral fluid devices were also diverse. There is a move towards the collection of oral fluid and the advancement of oral fluid devices since their introduction by Victoria, Australia in 2004 to the planned introduction by Norway in 2012 is encouraging. There is a consensus towards zero tolerance limits for illegal drugs and the need for evidence of impairment and the confirmed presence of a drug if the drug is a medicinal one. Countries have also included the use of RTIT and have introduced oral fluid devices to assist with enforcement of the zero limits. Oral fluid drug testing devices do not replace RTIT.

The Bureau has gained insight into how other jurisdictions deal with DUID and can now recommend the use of oral fluid devices in line with other EU countries. While there is no EU or international standards for the devices, the use of the devices internationally has demonstrated their general fit for purpose status. The Bureau will use the knowledge gained when setting out the device specifications including cut-offs and in the legislative provisions required to operate the devices effectively. There will have to be particular care and attention to the legal and operational requirements of the Irish Courts.

Chapter 8

Considerations and Options for Roadside Drug Testing

Chapter 8: Considerations and Options for Roadside Drug Testing

8.1: Introduction

In the preceding chapters we have considered; the effects of drugs on driving and the relationship between impairment and bodily fluids; detection of driving under the influence of drugs; previous studies and the status of roadside drug testing. We reviewed the selected current roadside chemical testing devices, as well as practices in other countries. We now consider the options to progress the detection, enforcement and prosecution of driving under the influence of drugs other than alcohol and four components must be considered:

- Legal
- Operational
- Scientific
- Medical

8.2: Legal Considerations

8.2.1: Type of Drug Driving Legislation Required

8.2.1.1: Impairment Approach

This is the current approach where the driver is arrested if the Garda is suspicious that the driver is under the influence of an intoxicant to such an extent as to be incapable of having proper control of the vehicle. The Garda has to prove driver impairment. No additional test either RTIT or chemical testing, is currently conducted. This approach does not support random roadside checking.

8.2.1.2: The Zero Tolerance Approach

A *zero tolerance* approach is where a zero limit is applied to controlled substances and any measurable amount of a controlled substance which is unequivocally identified in a specimen of blood/urine or oral fluid of the driver and a prosecution is made regardless of whether the driver showed signs and/or symptoms of being under the influence of drugs. The introduction of a *zero tolerance* will also apply to controlled drugs which, if authorised and requiring to be used in accordance with a prescription or medical or healthcare advice, are not so used. This approach gives rise to consideration that some drivers may have the confirmed presence of such drugs in their bodies but without evidence of impairment. The detection in a driver of such a product known to impair driving skills and thus constituting a risk to road safety is an offence under this approach.

8.2.1.3: *Per se* Approach

This approach sets out in law limits for certain classes of drugs such as opiates, cannabis, amphetamines, cocaine and benzodiazepines. This approach is similar to the *per se* limits for alcohol and it is in its very early stages of acceptance within the scientific and legal communities. This approach has not been adopted in too many countries. It is difficult to establish such ranges which would represent driving impairment in the general population due to the complex nature of how drugs interact with the body pharmacodynamically and pharmacokinetically. Appropriate and suitable levels would need to be

established but would be subject to variations as between and within individual drivers, tolerance to specific drugs, interactions between drugs and an interpretation of a given blood concentration of a drug at a specific time when the individual was actively driving. Research is continuing in this area and Norway has implemented legislation this year with *per se* levels set out for 20 named substances [35].

8.2.2: Mandatory Intoxicant Testing

The integration of detection of driving under the influence of alcohol and driving under the influence of drugs is a rational and logical development. Currently, the legislation provides for mandatory alcohol testing (MAT) only. Legislative provision for mandatory intoxicant testing (MIT) with authorisation for establishing MIT checkpoints to test for both alcohol and other drugs would allow for a structured and integrated procedural approach.

8.2.3: Mandatory Testing After a Collision

Mandatory alcohol testing after a collision was introduced in the 2010 RTA and again this would be the integration of both the alcohol and drug driving legislation. See point 8.2.2 above.

8.2.4: Powers of Detention of Drivers at the Roadside

The Garda has the legal authority to conduct roadside alcohol testing and this would need to be expanded to integrate the roadside drug testing. The period of detention of a driver is also a legal and constitutional consideration. The complete RTIT and oral fluid test could be carried out after a breath test for alcohol and this would lead to the driver being detained at the roadside for a much longer period. See points 8.2.2 & 8.2.3 above.

8.2.5: Order of Testing at the Roadside

The integration of the impairment or chemical test conducted at the roadside should be such that it does not interfere with the roadside alcohol test but should be part of the overall testing regime. The elements of such a regime are shown in Figure 8.1.

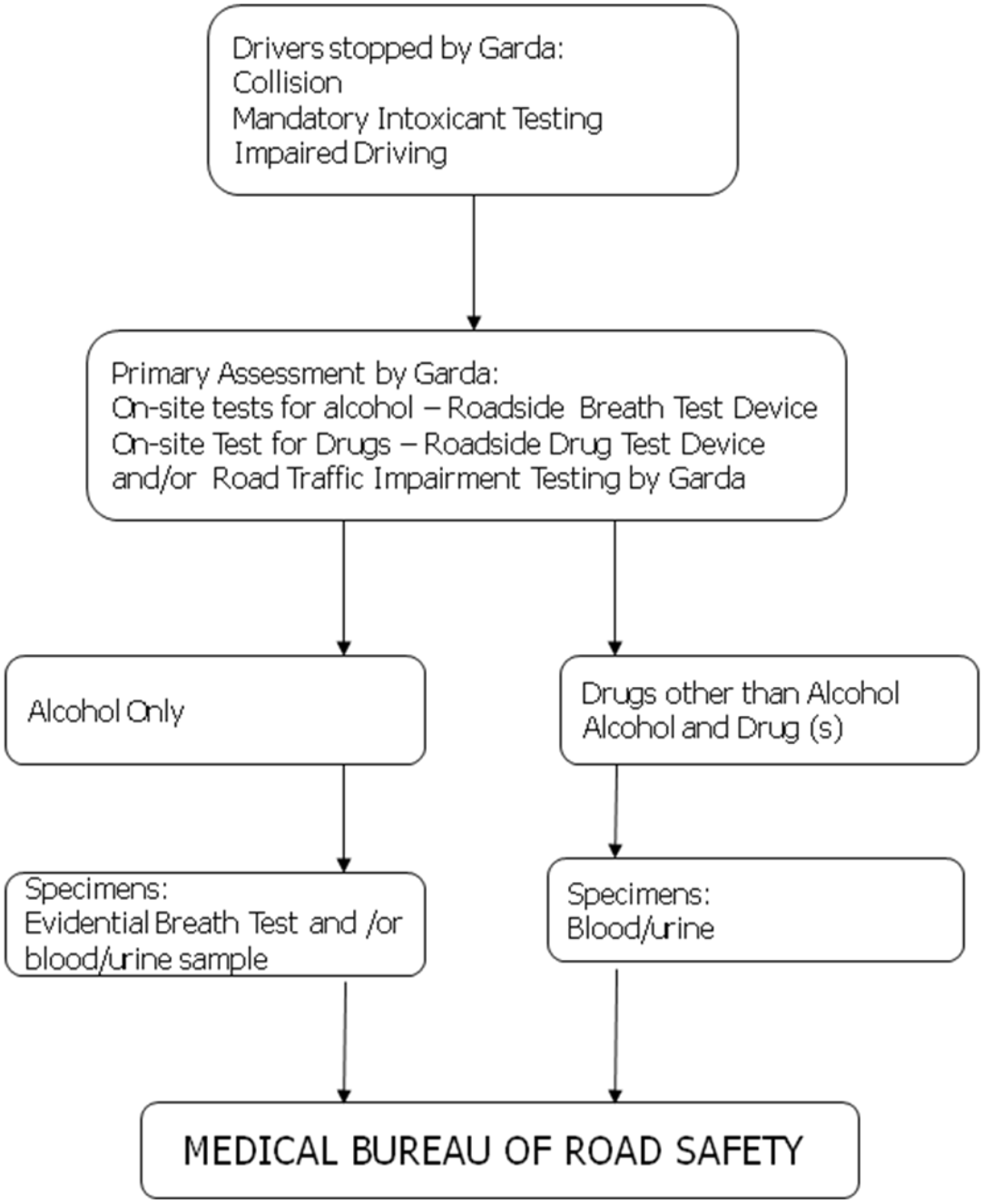


Figure 8.1: Proposed processing of drivers suspected of driving under the influence of alcohol and/ or drugs in Ireland and the type of specimen for analysis

8.2.6: Provision of Specimen for Testing

Provision of an oral fluid specimen is not invasive. However, privacy rights and, if and when an oral fluid specimen is required for confirmation analysis, the requirement for a second specimen from the suspect driver (as is the case with existing legislation for alcohol/drug testing) is a consideration at this point. Legal considerations should be explored with this possibility in mind. There will always be a need for confirmatory analyses. The problem of dry mouth, due to the drug taken or a medical condition, and thus the inability to provide the requisite specimen should also be given consideration at this stage.

8.2.7: Proscribed Protocols for Carrying Out and Recording Drug Testing at the Road Side

Careful consideration will have to be given to any protocols for roadside chemical testing. The question of whether they should be proscribed in legislation with accompanying proscribed forms and documentation arises in the context of ongoing research into the different types of drugs and tests which may be subject to change over time. The necessity for proscribed record documentation for the impairment testing is a different legal consideration.

8.2.8: Number of Drugs to be Detected if Using a Roadside Drug Testing Device

The prevalence of drugs will affect choice of targeted drugs and improvements in detection capabilities will also be an area for consideration. The number of drugs detected at present in the blood and urine specimens analysed is not set out in legislation and is necessarily subject to change especially with developing methods and prevalence information.

8.2.9: Cut-off Levels of Selected Drugs

In the absence of international agreement on cut-off levels for oral fluid roadside devices the cut-off levels will be a matter of either specification by the MBRS or by the level of detection which can be achieved by the manufacturers of the devices.

There is no international acceptance of cut-off levels for laboratory confirmation analysis for blood, urine or oral fluid. Some countries have set out limits and more rely on the analytical capabilities of the confirmation laboratory. Careful consideration on cut-off selection will still depend on continuous monitoring of international best practice for the selected specimen type.

8.2.10: Approval, Supply and Testing by the MBRS

Any changes required by legislation in relation to approval, supply and testing will have to be considered by the DTTAS and the MBRS.

8.2.11: Alcohol and Drugs

Consideration of graded penalties for combinations of intoxicants should be examined in the context of graded penalties for alcohol alone as currently exists.

8.2.12: Legislative Requirements Relating to Medical Fitness to Drive

Legislative requirements relating to medical fitness to drive and alcohol and drug use and dependency are a further area for examination (see Medical Considerations below).

8.3: Operational Considerations

8.3.1: Stand Alone or Electronic Analyser/Reader

This issue will only require consideration if roadside drug testing is chosen as an option. The pros and cons will be set out and considered by the GNTB and MBRS.

8.3.2: Test Protocols

The protocol for RTIT has been agreed and documentary recording of the evidence is currently being reviewed. A separate test protocol for roadside chemical testing will have to be devised if introduced. Careful consideration will need to be given to the documentary recording of the evidence required for this preliminary test.

8.3.4: Selection of Target Drugs for Roadside Chemical Testing Device

If a chemical test option is chosen then careful consideration will have to be given to the number and selection of the targeted drugs. From the information gathered from other countries any number between 2 and 7 drugs are currently targeted at the roadside using these devices. The Bureau will continue to review the 7 drugs or drug classes that it currently detects and will continue to review the prevalence information gathered within the country and internationally to allow appropriate flexibility in the choice of drugs targeted with the devices.

8.3.5: Training in Impairment Testing and Use of Roadside Chemical Testing Device

Training of Gardaí in RTIT was completed in collaboration with UCD and the MBRS and involved training of Garda trainers. This will continue as required. The training of Gardaí in the use of roadside chemical testing devices will be the responsibility of the MBRS as part of the supply of the devices and will be conducted on similar lines to the training of Gardaí as operators of the roadside alcohol testing devices. The MBRS will train the Garda trainers.

8.3.6: Costs

As already mentioned the running costs of using oral fluid roadside tests are significantly more than the running costs of breath alcohol roadside tests. If the expected use of the devices were similar to the use of the PBT devices then the cost of disposable materials to be used would be between 60 and 125 times more expensive. On the other hand, the cost of purchasing the respective devices and of calibrating them must also be factored in as discussed in section 6.6. However, the cost benefit of introducing the roadside drug testing devices would be the added significant deterrent factor generated for road safety and the improved detection and enforcement rates by the Gardaí in the ever increasing problem of drugs driving. The use of the devices will be discussed in the options presented.

8.4: Scientific Considerations

8.4.1: Scientific Specifications

The selection of scientific criteria and the suitability of the current devices to reach these scientific specifications such as acceptance criteria for specifcity, sensitivity and levels of detection will need to be considered if the way forward is to include roadside chemical testing. The acceptance rate of false positives and false negatives should be assessed in light of acceptance of any legal changes to the current system and public confidence in the devices.

8.4.2: Cut-off Levels for Each Drug or Drug Class

The cut-offs should not be confused with measurement of impairment but only considered in light of indicating the presence or not of a drug or drugs. The choice of the cut-offs will have to be considered in tandem with the confirmatory methods in the laboratory.

8.4.3: Selection and Testing of the Device

A testing protocol and specifications for the initial tender and the continuous testing of devices or analyser/readers will be required. The set-up of the oral fluid device testing laboratory will then be used for continuous quality assurance testing. This could include field trials, laboratory evaluation or combination of both.

8.4.4: Laboratory Confirmatory Analysis

In all cases confirmatory analysis is required whether the legal approach used is impairment, or zero tolerance or per se legislation. Scientific consideration of oral fluid as a specimen for confirmation should be made. Blood or urine specimens are currently used.

8.5: Medical Considerations

8.5.1: Medical Assessment of DUID:

The necessity for properly trained forensic medical examiners is also part of the DUID strategy. The availability of physicians and nurses trained in the assessment of persons under the influence of drugs and able to differentiate from medical conditions mimicking drugs intoxication is another consideration and submissions in this regard have been sent to the Department of Justice and Legal Reform and the Department of Health and Children [58].

The Faculty of Forensic and Legal Medicine of the Royal College of Physicians in London has produced comprehensive guidelines and *pro forma* document for the assessment of drivers under the influence of intoxicants ("section 4 RTA assessment") which can be found on the Faculty website at www.fflm.ac.uk

8.5.2: Medical Fitness to Drive

Another aspect of driving under the influence of drugs is the necessary connection with assessment of medical fitness to drive. The Driver Vehicle Licensing Authority (DVLA) in the UK and similar bodies in jurisdictions such as Australia and Canada as well as other EU countries has set out in detail how such guidelines should be implemented and enforced by a Driver Licensing Authority. This is currently the subject of detailed consideration by the Royal College of Physicians of Ireland working group on Road Traffic Medicine under the auspices of the National Programme Office for Traffic Medicine (Royal College of Physicians of Ireland and Road Safety Authority) of which the MBRS is a member. There is a subgroup of that working group dealing specifically with alcohol and drugs and the working group has a representative on the UK Medical Advisory Panel Alcohol and Drugs (Transport). In any consideration of DUID there must be overlap and coherence with licensing requirements and of licence suspension in the area of alcohol and drug misuse and dependence. The relationship between drugs of abuse, controlled drugs, prescribed medicines and over the counter medicines in the area of safe driving and

road safety is independent of the concepts of legality and should be considered solely in terms of their effects on the skills necessary for safe driving.

A recent High Court case considered the current regulations and the shared duties and responsibilities of doctors and patients in assessing and monitoring medical fitness to drive where patients have medical conditions and are on prescribed medications [59].

8.6: Options

8.6.1: Option 1 - Retain the Current Position

The current situation is the legal requirement of evidence of impairment by the Garda and the confirmed presence of a drug or drugs in a blood or urine specimen provided by the driver in a Garda station or in a hospital and analysed by the Medical Bureau of Road Safety. While this option calls for no changes in legislation or in operation nor does it require scientific or medical considerations to be altered it does not however address improvement in detection of DUID. The current option does not permit MIT or mandatory drug testing after a collision. Only evidence of impaired driving is permitted and only when the driver is very obviously impaired is the Garda able to form the opinion that the driver is impaired. The impairment based approach does not address the increased collision involvement risk of drug using drivers when driver impairment is not readily observable. Moreover the impairment approach does not provide a high level of deterrence from using drugs and driving as the enforcement is not generally visible [60]. The current levels of detection do not match levels of prosecutions and the level of successful prosecutions remains low.

8.6.2: Option 2 - Current Position (Option 1) in Combination with Road Traffic Impairment Testing (RTIT)

This option has been considered and is in the process of being introduced and is a clear improvement on the current position. The introduction of RTIT would assist the Garda in identifying impairment by the driver and improve the evidence of impairment required by the Courts. However while this position would assist with identifying impairment it would still not provide fully for mandatory drug testing or mandatory testing following a collision. Even with consideration of the time required for conducting the roadside testing and the additional recording of evidence this option is very workable and necessary.

8.6.3: Option 3 - Chemical Testing at the Roadside Alone

The introduction of oral fluid testing alone at the roadside would be a relatively quick method to detect presence of a drug or drugs using a non-invasive test. It could be used for mandatory drug testing and mandatory drug testing after collisions. However its main drawback is that it would not include all impairing drugs. It is not inexpensive. There are operational issues which can be addressed in training. The level of sensitivity and specificity are not as high for certain drugs and still requires improvement. The tests can lead to false positives and false negatives. This option on its own is an improvement but falls short of a comprehensive solution.

8.6.4: Option 4 - Chemical Testing at the Roadside and RTIT

This option has the advantages of option 2 and option 3 combined and provides the Gardaí with additional tests if the drug is not detected by oral fluid device and impaired driving due to drugs is still considered. It should increase the levels of detections. It would provide for mandatory intoxicated screening similar to the MAT. At an MIT checkpoint, the Garda would have the opportunity to make initial observation; followed by mandatory alcohol testing; followed by preliminary drug screening with a suitable device for the number of specified and appropriate drugs if the alcohol breathalyser was negative; and then proceeding to formal road traffic impairment testing if the drug screening also proved negative but in the presence of apparent observed impairment. Detection on the basis of observed impairment driving but not at an MIT checkpoint would follow a similar structured assessment and detection pathway. The main disadvantage of this process is the additional time that would be required at the roadside and the cost of testing. The Garda should have the choice whether to use a device of not. If alcohol over the limit is detected then it may not be necessary to check for drugs, however the level of drugs and alcohol in combination whilst driving is also an issue that needs to be addressed. With this option the Garda is not restricted to under the limit alcohol drivers being tested for the presence of a drug or drugs. It is not expected that each motorist will be checked with a drug test at a MIT checkpoint, it should depend on the Garda's initial observation and the use (and cost) of the drug test should be exercised with due diligence.

8.7: Recommendations

The considered recommendations of the authors of this report are that roadside drug intoxicant testing should progress in sequenced steps as follows:

Step 1: Continue the current position with the addition of RTIT being made operational as soon as practicable (Option 2);

Step 2: The introduction of roadside chemical testing as soon as practicable (Option 4).

The legislative framework modelled on the successful mandatory alcohol screening methodology should be introduced. This legislation should also allow for the *zero tolerance* approach for illicit drugs and drugs taken illicitly and the impairment plus presence for drugs which are authorised medicinal products taken in accordance with prescription or on healthcare (including pharmacist) advice.

Road traffic impairment testing will always be a required part of the strategy in assessing DUID at the roadside even when in the future roadside testing devices for certain classes of drugs are available, and their use implemented. This will include the fact that roadside screening devices will always technically and scientifically be behind the emergence of new classes of drugs or the modifications of existing drugs of which the "head shop drugs" were the most recent widely acknowledged example.

The MBRS thus recommends the implementation of these options 2 and 4 as the strategy which will increase the detection, enforcement and deterrence of drugs driving in Ireland.

Chapter 9

Implementation of the Roadside Drug Testing Recommendation

Chapter 9: Implementation of the Roadside Drug Testing Recommendation

9.1: Introduction

In order to progress Option 4, it is assumed that Option 2 (current situation with implementation of RTIT) will have been successfully commenced and that this chapter is addressing the introduction of oral fluid chemical testing devices under Option 4. Several steps will have to be taken and an agreed timeframe set out as between the DTTAS, MBRS and GNTB to commence the process. Resources and cost areas associated with the introduction are also identified where possible.

The following steps have been identified at this stage and are outlined below.

9.2: Formation of a Working Group

A working group comprising the three bodies concerned (MBRS, DTTAS and an Garda Síochána) would need to be set up immediately after the DTTAS requests the introduction of oral fluid testing at the roadside. The working group will need to address all the issues required to commence the process which include scientific, operational, legislative, resources and costs.

9.3: Development of a Knowledge Base

The working group will be charged with setting out the requirements of the devices. The MBRS scientists have a good understanding of the analytical technology employed in the devices but the working group would require more knowledge in the assessment and the procurement and operational set up processes. As can be seen from Chapter 7, these processes have been conducted by other jurisdictions and in the case of France have been successfully conducted twice in the past. Inspection and active assessments of existing programmes in one or two jurisdictions should be considered as this would assist the working group in obtaining an overall picture of the legal, operational and scientific requirements for the introduction of this new roadside drug testing. The costs of these inspections could be kept to a minimum if jurisdictions identified were nearby.

Another consideration is the possibility of a field trial being conducted as part of the process. A field trial was conducted before the introduction of evidential breath testing but the numbers gathered in the original 6 month time frame was too small and the trial had to be extended for a further 6 months and the final response from drivers was considered very low. The advantages of a field trial would be that both Gardaí and Scientists would gain experience with the devices, the MBRS would gain knowledge of the level of support from the manufacturers in troubleshooting and the experience gained would contribute greatly to the setup process. A field trial would also assist the DTTAS in drawing up legislation. There were legal restrictions with the EBT field trial and this could also be a possibility here. There would also be time, resources and cost considerations with this suggestion and the learning outcomes may not justify these outlays.

9.4: Establish Specifications

As already outlined in there are no international or EU standards set out for these devices unlike the breath alcohol testing devices and it will be necessary for the MBRS to set out its own specifications for device approval. It will take into consideration the advices from the working group and also the experiences of other jurisdictions. The specifications will be used for the procurement processes used by the MBRS.

The working group will have to decide on what type of device is best suited to Garda operators with special regard for proofs required. As can be seen from chapter 7 (Practices in Other Countries) each country has adopted its own approach and with advances in technology there are both stand-alone single use cassettes and electronic devices available. Electronic devices can issue printed reports. Each type can be considered either before setting out the specifications for procurement or as part of the evaluation process during procurement. In the case of electronic devices the specifications will be considerably more detailed and will include specifications in relation to power supply, radiofrequency, temperature and climate to name but a few. If no restriction on type is to be considered before procurement then the electronic specifications will need to be included and reflected in the timeframe for the commencement of the project.

The working group will also need to consider the number of drugs to be targeted by the device and again as outlined in Chapter 7 different countries and different jurisdictions have taken different approaches to this decision. The decision can be for legal, financial or operational reasons and all will have to be given careful consideration in reference to the situation here in Ireland.

9.5: Amend the Road Traffic Act

The working group will also need to identify legislative changes required and agree the timeframe for these changes to be in place. The working group members can also consult relevant bodies in relation to legislative issues that arise. Roadside drug testing will demand considerably more time at the roadside and legislation will need to permit detention of the driver, taking of oral fluid specimen, consideration as to the order of the tests and the reporting of the tests, It will be very important that legislation and protocols will not be too restrictive as the number and types of drugs will be subject to change (see chapter 2) and cut-off levels should not be included as they can depend on the analytical capabilities of devices currently on the market and into the future. The need for documentation should be given careful consideration and also the information to be given to the laboratory as a result of the roadside tests. This part of the process can be operating in tandem with the other steps identified.

9.6: Establish Oral Fluid Device Testing Laboratory

When the working party has agreed the specifications for the devices and estimated the quantities that will be required, the MBRS and the Gardaí will also have to agree a testing protocol for assessment of the devices and the MBRS will also have to set up a device testing laboratory. This laboratory will be used for the initial testing of the devices for approval by the MBRS but also for the ongoing testing of devices supplied to Gardaí on a regular basis into the future. It will be necessary to source relevant standards in oral fluids and develop tests to detect targeted drugs if not already being carried out in blood or urine specimens in the laboratory. It may also be necessary to outsource some of this testing if

narrow time constraints are placed on the project. In the case of an electronic device being considered, the testing protocols will need to include additional laboratory tests for evaluation of specifications in a similar way to electronic breath alcohol testing devices including; radiofrequency, power supply and temperature. It will be necessary to validate the test method for whatever device is selected and the MBRS will seek accreditation for the test procedure. Accreditation will be sought for the testing of the devices before issue. In the case of electronic devices there will be a need to set up an inspection and calibration checking programme similar to the current regime for the roadside alcohol testing devices. The latter issues will not affect the timeframe for the introduction of the devices. The MBRS has the infrastructure and scientific knowledge to set up the laboratory but will require additional scientific resources for this task at the initial stage of the process and in the case of electronic devices for testing into the future. If the MBRS is required to rely on current resource levels, the timeframe for implementation will of necessity be extended.

9.7: Procurement Process

The tender process will be conducted according to EU procurement requirements and the appropriate timeframes will have to be adhered to. However additional time may be required to assess the devices depending on the agreed testing protocol. The testing of electronic devices as outlined previously will also need time consideration in the procurement timeframe.

9.8: Approval, Supply and Testing of Devices by the MBRS

Following the successful completion of the procurement process, the MBRS will order the agreed required amount of devices. The lead-time for the initial order may depend on whether the order requires modifications unique to the Irish jurisdiction or not. If the vendor has a suitable off the shelf product available there should be minimal lead-times and the quantities of devices required should be the only consideration at this stage. However if the order is a bespoke order then additional time may need to be factored into the timeframe. The devices must be approved by the Board of the MBRS before use. They will also be tested by the MBRS before issue to the Gardaí. This testing would need to be included in the timeframe. Future orders would then be planned in a similar manner by the MBRS in consultation with the GNTB on an annual basis.

9.9: Training

These devices will be used by any Garda operator as a preliminary drug screen and should not require extensive training. The operator of the device will follow the instructions of the manufacturer and the legal protocol as proscribed. The manufacturer or their agent and the Bureau will train the Garda trainers. The Garda trainers will then be in position to train the Garda operators. This is similar to the training of Gardaí in the use of the roadside breath test devices. Training will also be part of the overall timeframe for the introduction of the devices. Costs for training the Garda operators will be a matter for the Garda authorities. The cost of the training courses of the trainers will be borne by the Bureau.

9.10: Timeframe for Implementation of Roadside Drug Testing Recommendation

It is estimated at this stage that the process set out above would take at least two years. By comparison, this is similar to the timeframe as set out for the United Kingdom in the North Report (Recommendation 11 of that report) [11]. However this timeframe is a preliminary estimate which could only be finalised following the deliberations of the working group as it depends on a number of critical decisions of the working group.

The legislative process timescale is separate and distinct.

Glossary of Terms and Acronyms

Accuracy:	Accuracy is a mathematical combination of specificity and sensitivity and is the measure of the tests ability to return the correct result whether it is positive or negative.
Antibodies:	Proteins produced by animals which have highly specific binding properties to specific chemicals.
Buffer:	Fluid which when oral fluid is added to it maintains its original pH.
CEN:	European committee for standardisation.
Centrifugation:	A method of separating components in a mixture using centrifugal force.
CIT:	Compulsory Impairment Test.
CLT:	Confirmatory Laboratory Test.
CNS:	Central Nervous System.
Cut –off:	A concentration level at or above which a result is deemed positive and below which it is deemed negative.
Diluent:	Fluid used to dilute.
DIT:	Dublin Institute of Technology.
Drug Recognition Expert:	Suitably trained individual who conducts a series of tests, including impairment and physiological tests, in order to determine driver impairment and also the likely drug class causing such impairment. Drug Recognition Experts usually carry out their tests in a police station.
Drug:	In the context of this report a drug is any chemical substance other than alcohol which can impair driving.
DRUID:	Driving Under the Influence of Drugs.
Dry Mouth:	A condition which can be pathological or drug induced, which results in a reduction in saliva production.
DTTAS:	Department of Transport, Tourism and Sport.

DUID	Driving under the influence of a drug(s).
DVLA:	Driver Vehicle Licensing Authority, U.K.
EMCDDA:	European Monitoring Centre for Drugs and Drug Addiction.
ESTHER:	Evaluation of oral fluid Screening devices by TISPOL to Harmonise European Police Requirements.
Field Impairment Test:	Impairment test carried out at or close to the location where impairment is suspected (See impairment test below).
GC-MS:	Gas Chromatography-Mass Spectrometry.
GC-MS-MS:	Gas Chromatography-Tandem Mass Spectrometry.
GNTB:	Garda National Traffic Bureau.
HRB:	Health Research Board.
IMMORTAL:	Impaired Motorists, Method Of Roadside Testing and Assessment for Licensing.
Immunoassay:	A test that utilises purified antibodies to determine the presence of a drug.
Immuno-chromatographic device:	A drug testing device which incorporates a simple sample preparations step and an immunoassay.
Impairment test:	A test or series of tests which are used to assess a person's psychomotor and cognitive skills.
Impairment Threshold	Refers to level at which a person is deemed to be impaired.
Intoxicant:	Alcohol and drugs and any combination of drugs or of drugs and alcohol.
Last Month Prevalence:	Refers to the proportion of a sample of a population who have reported using a drug in the last 30 days.
LC-MS:	Liquid Chromatography-Mass Spectrometry.
LC-MS-MS:	Liquid Chromatography-Tandem Mass Spectrometry.
Lifetime Prevalence:	Refers to the proportion of a sample of a population who have reported ever having used a drug.

Limit of detection:	Lowest detectable level permitted by the detection system used.
Limit of quantitation:	Lowest detectable level that can be quantitated accurately by the detection system used .
Lipophilic:	Term used to describe chemical entity which dissolves well is lipid based system rather than aqueous based systems.
MAT:	Mandatory Alcohol Test.
Matrix Effects:	Factors which can affect the detection of drug in a particular matrix such as oral fluid or blood.
MBRS:	Medical Bureau of Road Safety.
Medicinal Product:	Drug or Drug preparation authorised for human use.
mg/100ml:	Milligram per 100mL, unit of measurement used to describe the concentration of alcohol in blood or urine. 1mg/100ml is equivalent to 1 part per 100,000.
MIT:	Mandatory Intoxicant Test.
NACD:	National Advisory Committee on Drugs.
NDRDI:	National Drug Related Deaths Index.
ng/ml:	Nanogram per millilitre, unit of concentration commonly used to express the concentration of drug in a particular biological specimen. 1ng/ml is equivalent to 1 part per billion (ppb).
NHTSA:	National Highway Traffic Safety Administration, U.S.A.
OIML:	International Organisation for Legal Metrology.
On-Site Oral Fluid Test:	A test that can be conducted at the road side.
Oral Fluid Collection Device:	A device used to collect oral fluid for testing.
Oral fluid:	Fluid produced by glands in the mouth which contains a mixture of saliva, proteins and other materials.
Per se:	Refers to legislation which specifies concentration levels for a drug and/or alcohol. A per se level is the maximum allowable concentrations above which an offence is committed.

pg/ml	Picogram per millilitre, unit of concentration used to express the concentration of drug in a particular biological specimen. 1ng/ml is equivalent to 1 part per trillion (ppt).
pH	Measure of the acidity/alkalinity of a material. The pH scale is 0-14. pH 7 is neutral, <7 is acidic, >7 is alkaline.
Pharmacodynamics:	The effect the drug has on the body.
Pharmacokinetics:	How the body processes a drug e.g. Transport and Metabolism.
PHIRB:	Public Health Information and Research Branch.
pKa:	Dissociation constant of a molecule.
RCPI:	Royal College of Physicians Ireland.
RTIT:	Road Traffic Impairment Test, the name given to the impairment tests to be carried out in the Republic of Ireland.
ROSITA:	Roadside Testing Assessment.
RSA:	Road Safety Authority.
RTA:	Road Traffic Act.
RTC:	Road Traffic Collision.
Saliva:	Fluid produced by parotid, sub-maxillary and sublingual glands in the mouth.
Sensitivity:	The ability of a particular test to determine a positive test result when it should. This is often expressed as a percentage 100% is completely sensitive, 0% is completely insensitive.
Specificity:	The ability of particular test to correctly determine a negative result when it should. This is often expressed as a percentage 100% is completely specific, 0% is completely unspecific.
THC:	Δ^9-Tetrahydrocannabinol.
Zero Tolerance:	Offence committed if any detectable level of the drug is found.

Appendix 1

Results of MBRS DUID Survey March 2012

The Bureau contacted colleagues in 13 different countries and presented a DUID questionnaire to them. There were 8 completed questionnaires. Another 2 colleagues started but did not complete the questionnaire, the first person did not consider that the questionnaire applied to their country and the second was not in position to provide cut-off information. Colleagues from 3 countries did not respond.

The countries that replied to the questionnaire were as follows: France, Switzerland, Canada, Germany, Norway, Belgium, USA and Denmark, both Sweden and Finland replied by Email.

The following information was obtained from the 8 questionnaires:

Q1. When was legislation introduced in your jurisdiction?

The date of implementation varied from the 1950s for the USA to 2012 for Norway who introduced a legal limit for 20 specified drugs this year.

Q2. When can police stop the driver?

- 7 indicated on suspicion of DUID
- 3 indicated at random
- 3 indicated mandatory after a collision
- And only one indicated that a traffic offender can be stopped.

Q3. What type of test is permitted?

- 6 indicated roadside assessment of driver
- 3 indicated legislation based specific performance impairment tests
- 4 indicated oral fluid tests
- 1 indicated oral fluid available in law but not in use yet.
- 1 indicated performance test used only when prescribed medicine is used
- Only 1 indicated that a urine test is permitted

Q4. What is the average completion time for the process at the roadside?

- 3 indicated less than 10 minutes (with one person qualifying their response)
- 3 indicated 10-20 minutes
- 1 indicated 20-30 minutes
- 2 indicated greater than 40 minutes (with one person qualifying their response)

Q5. What evidential standard is required?

- 6 indicated evidence of impairment is required
- 6 indicated *per se* limits for some specified drugs
- 2 indicated zero tolerance for illegal drugs
- 1 indicated *per se* limits for medicinal drugs without prescription

Q6. What drugs are specified in legislation?

- 5 indicated illegal drugs only
- 3 indicated all impairing drugs
- Marijuana is exempt from the illegal drugs list in some States in the USA.
- Norway indicated that 20 drugs are now specified in legislation since February 2012

Q7. Please describe the roadside testing device used in your jurisdiction?

- 4 indicated none used
- 3 indicated Drugwipe5 used
- 1 indicated that different devices are used by different police forces

Q8. In the case of oral fluid what are the cut-off concentrations (ng/ml) for the following drugs? The number of respondents reporting specific cut-offs are in parentheses.

- Amphetamine 50ng/ml (2), 100ng/ml (1), MDMA 50ng/ml (1), MDEA 100ng/ml
- Methamphetamine 50ng/ml (3)
- Opiates 10ng/ml (2), Morphine 20ng/ml (1)
- THC 15ng/ml (1) , 25ng/ml (1), 30ng/ml (1)
- Cocaine 10ng/ml (1), 20ng/ml (1), 50ng/ml (1), Benzoylecgonine 100ng/ml (1)

Q9. What specimen type(s) is used for confirmation?

- 1 Oral Fluid & Blood
- 1 Oral Fluid & Urine
- 1 Blood & Urine
- 4 Blood
- 1 Urine

Q10. What is the confirmation cut-off concentrations (ng/ml) for the following drugs?

In all 2 countries gave no indication, 1 country indicated that it varied by State and laboratory. The results of the remaining 5 countries are as follows and are blood cut-off levels:

- Amphetamines range; 15-50ng/ml and 0.03mg/kg
- Methamphetamine range; 15-50ng/ml and 0.03mg/kg
- Benzodiazepines
    - 2 did not indicate that benzodiazepines were applicable
    - 2 indicated that there are different cut-offs for the different benzodiazepines
    - 1 indicated that cut-off was limit of quantitation of the laboratory
- Opiates
    - Morphine range 9-15ng/ml and 0.015mg/kg
    - Opiates range 10-20ng/ml
    - Others indicated limit of quantitation of laboratory as the cut-off
- Cannabis (THC)
    - Range 0.6-1.5ng/ml and 0.0015mg/kg
    - Cannabis (THC acid)
        - 4 indicated 'not applicable'
    - 1 indicated limit of quantitation of laboratory as the cut-off
- Cocaine range; 15 -50ng/ml and 0.015mg/kg
    - 1 indicated that metabolites cut-off was limit of quantitation of the laboratory
- Methadone
    - 1 country had a cut-off value of 19ng/ml
    - 1 country had a cut-off value of 0.075mg/kg
    - 1 country indicated the limit of quantitation of the laboratory as the cut-off
    - Other countries did not indicate whether methadone is tested for or not

- One country indicated its cut-off levels for Oral Fluid in ng/ml
    - Amphetamine 25ng/ml
    - Methamphetamine 25ng/ml
    - Opiates 5ng/ml
    - THC 10ng/ml
    - Cocaine 10ng/ml

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