Institution: King's College London		
Unit of Assessment: UoA2		
Title of case study: Improving Road Safety by Supporting Drink- and new Drug-Driving Legislation in England and Wales		
Period when the underpinning research was undertaken: 2000-2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Prof Kim Wolff	Professor Analytical, Forensic & Addiction Science	07/01/1997-present
Dr Jane Marshall	Hon Senior Lecturer Addiction	01/06/1997-present
Prof David Cowan	Emeritus Professor Pharmaceutical Toxicology	01/10/1978-2018
Dr Ivana Gavrilović	Post-doctoral researcher	2010-present
Prof Roy Sherwood	Hon Professor Clinical Biochemistry	1995-2017
Period when the claimed impact occurred: 2014-2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

King's researchers worked closely with the Department for Transport (DfT) Drink and Drug Driving Policy Unit, playing a leading role in the use of biomarkers to assess fitness to drive. King's research supported the introduction of a new biomarker for mandatory 'Fitness to drive' reassessment of drink-drivers. King's then led a systematic review for DfT on the growing problem of drug driving, recommending 17 controlled and illicit drugs as dangerous for driving. This provided the evidence for the UK's first strict liability drug-driving offence (s5A Road Traffic Act) in 2015. In the first 316 days after legislation came into effect, approximately 8,599 convictions took place; this trajectory has continued, with >10,000 drug driving convictions in 2018. King's is contributing to innovative approaches for robust roadside testing of evidential samples and plans for a high-risk drug-driving offender scheme. King's research has improved UK road safety and helped establish the UK as a policy leader in this area.

2. Underpinning research

King's develop biomarker led assessment of high-risk drink-drivers allows more accurate relicensing decisions. As described in a REF2014 case study, King's researchers have worked closely with the UK Department for Transport (DfT) and the Driver and Vehicle Licensing Agency *(*DVLA*)* since 2006. This research focused on developing biological measures (biomarkers) to increase the ability of law enforcement agencies to act against drink-driving. King's secured DfT research funding (2006) to identify a biomarker to screen high-risk drink-drivers on the DVLAs High Risk Offender Scheme, (for drivers who are convicted of repeated or serious drink driving offences) **[1]**. King's showed that testing for Carbohydrate Deficient Transferrin (CDT, a protein produced by the liver) could be used as a sole blood test to identify continuing alcohol consumption in disqualified drivers applying for re-licensing **[2]**. King's then developed a traffic light system, based on detected CDT concentration to aid decision making for medical staff at the DVLA. Subsequently, we showed CDT to be superior to other blood markers such as gamma glutamyl transferase because it enables better differentiation of dependent versus social drinking **[3]**.

Drug-driving road traffic collisions are a serious and increasing issue in the UK. The issue of rising road-traffic collisions (RTCs) caused by drink- and drug-driving came to a head following a public campaign (2012-2015) after a young girl was killed by a driver intoxicated with cannabis. At that time, and in contrast to drink-driving: (i) there was no systematic understanding of whether or which drugs dangerously impacted safe driving; (ii) the Police had limited options for reliable roadside drug testing; and (iii) there was no UK strict liability offence to prosecute drug-driving offences. This campaign led to a public petition presented to the Prime Minister with 22,000 signatories calling for specific action on drug-driving, alongside tightening action on drink-driving.

Based on her expertise in forensic toxicology in relation to drink-driving, Professor Wolff was appointed to Chair the Government's expert technical panel (DfT Road Safety Division) on Drug Driving and was awarded UK Government funding to carry out a systematic review of all available research, to identify specific drugs that were unsafe for driving **[4,5,6]**.

King's researchers provide new evidence of drug-driving harms. A King's-led systematic review introduced the concept of risk-based road safety. This statistically driven approach identified the risk of a RTC when under the influence of certain drugs. For instance, drivers under the influence of cannabis (blood concentration ≥ 1 µg/L) have twice the risk of a RTC compared to drivers who have not taken the drug (OR: 1.89; CI 1.43-2.51). King's brought to the attention of the Government that alcohol use alongside cannabis increased this RTC risk significantly: drivers being 16 times more likely when compared to a non-using driver. In addition, King's highlighted that driving under the influence of medicinal controlled drugs such as benzodiazepines increased the likelihood of a RTC 8.5 times. Overall, King's identified 17 medicinal controlled and illicit drugs known to increase the risk of RTCs and made recommendations for blood concentration limits, particularly concerning cannabis (the most used illicit drug in the UK) for the new strict liability offence **[4,5,6]**. King's researchers advocated changing the assessment of driving under the influence of drugs from an impairment (subjective) model to an evidence-based approach.

King's use expertise on drug-driving toxicology to lead a systematic review of alternative biological matrices for use as an evidential sample for drug driving. Proving a suspected driving offence requires drug tests following blood sampling; for accurate evidence, confirmatory blood samples must be obtained quickly. However, in RTC scenarios, the practical difficulties of obtaining blood tests often hamper drug testing. A second King's-chaired expert panel (2015-17), a collaboration with Queen Mary University, evaluated the potential of different biological samples for tests to confirm drug-driving offences. Oral fluid (saliva) was identified as a viable alternative to blood testing for illicit drugs compared to sweat, hair and urine because it can be easily collected, including at the roadside. This review was published by the DfT in August 2017 **[7]**.

King's investigate synthetic oral fluid for type approval of roadside drug-driving tests. Currently, the only roadside drug-driving tests are non-quantitative screening devices, which detect the presence of cannabis or cocaine in saliva (oral fluid) collected from the tongue. These tests need to be confirmed by quantitative analyses, which require collecting a blood sample, before results can be used as evidence in court. King's was funded by the Home Office Centre for Applied Science and Technology (CAST) to explore whether *quantitative* oral fluid tests could be undertaken at the roadside (2016-2018). A significant challenge is calibrating potential roadside devices for Home Office approval ('type approval'). This process requires much larger volumes of oral fluid than is practicable to collect from humans. King's therefore characterised a Home Office formula for synthetic oral fluid (SOF) to develop a viable synthetic oral fluid (SOF) alternative **[8]**.

King's demonstrated that SOF samples can be kept stable and sterile, crucial for roadside drug testing. King's then successfully bid for further CAST funding to investigate drug stability in SOF, another crucial element of type approval testing. King's employed state-of-the-art laboratory instruments (hyphenated liquid chromatography-mass spectrometry-LC-MS/MS) to show that SOF drug solutions performed as well as blood samples, with highly reproducible results. King's led research in this area, conclusively demonstrating the stability of the most used illicit drugs (cannabis and cocaine) in SOF, giving a viable means to approve roadside drug-testing devices. **[8]**. We further determined whether SOF is susceptible to microbial contamination, and whether this impacts the stability of SOF containing drug samples. SOF samples challenged with five common microbial species – two fungal species (*Candida albicans* and *Aspergillus brasiliensis*) and three bacterial species (*Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*) – were tested alongside two separate antimicrobials (sodium azide and ProClin®300). We confirmed that it is feasible to maintain sterility and stability using SOF in combination with ProClin®300 antimicrobial agent **[8]**. Collectively, this work demonstrated that SOF provides a feasible, practical alternative approach to develop roadside evidential drug testing.

3. References to the research

1. Wolff K, Gross SS, **Marshall EJ**, Walsham N, Keaney F, **Sherwood R**. *The Role of Carbohydrate Deficient Transferrin as an Alternative to Gamma Glutamyl Transferase as a Marker*

of Continuous Drinking in High-Risk Drivers - Road Safety Research Report S. 104 (Paperback) 2010. Department for Transport. ISBN 9781848640016
2. Walsham N & **Sherwood R** (2015) *CDT: a sensitive, specific marker of alcohol misuse.* Hospital Healthcare Europe. https://hospitalhealthcare.com/latest-issue-2015/cdt-a-sensitive-specific-marker-of-alcohol-misuse/
3. Wolff K, Gross S, **Marshall EJ**, Walsham N, Robson-Zurani N, Keaney F, **Sherwood R** (2019). *Carbohydrate deficient transferrin (CDT) as an alternative to other biomarkers of continuous drinking in High Risk Drink-Drivers.* Advances Clinical Toxicology, 4;3:1-11. ISSN: 2577-4328
4. **Wolff K**. Drugs and Driving, Chapter 13 (2016). *In Forensic Toxicology: Drug Use and Misuse.* (Ed. Davies S, Johnston A, Holt D) ISBN**:** 978-1-78262-156-0. The Royal Society of Chemistry.
5. Wolff K Agombar R, C.A., **Cowan D**, Forrest AR, Osselnton MD, Scott-Ham M, Johnston A., *Driving under the Influence of Drugs: Report from the Expert Panel on Drug Driving.* (2013). Department for Transport: London.
6. Wolff K, Johnston A. (2014) *Cannabis use: a perspective in relation to the forthcoming UK drug driving legislation.* Drug Testing Analysis. Invited review. 6(1-2):143-54. DOI: 10.1002/dta.1588.
7. **Wolff K**, Agombar R, Clatworthy A, **Cowan D**, Forrest R, Osselton D, Scott-Ham M, Johnston A. (2017). *Expert Panel Review of alternative biological matrices for use as an evidential sample for drug driving.* Reference RM4825 SB-2988
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/624915/expert-panel-report.pdf/
8. Gavrilović, I, Cowan D, Woffendin A, Smart A, Gong F, Harding D, **Wolff K**. *Characterisation of Artificial (synthetic) Oral Fluid: its usefulness as a matrix for drug testing quality assurance systems.* (2020). Drug Testing & Analysis. DOI: 10.1002/dta.2938

4. Details of the impact

The public health importance of substance abuse was recognised in the UN Sustainable Development Goals (SDG3) which aim to strengthen the prevention and treatment of substance abuse and harmful use of alcohol, as well as aiming to halve the number of global deaths and injuries from road traffic collisions (RTCs).

King's research improved the UK DVLA's medical re-assessment of disqualified drink-drivers to allow more accurate relicensing decisions. Before 2014 the DVLA employed a suite of liver function tests (LFTs) to re-assess high-risk drink-drivers, and decisions were often delayed because other common medical problems (e.g., hypertension, non-alcoholic liver disease) might confound test results. Following King's research on biomarkers for drink-driving originally described in a REF2014 case study (1-3), the UK Department for Transport (DfT) introduced Carbohydrate Deficient Transferrin (CDT) testing in the mandatory medical reassessment of all drink-drivers as part of the relicensing process. Since full adoption as the sole biomarker by the DVLA in 2014, it has been mandatory in England and Wales for the CDT test to be included in the 'Fitness to Drive' assessment for high-risk offenders (HROs) **[A]**. Within this REF period (1 August 2013 onwards), there have been an estimated 23,000 CDT tests carried out in the UK per year for relicensing high-risk drink drivers **[B]**. During 2015, 25,933 HROs were referred for CDT testing, of which 90.7% fell into the green CDT range and were issued a licence (CDT <2.1%); 3.1% an amber range CDT requiring further investigation; and 6.2% had a CDT in the red range (>3%) and, were refused a licence **[B]**.

Providing evidence and expert advice to support the first ever UK Drug-Driving legislation. Road traffic injuries are a growing public health problem causing emotional and economic harm. The World Health Organization (WHO) noted that crash survivors, their families, friends, and other caregivers often suffer adverse social, physical, and psychological effects, taking an enormous toll on individuals and communities as well as on national economies **[C]**. Before 2015, UK police relied on Section 4 of the Road Traffic Act 1988, which requires evidence of being "unfit to drive through alcohol or drugs"; this was assessed using a field impairment test (FIT) such as walking in a straight line. The legislation was limited in scope for policing and convicting drug drivers. Professor Wolff's expert Panel report (**5**; published by the DfT in 2013) gave key evidence for developing the UK's first ever strict liability drug-driving offence **[E1]**. In 2014 Professor Wolff was appointed to the Home Office CAST expert committee, tasked with setting thresholds for drug-driving to be included in the new legislation **[D]**. The strict liability offence, outlined in Section 5A of the Road Traffic Act, became law in England and Wales in March 2015 **[E]**, including the 17

drugs (8 illicit substances and 9 controlled medicines) identified by the DfT Expert Panel to increase the risk of RTCs (**5**), and cut-off levels endorsed by the CAST committee, above which an offence has occurred **[E]**. Similar legislation came into effect in Scotland in 2019 **[E4]**. The new legislation for the first time allows the police to test for drugs at the roadside, and legislators to bring prosecutions more objectively and effectively for drug-driving. The DVLA explained that "(Prof Wolff's) knowledge especially in the area of drug and drink driving has been pivotal in the formulation of our policies in relation to driver licensing" **[E5]**.

King's research has improved road safety in the UK, with greater awareness of drug-driving harms, and an increasing number of drug tests and prosecutions. Data from freedom of information requests made in 2018 by the BBC to 40 police forces showed that the new drug-driving legislation led to a significant increase in the number of drivers testing positive for drugs (almost 25,000 motorists in England and Wales) within three years **[F1]**. This indicated growing awareness of drug driving amongst the Police and the removal of significantly more unsafe drivers on UK roads: the DVLA said *"(the) data shows that between March 2015 and 2018, the number of drivers disqualified for drug driving is 29,225"* **[E]**. In 2018, the DfT carried out a retrospective evaluation of the new legislation, which showed that it already had a substantial impact: in the first 316 days after the legislation came into effect, 8,599 convictions took place **[F2]**. Ministry of Justice (MoJ) data from every police force in England and Wales showed over 2000 roadside screening tests were undertaken, with 1718 individuals providing a blood sample for a confirmatory test at a police station. Of these, 750 drivers were subsequently charged with a section 5A offence (49 %), with most offenders males aged 18-29 years **[F3]**. Evidential drug testing has also led to an increased number of prosecutions. In 2014, 17 prosecutions were brought for causing death by careless/dangerous driving under the influence of drink or drugs whereas in 2019, 4 years after the introduction of the Section 5A drug-driving offence, there were 80 prosecutions for causing death by careless/dangerous for drug-driving alone. In 2019, there were 1,321 RTCs involving a driver under the influence of prescription and illicit drugs compared to 594 in 2013 and data from 43 UK Police forces showed that between March 2015 and January 2018, 8,336 drivers tested positive for cannabis and 3,064 for cocaine **[F]**. This illustrates the extent of previously undetected drug-driving in the UK and the significance of introducing this legislation. As the DfT Policy lead for Drink and Drug Driving says *"King's work brings significant societal impact for road safety and has helped in establishing the UK as a policy leader in this area"* **[E1]**.

Alongside the new legislation, the DfT rolled out an associated £2m public awareness campaign (THINK!) on the dangers of drug driving, targeting young people **[G1]**. There were 446 pieces of media coverage, 7m YouTube views of THINK! 'Paranoia' film and King's researchers joined radio campaigns that reached 61% of the target audience. Awareness of the personal consequences of drug driving increased significantly from 45% pre- to 51% post-campaign **[G]**.

Changing UK national clinical and healthcare professional guidelines on drug-driving. In 2016, Professor Wolff was invited by the UK Government Department for Health and Social Care (DHSC), to update the 'drug-driving' section of the DHSC's National Guidelines on Drug Misuse and Dependence ('Orange Guidelines') **[H1]**. The update was based on the scientific evidence produced by the DfT expert Panel report. These guidelines are recognised as being evidence-based best clinical practice and used by all UK specialist addiction doctors and nurses. King's also helped produce the drug-driving guidance for healthcare professionals approved by the Secretary of State for Transport's Honorary Advisory Panel on Alcohol, Drugs and Substance Misuse **[H2]**.

Influencing the development of European policies to improve road safety. Professor Wolff has given expert advice and evidence in fora influencing European drug-driving policy development and worked with the European Transport Safety Council (ETSC), a network of 200 internationally renowned transport safety experts, to publish a report for a debate on drug-driving at the European Parliament on 8th March 2017 **[I]**. Collaboration with the ETSC included presentations in Spain and Poland to raise awareness of the need for a systemic approach to reduce drug driving amongst EU policy makers, the private sector and key opinion leaders. Prof Wolff contributed to a symposium on the dangers of cannabis use and driving alongside speakers from EU Member States; the National Highway Safety Transport Administration, USA; Centre for Accident Research & Road Safety, Australia and the Canadian Centre on Substance Use and Addiction; the resulting report was published by the European Monitoring Centre for Drugs and

Drug Addiction (EMCDDA) – known as the 'reference point' on drug use for EU member states **[I]**. The ETSC called this work *"instrumental in raising political awareness of the problem of drug driving, the necessity to enforce rules on drug driving, and the technical possibilities for enforcement through the detection of (il)licit substances…",* and *"key in raising awareness among Members of the European Parliament… of the problem of drug driving"* **[I3]**.

King's make synthetic oral fluid fit-for-purpose for type approval of confirmatory tests for roadside testing. King's researchers refined SOF to be fit-for-purpose in calibrating drug driving testing and quality control management of drug screening and championed the development of oral fluid testing to the Home Office Centre for Applied Science and Technology (CAST). As the Type Approval Manager for Drugs at CAST explains: *"The testing of suspected drug drivers at the roadside is a key element of the implementation of the s5A offence. Testing is undertaken on a sample of a suspected drug drivers' oral fluid (saliva), using preliminary drug testing devices which have been Type Approved for that purpose by the Home Office."* **[J]**.

King's lead a Government panel to devise a High-Risk Offender Scheme for drug-drivers. Since 2015, according to the Crime Survey for England and Wales (CSEW), self-reported drug-driving as a proportion of all drivers who have taken illicit drugs in the previous 12 months has steadily increased **[K]**. Between 2007 and 2017, both the number of casualties and the number of fatalities involving drug-driving have also risen: casualties increasing from 869 to 1889, and fatalities from 41 to 105. In recognition of this growing problem, the UK DfT made a commitment in the 2015 Road Safety Statement (Parliament's priorities for improving the safety of Britain's roads) to consult on the issue of high-risk drug-drivers (those who drive under the influence of particularly high concentrations of drugs or commit multiple drug-drive offences) and the 2019 Road Safety Statement subsequently recognised the need for expert advice to explore options for a High-Risk Offender (HRO) scheme for drug drivers **[K]**. Prof Wolff was asked to chair the DfT Panel (2019-2020) tasked with making recommendations for introducing a scheme to run in parallel with the High-Risk Drink-Drive Scheme. The Panel of 6 experts used DVLA data to make recommendations to the Government on a framework, including criteria for determining which individuals should be on the scheme (report signed off by DfT, out for consultation Jan 2021) **[E]**.

5. Sources to corroborate the impact

[A] Evidence of full adoption of the CDT biomarker into 'Fitness to drive' DVLA testing [PDF]
[B] DVLA data on CDT testing numbers and outcomes (2015)
[C] WHO global status report on road safety 2013, 2015, 2018 [PDF]
[D] Minutes of the meeting of the secretary of State for Transport's Honorary Medical Panel on Alcohol, Drugs and Substance Misuse and Driving (March 2015). [PDF]
[E] UK Drug driving offence legislation: **E1** Testimonial, DfT Policy Lead, Drink and Drug Driving. **E2** The Drug Driving (Specified Limits) (England and Wales) Regulations **E2** Responses to the DfT Consultations (2014) **E4** Scottish legislation, 2019. **E5** Testimonial, DVLA [PDF]
[F] Evidence of impact of new drug driving legislation on arrests, convictions and publicly available data on RTCs. **F1:** BBC News article, March 2018; **F2:** *Evaluation of the new drug driving legislation, one year after its introduction.* 2017, DfT report. **F3:** Ministry of Justice Criminal Justice Statistics quarterly, England and Wales, 2018-19. **F4:** Sun article, Oct 2019. [PDF]
[G] UK Government drug driving public awareness campaign. **G1** Road Safety GB Launches THINK! Drug Drive Campaign, 2015. **G2:** DfT THINK! marketing plan 2015/16 & 16/17 [PDF]
[H] Changing UK clinical and professional guidelines on drug-driving: **H1** DHSC Orange Book clinical guidance. Drug misuse and dependence: UK guidelines on clinical management 2017. **H2** DfT (2014) *Guidance for Healthcare Professionals on Drug Driving.* [PDF]
[I] European drug driving policy discussions. **I1** Drug Driving in Europe: Policy Measures for National and EU action. European Transport Safety Council, 2017. **I2** Drug-driving and Cannabis: Questions and answers for policymaking. **I3** Testimonial, ETSC [PDF]
[J] J1 Testimonial, Type Approval Manager for Drugs and Head of Chemistry, Home Office CAST. **J2** Home Office CAST type approval guidance for drug testing devices. [PDF]
[K] K1 Crime Survey for England and Wales Self-reported drug driving; DfT Road Safety Statistics 2019. Data at: https://www.gov.uk/government/statistical-data-sets/reported-drinking-and-driving-ras51. **K2** DfT Road Safety Statement 2019; section 2.56 [PDF]