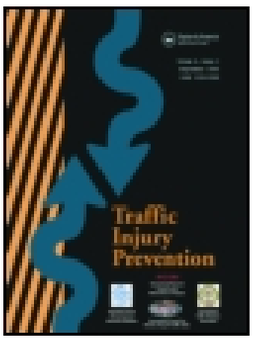

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The implementation of per-se limits for driving under the influence of benzodiazepines and related drugs: No increased risk for arrest during therapeutic use in Norway

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ABSTRACT

Objective: To investigate whether the use of recommended therapeutic doses of medicinal drugs has led to suspicion of driving under the influence of drugs (DUID) after implementation of legislative limits for illicit and medicinal drugs in 2012.

Methods: Data from suspected drug-impaired drivers apprehended by the police from 2013 to 2015 were selected from the Norwegian Forensic Toxicology Database. The blood samples had been analyzed for benzodiazepines (BZDs), z-hypnotics, opioids, stimulants, certain hallucinogens, and alcohol. Drivers who tested positive for one BZD or a z-hypnotic only, were included in the study. Drug concentrations measured in their blood samples were compared to the maximal obtainable steady state concentrations if the drug had been used in accordance with the recommendations set by the Norwegian Directorate of Health.

Results: BZDs or z-hypnotics were found in 10 248 samples, representing 59.6% of the total number of drivers arrested for suspected DUID (n = 17 201). Only one BZD or z-hypnotic with a blood drug concentration above the legislative limit was detected in 390 (2.3%) of the total number of samples. Clonazepam was the most frequently detected BZD (n = 4656), while as a single drug above the legislative limit, it was detected in only 3.6% (n = 168) of the clonazepam-positive blood samples. For drivers testing positive for only one z-hypnotic, drug concentrations above the legislative limit were found in 27% (n = 55) of the blood samples that tested positive for zolpidem and 12.4% (n = 53) of the samples that tested positive for zopiclone. In total, 155 subjects out of 10 248 testing positive for BZDs or z-hypnotics displayed concentrations above the legislative limit but within the concentration ranges that are expected when taking recommended therapeutic drug doses, and 77 below the legislativel limit.

Conclusions: The results show that the implementation of legislative limits for BZDs and z-hypnotics may have contributed to DUID suspicion for a small group of patients using therapeutic drug doses; only 1.3% of the suspected DUID offenders had concentrations of only one of those drugs in-line with recommended therapeutic dosing.

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Benzodiazepines; z-hypnotics; therapeutic use; per-se limits; driving

Introduction

Driving under the influence of alcohol has been a known risk factor in road traffic safety for approximately a century (Borkenstein et al. 1974; Blomberg et al. 2009; Jones et al. 2019). Most countries, apart from certain low- and middle income countries, have therefore implemented legislative (legal) blood alcohol concentration (BAC) limits (WHO 2014; Christophersen et al. 2016).

Norway was the first country in the world to implement a legislative limit for driving under the influence (DUI) of alcohol in 1936; the chosen limit was 0.5 g/kg (0.53 g/L). The limit was lowered to 0.2 g/kg (0.21 g/L) in 2001, based on an expectation that the incidence of driving after drinking alcohol would have been reduced.

For non-alcohol drugs, knowledge regarding the negative effect on road traffic safety came much later (Mørland 2000; Christophersen and Mørland 2008; Christophersen et al. 2016; Jones et al. 2019).

The Norwegian Road Traffic Act was extended in 1959 to include driving under the influence of non-alcohol drugs (DUID). The standard routine for drivers apprehended by the police under suspicion of DUID included a clinical examination of impairment combined with blood sampling performed by a physician (Christophersen and Mørland

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2008; Christophersen et al. 2016). Each case was evaluated individually based on the results of the clinical examination and blood drug analysis.

During the last 40 years, illicit drugs and psychoactive medicines have gained heightened attention based on an increasing number of scientific studies (Berghaus et al. 2011; Dassanayake et al. 2011; Christophersen et al. 2016; Jones et al. 2019). In order to harmonize DUI legislation for alcohol and drugs, the Norwegian Road Traffic Act was changed in 2012 with the implementation of legislative concentration limits for 20 non-alcohol drugs in blood, including those for the use of both illicit compounds and non-prescribed psychoactive medicines (Vindenes et al. 2012). Legislative limits were implemented for eight more drugs in 2016. Results from many scientific studies were used as the basis for determining legislative concentration limits (Vindenes et al. 2012; 2015). Compounds with assigned legislative limits represent those that are most frequently found among drug-impaired drivers (Christophersen and Mørland 2008; Bogstrand et al. 2011) or those seized by police and customs agents (Vindenes et al. 2012), as well as certain hallucinogenic drugs.

DUI sentencing depends on the concentrations of alcohol and/or drugs in the blood sample. There are three concentration limits: for alcohol the limits are 0.20, 0.50, and 1.20 g/kg blood. For BACs of 0.20–0.49 g/kg, the sentence is a fine equivalent to 1.5 times the gross monthly salary; for BACs of 0.50–1.19 g/kg, the sentence in most cases involves a conditional prison sentence in addition to the fine, as well as suspension of the offender's driver's license for a minimum of one year. For higher BACs, the sentence is unconditional imprisonment in addition to the fine, as well as suspension of the driver's license for a minimum of two years. Repeat offenders receive stronger sentences (Christophersen et al. 2016). The sentencing is the same for BZDs and z-hypnotics at three defined concentration levels (Vindenes et al. 2012) if the driver does not have a valid prescription. A suspected drug-impaired driver who tests positive for a psychoactive drug obtained with a valid prescription and used in accordance with recommended doses cannot be judged according to the legislative limit alone (Vindenes et al. 2012). Instead, an expert report is composed that takes into consideration the results of the clinical test of impairment (Bramness et al. 2003), drug concentrations present in the blood sample, and medical history of the patient in order to evaluate the extent of the driver's impairment. If the medical doctor who examined the driver concluded that he/she was significantly impaired or intoxicated, the driver might be sentenced for DUI, but the judicial process requires an expert witness statement granted by a clinical pharmacologist.

The most common reasons for DUI suspicion are involvement in vehicle crashes, erratic or suspicious driving, and reports of suspected DUI received by police from other motorists; a small proportion of cases involve arrest during routine roadside checks. The number of suspected drug-impaired drivers has increased steadily over the last 40 years, from less than 500 in 1980 to more than 6000 in 2017. The annual number of blood samples taken in suspected DUID cases increased by 20% after the introduction of legislative limits (3320 cases in 2010 and 3970 in 2013). The number of samples with at least one drug above the per se limit corresponding to a BAC of 0.20 g/kg increased by 17%, while the number of expert witness statements was reduced by half (Vindenes et al. 2014). The most frequently detected compounds in blood samples from suspected DUI offenders besides alcohol during the period 1990–2015 were benzodiazepines (BZDs), tetrahydrocannabinol (THC), amphetamines, and opioids (Valen et al. 2017); multi-drug detections were common.

All psychoactive medicines registered in Norway that have the potential to increase vehicle crash risks have been labeled with a red warning triangle for many years. There have been concerns that patients taking medicinal drugs in accordance with prescribed doses may be apprehended by the police under suspicion of DUID. The aim of this study was to investigate whether the implementation of legislative limits for medicinal drugs had resulted in arrest for suspected DUID of a large number of patients using medicinal drugs as prescribed by their physician. In addition to facing arrest by the police per se, these patients incur additional problems, namely, submitting to a police physician for blood sampling and a clinical examination and having their driver's license suspended for approximately three weeks until drug analysis and expert witness statement reports to the police are complete, all of which represent substantial inconveniences.

Materials and methods

All blood samples from suspected DUID offenders are submitted to the National Forensic Toxicology Laboratory in Oslo, which during the study period from 2013 to 2015 was operated by the Norwegian Institute of Public Health (NIPH). Analytical findings were recorded in the Norwegian Forensic Toxicology Database.

During the study period, all blood samples were analyzed using standard protocols and analytical methods accredited by Norwegian Accreditation (Lillestrøm, Norway). This included primary screening for all compounds on the assigned legislative limit list (BZDs, z-hypnotics, opioids, stimulants, and certain hallucinogens) as well as other commonly used drugs (e.g., pregabalin and tramadol) using ultra high-performance liquid chromatography-mass spectrometry (UHPLC-MS); drug detection was confirmed and quantified by alternative methods (Valen et al. 2017). A safety margin of 34% was deducted from the quantified concentrations for all BZDs and z-drugs included in this study (Kristoffersen et al. 2016).

Data on suspected drug-impaired drivers apprehended by the police during the study period were extracted from the Norwegian Forensic Toxicology Database. We chose to investigate the most commonly prescribed medicines, including the BZDs alprazolam, diazepam, clonazepam, oxazepam, and nitrazepam, and the z-hypnotics zopiclone and zolpidem. We selected cases with only a single detected BZD or z-hypnotic in the blood sample because a combination of two or more such compounds and combinations of one BZD with other psychoactive drugs do not correspond with the recommendations for drivers (Norwegian Directorate of

Table 1. Legislative limits, maximum allowed daily doses, and finding of benzodiazepines (BZDs) and z-drugs in samples of whole blood from suspected drug-impaired drivers in Norway from 2013 to 2015.

	Alprazolam	Diazepam	Clonazepam	Nitrazepam	Oxazepam	Zolpidem	Zopiclone	Total
Legislative limit (ng/mL)	3	57	1.3	17	172	31	12	–
Maximum allowed daily dose (mg)	1 mg × 2	5 mg × 2	0.5 mg × 2	7.5 mg	10 mg × 3	10 mg	7.5 mg	–
Expected maximum therapeutic concentration (ng/mL)	27.8	213.6	11.1	101.3	974.9	64.6	27.2	–
Number of drivers testing positive for BZDs or z-drugs (n)	1073	2852	4656	566	471	204	426	10248
Single drug findings ≥ legislative limits[a], % (n)	2.4 (26)	2.0 (57)	3.6 (168)	1.4 (8)	4.9 (23)	27.0 (55)	12.4 (53)	3.8 (390)
Single drug findings ≥ maximum therapeutic concentrations[a], % (n)	1.8 (19)	0.7 (19)	2.2 (102)	0.7 (4)	1.1 (5)	26.0 (53)	7.7 (33)	2.3 (235)
Single drug concentrations above legislative limits but below maximum therapeutic concentrations, % (n)	0.7 (7)	1.3 (38)	1.4 (66)	0.7 (4)	3.8 (18)	1.0 (2)	4.7 (20)	1.5 (155)
Single drug concentrations below legislative limits	0.2 (2)	0.8 (24)	0.1 (4)	0.7 (4)	2.1 (10)	3.9 (8)	5.9 (25)	0.8 (77)
Females, %[b] (n)	11.1 (1)	22.6 (14)	21.4 (15)	25.0 (2)	39.3 (11)	60.0 (6)	57.8 (26)	32.3 (75)
Age > 40 years, %[b] (n)	33.3 (3)	48.4 (30)	42.9 (30)	75.0 (6)	50.0 (14)	70.0 (7)	91.1 (41)	56.5 (131)

[a]An analytical safety margin of 34% was deducted from quantified drug concentrations in whole blood.
[b]Percent of drivers with single drug concentrations below the expected maximum concentration when taking maximum allowed drug doses.

Health 2011). Samples with BAC ≥ 0.2 g/kg, samples testing positive for more than one BZD or z-hypnotic, as well as samples testing positive for any other psychoactive substance in addition to one BZD or z-hypnotic were thus excluded.

The Norwegian Directorate of Health (2011) has published limits for daily doses of medicinal drugs for drivers. If a patient requires larger daily doses, their driver's license will be suspended. The expected maximum drug concentrations were estimated for the inter-dosing levels at steady state according to the following formula:

$$\text{dose} \times \text{drug half} - \text{life} \times 1.44/\text{dosing interval} \times \text{volume of distribution}$$

(Rowland and Tozer 2010).

Volumes of distribution for different drugs were applied as indicated by Dollery (2011). Drug doses and drug half-lives were as given in the guidelines from the Norwegian Directorate of Health. A plasma/whole blood concentration ratio of 1.8 was applied for diazepam and 1.54 for clonazepam (Moffat et al. 2011). For the other benzodiazepines/z-hypnotics the ratio was not found to deviate significantly from 1 (range of values retrieved 0.7 – 1.35) (Longo et al. 2001; Moffat et al. 2011; Verstraete et al. 2011). To ensure maximum values, the longest half-life within the given range and the lowest volume of distribution (if the range was provided) were chosen for the estimates. The blood drug concentrations measured in the selected samples were evaluated against the legislative limits and against expected maximal blood concentration levels after recommended therapeutic use (Table 1).

Ethics

According to the Norwegian Research Ethics Act of June 2006 and the Act on Medical and Health Research of June 2008, projects handling data anonymously do not require approval from the Regional Committee for Medical Research Ethics. Only anonymous data were used in this study in accordance with the data processing agreement with the Norwegian Higher Prosecuting Authority, which is the legal owner of forensic materials in Norway.

Results

From 2013 to 2015, the blood samples of 17 201 drivers arrested due to suspected DUID were received at the NIPH for analysis. BZDs or z-drugs were detected in 10 248 (59.6%) of the blood samples; only one BZD or z-drug was detected at or above the legislative limit in 390 (2.3%) of the total number of samples collected from drivers suspected of DUI by the police. Table 1 shows an overview of the total number of individual samples with BZD and z-drug detections.

The most frequently detected drug among the selected cases was clonazepam, occurring in a total of 4656 cases. In only 168 (3.6%) of these cases, clonazepam was the only substance detected in these blood samples in concentrations above the legislative limit; the remaining drivers had clonazepam combined with other medicinal or illicit drugs or with BAC above the legislative limits.

For other BZDs, the vast majority constituted combinations with other drugs; single drug detections ranged from 1.4% of the samples with nitrazepam above the legislative limit to 4.9% of the samples with oxazepam above the legislative limit. Among drivers with concentrations of zopiclone or zolpidem above the legislative limits, the proportions with only one substance detected were higher: 27.0% of the samples with zolpidem above the legislative limit and 12.4% of the samples with zopiclone above the legislative limit (Table 1).

Expected blood concentrations based on maximum therapeutic repeated doses that are compatible with retaining a driver's license are also given in Table 1. The results indicate that among the 390 drivers with only one BZD or z-hypnotic above the legislative limit, 235 drivers (60.3%) had used more than the maximum dose. Thus, 155 drivers suspected of DUID could have used recommended therapeutic

doses and had blood drug concentrations above the legislative limit; this corresponds to 0.9% of the suspected DUID offenders. In addition, 77 drivers had blood drug concentrations below the legislative limit, corresponding to 0.4%. Nearly one-third of these were females and more than half of them were above 40 years of age.

Discussion

BZDs or z-drugs were detected in the majority of the blood samples from suspected drug-impaired drivers, but only 2.3% of all suspected drug-impaired drivers tested positive for only one drug of this type. More than half of the drivers who tested positive for a single BZD or z-hypnotic with blood concentrations above the legislative limit seemed to have taken more than the maximum dose limit determined by the Norwegian Directorate of Health (2011) for motor vehicle drivers.

Clonazepam was the most frequently detected BZD, despite the fact that it is rarely prescribed in Norway. It is well known that large quantities of clonazepam tablets have been imported illegally into Norway and sold to drug users on the street. It is one of the medicinal drugs seized most frequently by police and customs and has very often been detected in samples from arrested drug-impaired drivers (Bogstrand et al. 2011). It is likely that many of the clonazepam-using drivers in our study had obtained the drug from the illicit drug market (Bogstrand et al. 2011); they were also among those with low blood drug concentrations.

The results also show a relatively high prevalence among females for both z-hypnotics and some BZDs (nitrazepam, oxazepam) (Table 1). According to data from the Norwegian Prescription Register, the z-hypnotics and some BZDs are more often prescribed to females; these drugs are also more often prescribed to patients over the age of 40 according to the Norwegian Prescription Database (http://www.norpd.no/. . . . .).

In total, 1.3% of the suspected drug-impaired drivers had BZD or z-hypnotic concentrations that complied with the allowed therapeutic dosing, 0.9% with blood drug concentrations above the legislative limit. These drivers would probably not be sentenced to DUID if they had a valid prescription and few to no signs of impairment upon clinical examination.

Among the drivers in this group, almost one-third were women and more than half were above 40 years of age, similar to the proportions of women and drivers above 40 years of age in random road traffic (Gjerde et al. 2013; H. Gjerde, personal communication). Among drivers arrested by the police suspected for DUID from 2013 to 2015, only approximately 13% were female and nearly one-third were above 40 years of age, according to data extracted from the Norwegian Forensic Toxicology Database (Division of Forensic Sciences, Norwegian Institute of Public Health, Oslo, Norway). Thus, drivers with concentrations of BZDs or z-drugs in accordance with maximum allowed daily drug doses were more similar to drivers in random road traffic than to those arrested for DUID. Our hypothesis is that the reason for suspecting these drivers of DUID might to a lesser extent be dangerous or erratic driving patterns, but more likely crash-involvement; in the latter cases, a blood sample may be taken for alcohol and drug testing without any suspicion or clinical indication of impairment.

Our results thus show that the implementation of legislative limits for BZDs and z-hypnotics may have contributed to problems for a very small number of patients using therapeutic doses in accordance with the maximum doses that apply to drivers.

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