DRUID – review and perspective

Driving under Influence of Drugs, Alcohol and Medicines

ICADTS meeting
Oslo, 24.08.2010
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What is DRUID

- 6th EU Framework Program project
- Start: 15.10.2006
- Duration: 5 years
- Budget: 24 Mio. €
- EU contribution: 19 Mio. €
- 37 partners
- 17 EU Member States and Norway
Unique features of DRUID

- Integrative effort to address the danger of all psychoactive substances in traffic: alcohol, medicines and illicit drugs
- European dimension
- Common objectives - but national legal peculiarities
- Deals with a very sensitive problem: ethic issues have to be tackled correctly
- Brings together partners that have different attitudes and different scientific traditions concerning the project subjects
European Commission requests

- To recommend reference thresholds for driving a motor vehicle
- To deliver reference studies for alcohol, illicit drugs and medicines
- To evaluate and recommend best on-road testing devices
- To enable legislators to introduce a labeling system for medicinal drugs compatible with the European classification
- To enable legislators to propose/impose effective and flexible driver rehabilitation schemes
- To develop strategies of driving bans addressing both the road safety and mobility objectives
- To develop guidelines concerning doctors’ responsibility vis-à-vis patients consuming psychoactive substances and their possible role in road safety assurance
Work Packages

0 – Management
Financial and scientific co-ordination

1 – Experimental Research
Recommendation of thresholds for certain psychoactive substances

2 – Epidemiology
Prevalence of drug-driving in Europe and risk estimation

3 – Enforcement
Evaluation of screening devices to detect drug-driving and training measures for road traffic police

4 – Classification
Establishing a classification and a labeling system for medicines affecting driver fitness

5 – Driver Rehabilitation
Evaluation of existing rehabilitation strategies and recommendations of „good practice“

6 – Withdrawal
Definition of strategies for driving bans

7 – Guidelines and Dissemination
Development of guidelines and information materials for the general public and health care professionals
Work package 1 - objectives

- Risk estimation for driving under the influence of psychoactive substances:
  - Conducting experimental studies
  - Developing the methodology for integration of results different studies (experimental, epidemiological, etc.)
- Recommendation of regulations against DUI
- First conclusions will be presented on Wednesday at the DRUID Experimental Workshop
Work package 1 - challenges

- Ethical and judicial restrictions
- **Calculation procedure** to integrate results of the different studies despite differences in empirical methods:

<table>
<thead>
<tr>
<th></th>
<th>Epidemiology</th>
<th>Experiment</th>
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<tbody>
<tr>
<td>Statistical analysis</td>
<td>Risk estimation calculated with odds ratios (OR)</td>
<td>Interference statistics</td>
</tr>
<tr>
<td>Dependent variable</td>
<td>Number of accidents</td>
<td>Driving parameter (e.g. reaction time)</td>
</tr>
<tr>
<td>Independent variable</td>
<td>Substance concentration in blood (2 ng THC/ml plasma)</td>
<td>Amount of substance consumption: Dosage (2 mg THC smoked)</td>
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Work package 2 - objectives

- To assess the situation in Europe regarding the problem of alcohol and/or other psychoactive substances in relation to road safety
- To assess the accident risk for psychoactive substance impaired driving
- To assess the risk of a fatal accident due to psychoactive substance impaired responsible driver
- To identify characteristics of psychoactive substances impaired drivers
Work package 2 – challenges and response

Challenges

• In almost all roadside surveys only saliva samples are collected
• In hospital studies blood samples are collected
• Conversion method must be developed

Response

• Working Group was established to calculate conversion factors
• Literature search and DRUID data analysis in order to establish conversion factors (ongoing)
• First results will be presented today at the DRUID Epidemiological Workshop
Work package 3 - objectives

• A set of user specifications, functional requirements and recommendations for on-site drug screening devices

• Recommendations for the roadside selection procedure of drivers of drug-related impairment, focused on the reliability of the selection procedure

• A cost-benefit analysis of drug-driving enforcement by the police
Work package 3 - results

- 8 out of 13 devices are qualified as “promising” by the police
- Police user requirements have been formulated concerning:
  - Training of police officers
  - Operational testing of drivers at the roadside or at the police station
  - Documentation: user manuals and electronic readers in native languages
- In combination with blood tests only one device was evaluated positively
- After completion of ROSITA (2000) and ROSITA II (2005) the quality and capacities of devices with regard to specificity and sensibility were not substantially improved
Cost-benefit analysis conclusions:

- The choice of screening device might make a difference with regard to resulting CB ratio.
- Increased drug driving enforcement based on roadside saliva screening is potentially beneficial – especially for countries with lower baseline enforcement level.
- Yet, if the drink driving enforcement will be decreased for the sake of increasing the drugs driving enforcement, the net benefit will decrease.
Work package 4 - objectives

• To reach a broad consensus among involved authorities, the industry and healthcare institutions on the criteria and the methodology for establishing a common European categorisation system for medicinal drugs and their impact on fitness to drive

• To propose a labelling system for relevant therapeutic groups of medicines available on the market.

• To develop a methodology to continuously update this system (concerning new medicines)
Intake of medicinal drugs p.p., Germany

DDD = Defined Daily Doses
• Reaching a broad **consensus** is pre-conditional to successfully implementing a classification system

(i.a. EMA, national regulatory authorities, scientists, pharmaceutical industry, medical professionals, lawmakers)

• Panel of experts within DRUID to reach consensus involving all participating groups on:
  – **4-level-classification system** for medicines
  – Proposal to EMA to **modify SPC**

  EMA has accepted DRUID recommendation and implemented it in 2009
# 4-level-classification system

<table>
<thead>
<tr>
<th>Category 0</th>
<th>no or negligible influence</th>
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<tr>
<td>Presumed to be safe or unlikely to produce an effect on fitness to drive.</td>
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<tr>
<th>Category 1</th>
<th>minor influence</th>
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<tr>
<td>Likely to produce minor adverse effects on fitness to drive.</td>
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<th>Category 2</th>
<th>moderate influence</th>
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<tr>
<td>Likely to produce moderate adverse effects on fitness to drive.</td>
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<tr>
<th>Category 3</th>
<th>major influence</th>
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<td>Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.</td>
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Labelling medicines:

“French Model”

Be careful!
Read the patient information leaflet before driving.

Be very careful!
Don’t drive without the advice of your GP or pharmacist.

Attention: danger!
Do not drive. Seek medical advice before driving again.

DRUID Model

Warning level

0 1 2 3

Warning level

0 1 2 3

Warning level

0 1 2 3

Dr. Horst Schulze, BASSt, Germany
DRUID contributions

- **Incorporating** all relevant medicines available in Europe in the new classification system
- Developing **Fact sheets** for all medicines of the group N - nervous system (ATC-Code) for physicians including information on:
  - Undesired influence on driving performance
  - Physicians advises to patients
- Introducing an **algorithm** for classification of the new substances entering the market
Application by physicians and pharmacists

• Assessment of possibilities on integrating the new classification system in the physicians’ praxis and using it for dissemination

• Pilot studies involving physicians, pharmacists and patients in three Member States (B,E,NL):
  – **Training for** physicians and pharmacists (information seminar)
  – Distribution of **Information** (brochures, internet, etc.)
  – Using a **modified PC-software** (Integrating the warning notices in already existing physicians’ office software and linkage to DRUID data bank)

• Developing an Internet based database (website) to inform medical personnel
Policy implications

• European Commission and Member States have the decision competence

• An EC directive on medicine classification would be a preferred solution from a point of view of the DRUID consortium

• Some EU member states (France, Spain) have made already efforts to introduce a medicines classification system with regard to impairing effect

• DRUID results are compatible with any existing national system and could be integrated in them

• DRUID results are compatible with PC based reference systems for physicians available currently on the market and could be integrated in these instruments
Work package 5 - objectives

- Identification of different types of DUI
- Review of existing assessment procedures and rehabilitation measures
- In-depth studies on reasons for recidivism drivers who participated in rehabilitation programmes
- Analyses of existing quality management systems
- Development of an evaluation instrument for best practises
- Validation of existing rehabilitation schemes
- Recommendation of rehabilitation schemes for drivers, adapted to his/her personal situation
Results of Provider Survey

• The survey revealed that currently at least 47 providers in 12 European countries offer DR services on a regular base.

• In total 87 DR programs are in use, 53 for DUI offenders, 21 for DUID offenders and 13 for mixed groups.

• Participation in DR programs is most often legally regulated and often linked to re-licensing.

• Participation is not always mandatory, about half of the programs are voluntary.

• Addicts are mostly excluded.

• Half of the providers report to have a quality assurance system.
Results of a Case-Control Study to Analyse the Reasons for Recidivism of Drivers Who Participate in DR Programmes

• 303 recidivists are compared with a matched control group of 303 non-recidivists

• Risk profile of DUI offenders who might not profit from a DR course:
  – high BAC level or breath test refusal
  – prior DUI offences and consequently longer suspension period
  – habitual drinking pattern and periods of increased alcohol tolerance
  – denial of alcohol-related health problems
  – unrealistic self-perception and self-reflection
Assignment to Driver Rehabilitation

- Legal regulation of DR participation in order to systematically bring offenders to intervention
- Linkage of participation and licensing procedure, e.g. participation in DR as a condition for the reduction of the suspension period or as a condition for license re-instatement.
- Formal criteria for directly assigning DUI/DUID offenders to DR or at least to counselling in order to initiate problem awareness and screen for a severe alcohol or drug problem.
- Driver assessment prior to DR in case of suspicion of addiction in order to match offenders to appropriate treatment.
- Mandatory DR participation for high-risk offenders, repeat offenders and young (novice) drivers.
European Initiative

WP5 strongly supports a preventive DR concept which is compatible with the overall objective of mobility of European citizens without endangering traffic safety. Therefore...

• DR for DUI/DUID offenders should be an integrated part of a comprehensive countermeasure system against intoxicated driving in Europe.

• in a next working step, European guidelines for legally regulated DR systems and procedures should be established taking the WP 5 results into account.
Work package 6 -

Objectives

• To collect and evaluate information regarding withdrawal practices in various European countries based on former studies
• To assess the effects of various strategies regarding withdrawal of driving licence with focus on the conditional driving license withdrawal
• To develop recommendations taking into account all facets of the problem

Interim results

• Overview of withdrawal strategies completed: 27 EU Member States, Croatia, Norway and Switzerland were involved
Work package 7

Objectives

• To develop guidelines for physicians and pharmacists to select the least impairing medicine
• To develop information materials for risk communication aimed at the general public, drivers as patients, young drivers, health care professionals and politicians
• To evaluate practice guidelines and protocols used in day-by-day medical and pharmaceutical activities

Interim results

• PC-based tool for physicians and pharmacists to be used for assessment of impairing effect of a medicine and for information
• Recommendations for improving medical guidelines (assessing fitness to drive for patients using psychotropic medicines)
DRUID main results at a glance

- **Methodological framework** for integrating results of experimental and epidemiological studies
- **International database** of samples collected Europe-wide from 50,000 drivers and 3,000 injured drivers using uniform study design
- Recommendations concerning the **practical use** of oral fluid screening devices and Cost-Benefit Analysis of increased enforcement applying such devices
- European consensus on **4-level-classification system** for medicines (more than 600 medicines reviewed and classified)
- Overview of European **rehabilitation schemes**, including recidivism reasons analysis, quality assurance measures and recommendations concerning best practices
- Overview of **withdrawal/ licensing** legislation in Europe
- Recommendations for **improving medical guidelines** (assessing fitness to drive for patients using psychotrophic medicines)