DRUID – review and perspective

Driving under Influence of Drugs, Alcohol and Medicines

ICADTS meeting

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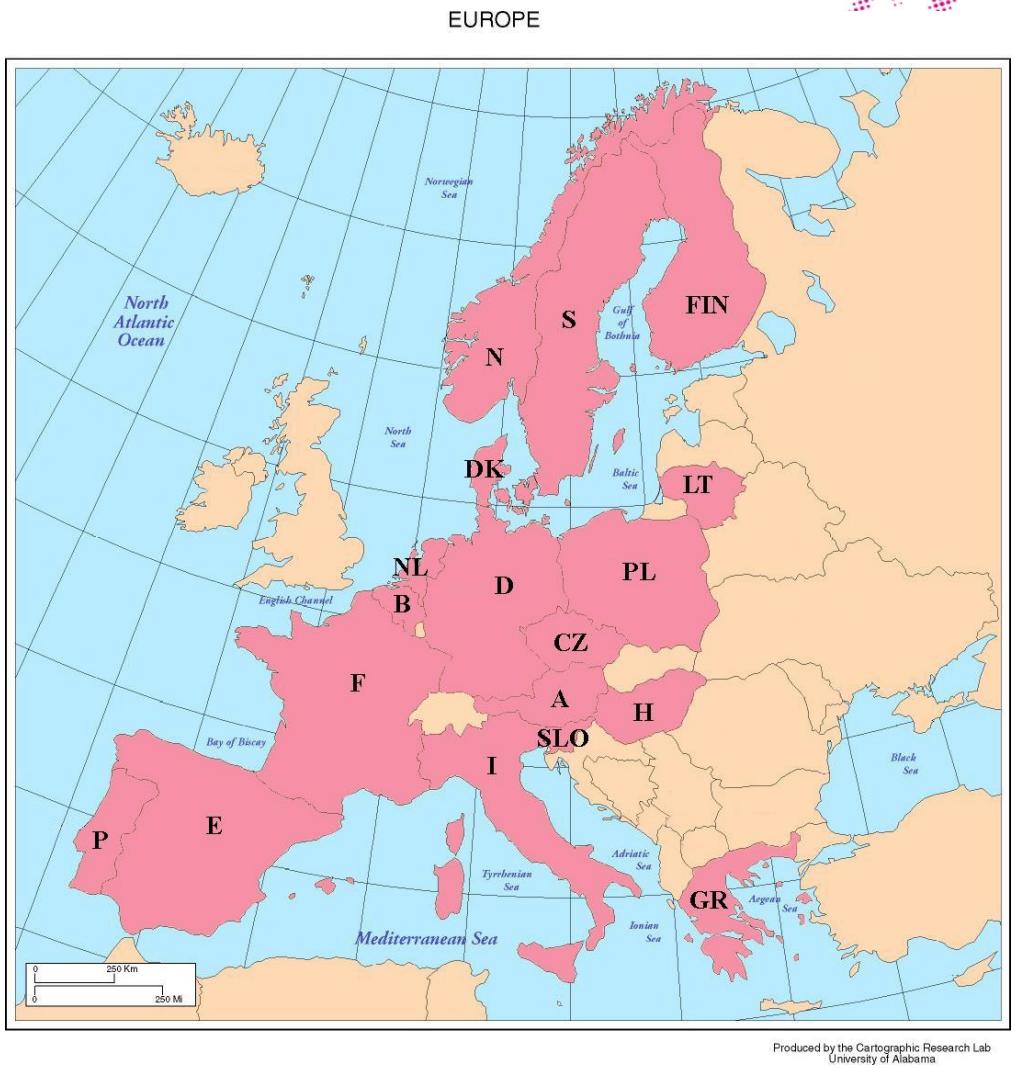
What is DRUID

- 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:

	Epidemiology	Experiment
Statistical analysis	Risk estimation calculated with odds ratios (OR)	Interference statistics
Dependent variable	Number of accidents	Driving parameter (e.g. reaction time)
Independent variable	Substance concentration in blood (2 ng THC/ml plasma)	Amount of substance consumption: Dosage (2 mg THC smoked)

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

Work package 3 - results

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

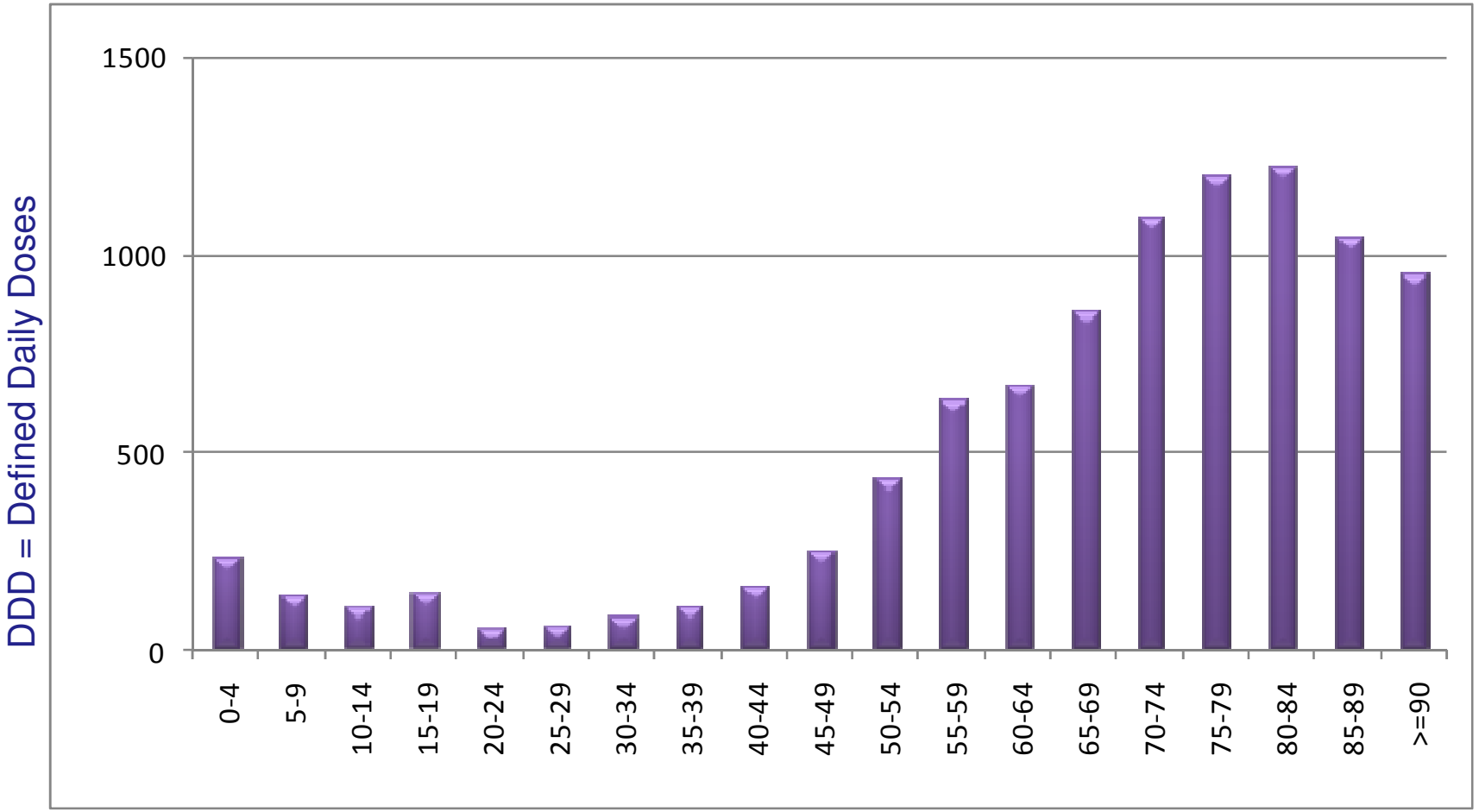
Work package 4 - objectives

- 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



European approach to a classification system

- 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

Category 0	no or negligible influence
Presumed to be safe or unlikely to produce an effect on fitness to drive.	
Category 1	minor influence
Likely to produce minor adverse effects on fitness to drive.	
Category 2	moderate influence
Likely to produce moderate adverse effect on fitness to drive.	
Category 3	major influence
Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.	

Risk communication

Labelling medicines:

"French Model"

Be careful!

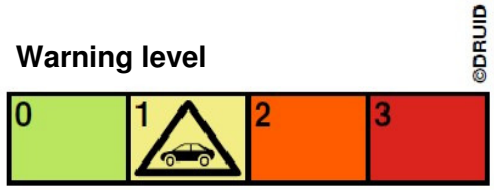
Read the patient information leaflet before driving.

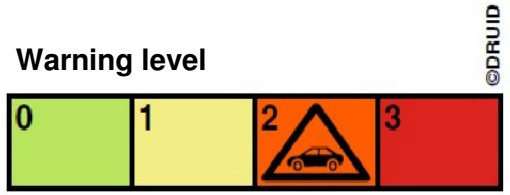
Be very careful!

Don't drive without the advice of your GP or pharmacist.

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

DRUID Model





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

Work package 5 - results

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.

Work package 5 - results

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

Work package 5 - recommendations

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.

Work package 5 - recommendations

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 psychotropic medicines)