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DRUID
Driving under the Influence of Drugs, Alcohol and Medicines

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Report on the implementation, evaluation and new technologies of practice guidelines and information materials

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Task 7.4: Evaluation and implementation of new technologies

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Note

This deliverable is divided in two main parts. **Part A** provides a general overview of the research undertaken and cross-countries' comparisons. **Part B** includes in depth analyses and descriptions of each country study.

Glossary

In order to ensure the delivery of a harmonised effort some terms will be clarified regarding how and why they are used in this deliverable.
The term *ICT literacy* which is a separate section in the questionnaire administered to the participants reflects their *familiarity* rather their competence in operating a PC.
Health professionals in this study are: a) physicians, b) pharmacists, and c) nurses.

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Executive Summary

PART A

Introduction: Research has shown that certain diseases and disorders may affect driving performance. However, the medicines prescribed for many diseases and disorders can make us just as dangerous being behind the wheel. Current research focuses primarily on the Central Nervous System impairment brought even by some over-the-counter medicines. The realisation of the need for alterations in existing guidelines on the way physicians and pharmacists prescribe and dispense medicines is a general goal of WP7. Experts have formulated new guidelines and protocols within the framework of the European DRUID project.
Professional guidelines provide the foundation for better and cost-effective practice. The rising of comparability in medical practice ensures the development of collaboration between research findings and evidence-based medicine. Increased application of methodological frameworks and criteria has increased the capacity of research-based evidence to derive information from relevant research outcomes. In other words, similar clinical practices allows for translation of their findings into applicable ideas.
Extensive reviews on guidelines implementation have half-heartedly reported limited and non-consistent effect of guidelines in changing physicians' behaviour (Cabana et al, 1999). The processes and factors involved in health care professionals' adherence to guidelines have not been investigated in depth and little is known with regards how it could successfully be succeeded (Cabana et al., 1999). The adopted theoretical model was the one proposed by Cabana and colleagues (1999) and advocates that guidelines adherence should follow change in behaviour, knowledge and attitudes.
Prescribing and dispensing guidelines developed within the DRUID project were evaluated in clinical practice settings as one of the tasks in Work Package 7. The primary goals of this task were to evaluate the effectiveness of the implementation of developed protocols and guidelines on healthcare professionals' (physicians, pharmacists, nurses) attitude, knowledge and reported behaviour via two different approaches: i) by using an integrated (ICT) tool (additional software integrated into the ICT software used by the professional in his daily practice; country specific development) and ii) by using a non-integrated tool for presenting the protocols and guidelines (ICT tool developed within the framework of the project).

Materials and Methods:

The target populations were health care professionals in the primary care setting: i) physicians (Belgium, Spain), ii) pharmacists (Belgium, the Netherlands, Spain) and iii) Nurses (Spain).
In addition, a "pure" control group was added to evaluate the effectiveness of current practices with no DRUID-relevant information.
Participants were introduced to the tools/software(s) used through a training scheme. Some of the participants did not receive training (e.g. the integrated group of physicians (SoSoeMe)). In addition, participants were informed about the DRUID guidelines regarding driving and medicines intake. The time sequence involved a standard procedure of recruitment, briefing, and consent. Participants filled in the pre-questionnaire at the start of their training and a post-questionnaire after six months of using the DRUID guidelines in their practice).
They used the software during their daily practice for either prescribing or dispensing medicines depending on the professional groups they belonged to and after the testing period ended they filled in a post-questionnaire investigating the same artefacts more or less as the initial one in order to enhance and allow comparability and evaluate the effectiveness of the tool and the applied guidelines.
Procedural differences exist and were discussed in depth in the respective reports; however, the framework was not significantly violated allowing for similar up to a certain extent data analysis.

A step further in analysis (Part A) was the creation of composite scores to facilitate between countries potential comparisons and present the opportunity of an overall evaluation of the effect of guidelines. Overall composite scores were based on commonalities' analysis across national studies with clustering of questionnaire items taken into account. Composite scores were created for three behavioural clusters: a) Reported Behaviour, b) Attitudes/Awareness, c) Actual Knowledge. The Reported Behaviour cluster included question items about how much health professionals take into account the impairing effect of medicines in their daily practice. The Attitudes/Awareness cluster included items about health professionals' attitudes towards prescribing/dispensing drugs that may have an impairing effect on driving fitness. The Actual Knowledge cluster included items about health professional's knowledge of specific effects of certain medicines on driving fitness. These clusters correspond to questionnaire items that were common for all studies.

Results:

Physicians
Almost 74% of participants received no education regarding medicines and driving during their academic studies and their professional participation in post-graduate education.
The knowledge received during the training did change their knowledge about the potentially detrimental effects of medicines on driving fitness for more than half the participants (55%). After the implementation of DRUID guidelines, a 10% increase difference in the positive change in Reported Behaviour was observed in the overall physicians' samples across the country studies. Changes only in Reported behaviour for the physicians have been detected mainly for the following reasons. Reported behaviour questionnaires are straightforward, therefore easier to detect change. Usually, question items related to knowledge and attitudes/awareness have more associations with other personality characteristics such as target characteristics (e.g. self-esteem, intelligence) and other source (e.g. atracttiveness) and message characteristics (e.g. nature), therefore it is more difficult to be studied and isolated, especially in a cross-country study with limited time available to extrapolate findings of certain magnitude. The same outcome with regard to Reported Behaviour holds true for pharmacists as well.

Perhaps pharmacists are more used to focus on medicines side effects and instructing patients on how to use their medicines safely, physicians might be more focussed on disease issues, anamnesis and treatment decisions, and less involved in deciding on medicines' behavioural side effects, such as impairing effects on driving fitness.

Pharmacists
The majority of pharmacists (67%) had not received any type of (post-graduate) education on medicines and driving with the exception of the participants in the Spanish study where half the participants had received relevant education (51%).
Pharmacists showed an overall positive change in all behavioural clusters under study.
Pharmacists incorporated driving related information in their daily dispensing practice. The DRUID guidelines were well received and viewed as an addition to existing guidelines.

Conclusions:
Part A
Positive change has been found for both professional groups but for pharmacists this was revealed for all clusters of behavioural items under investigation.
The application of DRUID guidelines was successful and pinpoints the readiness of health care professionals to adopt them. The findings should be treated with caution as extrapolations and generalisations are limited mainly because of design variations in the separate country studies. Moreover, these findings support the statement that guidelines are important and can improve the quality of health care. Physicians and pharmacists have shown a change in behaviour after the implementation of DRUID guidelines, therefore these guidelines could be successfully incorporated in existing decision support systems. These guidelines fill in an important "gap" linking prescribing and dispensing of medicine with both patient and road safety. Physicians are affected by the DRUID material training but this should not be a short-term endeavour but be flexible, adaptable, and personalized to local settings.

Overall

Overall, the country studies showed that decision support tools are welcome and usable, DRUID materials fulfilled a need and most participants anticipated the ultimate integration of these materials to their own software packages.

Based on the comments made by the health professionals within the country reports, the implementation of computerised guidelines and DRUID categorisation was highly accepted as practical information by both physicians and pharmacists and participants were willing to continue using the DRUID information if integrated in their prescribing and dispensing computer systems for easier incorporation in their daily practices. Participants offered ideas for future developments such as inclusion of other medicines in the categorisation scheme and the information should be adjusted to the native language. Future recommendations should also include specialized and elderly directed advices incorporated in the system and adaptation to other target groups and not only drivers (e.g. heavy machinery usage and senior people information).

A long term goal would be to evaluate the impact to the health care system, to various stakeholder groups associated with the implementation of health care professionals' guidelines and compare it with other related studies' findings. In addition, further research could facilitate its adaptation and customisation for different groups of health care professionals and national settings. A set of DRUID recommendations has been derived from the main conclusions of both composite cross comparisons and country studies. The key message is clear about the necessity of diffusion of DRUID information to physicians, pharmacists, and nurses in all clinical settings.

PART B

Belgium

Physicians study

Objective: To measure the effectiveness of physicians' training on the guidelines for prescribing medicines with an influence on driving abilities, as well as the use and user acceptance of the developed prescribing support tools in which medicinal risk classification system was integrated.

Method: The effectiveness was measured through the actual use rates of the integrated and stand-alone ICT support tool and in a questionnaire survey (compared to baseline measurement), after 6 months as a change in attitudes/awareness, knowledge and (reported) behaviour due to the implementation of the training. The study has a controlled experimental design, including pre- and post-conditions and includes two experimental (training + intervention) and one control group. (1) Integrated software group, SoSoeMe group: a group of physicians using the SoSoeme prescribing system in their daily practice. The DRUID WP4 and WP7 information was integrated into the SoSoeMe software. (2) Stand-alone software group, USB group: a group of physicians from East Flanders.The DRUID WP4 and WP7 information was delivered through an USB stick to be installed on the physician's computer, together with a paper tool or compendium including the same information. (3) Control group, a group of physicians in East Flanders. This group did not receive the DRUID information.

Results
Except for years practicing as a physician the three groups (SoSoeMe, USB and Control group) did not differ significantly regarding personal or practice related background variables**.** The three groups were similar with regard to information sources for medicinal driving risk, pre-level attitudes and awareness, knowledge, willingness to use a prescribing support tool that takes driving risks into account). Two significant differences were found though with regard to reported behaviour (1) and knowledge (1): the SoSoeMe group at baseline significantly indicated to provide less detailed information when prescribing as compared to the USB and Control group. On the knowledge question on Amitriptyline the participants from the control group gave significantly less correct answers than the other two groups. The participants in the present study (in all groups) had a high ICT familiarity. Despite the high use of the Internet and use of medical software only half of the physicians stated to have easy access to data and information on the topic 'medicines and driving'. Overall the physicians had a positive attitude towards the importance of being well informed on the topic drugged driving and the potential role they can play in providing information on the potential risk of medicines to the patient. Remarkably, half of the physicians in all groups felt not being well aware of the effects of medicines on driving skills. In general a low knowledge on the topic 'medicines and driving' was measured. The physicians were more informed about legal obligations and responsibilities of physicians/pharmacists and patients.

Little pre-post questionnaire change was found on attitudinal level. a significant pre-post change was found Only for the SoSoeMe group with regard to reported behaviour. The SoSoeMe participants provided the patient significantly more with written information materials after the trial period. Two positive pre post change trends were found for the USB group on the questions if the physicians provided a patient with written information materials and if the discussed medicinal drug consumption and driving related responsibility issues with the patient. However not significant, it can be said that a positive change in reported behaviour was measured after the training/ trial period. No significant pre-post changes were found with regard to the knowledge questions in the SoSoeMe group and the USB group. For the control group a significant negative pre post change was found for both composite scored and the question on Amitripthyline. The physicians in the control group gave significant less correct answers in the post questionnaire.

Conclusions. we observed few significant pre-post changes in attitude & awareness, reported behaviour and knowledge. We did expect, conform with the results from the

pharmacist study, to find more (significant) positive changes for the SoSoeMe group. A possible explanation could be the lack of contact between the research team and the participants. This group had no training and received no newsletters during the trial period. Also no follow up (e.g. when some problems raised when updating the software) could be foreseen. At the start of the study this group was not very eager to fill in questionnaires but they did want to use the information integrated in SoSoeme. About 90% of the physicians that used SoSoeMe had used the information on a quite regular base. Their feedback was very positive and all physicians wanted a continuation of the DRUID information into their daily used software. Therefore the lack of positive change found in attitude, behaviour and knowledge should be nuanced and it is very plausible that the found results are an underestimation of the real impact of the study.

The lack of (significant) pre post changes in the USB group could be explained by the low use of the USB tool. Few physicians used the tool, not even on a sporadic base, but several physicians used the manual very often. Most physicians did prefer a manual above the tool.

In the control group significant pre-post changes were found on the knowledge questions. A possible explanation could be that the physicians were, after filling in the pre-questionnaires, confronted with their low knowledge on the topic 'medicines and driving', and paid more attention to the potential risk of medicines on driving.

The physicians are willing to use a prescribing support tool when this tool is integrated in their daily used software, asks no extra efforts or time to update, is easy to use and contains practical information. The physicians underlined the need for more information on the topic 'medicines and driving'. This information should not only be made available to physicians but also be integrated in the patient leaflet or on the medicine box.

Pharmacists study

Objective: To measure the effectiveness of pharmacists' training on the developed dispensing guidelines for delivering medicines with an influence on driving abilities, as well as the use and user acceptance of the developed dispensing support tools in which the medicinal risk classification system was integrated.

Method: The effectiveness was measured through the actual use rates of the integrated and stand-alone ICT support tool and in a questionnaire survey (compared to baseline measurement), after 6 months as a change in attitudes/awareness, knowledge and (reported) behaviour due to the implementation of the training**.** The study has a pre- and post-design and includes 2 intervention groups (training + implementation support tool) and one control group: (1) An integrated software group, the ViaNova group: a group of pharmacists using the ViaNova dispensing system in their daily practice. (2) Stand-alone software group (USB group): a group of pharmacists in East Flanders. The DRUID information was delivered through an USB stick to be installed on the pharmacists' computer. (3) Control group: a group of pharmacists in East Flanders. This group did not receive the DRUID information.

Results

The three groups (ViaNova, USB and Control group) did not differ significantly regarding personal or practice related background variables except for the number of inhabitants in the practice area (a measure of more rural versus more urban practice area)..

The three groups were quite similar with regard to pre-level ICT familiarity, attitudes, awareness, reported behaviour and knowledge. The participants in the present study (in all groups) had a high general ICT familiarity and indicated a high access to information (on the potential effect of medicines on driving). Despite the high access to information the participants did report a lack and need for information, and there seemed to be a low knowledge on medicinal driving risk specifics. The pharmacists had positive attitudes towards the importance of being well informed on the topic and on the potential role they can play. Contrary to the positive attitudes, low frequencies of reported behaviour that considers medicinal driving risks' were found prior to the training/intervention in all groups. With regard to user acceptance of possible dispensing support tools, more than 90% of the ViaNova respondents and over 70% of the respondents from the USB and Control group stated that they would be willing to use a dispensing support tool to easily find information regarding

medicinal drugs and driving. Their first choice was software integrated in the daily used software, second choice was a website, and third a manual; a stand-alone software (like cd-rom or USB stick) was generally not preferred.

Significant pre-post changes at composite score level were only found in the ViaNova group: reported behaviour and medicinal risk specific knowledge increased significantly. Furthermore, taking a look at the number of significant pre-post changes on individual statements or questions, the ViaNova group had in total 10 significant positive changes (on a total of 20 statements/questions), compared to just 2 in the USB group and none in the Control group. Little pre-post questionnaire change were generally found on pharmacists' attitudinal and awareness level. Very good results were found on the pre-post reported behaviour comparison of the integrated software group. Rather limited pre-post change was generally found on knowledge of individual medicinal risks on driving; this knowledge remained generally at a low level.

Conclusions. Most changes were found in the integrated ViaNova software group, as compared to far less in the stand-alone USB group and none in the Control group, after the DRUID training and intervention phase. Most positive changes were found on specific reported behaviour, on which the pharmacists were specifically trained. Almost no change on attitudinal level for none of the three groups was observed, which can be related to an already rather a priori good attitude towards the topic medicinal driving risks of the participating pharmacists. One could say that the pharmacists who participated in this study firmly underline the importance of being well informed and aware of the possible risks of medicines on driving. In other words their positive attitude was a motivation to take part in the present study. Although the training and 6 months trial increased some awareness for risks of medicines for driving (also related to fine-tuned knowledge about specific medicines' risks), more effort still seems to be required in order to further help pharmacists increase their awareness and knowledge.

The DRUID dispensing guidelines were well accepted and liked. What stands out most strikingly from all results (questionnaire changes, tools' observed use data and user friendliness rates, and mentioned requirements/wishes for dispensing support tools), is the importance of having a support system integrated in the daily dispensing software in order to be effectively used. The majority is willing to use a tool in their daily practice, as long as it is integrated into their daily software, updated automatically, easy to use, focus on first deliveries, cost- and time-efficient, contain concrete & detailed information and if possible safer alternatives.

The Netherlands

Background: The present study refers to the development, and consequent evaluation, of a training session that was carried out with the intention of informing Dutch pharmacists, who are not actively using their Pharmacom® computer system, about the influence of medicines on driving fitness. The materials provided during the training were developed within DRUID WP7 (task 7.4) and aim to assist pharmacists with more background information to be provided to patients while dispensing medicines that are known to influence driving fitness.

Objectives: i) to determine the effectiveness of pharmacists' training activities related with dispensing driving impairing medication as well as the use of ICT tools; ii) to determine the effect of the pharmacists intervention at the patient level by investigating a change in patients' knowledge, attitudes/awareness and (reported) behavior; and iii) to determine, the dispensing patterns of medicines that might impair driving fitness.

Methods: This study was conducted in the Netherlands and consisted of the training of community pharmacists who do not actively use the Pharmacom® system for the first-time dispensing counselling (EUB) and the second-time dispensing counselling (TUB), with respect to anxiolytic (ATC code: N05B), hypnotic (ATC code: N05C), and antidepressant (ATC code: N06A) medicines, known to impair driving fitness. Those pharmacists were randomly and equally distributed in the intervention group (pharmacists were given the training) and in the control group. The training was evaluated by means of a questionnaire that was presented to pharmacists before (T0) and 6 months after (T1) the training had been

carried out. The information that was provided to pharmacists regarding the information about the influence of medicines in driving fitness, which should be provided to patients while dispensing driving impairing medicines, was evaluated at the patient level. This was done by means of a patient questionnaire, sent to patients visiting the participating pharmacies and who were taking any anxiolytic, hypnotic or antidepressant medicine(s) for the first time before (T0) and 6 months after (T1) the training.

Results: A total of 277 pharmacists (26.9% response rate) responded to the invitation and agreed to participate in this DRUID study. Drop-outs were verified and the final number of participants was as follows: 49 in the intervention group and 42 in the control group, which means a total of 91 pharmacists enrolled in the study. Pharmacists' awareness about the side effects of medicines on driving skills significantly increased after the training (p-value < 0.001). Pharmacists' reported behaviour and actual knowledge significantly improved after the training. Pharmacists' user acceptance of the materials and usability of the tool was very positive. Pharmacists used the materials to train and inform their assistants but failed to share that information with general practitioners.

A total of 930 patients (15.2% average response rate) participated in the study (421 at T0 and 509 at T1). Regarding patients' knowledge about causes of road accidents, no significant differences were found between time measurements, despite a general improvement had been observed in the follow-up measurement. After the training, patients visiting pharmacists belonging to the intervention group were significantly more spontaneously informed about the influence of medicines on driving fitness than patients visiting pharmacists belonging to the control group (p-value 0.007). After receiving information about the possible impairing effects of the medicines, patients decided not to change their driving behaviour and no statistically differences were found between time of the measurement or between pharmacy group.

For the dispensing data analysis, only the data of 77 pharmacies (43 from the intervention and 34 from the reference group) was used. The mean number of patients registered in both groups of pharmacies was similar. The number of new users of N05B, N05C and N06A medicines was always higher during the follow-up period, but the difference was never statistically significant. Regarding the dispensing pattern of these groups of medicines, no changes in the follow-up period were verified. Considering the 3 categories on the different levels of impairment, it was not possible to see a decrease in the dispensing of higher categories medicines and a consequent increase in the safer alternatives.

Conclusion: It can be concluded that the training positively changed pharmacists' reported behavior and knowledge. The positive outcome related to these two variables was expected as the training aimed at improving pharmacists' knowledge and behaviour. Pharmacists' awareness, however, did not significantly change after the training which could be explained by pharmacists' positive attitudes already at the baseline measurement (T0). In fact, pharmacists' awareness towards the use of driving impairing medicines might have contributed to pharmacists' willingness to participate in the study. The training and the information materials developed helped pharmacists to improve some daily routines and contributed greatly to improve the information provided to patients, which became more adequate. According to patients, pharmacists are considered to be the main source of information about medicines and the message was spontaneous and successfully transmitted to patients. Patients did not change their driving behavior, despite all the efforts from the pharmacist to transmit adequate information to patients. The training did not have any influence in the dispensing of safer alternatives of driving impairing medicines to new users.

Patient study: The majority of patients knew that some medicines can influence fitness to drive, and most patients (83.4%) interviewed would reduce the frequency with which they drove if they were prescribed a "medicine which has the pictogram concerning driving on the packaging".

Overall conclusions: The health professionals (pharmacists) that attended the training courses showed six months later a trend towards a more positive reported behaviour and actual knowledge regarding medicines and driving, while there is no (clear) change in attitudes/awareness on medicines and driving.

Spain

Background: In Spain from 2011 medicines that can may influence the ability to drive, must carry a symbol, pictogram in the package, to indicate to drivers carefully read the package insert for extra precautions if they drive a vehicle (Royal Decree 1345/2007 of 11 October). The present study refers to the development, and consequent evaluation, of a training course that was carried out with the intention of informing at Health professionals of the Spanish National System of health (Physician and nurses) and pharmacist, about the influence of medicines on driving fitness, the categorization system and implementation of the pictogram on the packaging of certain medicines in Spain. The materials used during the training course were developed within DRUID WP7 (task 7.4) and aim to assist at health professional with more background information to be provided to pastients while prescribing and dispensing medicines that are known to influence driving fitness.

Objective:

Study 1: health professionals: physicians, pharmacists and nursing staff

i) To assess health professionals' attitudes/awareness, reported behaviour and actual knowledge on the topic of medicines and driving (pre-training, pre-questionnaire)).

ii) To assess possible changes in these dimensions six months later, after the training activities (post-training, post-questionnaire).

Study 2: patient questionnaire

i) To find out whether the users of medicines know that some medicines can negatively affect their fitness to drive, and to evaluate the influence that the pictogram on medicines and driving that is printed on the packaging of the medicine could have on the patient's attitude to driving.

Methods:

Study 1: health professionals: physicians, pharmacists and nursing staff

This study was conduced in Spain, in Valladolid. To give a training course on medicines and driving in three groups of health professionals: Physicians and nurses working at primary health care centres, as well as community pharmacists. The study was carried out in 10 primary care health centres in the Province of Valladolid and among the pharmacists working within the area of influence of these 10 primary care health centres.

Health professionals were divided into three groups:

a) Intervention group: Computer science (information through a computer science tool)

b) Information Group: Printed (information through printed documents).

c) Control group: Group that does not receive specific information on medicinal drugs and driving.

The training was evaluated by means of a pre-questionnaire completed before the training.. and post questionnaire completed 6 months after training started.

Study 2: patient questionnaire

The target population is made up of "health service users" into contact with the National Health Service through Primary Care, Hospital-Specialized Attention or as consumers in pharmacies. Throughout the current text, they shall be referred to as "patients". The sample size was established at 300 people in each of the three spheres of study (a total of 900 people). Finally, 1,385 valid interviews were carried out.

The questionnaire used for this study, which can be seen in Annex IV, have been analyzed as was agreed by the partners of task 7.4.

Results:

Study 1: health professionals: physicians, pharmacists and nursing staff

Pre-questionnaire: 141 physicians, 127 community pharmacists, and 139 nurses were invited to participate in this DRUID study, finally 72 physicians, 75 community pharmacist, and 36 nurses health professionals responded to the study (44.9% response rate) (Table 123). Referred to a lack of training on medicines and driving, in both university studies and after finishing their university degree. They showed a high positive attitude/awareness regarding medicines and driving, but reported a low reported behaviour, and show a very low knowledge regarding medicines and driving. They consider medicines and driving in the daily practice to be a relevant issue (score 7.4 on 10).

Pre-Post questionnaire comparison: For the comparative analysis between the answers obtained in both questionnaires, we therefore had 38 questionnaires: 22 corresponding to the information group and only 6 to the intervention group (Table 156).The study shows a "positive" change in the reported behaviour and in the actual knowledge of health professionals after the training course on medicines and driving. After the training course, pharmacists, but not physicians, give higher scores to the importance given in their daily practice to medicines and driving.

Study 2: patient questionnaire

1,385 patients responded to interview-questionnaire, the interview-questionnaire was conducted only once, when the patient visited a health service or a pharmacy. The majority of patients knew that some medicines can influence fitness to drive, and most patients (83.4%) interviewed would reduce the frequency with which they drove if they were prescribed a "medicine which has the pictogram concerning driving on the packaging".

Overall conclusions:

Study 1: health professionals: physicians, pharmacists and nursing staff

The health professionals (physicians and pharmacists) that attended the training courses showed six months later a trend towards a more positive reported behaviour and actual knowledge regarding medicines and driving.

After the training course has been a significant change in the whole sample and particularly among physicians, leading to an increase in line with the will to take into account the effects of drugs on driving skills when they prescribe/dispense medicines. However, health professionals would only be willing to change the prescription for another drug with less effect on driving, when the patient was a professional driver or take other drugs that act on the CNS

Across the sample and particularly among physicians, there has being a significant shift in favour of asking patients about their driving exposure when choosing/dispensing a medicine, and for a systematic record of the patient's traffic participation and the advice offered a patient when and how he/she can consider driving a car when using a driving impairing medicine. Also increasingly the willingness for provide a patient with written information materials when prescribing/dispensing a driving impairing medicine. This significant changes point to an increase in the effort health professionals make both to inform the patient about medicines and driving and to inform him/herself about the patient's involvement in driving and to leave a record of these aspects in the patient's medical history.

For both the whole sample as well as for physicians and pharmacists separately, a significant positive change can be observed in the evolution in knowledge concerning the effects of some medicines on driving. As for as, the importance given in their daily practice to medicines and driving by health professionals.

Study 2: patient questionnaire

A significant proportion of patients who have been prescribed a drug with a pictogram on the package would, decrease the frequency of driving, would not lead without having read the prospectus before. The physician is the health professional to consult when they first had to take a medication on driving with a pictogram on the package, followed by the pharmacist and nurse.

PART A: GENERAL OVERVIEW
&
OVERALL COMPARISONS

List of Abbreviations

ACRONYM / ABBREVIATION	FULL DESCRIPTION
A	Attitudes
AK	Actual Knowledge
CERTH-HIT	Centre for Research and Technology Hellas-Hellenic Institute of Transport
IBSR	Institut Belge pour la Sécurité Routière
ICT	Information & Communication Technologies
PC	Personal Computer
RB	Reported Behaviour
RuGPha	University of Groningen, Department of Pharmacotherapy and Pharmaceutical Care
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
SQL	Structured Query Language
Ugent	University of Gent
UVa	Universidad de Valladolid
WP	Work Package

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1 Introduction

Physicians frequently prescribe medicines that may affect driving fitness. In addition, pharmacists dispense medicines they know that may affect their clients' performance behind the wheel. Driving is a complex task, and both prescribers and dispensers know that the guidelines at hand should ensure that their patients receive the maximum available information.
This document intends to describe the overall evaluation activities of Task 7.4.2. The document is divided into two sections as the prime aim of the task is twofold. The first part includes the overall consolidation and representation of the effort involved and the second part corresponds to the national reports. Consequently:
The first section describes the evaluation activities for investigating the application of driving specific guidelines in prescription/dispensing of medicines (A).
The second section of this deliverable illustrates the activities conducted in each separate country (Belgium, The Netherlands, Spain) (B).

1.1 Evaluation aims & objectives

Firstly, a major objective of WP7 was to produce protocols and guidelines on driving impairing effects of medicines for health care professionals who prescribe and dispense medicines. Secondly, the effectiveness of the application of the proposed guidelines to health care professionals is assessed to the extent this is feasible. It is essential to note that this is not a study that is carried out for many years but a small scale effort and therefore its effectiveness is expected to be moderate but its qualities and drawbacks are of equal importance for future efforts. Thirdly, the assessment focus turns, also, towards the intervention/administration method (e.g. Integrated vs. paper version). An in depth analysis of the primary and secondary objectives is presented in the second part of this deliverable, where the country specific investigations are illustrated.

1.1.1 Evaluation team (partners)

The evaluation activities are usually the last part on long research collaboration towards the implementation of driving-related protocols and guidelines.
The WP7 partners involved in the evaluation activities and their roles are shown in Table 1.
Table 1: Roles and Responsibilities of the Evaluation Team Members

Table 1: Roles and Responsibilities of the Evaluation Team Members

Partner	Title of Role	Responsibilities
UGent/IBSR	Test& Evaluation partner	National study description
		Study conduction
		Data gathering
		National report
UVa	Test & Evaluation partner	National study description
		Study conduction
		Data gathering
		National report
RugPha	Test & Evaluation partner	National study description
		Study conduction

		Data gathering
		National report
CERTH/HIT	Evaluation partner	Evaluation plan
		Consolidated data report
		Overall statistical composites
		DRUID Tool's development
All partners	Collaboration	Feedback,comments, amendments

According the Table above, the allocation of workload illustrates the inter-connective and collaborative character of the implementation and evaluation of this study.

2 Background and theoretical model

Research has shown that many diseases may affect driving performance. However, the medicines prescribed for most diseases can make us being behind the wheel just as dangerous. Current research focuses on the Central Nervous System impairment brought even by the over-the-counter medicines. The realization of the need for alterations in existing guidelines on the way physicians and pharmacists prescribe and dispense medicines is a general goal of WP7. Experts have formulated new guidelines and protocols within the framework of the DRUID European project.

2.1 Brief literature review

It is important to note that there is no magical way to improve the way health professionals advise their patients. According to the literature effectiveness is context related. In other words, the communicated meaning and its periphrastic qualities are the essential "pass" to successful conferment. Likewise, clarity, wording, and simplicity are key parameters to the conveyed messages. In line with current research, focus has been shifted towards the amalgamation of techniques (e.g., pedagogical, learning, training) in increasing the effectiveness and, therefore, probably in the long run, the impact on the target population.
Protocols and guidelines may be regarded as tools to improve clinical practice. Optimal guidelines will facilitate prescribers/dispensers to provide more appropriate treatments to their patients.
It was essential to provide an adequate and acceptable definition of protocols and guidelines so as to establish the foundation for the conceptualisation of the evaluation plan. Moreover, a consensual glossary enabled DRUID partners to support the chosen theoretical framework.
According to Prior and colleagues (2008) "Guidelines are defined as systematically formulated documents that assist practitioners to make clinical decisions informed by best available evidence." Professional guidelines provide the foundation for better and cost-effective practice. The rising of comparability in medical practice ensures the development of collaboration between research findings and evidence-based medicine.
Grimshaw and Russell (1993) investigated the effectiveness of medical guidelines in everyday practice and they found that for guidelines to be effective, the strategies implemented are crucial. They found 4 out of 59 studies to report effective implementation of guidelines in a vast array of clinical and preventive care environments. It is important to emphasise that the randomised studies that proved higher effectiveness of applied medical guidelines were the ones that they applied a specific educational intervention, specific patient information and reminders with internal development strategy. In this study extra effort was placed on the wording of guidelines and the information provided for both practitioners and patients.

Table 2: Classification of clinical guidelines (Grimshaw & Russell, 1993)

Probability of being effective	Development strategy	Dissemination strategy	Implementation strategy
High	Internal	Specific educational intervention	Patient-specific reminder at time of consultation
Above average	Intermediate	Continuing education	Patient-specific feedback
Below average	External, local	Mailing targeted groups	General feedback
Low	External, national	Publication in journal	General reminder

Rousseau and colleagues (2003) conducted a practice based, longitudinal, qualitative interview study in five general practices in north east England in order to understand the factors influencing the adoption of a computerised clinical decision support system for two chronic diseases in general practice.
Negative comments about the decision support system significantly outweighed the positive or neutral comments. Three main areas of concern among clinicians emerged: timing of the guideline trigger, ease of use of the system, and helpfulness of the content. Respondents did not feel that the system fitted well within the general practice context. Experience of "on-demand" information sources, which were generally more positively viewed, informed the comments about the system. Some general practitioners suggested that nurses might find the guideline content more clinically useful and might be more prepared to use a computerised decision support system, but lack of feedback from nurses who had experienced the system limited the ability to assess this.
Significant barriers exist to the use of complex clinical decision support systems for chronic disease by general practitioners. Key issues include the relevance and accuracy of messages and the flexibility to respond to other factors influencing decision making in primary care.
An overview of existing literature is disappointing but it shows the importance of the development of evaluation techniques for computerised protocols and more importantly for their application in driving as relevant literature is scarce to non existing.
Similar findings have been reported by Grol and Grimshaw (2003). They have suggested that change in behaviour is possible. They continue with emphasizing that change is possible if it occurs at different levels (doctor, team practice, hospital, wider environment), tailored to specific settings and target groups. Plans for change should be based on characteristics of the evidence or guideline itself and barriers and facilitators to change. Therefore, the adopted framework described in section 2.2 takes into account related barriers (Figure 1). In general, evidence shows that none of the approaches for transferring evidence to practice is superior to all changes in all situations.
Grol and Wensing (2004) have proposed a multilevel approach to examining incentives and barriers to change based on literarure and research conduced at their research centre. They proposed that barriers should be examined at six levels:the innovation itself, the individual professional, the patient, the social context, the organisational context, and the economic and political context. In this study not all these different levels were taken into account due to the limitations in both time and resources. However, type professional (e.g. medical practitioner and nurses), patients, and new guidelines were taken into account. It could be argued that the social, organizational, political and economic levels were all part of the study as different countries participated. However, not investigated on individual level.
Shiffman and colleagues carried out a review of current literature and found that 14 out of 18 studies investigatingcomputerised guidelines' mplementation have showed improvement in guidelines' adherence because of application of strategies based on computers. The guidelines in most cases were integrated in the existing clinical information system.
Before focusing on to the theoretical background that the evaluation materials' construction was based on, three targets were set: a) strategies should target also patients, b) content of

guidelines should be coherent and clear, and last but not least, c) the study should have clear objectives.
The brief literature review was conducted in order to identify the parameters and measurements that could be important for the deveplement of both the guidelines and the questionnaires that were used in the country studies. The next step was to find the theoretical framework that would be the base of the evaluation. The research teams were aware of the limitations present in empirical research and the inherent difficulty of finding strong evidence when diverse study designs and populations are investigated. However, the framework described in the next section was based on the review performed.

2.2 Adopted theoretical framework

The vital long-term role of this endeavour is to embed the concept of the impairing effects of medicines in the daily professional practice. Albeit, the impact of the implementation is beyond the direct goals of this task, it could be an important one for furthering this study.
With regards the professional groups, the change in practice routines implies change in beliefs and opinions, by enhancing/updating existing knowledge. Therefore, the aim is to achieve change in personal professional level and simultaneously evaluate the most effective medium to achieve this. The effectiveness of a programme is more sensitive to context (Davies et al., 2010). The context was not identical in all groups the guidelines were provided. However, as the content is critical for the effectiveness of the implemented guidelines, then a group of health care professionals receiving no information relevant to DRUID outcomes allowed content comparison. The design of the study is explained in detail in the methodological section of this deliverable (section 4).
The list of intervention studies is long (230 methodological adequate studies), but there is no clear basis for understanding which procedures are effective in which contexts. In a nutshell, the conclusions drawn from the literature search do not shed light on the “how” component in case they were successfully implemented. The main reason why it is unclear how these interventions have been successful is the absence of adequate information explaining the processes underlying the behavioural change (Michie and Johnston, 2004). The aims, goals, context and timelines direct us towards the adoption of the appropriate theoretical foundation for this task.

Extensive reviews on guidelines implementation have half-heartedly reported limited and non-consistent effect of guidelines in changing physicians’ behaviour (Cabana et al, 1999). The processes and factors involved in health care professionals’ adherence to guidelines have not been investigated in depth and little is known with regards how it could successfully be succeeded.

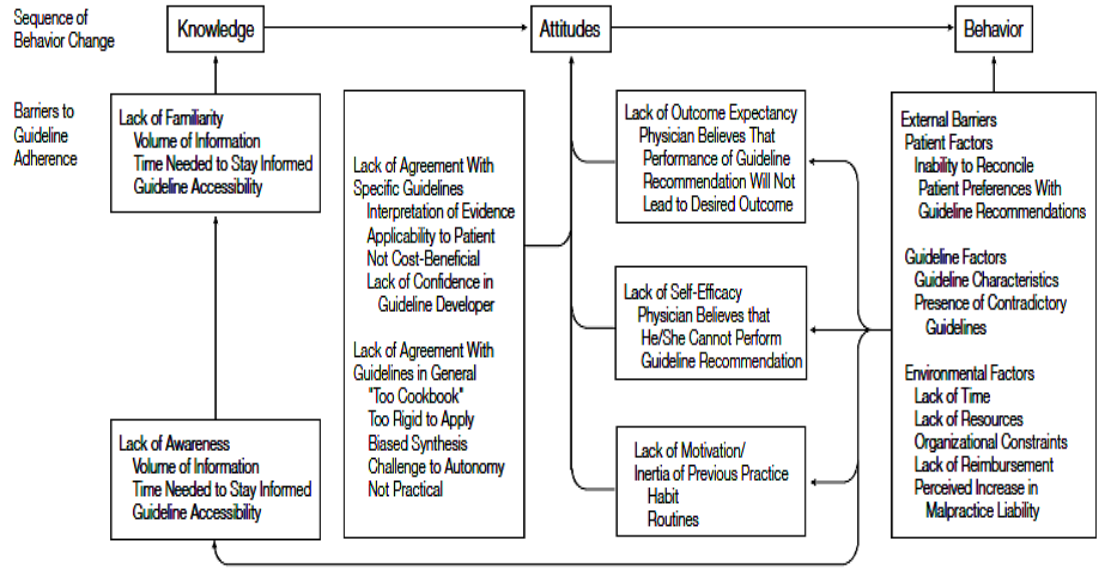


Figure 1: Barriers to health care professionals' guidelines adherence (Cabana et al., 1999)

The diagram above provides a theoretical model incorporating the terms of knowledge, attitudes, and behaviour, which are the main constructs in the proposed questionnaire (see Annex I).

The aforementioned barriers are pertinent to be taken into account in this attempt to evaluate the guidelines effectiveness as they are relevant to the artefacts (i.e., knowledge, attitudes, behaviour) investigated in the constructed questionnaire discussed later on in this document. The model adopted was based on the evaluation review of Cabana and colleagues which provides a mostly linear relationship between guidelines implementation and their effectiveness. In other words, we assume that a behaviour change will result from changes in knowledge and attitudes. As the authors clearly state in their review, behavioural changes may arise but their affect in daily practice will be time limited. Moreover, the components and the sequence of the model were further clarified by providing a process enabling the model to sketch the procedure adopted so as to target the desired effect (i.e., successful implementation of professional guidelines to inform patients on driving impairing effects of prescribed/dispensed medicines). The assumption that behavioural change is the result of change in knowledge and attitudes should be incorporated in the current methodology, leading to the construction of an instrument that encompasses the components (items) that could measure such change. The latter is the prerequisite for measuring the effectiveness of implemented tools.

The procedure is schematically presented below and is comparable to learning steps of behavioural change.

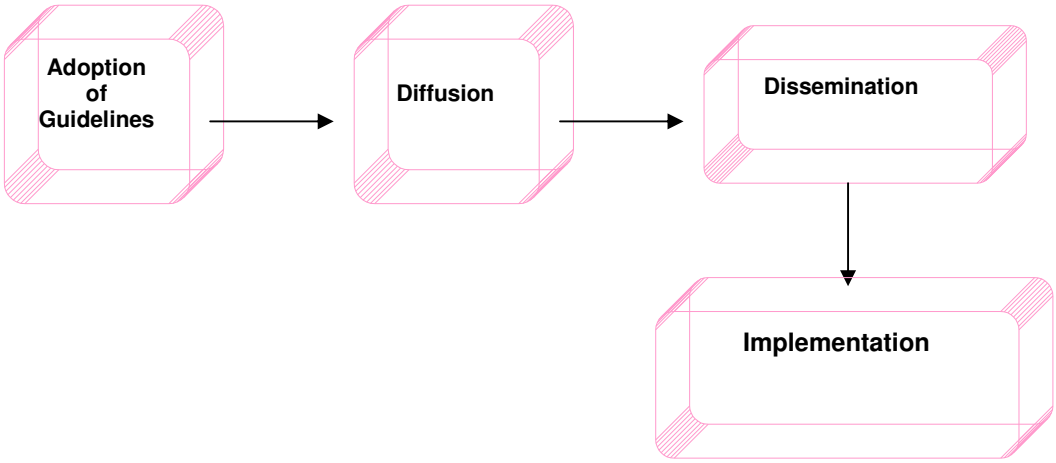


Figure 2: Diagram on the process of guidelines adherence (based on the flow chart of Davis & Taylor-Vaisey, 1997)

The adoption of guidelines is an agreement/contract between the developers and the physician/pharmacist to implement and use the guidelines in their practice. If the professionals have committed to implement the suggested guidelines, then they would diffuse acquired knowledge unaided to their implementation in their daily practice. Following the diffusion, then the actual communication of the newly acquired knowledge to their patients would improve their prescribing/dispensing practice by choosing medicinal drugs from lower DRUID categories (e.g. III to II).
The review described targeted physicians as the implementation group. In this task, we desire to generalise the same model to pharmacists as dispensing of medicines is a major objective. The assumption added to the above model is the fact that the behavioural changing process is common and can be generalised to all individuals, thus to pharmacists.
Similarly, the above mentioned factors should be taken into account during professionals training and data analyses.
The atheoretical perspective adopted by most methodologically sound studies has led to inconclusive and mixed findings. Most studies miss the link between the effect and the processes taken place to lead to the effective implementation of suggested guidelines. In order to determine the theoretical construct that could be applied in this context DRUID partners aimed at deriving the theoretical framework that best explains the behavioural change in health care professionals and not in general. An in depth description and discussion of the adopted model is beyond the scope of the evaluation plan.
Section 2.1 facilitated the identification of relevant models and allowed for the selection of the framework. In other words, guidelines developed within WP 7.4 was based on existing literature (2.1) and associated parameters and barriers identified in secion 2.2 were of importance for the development of the evaluation materials (i.e. questionnaires) for the evaluation of the implemented guidelines.
The next section sketches out the significant parts and procedures of a simultaneously multifocal investigation.

2.3 Evaluation logical model

The creation of a logical model facilitates and it is very useful through the design and evaluation process as it demonstrates the components and their co-relations. The layout presented below corresponds to the general functionalities and timelines of the design.
The flow diagram on page 32 describes the logical model developed to link the processes, partners, results and summarises the involved procedures. It is a static notional view of the involved elements.

The interconnection of the individuals, processes, instruments and external factors shown in the figure is taken into consideration in the following section where the methodological considerations are discussed in depth.

2.3.1 Need and target population

Need

The following questions were initially addressed when the overall design was prepared:

- What is the purpose of the study?
- What types of information will be gathered?
- What is the focus of the study?
- What methods and tools are appropriate?
- What are the units of analysis?
- Which sampling strategies will be employed?
- Where will the study be conducted and how will it be phased?
- How will ethical issues and matters of confidentiality be handled?

An effort was made by all partners to accommodate for these needs in the most productive way within the project's requested timelines.

Target population

The target populations were professionals in the primary care setting: i) physicians (Belgium, Spain), ii) pharmacists (Belgium, The Netherlands, Spain) and iii) nurses (Spain).
Moreover, physicians were sub-categorised to GPs and specialists (Neurologists, psychiatrists). The recruitment of stratified samples was not attainable by the partners; therefore the initial groups of physicians and pharmacists remained as the focus of evaluation.
If it was decided to implement it on specialty, then another number of users was required as the variables involved (i.e., type of specialization) would be incorporated to the existing design.
According to the Description of Work, participants could be General Practitioners and specialists. As the numbers per specialism were not known for all participating countries, it was not possible to stratify the sampling so as to accommodate for this sampling procedure. Physicians' recruitment was not feasible to be randomised in all countries. A detailed account of sample sources will be provided at the national level design descriptions (Part B). Physicians were essential for this study as they are the first in line health care professionals patients contact in order to get advice regarding medical problems.
The term pharmacists refers to community pharmacists who dispense medicines. Pharmacists may be able to prescribe medicines in some countries, but not in the respective countries involved in this deliverable, where physicians are the primary prescribrers. The selection process was as similar as possible to the one applied to the physicians to ensure the balanced conduction of the trials.
The term nurses refers to nurses recruited from primary health care centres (Spanish study only).

2.3.2 Objectives, inputs, activities, and outcomes

It is essential to pinpoint the criticality of ensuring that information concerning driving impairing effects of prescribed/dispensed medicines is communicated to healthcare professionals and consequently to patients.

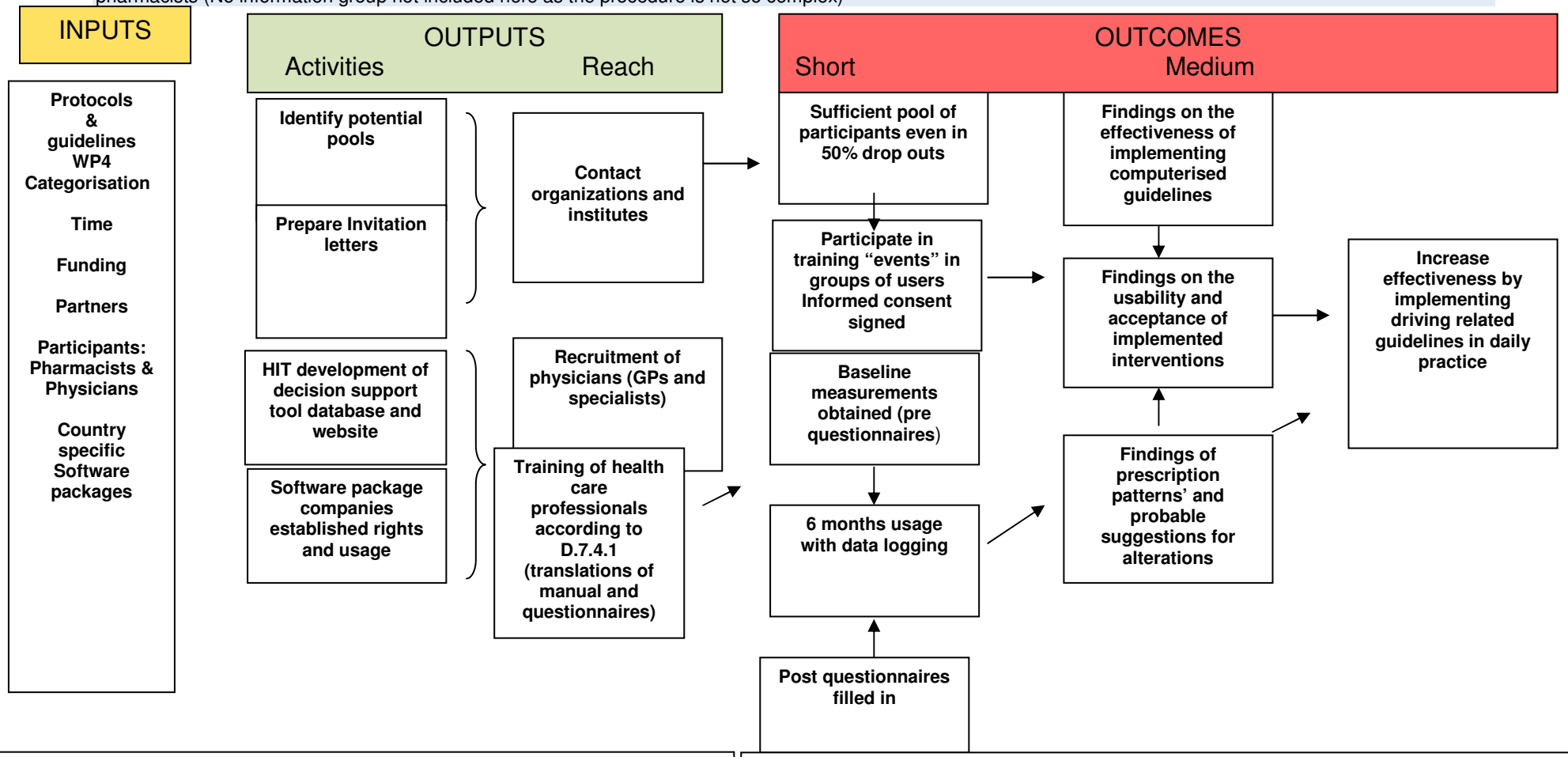
The primary goals of this task are clearly stated as to:

Evaluate the effectiveness of the implementation of developed protocols and guidelines to healthcare professionals via two different means:

- integrated (ICT) tool (additional software integrated into the ICT software used by the professional in his daily practice; country specific development)
- non-integrated tool of the protocols and guidelines (ICT tool developed within the framework of the project)

In addition, a “pure” control group was added to evaluate the effectiveness of current practices with no DRUID-relevant information. However, the latter may be hindered by socio-occupational networking elements. Researchers are aware of the limitations imposed upon the professional guidelines’ communication among physicians and pharmacists and possibility of information leakage was taken into serious consideration and effort was made to avoid this. Each coutry study researchers have taken leakage possibilities into consideration and this issue was raisen early in the project.
It is important to explain that health care professionas who were using the integrated ICT tool in their daily practices were not using the stand alone tool. The website access could enhance the computerised practice, but was not mixed with the administration of paper information as the latter is a distinct type of implementation (Spanish study). In addition, the USB stick had access to the internet (webpage) where DRUID information was accessible.
A detailed description of the software packages is included in the separate country reports and could help evaluators to sketch a representative account of possible interactions with measureable variables and their impact.
The application of different software packages could enlighten us on the most effective characteristics of each tool separately resulting into gathering valuable findings on the elements that may be necessary to be incorporated in future software package. Consequently, the respective companies might obtain important information for future more sophisticated software development.
In addition, health care professionals were trained in order to learn how to use the DRUID ICT tool. The integrated software group (SoSoeMe) of physicians in Belgium did not receive any training. Training usually is a familiarisation phase so as to avoid the investigation of confounding variables within a framework. In this case, it provides the transfer of DRUID knowledge to health care professionals comprising the target groups. The computerised protocols and guidelines were implemented and evaluated in the participating countries, thus apart from the general design methodology; an adjusted country-wise version was implemented to support the feasibility and validity of the process.

Situation: integrated implementation vs. Non-integrated version of protocols and guidelines and comparison to no-DRUID-relevant information to physicians and pharmacists (No information group not included here as the procedure is not so complex)



ASSUMPTIONS:
The increase of knowledge, attitudinal sensitivity, observed and subjective behaviour by the application of the drug-induced driving related guidelines is the result of the effectiveness of the guidelines

EXTERNAL FACTORS:
Impossible to control information flow and professional interactions, cultural differences, professional experience diversity

3 Focus of the evaluation

The overall evaluation aimed to deliver the objectives and goals of Task 7.4. Hence, in order to evaluate the effectiveness of the implementation of the developed protocols and guidelines within WP7 a summative approach was adopted. The application of this technique focuses on the examination and analyses of findings after the finalisation of work.
The following figure presents the necessary steps taken in order to conduct the studies and to accomplish their harmonisation and synchronisation throughout conduction. It is useful to follow an a priori structured plan to ensure that important evaluation steps have not been omitted.

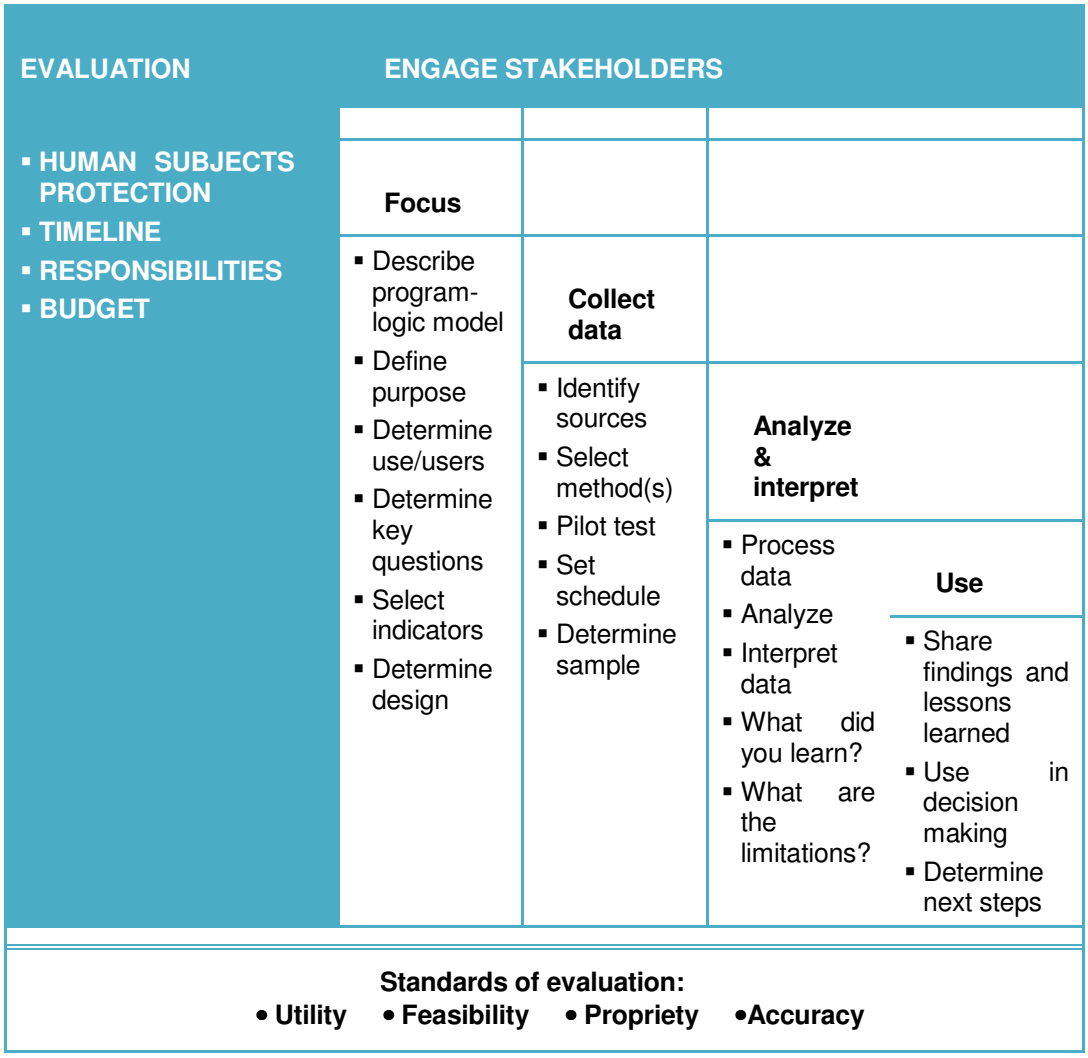


Figure 3: Evaluation plan steps

3.1 Research specific objectives

This section very briefly presents overall research questions that have been adapted later on to the needs of each separate country study.

3.1.1 Overall

The aim of the study is twofold:

a) Evaluate the integrated (ICT) vs. stand alone delivered guidelines and protocols (input from **Task 7.2**)
b) Evaluate the effectiveness of risk communication to patients through **leaflets** (input from **Task 7.3)** by the application of the developed **categorization system** (input from **Task 4.2**)

The key hypotheses of the study were:

$Hprof_o$: The application of integrated guidelines will not be effective in informing the professionals on prescribing medicines which may affect driving

It is tested against the following alternative:

$Hprof_1$: the application of integrated guidelines will be effective in informing the professionals on prescribing medicines which may affect driving.

3.1.2 Country specific

In this section the objectives of each study are briefly presented.

Belgium
The Belgium team focused on investigating the effects of integrated vs. non integrated software for delivering guidelines to physicians and pharmacists (SoSoeme and ViaNova, respectively). In addition, a control group was added.

Netherlands
The Dutch group performed two separate studies. A patient study investigated differences in patients' knowledge before and after training (6 months). A pharmacists' study investigated differences in guidelines adherence with the application of an integrated tool.

Spain
The Spanish team assessed the influence of health professional training about medicines and driving on i) the medicine prescription patterns to the driver patient, and ii) the information received by patients on the effects of prescribed medications on driving.
The Spanish team focused on three different types of health care professionals: a) medical practitioners, b) pharmacists, and c) nurses. They investigated the effect of computerised guidelines when compared to non-computerised method of administration of guidelines and protocols.

4 Methods

4.1 Sample size calculations

This section is divided in two parts. The first section encompasses the initial sample size calculations based on random sampling with no interest in correlation based on marginal error (5%), confidence intervals (95%) and population sizes. Typically the reported margin of error is about twice the standard deviation, the radius of a 95% confidence interval. As a "rule of thumb" an acceptable level of marginal error is between 3%-6%. The chosen one was 5%. In other words, if we were to conduct the same study 100 times, the results would be within ±5% of the first time we ran the study 95 times out of 100. It is impossible to estimate the SD and the exact effect size (based on mean differences) as no pilot testing has been performed in order to act as a base for further calculations.

A sample size calculator was used on the aforementioned parameters and the minimum sample sizes were estimated and presented in the following table.

Table 3: Initial sample size calculations

Country	Pharmacists	Physicians	
Spain	**383**	**377**	
Belgium	**377**	**380**	Neurologists:**166** Psychiatrists:**312** Neuropsychiatrists:**206**
Germany	**377**	**383**	
The Netherlands	**339**	**382**	

As shown above, if the population consists of just a few hundred people (i.e., specialists), it seems that we should need to survey almost all of them in order to achieve the desired level of accuracy. As the population size increases, the percentage of people needed to achieve a high level of accuracy decreases rapidly. In other words, to achieve the same level of accuracy:

Larger population = Smaller percentage of people surveyed

Smaller population = Larger percentage of people surveyed

It is essential to bear in mind that for the specialists' sample size calculations no stratification sampling was taken into consideration as it involves a different procedure.
The sample size calculations are important -as we are concerned in detecting an effect (i.e. difference between the intervention methods) so as to ensure that if an effect deemed to be important exists, then there is a high chance of it being detected, i.e. that the analysis will be statistically significant. If the sample is too small, then even if large differences are observed, it would impossible to show that these are due to anything more than sampling variation.

Moreover, literature on existing studies was not available so as to base for standard deviation estimates. Hence, calculations were based on:

a) proposed size of effect (medium=.25)

b) desired power=.8

c) desired significance level=.05

d) the hypotheses (two-sided)

Ideally, separate calculations per variable involved (attitudes, knowledge, behaviour etc.) could be performed but the data at hand were quite restricting.
Sample size calculations were performed with G*Power software (version 3.0.10). Total number of participants per level of independent variable was estimated at n=93.

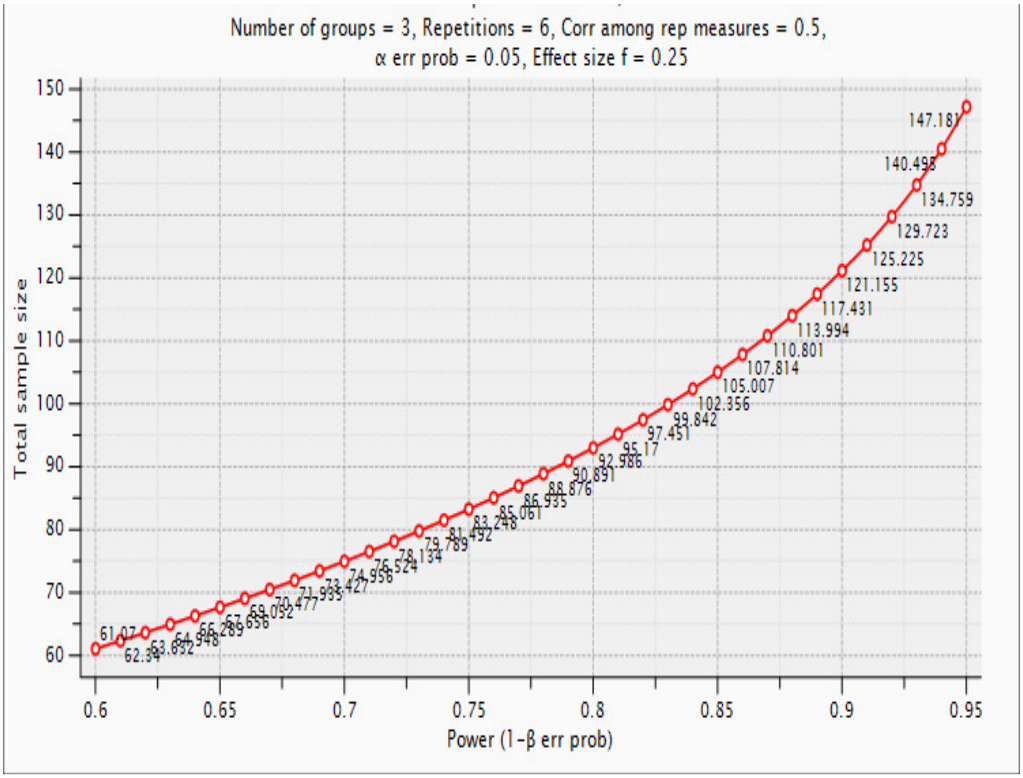


Figure 4: Sample size as a function of power

The experimental groups (integrated vs. stand alone) received information on **exactly** the same content. It is crucial to be cautious when selecting the users so as to avoid and obstruct the interaction and information "leakage" among participants. Moreover, the third group got no information relevant to DRUID material.
Nonetheless, it is impossible to control the exact information they receive on a daily basis.
It was mandatory to be as strict as possible when it comes to controlling the trials, because the sample size calculations were based and compromised on four assumptions:

1. The participants are randomly selected
2. The correlations are small (i.e., users should avoid contact)
3. No stratification was taken into account (specialty sub-groupings)
4. The participants' numbers apply only for controlled conditions (i.e., we all apply the same methodology)

The sample size calculations were not based on population characteristics (common to qualitative data handling methodologies) but to experimental manipulation methodology. Hence, the same sample sizes apply to all participating partners.
The above decision was based on the feasibility standing of the trials and followed the initial uncompromised sample size calculations. In addition, it was favourable to select participants from various parts of the country to avoid sample bias.
A common and affordable way to randomly choose and assign people to participate in the study is either in SPSS or Excel. Individual reports provide detailed account of sample sizes and deviations from original calculations.

4.2 Design

The studies were randomised controlled empirical trials. Moreover, the participants were allocated to pre and post conditions.
The study design can be depicted in notation form as follows:

$$\mathbf{RQ_1NQ_2}$$
$$\mathbf{RQ_1NIQ_2}$$
$$\mathbf{R\ Q_1\ Q_1}$$

Where:

R= randomly assigned participants
$\mathbf{Q_1}$= Pre-questionnaire
$\mathbf{Q_2}$= Post-questionnaire (adjusted for administration method)
I= Integrated guidelines and protocols
NI= Non-integrated guidelines and protocols

The aforementioned notation is graphically presented in Figure 5. It is important to take into account the internal (randomly assign participants to groups) and external validity (sampling issues-representativeness and generalisability). While the study sample may be considered representative of the original population of interest, generalisability is not a primary goal; the major purpose of this study is to determine whether a specific intervention method *could* work in an accessible context.

All participants were measured at baseline (pre-questionnaire) and six months after (post-questionnaire). It was essential to take into account the possibility of drop outs during the study as it is quite often in longitudinal methodologies. This was a topic of discussion before the implementation and conduction of the country studies. Each country developed the most appropriate methodology to deal with potential drop outs. Their own effort to keep participants involved is described in detail in each individual country report and by themselves these efforts serve as guidelines for related research that presents both experimental and empirical elements.
Participants consented and were debriefed after the completion of the study.

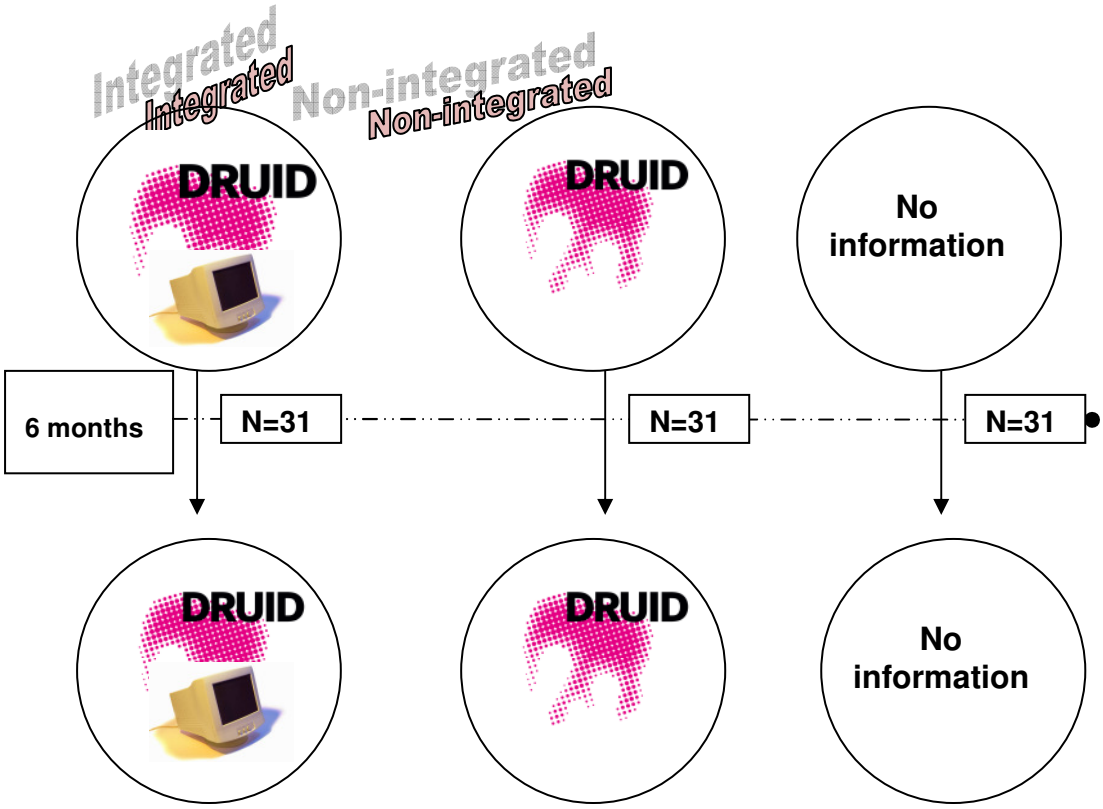


Figure 5: Health care professionals (N=93 per group)

93 physicians (if anticipated response rate is 50%, then double sample size was required) wouldparticipate in the study and would be randomly allocated to the 3 groups representing the respective independent variables' levels). Individual reports would include more detailed section of how each study partners handled low response rates and drop outs.

However, these calculations serve the main framework of research objectives of the overall aims of the task with regard health care professionals and computerised medical guidelines and protocols adherence regarding driving impairment due to medicines prescribed/dispensed.
The Dutch and Spanish team investigated, also, the effect to patients' risk awareness. The effect due to DRUID guidelines may be only of indirect nature, therefore the aforementioned calculations do not apply. However, an in depth discussion on sample characteristics of patients is provided in the respective reports and the increased number of filled in questionnaire ensures a valid outcome.

4.3 Materials

The independent variable (IV) of the study was the guidelines administration method. The IV factor is comprised of 3 levels (groups):

a) Computerised (electronic administration)- experimental group (EG1)
b) Non-integrated administration-Comparison group (EG2)
c) No DRUID-specific information –"Pure" Control group (PCG)

The dependent variable (DV) is the effectiveness of the method of administration.
Effectiveness is a qualitative term and it is mandatory to be specified with regards the study's theoretical framework. Effectiveness of the study was identified as change in knowledge, attitudes/awareness, behaviour due to the application of guidelines. Furthermore, user

acceptance, usability and probable (hypothesized) impact of the computerised protocols was estimated.
The instruments applied were pre- and post-questionnaires based on the items decided by the partners. Moreover, users were trained prior the participation according to the Training Manual (Del. 7.4.1). Baseline measurements (pre-questionnaire) were collected on site before training, to ensure transparency of data. In addition, this procedure is cost-effective and minimizes the possibility of wearing out the participants. However, in some cases this was not possible (e.g. in Belgium the respondents were selected whey sent their filled in questionnaires back to the study team with the exception of the ViaNova pharmacists group). The instrument was comprised of both close-ended questions and open-ended ones (comments sections were included).
The materials used in each country study range from subjective scales to objective measurements. A basic questionnaire was created for the pre and post testing conditions (Annex I).
The basic questionnaire was constructed in order to reflect the following clusters and reflect the theoretical framework adopted:

A. Background information (7 items)
Aiming at gathering information about basic demographic, educational background and expertise of participating professional.

B. New Technologies Literacy (6 items)
As already discussed in the Glossary, this cluster contained items that would target to investigate the familiarity of the participant with similar tools and, therefore, their willingness to apply them in everyday medical practice.

C. Attitudes/Awareness (6 items)
Professional judgments on medicines and driving were investigated.

D. Reported Behaviour (8 items)
These questions reflected what the professionals actually do in their daily practice.

E. Sources (4 items)
In order to get an idea of the various sources professionals use in order to gather information and knowledge, this section was added.

F. Actual knowledge (5 items)
Investigate acquired knowledge on medicines' effect in driving behaviour.

G. User acceptance (pre-2 items)
How willing are to use such a tool prior testing phase begins.

H. User acceptance (post tool-8 items)
Acceptance of the content and the functionalities of the tool after the testing phase ends.

I. Future use of the tool (3 items)
For what searches they would more likely use the tool for and which tool they preferred.

This questionnaire was the basic template and then adapted to the specific needs and requirements of each study; however the structure of the template questionnaire was kept. Data deriving by the answers of items in clusters C, D, and F were included in the consolidated database and were analysed (section 5). The findings presented in the first part of the deliverable are based solely on the analysis of pre and post questionnaires for these three clusters for physicians and pharmacists by using only the common items in all countries.

In addition to subjective data (questionnaires), objective data (logfiles) from the USB tool were kept in the system and sent to the test leaders (Belgium).

4.4 Tool developed with DRUID project

A special tool (USB) has been designed and developed to support the physicians and pharmacists of the project.
The DRUID Tool is a Java based application. The tool is able to run on different operating systems due to Java use. The only requirement is the runtime environment of Java (JRE) which is free on the web.
The tool is also based on MySQL. This is the database engine where the data is stored. MySQL has been selected to support DRUID tool due to its powerful engine. This is free and open source software. Partners filled in a database with all the medicines they were responsible for their categorisation with WP4 and this excel file fed the tool (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

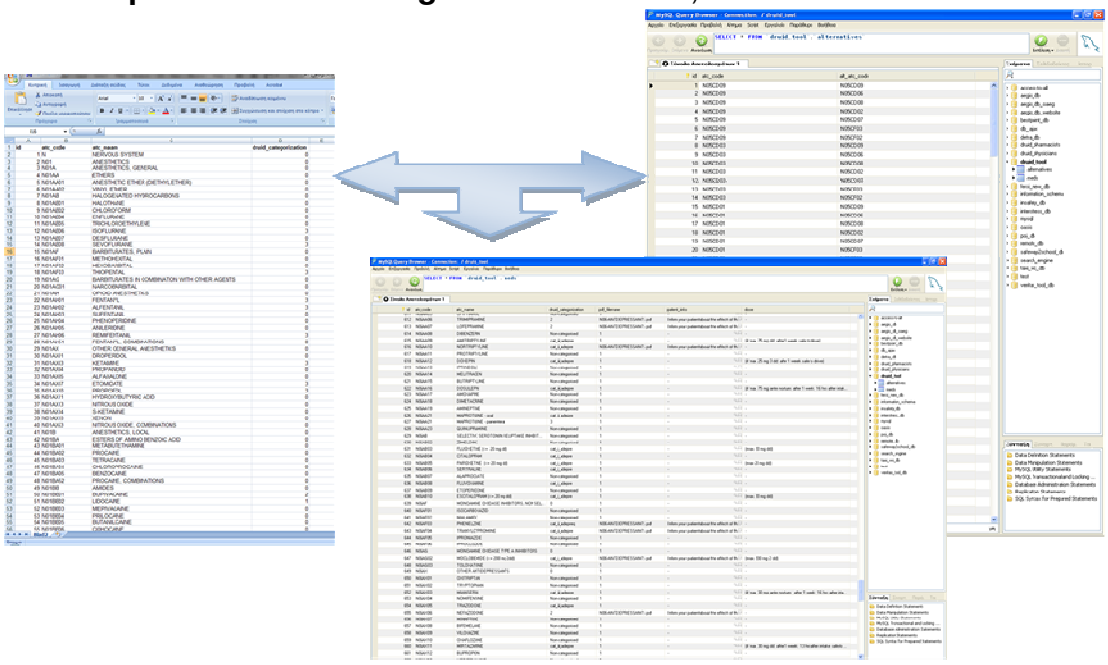


Figure 6: Transfer of medicine information from an Excel file to the tool's database

In more detail, the DRUID ICT tool can be used to find information about the driving impairing effects of medicinal drugs. The tool consists of an easy-access database with information about driving impairing medicines.
The tool is constructed in the following way:

1. Main Form window: In this window the substance can be selected in several ways.

2. Substance Information window: This window consists specific information about a medicine:
   - Categorization All driving impairing drugs are categorized into one of the three possible categories (1. likely to produce minor effect on fitness to drive, 2. likely to produce moderate effect, 3. likely to produce severe driving impairing effects)
   - Advice to the patient
3. DRUID Fact Sheet window: The tool contains the DRUID WP4 Fact Sheets with extended information about a medicine.
4. Alternative Medicines window: The tool allows physicians or pharmacists to find safer alternatives medicines that have less driving impairing effects.

DRUID Fact Sheets

- The DRUID WP4 Fact Sheet is attached to each categorized medicine.
- The information contained in the Fact Sheet is derived from the Summary of Product Characteristics (SPC) and the patients information leaflet, either in the WP4 countries, UK, Ireland or EMA.

4.5 Procedure

The underlying procedure was based on both within and between groups' comparisons.

Participants were introduced to the tools/software(s) through a training scheme. In addition, participants were informed about the DRUID guidelines regarding driving and medicines uptake. The time sequence involved a standard procedure of recruitment, briefing, and consent. Participants filled in the pre-questionnaire and after six months of using the DRUID guidelines in their practice (post-questionnaire).
They used the software during their daily practice for either prescribing or dispensing medicines depending on the professional groups they belonged to. After the testing period ended they filled in a post questionnaire investigating the same artefacts more or less as the initial one in order to enhance and allow comparability and evaluate the effectiveness of the tool and the applied guidelines.
Procedural differences exist and will be discussed in depth in the respective reports; however, the framework was not significantly violated allowing for similar up to a certain extend data analysis.

4.6 Statistical analysis

Statistical data handling depended on the sample characteristics and the inherent assumptions underlying them. In general, non parametric tests were performed due to either small sample size and/or violations of normality in data distribution. Moreover, as questionnaire items were answered in different type of scales (i.e. interval, ordinal, and binary choices) median values in some cases reflected in a more robust way data handling. In more detail, for within group comparisons the Kruskal Wallis test was used and for the between groups comparisons Mann Whitney *U* test was used.
Linear regression was performed for the patient questionnaire data in the Dutch study as its appropriateness was ensured by the big sample size. The regression analysis is discussed in depth in the analysis section of the respective report.
A step further in analysis was the creation of composite scores to facilitate between countries potential comparisons and present the opportunity of an overall evaluation of the effect of guidelines. Overall composite scores were based on commonalities' analysis across national studies with clustering of questionnaire items into account.
The α level was set at .05 and SPSS was used for analyses of data.

4.7 Standards, considerations, and limitations

Last, it was taken into account early in the design of that response rates and drop outs should be anticipated because of the empirical element and the cross-country testing for quite some time. It was agreed that partners would make an effort to accommodate for response rates, which is difficult to estimate as it is usually based on previous experience (country-wise). A conservative estimate was 50% and consequently doubled the required sample size. In this section, no country specific information is provided as the same number of participants was calculated for all national studies.
For some of the partners, the evaluation process was based on existing integrated decision support systems. In addition, in some countries the health professionals are more acquainted with ICT tools and rely more on their support.

5 Analyses

This section focuses on the analyses performed for the consolidation of the results. Each national report is based on the initial framework; however, deviations exist in each country report and in depth analyses of individual hypotheses and respective research questions are addressed by the national studies' researchers. Apart from in depth specific analyses it is of considerable importance to investigate if and how our initial framework -that the rest of the bottom-down studies are spreading from- accommodates our findings. The analyses are based on composite scores for the main behavioural clusters included in the basic questionnaire and are the following:

A. Attitudes

Strongly disagree	disagree	agree	Strongly agree
1	2	3	4

B. Reported Behaviour

Never	Seldom	Sometimes	Regular
1	2	3	4

C. Actual Knowledge

Sum of correct number of answers

Following the analysis, conclusions were drawn upon the interpretations of the findings and potentials for future recommendations related to guidelines development and adherence.

5.1 Overall demographics

In total, 230 participants ($N_{Physicians}$ = 68 and $N_{Pharmacists}$=162) were included in the overall analysis (descriptive statistics) were post test data were used (i.e. demographics). In the overall database, 2 missed cases were excluded. The numbers represent the participants of post conditions in order to control for overall drop outs.
It is important to note that the control group from the Dutch study and the nurses group from the Spanish study were not included in this analysis, as the first one acted as a reference group for the intervention and nurses were not included in the other studies. In other words, the overall sample comprised of the participants bearing comparable characteristics for the analyses performed latter in the analyses section (5.2 and 5.3, respectively). The demographic characteristics of these two groups are discussed in detail in the respective country studies section included in Part B of this deliverable.
The following graphs presents the basic demographics recorded as background information for the whole group in percentages (%).

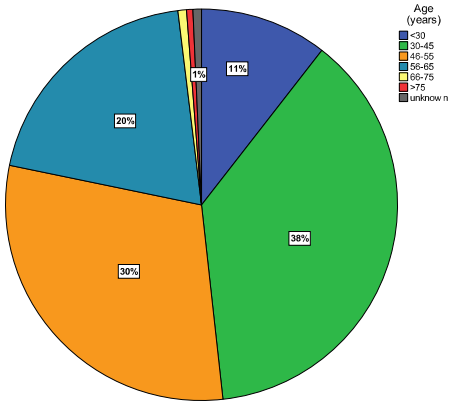


Figure 7: Age distribution

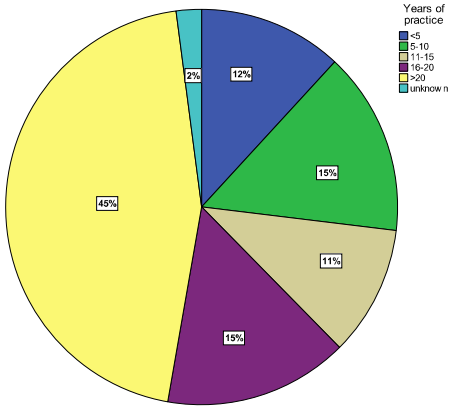


Figure 8: Years of practice

Almost a third of participants (68%) were between 30 and 55 years, which do reflect the normal age groups for health professionals. The group is slightly skewed due to physicians who get into medical practice much older (long period of studying).
Most participants (60%) have over 15 years of practice; hence the majority is experienced health professionals.
In addition, gender distribution was the "exact opposite" for physicians and pharmacists. The majority of participants were female in the pharmacist (66%) group and male in the physician (63%) group.

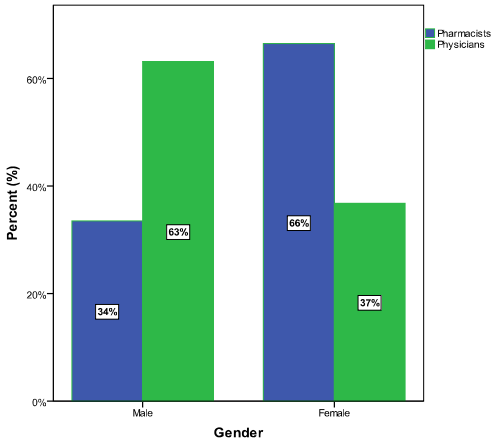


Figure 9: Gender distribution across groups

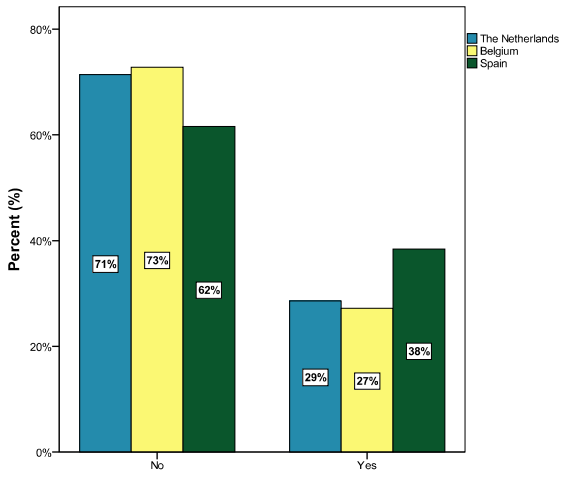


Figure 10: Education about medicines' driving impairing effects in driving

Significantly more participants (Yes: 60/No: 169) had no education regarding medicines and driving during their academic studies and their professional participation in postgraduate education (χ^2 (1) = 51.882, p<.001).
Additional comparisons were performed in order to examine if the differences in education among countries is of significance (Figure 10). Cross-tabulations did not reveal any significant differences among groups (p>.05).
The following graph depicts the percentages of physicians and pharmacists in before (T_0) and after (T_1) trial period. It is evident that physicians and pharmacists as experimental groups do not show similar variation across countries. The Dutch study focuses entirely on pharmacists dispensing habits; the Belgium study certainly shows increased participation by pharmacists

by approximately 10%. On the other hand, the Spanish study shows a harmonized distribution of participants with almost 30% less participants in the later part of the study.

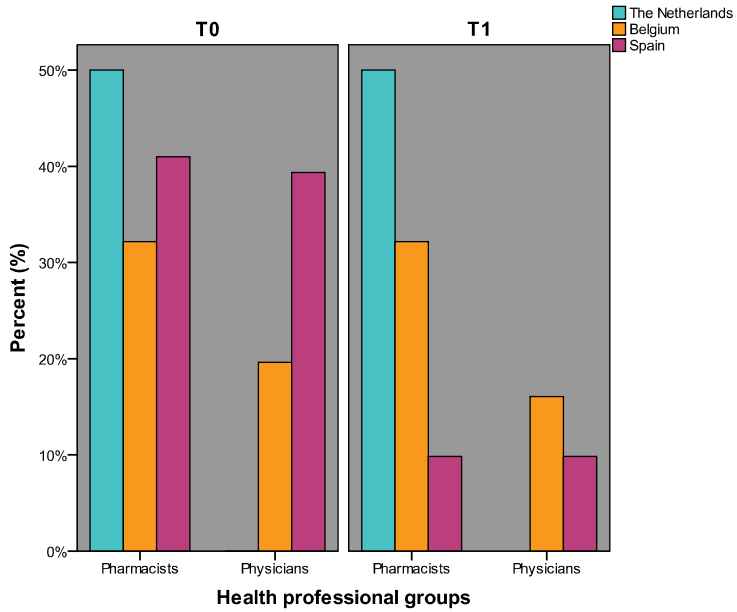


Figure 11: Health professionals across countries for both pre and post conditions

Overall demographics (percentages of participants within country and not within condition) are presented in Figure 11: Health professionals across countries for both pre and post conditions sketch a preference of pharmacists (60%) to test the DRUID developed guidelines. The latter may be the result of more pharmacists using computerised decision support systems in their everyday practice. Specifically, for the Belgian study, two possible explanations are that physicians are asked to participate in many studies and there is a possibility to be more selective than pharmacists who are less often asked. Moreover, in Belgium there is a change in pharmaceutical practice, with focus on pharmaceutical care and re-evaluation of pharmacist's role, which could explain the interest of pharmacists for an area where their consulting role is valuable.

5.2 Physicians

This group consisted of physicians participating in both pre and post condition from the Belgian (N=50) and the Spanish study (N=18). The following graph shows percentages (%) of physicians for each country for pre and post trial conditions. In addition, age distribution is presented in (Figure 12).

5.2.1 Background information

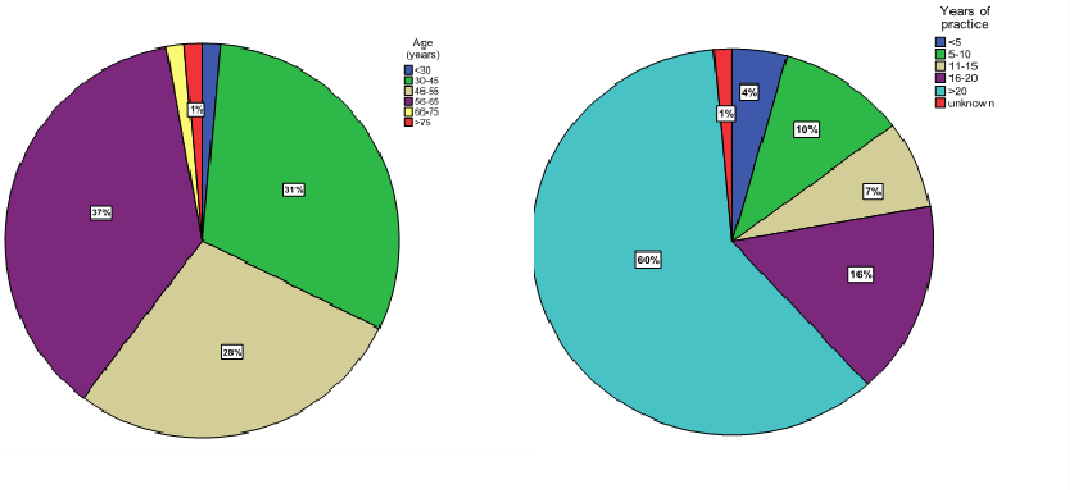


Figure 12: Age and years of practice distributions

Age distribution appears to be equal for the three age categories between 30 and 65 years of age (Figure 12).

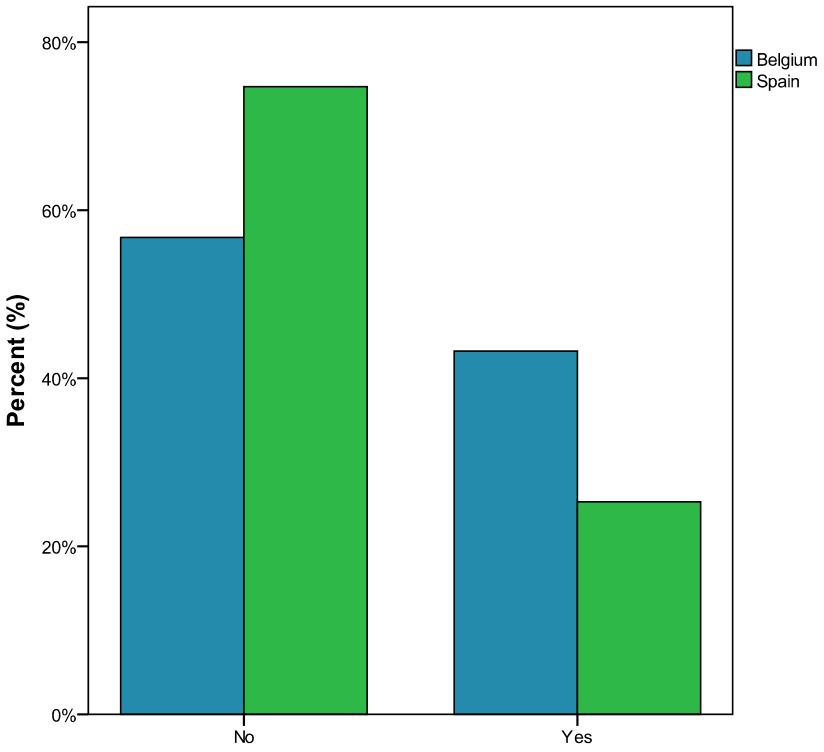


Figure 13: Education on medicinal impairing effects on driving

Overall, significantly more physicians in Spain had no education regarding medicines and driving during their academic studies and their professional participation in postgraduate education (χ^2 (1) = 16.99, p<.001) when compared to physicians in Belgium (Figure 13).

5.2.2 Pre and post comparisons

This section includes results from before and after the trial of the tool for a considerable period of time (6 months) for all countries. Data taken into consideration are from participants that filled in the pre and post questionnaires. This analysis is focusing on the effect of the intervention itself to the prescribing patterns of physicians and DRUID guidelines adherence. The interpretation of these results carries inherent limitations. First of all, although, we attribute them characteristics of one sample repeated measures for the shake of statistical testing, they are not really one sample. Therefore, the inherent differences lie within the group itself. On one hand, this is resolved by the combination of nonparametric tests and a large overall sample. On the other hand, only guidelines adherence is of investigation rather than the tools used themselves.
Overall statistically significant increase in Reported Behaviour (z = -2.153, p<.031) was found On the contrary, no significant differences in Actual Knowledge and Attitudes were revealed (p>.05). For almost half the participants (45%) the amount of related knowledge remained the same and was not affected by the training.

The significant difference reflects positive change in 43% of physicians in the frequency of applying the DRUID guidelines when they prescribe medicines that affect driving behaviour (i.e. from seldom to sometimes).

More specifically, further pairwise comparisons were perfomed for the aforementioned significant findings. Statistical significant differences for both pre and post conditions between the Belgian and Spanish study regarding Reported Behaviour and Actual Knowledge were found. It is always borne in mind that the differences may be partially affected by differences in the populations they represent and not the DRUID information only.

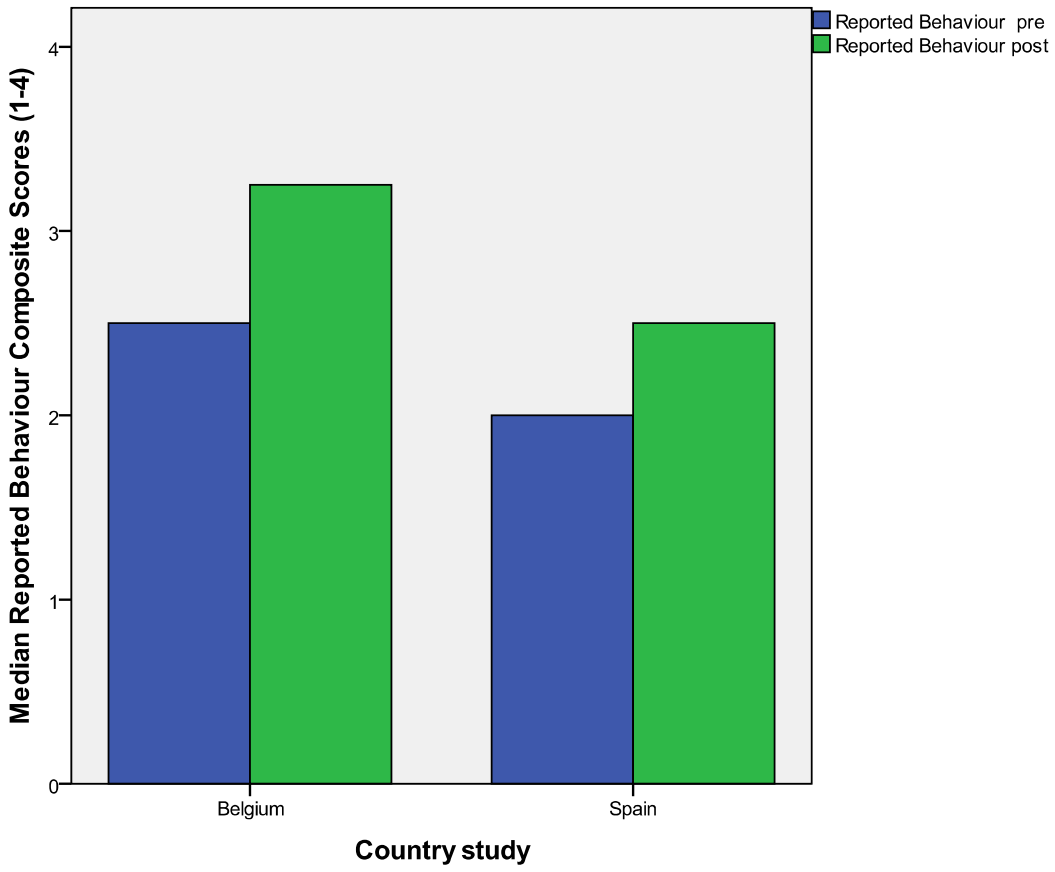


Figure 14: Median scores for Reported Behaviour per country study for both conditions

It is evident from the above graph (Figure 14) that Reported Behaviour in post condition differs significantly between Belgium and Spain (z=-2.127 p=.033). The difference for the pre

condition was not of significant values (p>.05). In the Spanish study, positive change is shown for the group of physicians although, they take into account less driving related guidelines when prescribing medicines compared to Belgium, a change after the application of DRUID guidelines is present. If we accept our sample as a whole, then 33% of Spanish physicians applied between “seldom” and “sometimes” the guidelines received; however, 30% of Belgian physicians showed increased frequency (i.e. from “sometimes” to “regular”).

In both Belgian and Spanish studies, increase in Actual Knowledge has been shown as a result of training and the application of DRUID guidelines (Figure 15). Actual knowledge was significantly higher in Belgium when compared to Spain in both pre (z=-4.695, p<.001) and post (z=-3.394 p<.001) conditions. The reported sum of correct answers for the artifact of Actual Knowledge showed a great difference. There is a chance this difference to reflect differences in focus (e.g. academic curricula) and training received by professionals within their educational programmes (i.e. academic studies) and during their participation in post-graduate education.

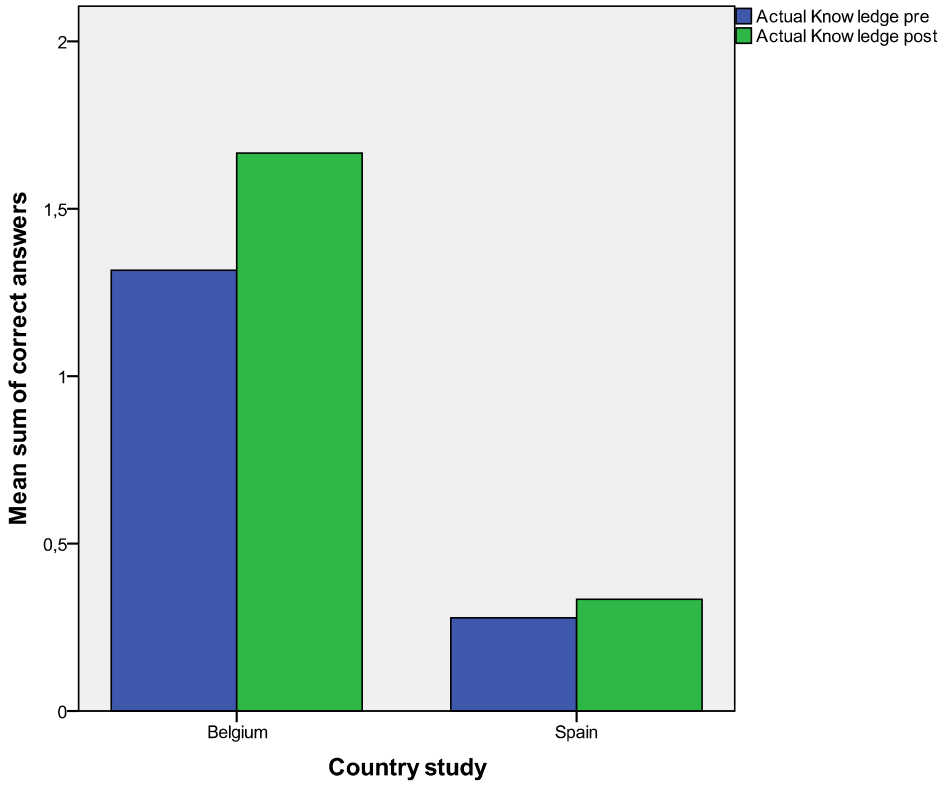


Figure 15: Mean sum of correct answers for Actual knowledge per country for both conditions

Before moving to the overall comparisons between Belgium and Spain on the amount of change in the selected clusters of behavioural items after the application of DRUID guidelines, it is interesting to consider the situation of the control group.
What happened to the physicians that did not receive any type of DRUID related guidelines for six months (control group)?
The only significant difference was found for the Actual Knowledge (z=-2.639 p=.008). All the other pre-post comparisons (i.e. Attitudes and Reported Behaviour) was not of statistical significance (p>.05). Almost 53% of participants in the control group showed increased correct answers in the post phase of the study. On the other hand, 75% of the control group retained the same attitude towards the effect of medicines to driving and Reported Behaviour scores were equally distributed across negative, positive, and ties (36%, 33%, 31%, respectively).

5.2.3 Between countries comparisons

Supplementary analysis to 5.2.2 was carried out in order to pay special attention to the differences that may exist in the size of differences from the pre to the post condition (δ). In other words, differences in change controls for the inherent differences discussed in the two previous sections. The groups included in this analysis are the participants who received the DRUID related training and guidelines.
The overall amount of change for all composite scores is small as it is evident from the values in (Table 4).

Table 4: Overall Mean±Standard Deviation statistics for the composite score for physicians

Change in composite score (δ)	**Mean±Standard Deviation**
Reported Behaviour	0.321±0.875
Actual Knowledge	0.071±1.112
Attitude	0.143±0.354

No Significant differences were found between the Belgian and Spanish studies with regard change (δ) in Reported Behaviour, Attitudes, and Actual Knowledge (p>.05). The change in professionals' daily practice because of the applicaton of the DRUID guidelines was not different between the Belgian and Spanish study.

The next step was to compare the change in our overall composite scores for the physicians that used the DRUID guidelines and categorization to the ones that did not use it at all (i.e. control group). The following graph (Figure 16) depicts the mean differences but it is important to keep in mind that the scale that corresponds to each cluster is different not only in rating order but more importantly in notation. All the lines have been included for summarizing purposes more than comparison between them. The comparisons that are meaningful are between the control and the DRUID information groups.

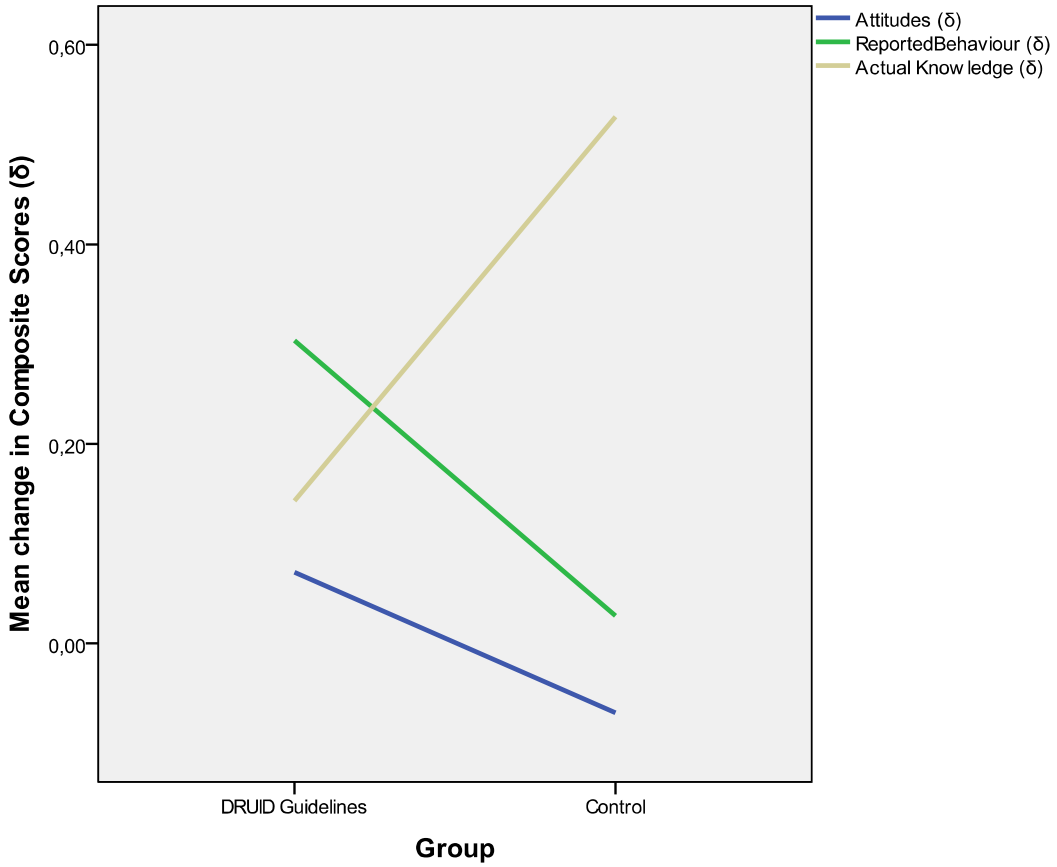


Figure 16: Mean change (δ) for all composite scores for the DRUID guidelines and control groups

The change in Attitudes (z=-2.234, p=.026) was significantly greater for the physicians who were trained with the DRUID guidelines. On the other hand, Actual Knowledge (z=-1.931, p=.05) showed that the increase in the control group was higher but of marginal significance. No statistical significant difference in amount of change was found for the Reported Behaviour (p>.05). As mentioned above, the interpretation of Figure 16 should be followed with caution as its line is measured with different unit and represents different scale as described in the introductory section of analyses section.
However, the interesting and very difficult to interpret finding is that Actual Knowledge increased for the control group much more than it did for the DRUID information group (Figure 16) although the difference is small. There is a possibility that participants received information (training based) via another educational programme and/or colleagues. However, these variables cannot be controlled for easily in an empirical research.

5.3 Pharmacists

Initially, 216 pharmacists participated in the pre condition and then the number dropped to 162 in the post condition. The following table presents the distribution of participants across conditions.

Table 5: Number of participants per country study for pre and post conditions

Time of the measurement * Country study Crosstabulation

Count

		Country study			
		The Netherlands	Belgium	Spain	Total
Time of the measurement	Pre	44	100	75	219
	Post	44	100	18	162
Total		88	200	93	381

The higher percentage of female participants (33%) is coming from Belgium and the smaller percentage of male (6%) is coming from Netherlands.

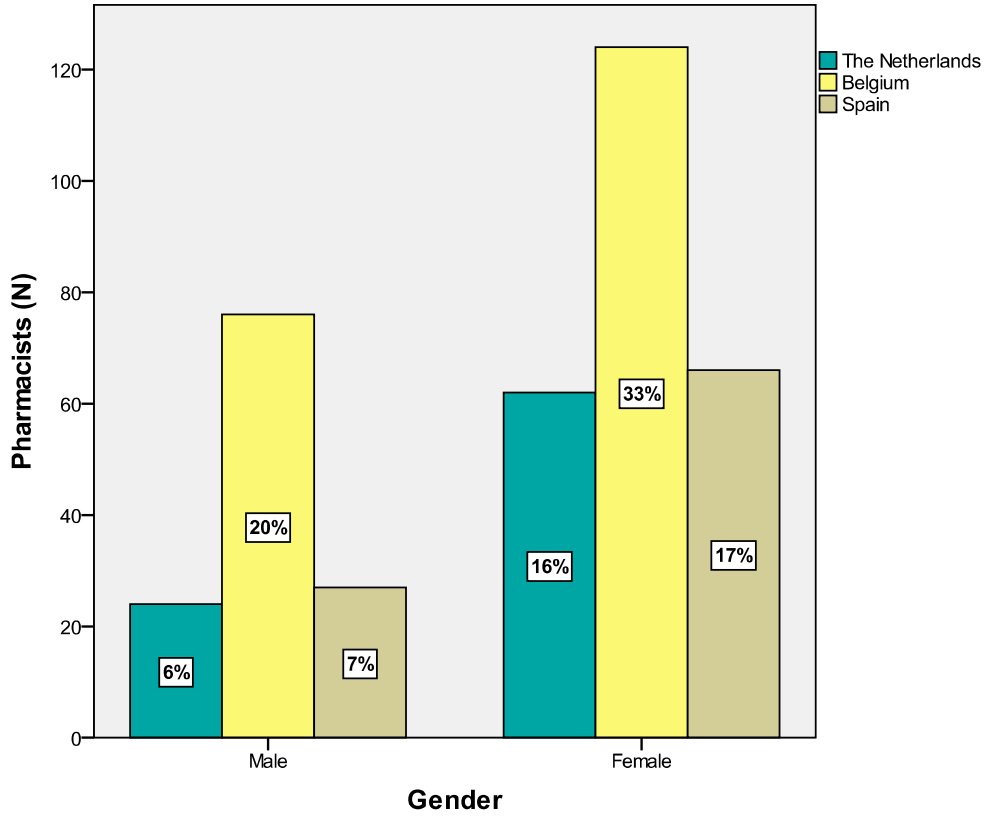


Figure 17: Gender distribution across country studies

5.3.1 Background information

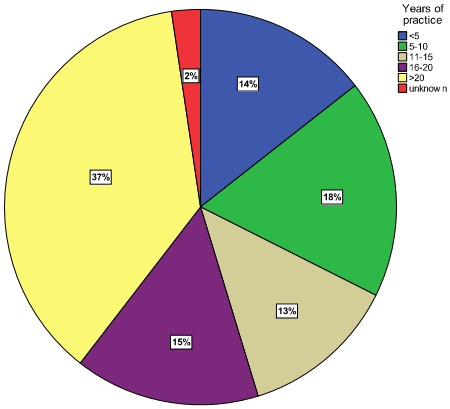


Figure 18: Distribution (%) of years of practice

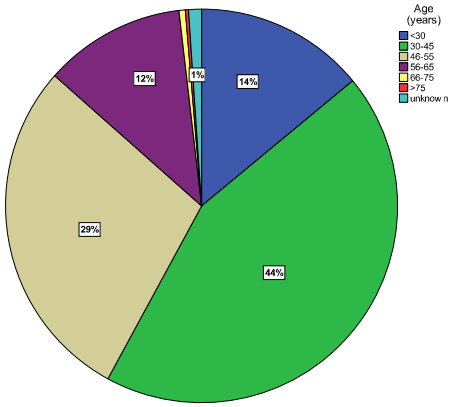


Figure 19: Distribution (%) of age categories

Half of the pharmacists (52%) have experience in their field for more than 15 years. In the pharmacist group, representation from different "experience" groups exists. Similar to the physicians group, the higher percentage of pharmacists (73%) belongs in the age categories between 30 and 55 years of age.

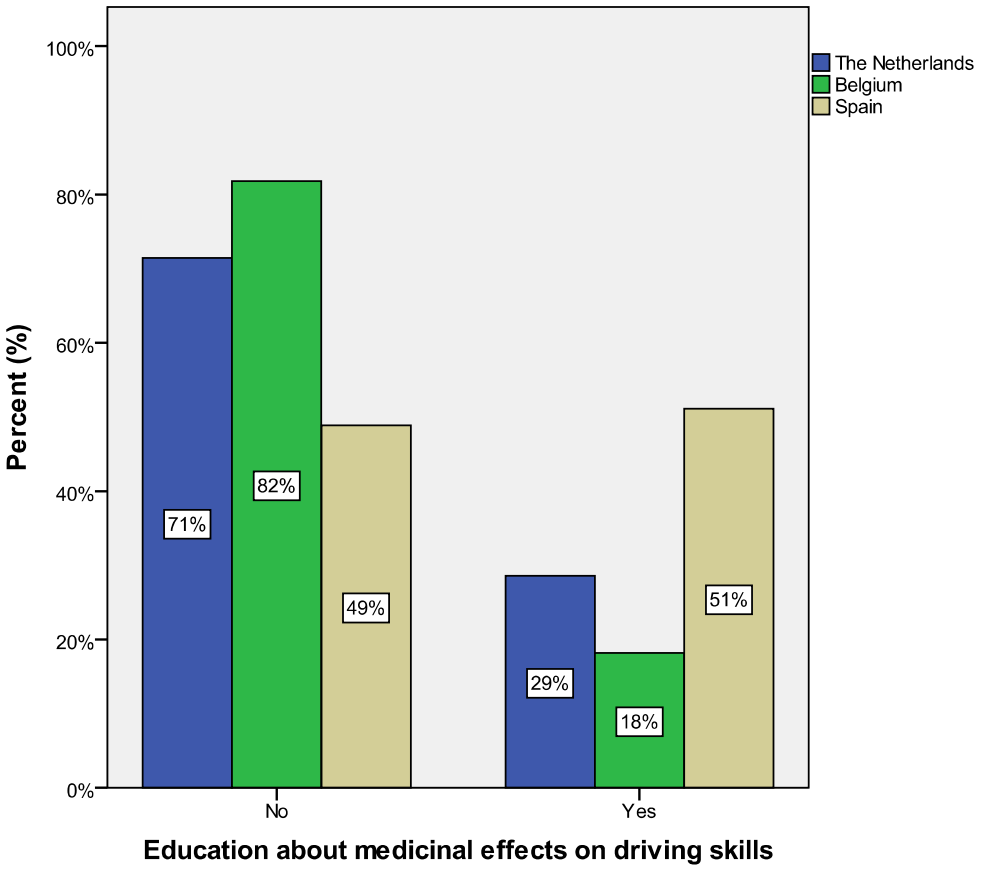


Figure 20: Percentage (%) of participants that received or not education about impairing effect of medicines in driving behaviour per country study

It is clearly depicted in the above figure that only in the Spanish study the percentage of pharmacists that received training or education about the potentially impairing effects of medicines in driving was slightly higher (51%) than those that did not (49%).For the rest of the participants less than one third of pharmacists had received any related education (29% and 18% for the Dutch and Belgian study, respectively).

5.3.2 Pre and post comparisons

Overall pre and post comparisons for the selected clusters related to guidelines adherence were conducted and significant differences were revealed for all of them. For the comparisons that are related to the effect of DRUID guidelines, it is self-explanatory that only the participants receiving the training and, consequently, the guidelines were included in this analysis. Separate comparisons with the control group were conducted and discussed in a later section of this document.
Attitudes and awareness were significantly more positive after the implementation of DRUID information (z=-5.678, p<.001).
Significant increase in Reported Behaviour (z=-4.680, p<.001) and Actual Knowledge (z=-4.653, p<.001) was found and it is clearly shown in the following graphs. Both composite scores increased by one (different unit for each composite, i.e. scale for Reported Behaviour and sum for Actual Knowledge). Median Reported Behaviour increased from “seldom” to “sometimes” and the mean sum of correct answers (Actual Knowledge) increased from 2 to 3.
Statistically significant difference has been shown for awareness after the implementation of DRUID related information to 33% of participating pharmacists (positive) when compared to those that they showed decrease (negative). However, the vast majority of pharmacists (65%) in the sample did not shown any change in their existing attitudes (ties). On the contrary, 58% of pharmacists had a positive change in their Reported Behaviour towards incorporating driving related guidelines in their daily practice and 49% of participants gave more correct answers about professional practice after the end of the trials. Reported Behaviour positive change in pharmacist between pre and post trial conditions is from “seldom” to “sometimes” that is translated in an increase in frequency of application of DRUID guidelines and categorization in daily dispensing practice.

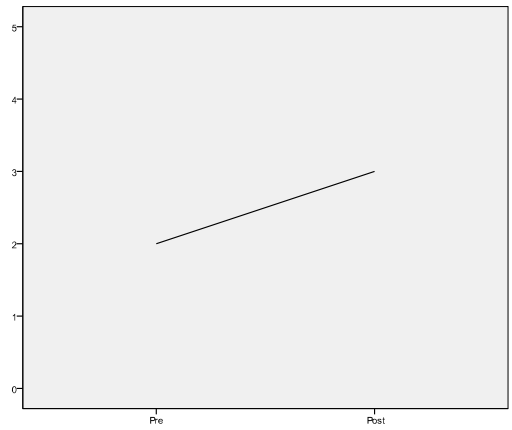


Figure 21: Median Reported Behaviour scores for pre and post conditions

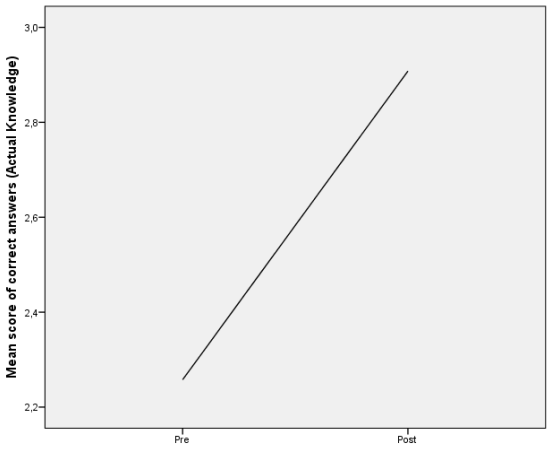


Figure 22: Mean sum of correct answers (Actual Knowledge) per condition

In general, participants showed change in both knowledge and everyday practice. It is important to investigate if the change was random or due to application of DRUID guidelines.
General comparisons between the overall DRUID information group (both intervention and information materials were included) and the control group which did not receive any DRUID related information and/or guidelines were carried out.

Firstly, an account of pre and post differences is presented and secondly, the investigation of differences in amount of change (δ) between the DRUID information group and the control group is provided.
No statistically significant difference in attitudes between the DRUID information and control group was shown for both pre and post conditions (p>.05).
On the other hand, the DRUID information group was significantly more "knowledgeable" (z=-3.691, p<.001) in the post condition (signified by the star in Figure 23). As it is evident in the graph, participants showed approximately increase of 20% in the sum of right answers they gave which is easily translated into one more right item in the post questionnaire.

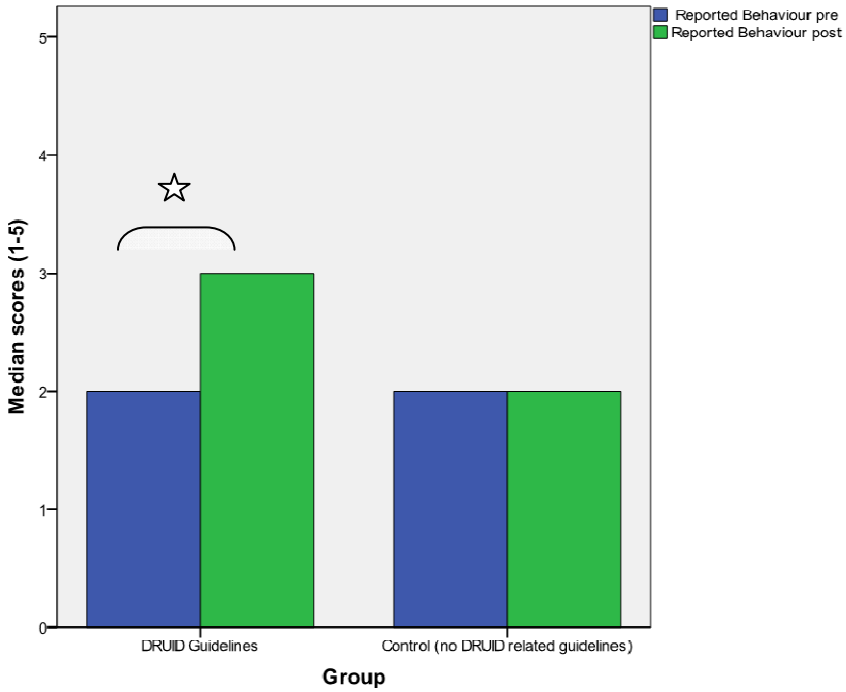


Figure 23: Median scores for Reported Behaviour for the DRUID information and control group in pre and post conditions

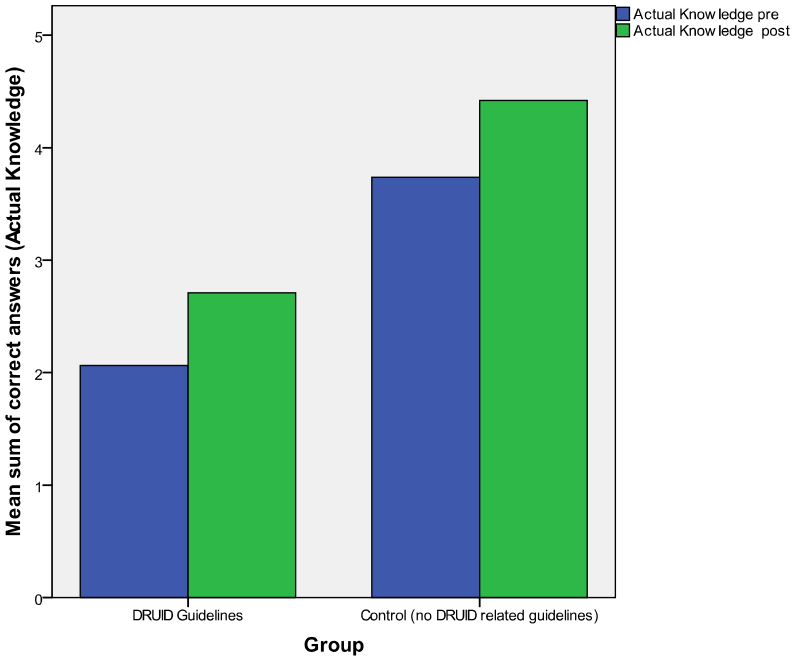


Figure 24: Mean sum of correct answers for the DRUID information and control group in pre and post conditions

It is obvious from the above graph that the control group overall showed increased knowledge compared to the DRUID guidelines group. In addition, change in knowledge was also noted in the pure control group. Therefore, their information source was different or they knew the right answers the second time around. However, the size of the control group (n=49, 20%) was very small compared to the DRUID information group (N=144) in order to yield reliable and interpretable results. No statistically significant difference was found for Reported Behaviour and Attitudes between the control and DRUID information groups (p>.05).
If our groups do or do not differ at baseline, then how do we know that the effect we measure at the end of the trials is the result of the application of DRUID guidelines?
The second step is to isolate the amount of change (δ) for each participant. The third step is to compare the amount of change in Actual Knowledge and Reported Behaviour for both DRUID information and control groups and investigate the size of the effect and if it is of significant value. Non parametric tests were conducted in order to investigate the differences in the amount of change (Levene test significant). No statistical significant differences were found for the three clusters of behaviour investigated between control and DRUID information group for the amount of change (δ) in Attitudes, Reported Behaviour, and Actual Knowledge (p>.05).

5.3.3 Between countries comparisons

Another step in the overall analysis is to investigate the potential differences among the different studies.

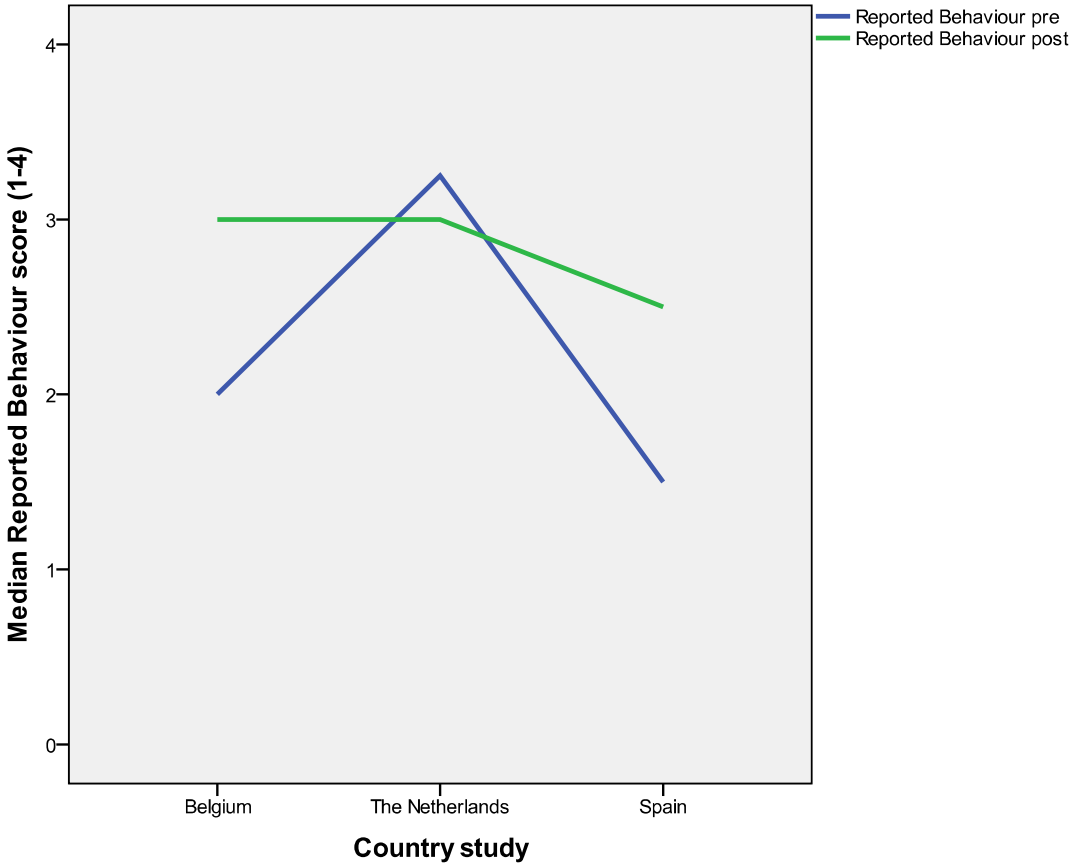


Figure 25: Median Reported Behaviour scores for pre and post conditions among countries

According to the graph, differences among countries appear before and after the end of trial period. The differences for Reported Behaviour seem to be higher in the pre condition when compared to the post condition. Pharmacists from the Dutch study appear to have a similar Reported Behaviour after the implementation of DRUID guidelines but in Spain and Belgium the situation is different. Pharmacists from all country report that sometimes they tend to use the DRUID information (guidelines and categorization) during their daily practice after the 6

months of trial. Initially, they seldom used any type of guidelines for informing their patients about the relation between medicine uptake and driving.
An overall Wicoxon Signed-Ranks test revealed statistical significant difference among groups ($p<.001$) and pairwise comparisons followed. Overall, the following figure presents the statistical results and provides the significant differences among countries. Non parametric between groups' comparisons (Mann Whitney U tests) revealed statistically significant differences between Belgium and Spain across all cluster categories

On the other hand, differences exist between The Netherlands and Spain for Reported behaviour and Attitudes but for Actual Knowledge is not significant ($p>.05$). Similarly, the differences between Belgium and The Netherlands are of significance except Attitudes (trend, though, exists). In Netherlands the pharmacists show more disagreement with the statements in the pre-questionnaire compared to pharmacists from the other two countries. However, as it will be shown in later analysis these differences disappear in the post condition. It is remarkable how attitudes are linearly transformed after the implementation of DRUID information to all country studies (Figure 25). Pharmacists show positive change towards increase in awareness by moving from "disagree" to "agree" in all countries (median values).
The following tables (Table 6 and Table 7) depict the significance of differences by colour in order to visualise the diversity brought upon by the inherent cultural and other potential sources. The colours do not carry a meaning but show the combination of differences in the clusters of behaviour under investigation (e.g. if significant differences reported only in Reported Behaviour were found, they are shown with turquoise colour and if differences in Reported Behaviour and Actual Knowledge were found they are depicted with light blue colour).

Table 6: Significant comparisons among country studies (pre conditions)

Country study	Belgian	Dutch	Spanish
Belgian		**RB, AK**	**RB, AK, A**
Dutch	**RB, AK**		**RB**
Spanish	**RB, AK, A**	**RB, A**	

RB: Reported Behaviour

AK: Actual Knowledge

A: Attitudes

Differences in all behavioural clusters were found between Belgium and Spain. A note should be made about potential influence of the importance of negative correlation of geographical distances and behavioural, social aspects and structures. Individuals that live in the same coutrny tend to show greater similarity in their attitudes and beliefs than people who have greater geographical distance. Therefore, there may be a negative correlation between geographical proximity and similarities in the behavioural aspects that are being examined in this deliverable.
As shown below, although significant differences were found among the three countries in attitudes, it seems that most pharmacists have a positive attitude and increased awareness across all countries. It is important to check the data in order to find where the differences lie that is not evident in the graph. The mean rank for Belgium was 57.78 and for Spain 73.45, which means that Belgian participants scored their attitudes a bit lower (more negative) than Spanish pharmacists before their participation in the trials. In addition, Dutch pharmacists seem to take into consideration most driving impairing effects of medicines when they dispense a potentially impairing medicine. On the other hand, Belgian pharmacists seem to know a lot more than their colleagues from Spain and Netherlands before they were trained with the DRUID materials and tools.

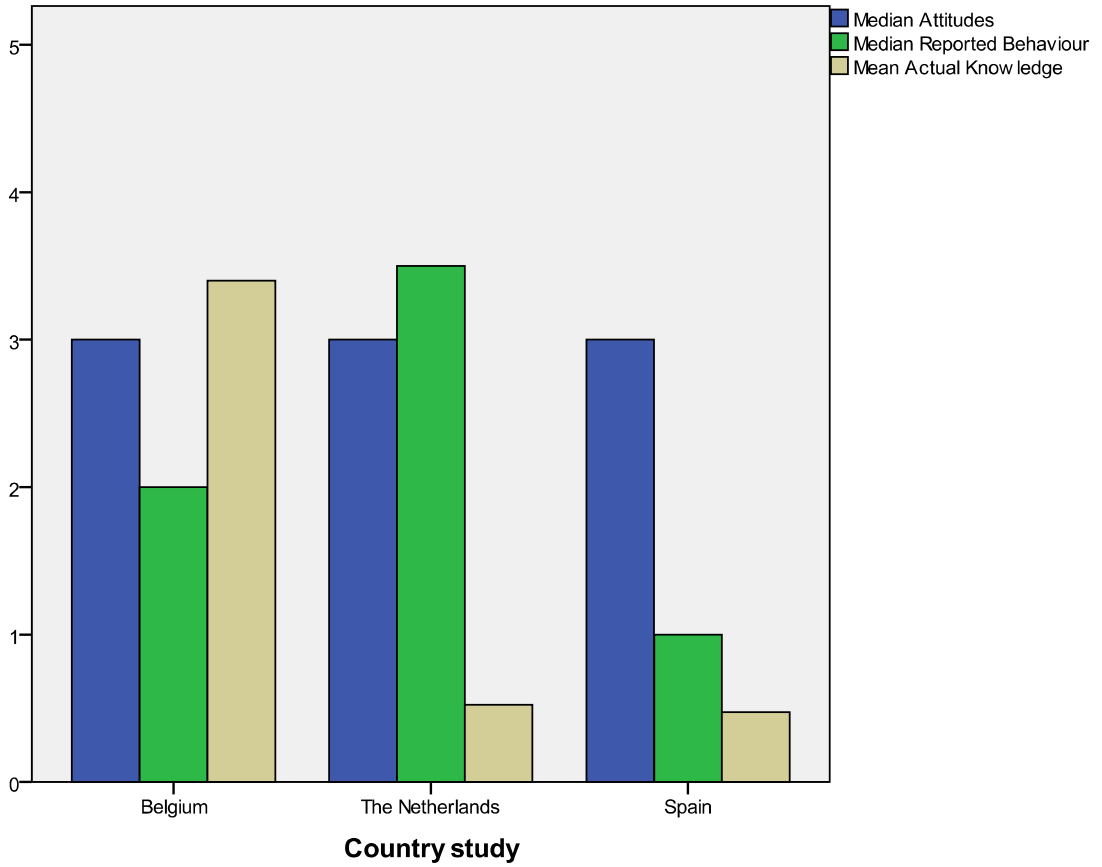


Figure 26: Scores for the clusters of behaviour per each country for the pre condition

Similar comparisons among the country studies for the three behavioural clusters were carried out. A significant Kruskal-Wallis rank test ($\chi^2(2) = 149.53$, $p<.001$) led to further pairwise comparisons in order to reveal where the significance lies and most importantly what it may mean for our samples.
The differences between Belgium and Spain pertain after the testing period ends for all clusters. Spanish pharmacists' positive change is remarkably reaching a very increased awareness compared to Belgian ($p<.001$ and $p=.019$, respectively) and Dutch pharmacists. However, only the first one reaches statistical significance as the mean ranks are 41.96 for Belgium and 67.29 for Spain. Additionally, Spanish pharmacists show significantly less incorporating in to every day dispensing of DRUID guidelines compared to Belgium and the Netherlands ($p=.011$ and $p= .036$, respectively). Significant differences in Actual Knowledge gained from the participation in the DRUID study was significant for all possible comparisons as shown in Figure 27.
The findings in the post condition overall should be treated with caution due to differences in the sample sizes.

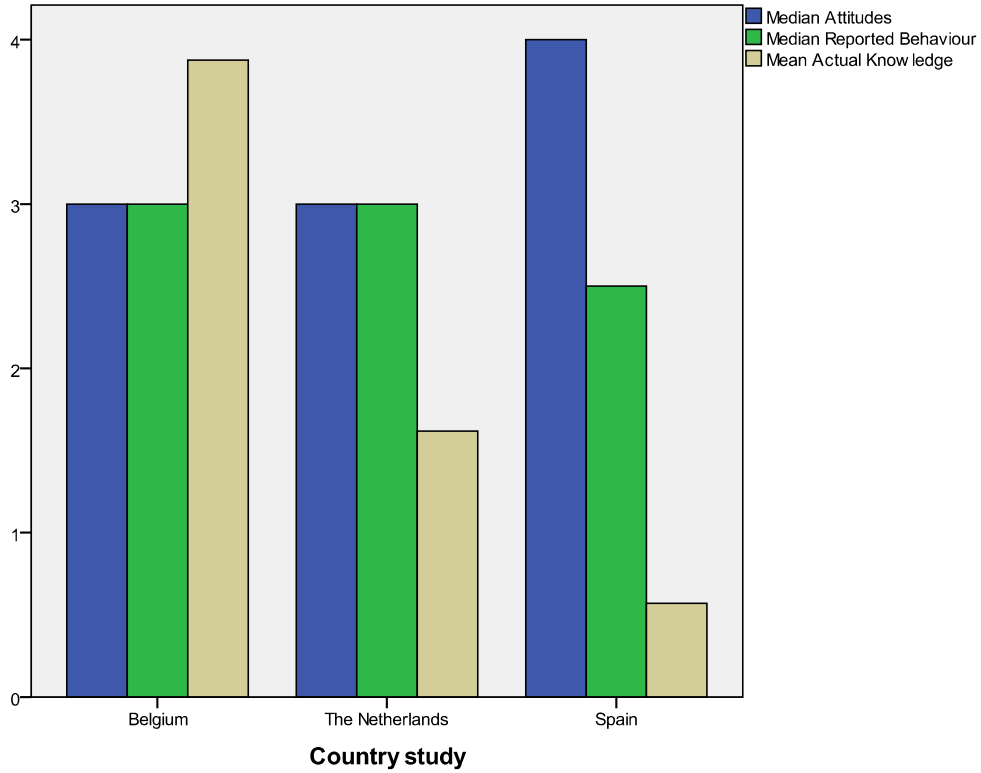


Figure 27: Scores for the clusters of behaviour per each country for the post condition

Finally, comparisons on the amount of change (δ) from the pre to the post condition for all countries that implemented the DRUID guidelines were carried out to simply evaluate the between groups size of effect, and indirectly effectiveness.
Overall Kruskal Wallis tests were carried out for all behavioural clusters led to pairwise comparisons Differences in amount of change were found in Actual Knowledge and Reported Behaviour and not Attitudes. The amount of change in Attitudes was not significant overall (p>.05).

Table 7: Significant comparisons among country studies (post conditions)

Country study	Belgian	Dutch	Spanish
Belgian		**AK**	**A, RB, AK**
Dutch	**AK**		**A, RB, AK**
Spanish	**A, RB, AK**	**A, RB, AK**	

Overall, significant differences were found in the amount of change from the beginning till the end of the study among the country studies. These differences in changes may be the result of many reasons and factors but before moving to the respective inferences, comparisons between countries would show where the differences may be found.

Further pairwise comparisons were conducted in order to investigate where the differences lie. Significant differences were found mostly between Belgium and Netherlands, and Spain and Netherlands. The amount of change may be different to Netherlands because in this study the within DRUID developed tool was not applied and only one tool was used for the evaluation. In the other two studies, they applied two different ICT tools for delivering the guidelines.

6 Discussion

6.1 Background characteristics

Most participants were experienced professionals between 30 and 55 years old in both professional groups. Female participants were over-represented in the pharmacists group (66%) and male participants (63%) were over-represented in the physicians group.

6.2 Physicians

Physicians have shown a positive change in their Reported Behaviour (43%). Therefore they incorporated DRUID guidelines in their daily practice regime. Although, differences for Attitudes/Awareness and Actual Knowledge were not different between the pre and post conditions, according to the adopted model, changes in these two clusters are important in order to find differences in Reported Behaviour. The majority of physicians who did not receive any DRUID related information did not change their daily practice or showed negative change (69%). The implementation of DRUID guidelines had a 10% increase difference in the positive change in Reported Behaviour in the overall physicians' samples across the country studies. This difference may be a simplistic measurement of effect size with all its respective limitations (discussed in the Limitations section) but serves as an estimate for the effect of the benefit the implementation of DRUID guidelines could impose on the quality of care. This finding also suggests the readiness of physicians to adopt DRUID guidelines. The next step would be appropriately target support strategies as discussed in the implementations' section.
Moreover, in the Belgian study, participating physicians have shown to be taking more into account the DRUID guidelines while prescribing medicines when compared to the physicians in the Spanish study. The number of participants in the Spanish study though is much smaller compared to the Belgian study. The difference may lie to the smaller number; however, the frequency is different between the studies. As discussed in the country reports, in some countries specific programmes and campaigns have been implemented targeting drugged driving. In both the Netherlands and Belgium the decision support systems have incorporated relevant information. Therefore existing familiarization may have enhanced the findings for these countries.
The aforementioned finding is in line with the fact that physicians in the Belgian study showed higher Actual Knowledge (i.e. higher sum of correct answers) about the effects of certain medicines and doses. Again, differences exist in both sample size and pairing of pre – post conditions (i.e. lower pairing of pre –post responses in the Spanish study).
With regard to difference in change in Actual Knowledge, it could be argued that the difference may reflect difference in relevant training during their studies (e.g. during residency or seminars). This argument might be supported by the fact that in the Spanish sample 20% less participants had received related training during their studies compared to their Belgian colleagues. If physicians were included in the Netherlands study, then it would be easier to sketch a geographical based profile on potential for guidelines' adherence. However, as it was discussed in the Dutch country report, the feasibility for such an option was limited and therefore dropped as physicians were less eager to participate.
Interestingly, most physicians in the group were not educated about the potentially impairing effects of medicines on driving fitness. Usually, patients have limited information about side effects of prescriptions they follow regardless if it is temporary or for a longer period of time. As information mainly comes from the patient information leaflet inside the medicine box, usually patients rely on this information. Consequently, the information they receive from their doctors or pharmacists is important not only in the communication of related side effects and dangers but for their compliance to patient instructions and warning. The relationship developed between the health professional and patient has been shown to be the most important ingredient in the compliance of patients to advice and guidelines.

Regarding physicians overall positive change was found for Reported Behaviour and not for Actual Knowledge and Attitudes for the comparisons before and after the usage of DRUID information. This finding does not fit well to the adapted framework, as changes in knowledge should precipitate changes in attitudes and then followed by changes in reported behaviour according to Cabana and colleagues (1999). Changes were found for the final link but not for the previous ones leading to behaviour. There may be several reasons explaining these

inferences. More than 45% of physicians did not report increased knowledge regarding medicinal impairing effects in driving behaviour. Change in attitudes is unstable and it is usually the result of intertwining between emotional and cognitive aspects (Eagly & Chaiken, 1995) through compliance, identification, and internalisation (Kolman, 1938). These processes might require more time than the six months period that the country studies lasted.
A question mark on this finding could be placed as the differences that we try to reveal may have a different basis after all. In other words, if Belgian physicians' awareness and application of relevant guidelines is of an adequate level, the change towards optimal behaviour is much more difficult to be attained, than from moving from a non awareness to an "acquaintance" level of practice.
Changes not revealed for all behaviour clusters may have happened for several reasons. On a practical level, it could be assumed that physicians have taken more consideration, effort, and time in order to inform their patients about driving and medicines, as from now on, it was an important "item" in the "professional daily agenda" (Reported Behaviour). But they did not spend more time in order to learn more about detailed accounts and more specific information about which dosages of which drugs are more dangerous to create a problem to patients and other driving related information (Actual Knoweldge).
Physicians who practice medicine for many years tend to be more empirical than when they begin their practice, as they rely heavily on their experience. The latter holds true for most professionals regardless if their occupation relates to medicines and health or not.
Therefore, this negative finding may be an important discovery that training should be rigorous and frequent in order to become cost-effective in the future.
In addition, significant changes between Belgium and Spain were shown for Reported Behaviour. Both countries have shown positive change in the frequency they inform patients about driving and medicines' effect. Change shows a trend towards regularity in the Belgian study and towards more frequent implementation in Spain. These are optimistic findings if we take into consideration that this study lasted only 6 months with diverse tools and diverse populations of both professionals and countries.
The general application of these findings could be a next step towards implementation and further enriching of the tool's content.
As discussed in section 5.2.2 significant difference in the amount of knowledge was found for physicians between the countries for both the pre and post comparisons. These amounts reflect only the participants that received the DRUID guidelines. It may be, though, that the differences are inherent to the educational system or the training itself. In addition, although, the overall analyses was adjusted to the composite scores sums needs, some of the questions included for both countries differ both in number and quality. Hence, their differences should be dealt with caution and considerable hesitation in deriving inferences.
The amount of right questions is small for both countries. The change may be the result of discussion with colleagues and/or personal search. Either way, it is a positive implication and affect of the training and trial experience.
The control group did not receive any DRUID related information, did not participate in the training schemes, and used probably the same tools they were using till now for their medical practice. However, a significant increase in the amount of correct answers (p=.008) was found. The effect may be additive in nature, meaning that physicians may have searched/read/discussed with other colleagues after filling in the first questionnaire and were motivated to find the right answers themselves the second time they were asked to complete the questionnaire (post questionnaire).
As physicians in the control group appear to try to find themselves the right answers shows the importance, the need, and the existing gap in training health professional about the consequences that prescriptions have on driving fitness as in other everyday activities.

Further comparisons were carried out in order to isolate the amount of change for each cluster of behavioural items (i.e. Attitudes, Reported Behaviour, and Actual Knowledge). The amount of change was comparable for Belgium and Spanish sample of physicians who were trained in the DRUID guidelines and categorization of medicines.
Similar comparisons between the DRUID information and control group showed that physicians who received training and used the DRUID information showed a statistically significant positive change in their awareness level about the potential detrimental effects of medicines on driving fitness and in their personal, professional medical practice. The only slightly "off" finding is that physicians who were regarded as the control group showed of

marginal significance increase in their knowledge of information. Could it be their own curiosity and professional motivation to search and look for correct answers to the respective questions and statements? Did the physicians who had all day access to the guidelines and categorization and a whole day of training about medicines and driving rely less on their knowledge and automatically adjust it to their integrated tool?
The training had an impact in the way they *think* and *behave,* but not in *what* they know? The latter might provide a basis for furthering this research for optimal communication and training. Physicians receive vast amounts of information every day and if they can rely on tools and paperwork to remind them of what they should apply; then they may leave for a while the practice to remember and rely the information and tool instead. The control group might be mostly driven by the curiosity of finding right answers just as most of us did when sitting exams. Other factors could be responsible for this overall finding which does not reflect the individual findings. Nonetheless, it should be borne in mind that the difference revealed is not of great significance and the differences in sample sizes could be a “thorn” in this overall evaluation’s “side”.

6.3 Pharmacists

Pharmacists showed positive change in all behavioural clusters that could form barriers to guidelines adherence (i.e. Actual Knowledge, Attitudes/Awareness, and Reported Behaviour).
It should be noted, though, that pharmacists use more frequently decision support systems when dispensing medicines, therefore this fact (e.g. easiness, less deviation from routine practices, familiarity) could have affected the findings and should be taken into serious consideration. Pair-wise country comparisons regarding the behavioural clusters (Tables 7 and 8) decreased between the Dutch and Belgian study but increased between these two country studies and the Spanish study. The latter probably was affected by the decreased sample size in the Spanish study (i.e. drop outs).
Pharmacists demonstrated increased readiness for the implementation of DRUID guidelines in their daily dispensing patterns.
An interesting finding was that pharmacists from the Spanish study (51%) seem well-informed about the potentially detrimental effects of medicines on driving performance as a result of their education or post-training.
The success in guidelines adherence in the study groups is a strong message for the feasibility of guideline implementation for both guideline developers and policy makers. Further research would be crucial for evaluating their effectiveness based on this and other empirical data. Moreover, these findings support the idea that the movement towards evidence-based health care could enhance the quality of health care. This is a step towards standardised best practice based on computerised protocols. The DRUID guidelines could support improvements in the information provided to both health care professionals and patients about the effect of medicines on driving.
Increase in the control group in the knowledge acquired was greater than the knowledge acquired by the health care professionals who received the DRUID guidelines.
The finding is mirrored into another professional group within the same cross country study, it seems almost certain that it carries a certain weight and significance.
It is difficult to direct the interpretation towards the cultural or personal and idiosyncratic variations. The multifocal aspect of training in the DRUID information group could provide an overload that is more difficult to be memorized and/or pay attention to. This could be a valuable input for future training scheme, tools training and professional information distribution to health professionals. Maybe information and training should be broken down to information blocks and/or topics with logical time lap between them in order to allow for adherence on a framework level. In other words, a future training scheme could provide at first the categorization proposed by DRUID to professionals and then guidelines, etc.
Then allow them to digest the information and come back to them in a second training scheme with guidelines and literature (e.g. monographs) on the effect of medicines to driving.
A third step could be then to provide a practical training, after a considerable time period with all elements incorporated and then the tool to be presented.
This training sequence is just a proposal for a future training programme based on the unexpected findings in the control groups about relevant acquired knowledge for both physicians and pharmacists. A very important point in this inference is the fact that pharmacists in the control group showed increased knowledge in the pre-condition and not only in the post-condition. Hence, people who participated in this group were people who

already knew a greater than the experimental groups to start with (i.e. participants were in most cases randomly assigned to control groups but those who participated in the control group were motivated to join and showed interested in the topic and probably processed some more baseline knowledge than average groups to compare with). A solution is to investigate a simple effect size (post-pre= δ) with its own limitations at hand. The differences were of no significant magnitude (p>.05). Thus, it is difficult to clearly state that the differences found were solely the result of the implementation itself (with regard these two groups only).
In addition, Belgian pharmacists seem very "knowledgeable" about the effects of medicines on driving fitness and the Dutch pharmacists incorporate more than their colleagues driving advice and recommendations when they dispense medicines affecting driving. These differences could reflect country variations about the focus of everyday pharmaceutical practice. However, these findings do not carry generalisable weight; therefore they should be treated with caution as it is clearly stated in the limitations section.

6.4 Limitations

Overall comparisons borne many limitations. The number of participants was different for each group (i.e. country). The Spanish study had an increased rate of drop outs. Participants have received the same guidelines but the design and procedure was adjusted to the local requirements for answering the respective research questions.
Sometimes it is easier to approach certain types of health professionals than others. For example, general practitioners in the Netherlands seemed hesitant to participate in the study and this was a significant reason for the decision to include only pharmacists in the Dutch study.
An important limitation for the overall analysis was the emphasis on the DRUID guidelines and not the tools themselves. However, the usage of different ICT tools probably had an impact on the guidelines adherence. The variation in the types of tools used did not allow for comparisons with taking the tool type into account. Hence, the inferences are made with certain hesitation. Although, statistical comparisons were applied, it is important to state that the findings do not aim to be generalized on a European and/or country level but mostly to present the feasibility of applying the DRUID guidelines, the probable need for such guidelines to be implemented and the value of furthering research on guidelines about drugged driving and their probable effectiveness for the health care system.
Finally, the overall composite scores are different from the country based and included items common to all countries. Therefore, these composite scores were commonalities scores and were calculated in an attempt to exclude differences in the analysis. The process of excluding differences in order to keep common items has an effect in the definition of the behavioural clusters themselves. For example, overall Reported Behaviour calculated in this section is the same for all country studies but different for each individual country study (Part B).
The reason for including these analyses was to provide a salient overview of the DRUID guidelines feasibility for adherence based on the Cabbana and colleagues model of barriers.

Differences may have not been revealed because of the inherent robustness and resistance in change in those two clusters. Moreover, the questionnaires applied were not validated, therefore inferences are not generalisable. In addition, diversities in the designs applied could have influenced the findings. It is also important to take into account the variations in both the tools and the different country settings. Context is an important factor for bringing up confounders into the analysis.

6.5 Implications: *Considerations about development, dissemination and implementation of DRUID guidelines*

Health care costs have been rising the last decades and have been highlighted as a core problem that affects practitioners, managers and governmental agencies alike (Shaneyfelt et al., 1999). The health care system is based on a cost-benefit methodology and sometimes pressure is exerted to practitioners so their practices to be effective, safe, and efficient (Forbes and Griffiths, 2002). Clinical guidelines are viewed as one of the most promising and effective advances for improving the quality of health care (Grol, 2001).
The benefits exerted by the implementation of effective guidelines have been associated with decreased mortality and morbidity, improved efficiency and cost containment (Cluzeau et al.,

1994). Current literature emphasizes the importance of effective guidelines and most importantly viable ones that can "survive" the scrutiny of daily practice (Miller and Kearney, 2004). It is agreed that guidelines are essential but their development, implementation and dissemination is unfortunately much more difficult to assess and surely is not straightforward. This is evident by the country studies conducted within the framework of DRUID. Attitudinal changes were sometimes positive but probably the most difficult to be attained. The following sections will focus on issues related to the implementation of DRUID guidelines and, consequently, for guidelines in general in the health care sector. Mostly, the focus is shifted towards the benefits and limitations based on the DRUID experience. These findings would be of value for several stakeholder groups and taken into consideration that medical guidelines are an international "tool" of communication among health professionals and between practitioners and patients, then their application significance becomes universal.
The aim of this section is to identify and address certain issues surrounding the application of guidelines with regard to **context, content, ICT tools' development**, and discuss considerations for **potential target groups**.

6.5.1 Context

It is important to note that the following parameters should be taken into account when an experimental research design is implemented in an empirical evidence sector such as decision support systems in everyday clinical practice.
The findings direct us towards positive change in behavioural aspects that are important in change and guidelines adherence in everyday practice. To be more specific in transferring these results into a future direction, communication to specific groups could follow a path adapted to the group itself. Context within this deliverable is defined as the local setting of the application of guidelines as the studies undertaken were implemented in different EU countries and different professional populations.
As guidelines are derived by empirical evidence and are theoretical constructs, they should be then directed to the groups they aim to be implemented. In other words, these guidelines have been developed with taken into account the considerable gap in existing information for both health care professionals and patients regarding the effect medicines may have not only on daily activities but, also, on driving fitness, which cannot be isolated by the rest of everyday activities (e.g. even commuting requires an individual to use a vehicle).
The positive feedback sprung by the country studies and the overall comparisons have shown that although there were differences between the countries, change within the countries was attained. These differences seem to increase as geographical distances increase. It could be argued that there might be a positive correlation that is an amalgamation of complex factors that become even more complex by their interactions. For example, legislation regarding prescribing and dispensing medicines in a country interacts with the educational background, awareness about driving dangers due to medicines' uptakes, personal and socio-cultural characteristics. Hence, the context should be personalized and adapted to the local needs, requirements and settings of each country and to each professional group.
In order to proceed to the implementation of DRUID guidelines in a country, guidelines should first be compared to existing guidelines with respect medicines intake and driving.
Therefore, the adaptation and customisation to local circumstances should be the result of a systematic and active comparison to existing guidelines. The latter requires the participation of target groups discussed later on in this section. DRUID guidelines should be able to accommodate for questions, specific needs, policies and resources available in the local health services. In conclusion, the variations within the local health setting will hinder the adaptation process but in the long run it may prove vital for its flexibility and, in the end, their usage. Health professionals show variations between countries and within, also. They will be able to enrich the aforementioned endeavour of adaptation with recommendation, on hand experience about medicinal uptake in their country/community/hospital and assist in the creation of priorities and considerations based on the local evidence.

6.5.2 Computerised guidelines (ICT tools)

As discussed above, guidelines should be based on scientific evidence and be attractive to the end users (Selker, 1993). Computerised clinical guidelines are increasingly developed for health care and aim to increase to effectiveness of the guidelines in order to influence

physicians' practices. A main outcome in the undertaken study is that participants showed preference towards the integrated tool. The implementation of the guidelines showed statistically significant positive change in their reported behaviour with regard to the application of the guidelines to prescribing and dispensing of medicines that affect driving behaviour and, also, in finding safer alternatives. This finding is in line with current research that advocates that computers may have an important role in guidelines implementation as incorporation of guidelines and reminders into integrated special software packages facilitates both updating about the cutting edge of medical knowledge but, also, may assist and support evaluation, clinical decision making and provides feedback about prescription and dispensing patient status (Heathfield and Wyatt, 1993).
The implementation of computerised guidelines and DRUID categorisation was highly accepted by both physicians and pharmacists and participants were willing to continue using the DRUID information. Many of them requested to have this information integrated in the system they already use. Therefore, the acceptability and usability of the computerised delivery system was well-received, described as easy to use and that it contained practical information.
Participants offered ideas for future developments such as inclusion of other medicines in the categorization scheme and the information should be adjusted to the native language.
Future recommendations should include specialized and elderly directed advices incorporated in the system and adaptation to other target groups and not only drivers (e.g. heavy machinery usage and senior people information).

6.5.3 Target groups

This section is not exhaustive by nature but indicative as other groups may emerge by the categories mentioned below.

6.5.3.1 Physicians

Adherence to medical guidelines is not a road towards strict implementation but a "guide" for professional improvement and it is a challenge as the tool for each physician is their relationship with the patient. It was anticipated that physicians will emphasize more on the physiological well-being of the patient and not so on the driving related guidelines developed within DRUID. However, the results were a positive surprise as physicians collaborated in the application of both the categorization system and the guidelines. Changes in reported behaviour were found. Physicians took the information into account. The message is strong for further research to be based on these findings. Attitudes are more resistant in change but the studies were for a short period of time to evaluate impact and training was short term oriented mostly on a training manual basis rather than training on enriching their awareness.
Hence, computerised and decision support systems are on the way to improve the quality of health care, professionals should receive this information by their affiliated routes and organizations. They will be the ones that will facilitate in the improvement of these guidelines, as more physicians will evaluate and help to improve DRUID information.
Physician groups and organization should be informed about the DRUID information and categorization in order to be able to assess the impact and the effectiveness of this information on a large scale.

6.5.3.2 Pharmacists

Positive changes were found and pharmacists reported that they were using the guidelines and the categorization scheme in their daily practice. Attitudes are the strong frontier for pharmacists as well as found in the country studies but in the overall analysis positive changes in all clusters were reported. The same discussion as in previous section applies to pharmacists. However, pharmacists are more used to applying decision support system in their pharmacies as it is a common practice in dispensing process throughout Europe. According to comments derived by the country studies, emphasis was given on the need for EU approval in order to incorporate it in their work. The necessity for pharmacists to have a support tool seems to be greater than any other health care professional group.

Similarly to physicians, pharmacists should be informed about the results and findings of these studies, through conferences, publications, and training schemes in order the evaluation to reflect and be further adapted to their needs.

6.5.3.3 Governmental agencies/policy makers

Guidelines are a common point of reference for prospective and retrospective audits of clinicians' or hospitals' practices: the tests, treatments, and treatment goals recommended in guidelines provide ready process measures (review criteria) for rating compliance with best care practices (AHCPR, 1995).
DRUID guidelines have been supported by evidence in these studies that they are useful, well-accepted by various professional groups in three different countries of implementation.
As evidence supports these recommendations, international and national agencies on first basis should be informed that issue guidelines. In addition governmental agencies, medical specialty societies and professional organizations should be formally informed about the findings of these studies either electronically and/or through an event. These DRUID materials (guidelines and categorisation) are supported by the references of the three studies included in this deliverable.
The effort encompassed in this deliverable attempts to fill in a very important gap of knowledge about the impairing effects on driving fitness. Alcohol remains the “number one” cause of accidents. Medicines may not be the most important cause but remain a “silent” cause that as medicines intake increases in EU over the years (especially anxiolytics and antidepressants) their association with road accidents increases. Sensitization about the relation of accidents, diseases, medicines, health care professional should be channeled through policies that would consider the effectiveness of information provided into consideration.

6.5.3.4 Developers

Developers are the professional who develop decision support system as the field of medical engineering has spread in the medical profession. Their role is critical with regard both in delivering a bugs-free tool but, also, to create interfaces that are accepted by diverse professional groups. Within DRUID a research oriented tool was used (stand-alone) for the first time within the framework of DRUID project. Therefore, it was more a proof-of-concept structure rather than complete and ready-to-use software. However, its usability could be of significant value for future research in order to be optimised in order to have info-on-the-go without any other programme needed to be installed. Its development process model has a good theoretical basis which needs further work to be refined.
The integrated tools used already exist in the market, therefore they are complete software packages evaluated and assessed long prior the studies undertaken. Usually commercial software packages have been evaluated in a series of itenary cycles of software development (with regard their interface usability, appearance, etc.) before entering the market.
Software companies could be contacted in order to participate from the beginning and develop a specific structure just for the DRUID materials that could be integrated in various software packages and, also, to be available as a database on the internet. For maintenance of data to be used in guidelines, national and international organizations could be prepared by developing strategies and seeking collaboration with institutes where expertise and experiences with designing databases and maintaining the data sets for the DRUID categorization and guidelines have been presented.

6.5.3.5 Other

The human element remains the most important link in the chain of successful implementation and dissemination of DRUID information. Patients could be informed about the impairing effects of driving under the influence of medicines. DRUID advice to the patients could be made available by patient information leaflets and communicated to patients and to the general public by means of a general website. Within WP7 certain efforts and work has been done in order to create risk communication means and guidelines for several target groups. These target groups could, also, benefit by getting to know DRUID professional and patient information through various media means such as internet sites and social networking

6.6 Main conclusions and recommendations

The conclusions section is divided in two parts. The first part is dedicated to the discussion of results derived by the analysis of composites scores for the chosen clusters for both health professional groups. The second part provides an overview discussion about the overall findings (i.e. Part B) based on the critical analysis of the country studies and in some cases in comparison to the Part A comparisons.

6.6.1 Part A

Before pharmacists receive the DRUID information, Belgium shows increased awareness, pharmacists in The Netherlands seem to have incorporated driving related guidelines in their daily dispensing regime (higher Reported Behaviour) and pharmacists in Spain show increased knowledge about medicines effect on driving fitness The post-testing findings are more harmonised with regard to Attitudes and Reported Behaviour across countries, but Belgium shows a far more increase in Actual Knowledge.

Changes in Reported Behaviour have been reported mainly for the following reasons. Reported Behaviour questionnaires are straightforward, therefore easier to detect change. Usually, question item related to knowledge and attitudes/awareness have more associations with other personality characteristics, therefore it is more difficult to be studied and isolated, especially in a cross-country study with limited time available to extrapolate findings of certain magnitude. However, the findings are of importance in most cases even changes were not reveal in specific cases.

Post-test comparisons unravel if differences prevail and if training and DRUID information were effective. The post-testing scenery changes enough, as Spanish pharmacists awareness increases significantly compared to their other colleagues but actual practice is less than their colleagues. Differences in knowledge remain the same, with Belgian pharmacists to be the most well-informed and Spanish pharmacists to have incorporated less the knowledge received during the DRUID training scheme and the trial followed.

Overall the consolidated findings sometimes differ from the findings in the country reports because the questionnaire items included in the consolidated effort (i.e. the clusters) are not all of the items used in the analyses in the country reports because of questionnaire adaptations. Therefore the composite scores constructed within the analysis framework of a country is not necessarily identical to the composite scores in the consolidated effort. The consolidated analysis by no means replaces the in depth analysis within each national report It is a supplementary statistical overview under a different prism in an attempt to focus on potential commonalities and draw a “greater picture” to be the canvas for a future research study of larger scale with even more specific and personalized characteristics and criteria.

6.6.2 Overall

Physicians and pharmacists prefer integrated tools that are not cumbersome, could provide flexible options with safe alternatives. However, they believe that the categorization scheme offered should be applied to other medicines and many participants queried about the possibility of implementing the DRUID materials to their own software packages.

The software developed within DRUID was a research tool customized to the needs and requirements of the categorization system developed within WP4 (see Annex II for screenshots describing a search example). It was a research tool developed and used for the very first time within DRUID and stand alone in nature, therefore its testing was actually its first iterative cycle. Participants preferred the integrated tool as it does not interfere with their work.

Overall, studies showed that decision support tools are welcome and usable, DRUID materials was indeed a need that waited to be accommodated for and most participants anticipated their ultimate integration to their own software packages.

A long term goal would be to evaluate the impact on the health care system, on various stakeholder groups associated with the implementation of health care professionals’ guidelines and compare it with other related studies’ findings. In addition, further research

could facilitate its adaptation and customisation for different health care professional groups and national settings.

The importance of diffusion of guidelines in daily practice has been discussed in the introduction. It is difficult to incorporate evidence into different populations' daily practice which would be the next step for these findings.
Overall findings suggest that change in health professionals is possible with regard to taking into account impairing effects of medicines on driving fitness. Moreover, the evaluation was based on the importance of barriers and facilitators to be considered for this change to be achieved. The main outcome of all country studies is in agreement with current literature that in order to achieve successful implementation strategies the fact that 'one size does not fit all' should be taken into serious consideration (Grimshaw et al., 2002). The differences across the country studies emphasise the importance of personalized strategies for change. The advantages and weaknesses of adopted systems highlight the fact that there is no "golden rule" and probably one methodological and/or strategical approach is not superior to the other; hence the implementation of guidelines from evidence based research should be tailor-made but could benefit from a generalized directory of guidelines regarding impairing effects of medicines on driving performance.

6.6.3 Application of guidelines

In conclusion, the following tables present the main outcomes of the study based on both overall and cross-country comparisons, and comments made by the participants. It serves as a basis set of recommendations for medical guidelines implementation in order to be communicated to interested parties across Europe. Each recommendation contains the statement, the aetiology (need and or gap), and the rationale (inferred finding). Recommendations are distinguished to: a) DRUID guidelines and tools' oriented (e.g. ICT, decision support systems), b) Health care professionals (e.g. general practitioners, nurses, etc.), c) patient specific, and d) methodology oriented. Recommendations have been named according to their distinction (e.g. REC1/a means that this is a recommendation number for ICT tools. If not specified in the respective groups (b and c), the recommendations proposed to be applied regarding DRUID guidelines correspond to all health care professionals who participated in the country studies.

DRUID guidelines and ICT tools

REC1/a	DRUID guidelines should be incorporated into integrated tools to maximise potential for successful implementation and consequently be more effective and efficient in daily practice
Aetiology:	Diversity of available software packages and increased flexibility of offered programmes in combination with rapid technological breakthroughs imposes a requirement for sophisticated and at the same time user-friendly decision support systems. The existing systems lack the specificity and categorisation schemes offered by DRUID guidelines
Rationale:	Participants showed higher preference for integrated decision support systems that do not require extra time and effort for updating

REC2/a	DRUID guidelines should be available in native languages to avoid any difficulties time spend because of misinterpretations
Aetiology:	Guidelines adherence is sensitive to wording, content, and context. Translation to native language would protect these three important elements of quality of guidelines
Rationale:	Participants preferred the guidelines to be in their own native language. Their time is strenuous as it is and they do not want to spend any more time because they have difficulties in understanding the context or translating text parts.

REC3/a	The DRUID categorisation system could serve as a tool to improve prescribing and dispensing practices both at national and European level

Aetiology:	Health care professionals might be informed about the impairing effects of medicines on driving fitness but a standardised system (four levels of impairment with safe alternatives) would harmonise the effort
Rationale:	Participants applied the categorisation system in their daily practice and for communication with patients

Health care professionals

REC1/b	The effective implementation of DRUID guidelines would be enhanced and maximised by the productive collaboration of different groups of health care professionals involved in prescribing/dispensing medicines with regard to patient decision making.
Aetiology:	There is a "missing link" between physicians and pharmacists which sometimes leads to difficulties which might be both time consuming and less cost-effective.
Rationale:	Researchers and participants demonstrated willingness for involved health care parties to be of close collaboration, especially if a uniform set of DRUID medical guidelines would be available.

REC2/b	The DRUID warning label could be applied in order to facilitate health practitioners' and patients' communication
Aetiology:	Labelling has been proven very helpful in order to communicate risks and side effects to patients. It gives a strong message with limited attention required by the dispensee.
Rationale:	Pharmacists found the DRUID warning label very clear and useful to provide information

REC3/b	Pharmacists should be informed about safer alternative medicines with regard to driving
Aetiology:	The well-being of the patient is mainly viewed by the physiological and therapeutic standpoint and less context driven, e.g. driving appears a secondary aspect.
Rationale:	No shifts to less impairing medicines was found for the intervention pharmacies (Dutch study)

REC4/b	DRUID guidelines should be personalised and adapted to local services idiosyncrasies, local strategies, cultural perspectives, and legal/political frameworks
Aetiology:	Medical and pharmaceutical guidelines should be harmonised and be universal on a general level but if they are not relevant to local medical practice and culture and not adopted to the needs and requirements of local health care professionals, they will gradually be rejected by the local health care professionals
Rationale:	Health care professionals (above 90%) had negative attitude towards the usefulness of the information they provided to their patients; they believed the information would not influence their driving behaviour (Spanish study)

Patients

REC1/c	Patients should be trained about the impairing effects of training and the potential consequences (training should be adjusted to general population and probably through edutainment)
Aetiology:	Patients who are drivers –also the general public- are well-informed about the effects of alcohol and drugs on driving but not of medicines. The latter is the result of campaigns and combinations of various interventions. Thus patients should receive multifaceted intervention with priority given to media.
Rationale:	Patients' knowledge and attitudes did not significantly change after training (Dutch study) However the probability that their attitudes and knowledge were already alleviated because of the conduction of a huge national campaign (2008).

REC2/c	A straightforward grading system and description of actions to follow could be included in the patient leaflet (the warning label could be printed on the medicine box) similar to the one described for health care professionals (REC2/b)
Aetiology:	Patients do get information from the patient leaflet. This process could facilitate previous risk communication efforts made by the health care professional (i.e. easier recall for the patient and a reminder)
Rationale:	Warning labels were well-accepted by the patients and messages in the leaflet could facilitate patients to conform with advice and maybe seek further related information by their physician and/or pharmacist

Methodology

REC1/d	The conduction of evidence based studies seriously benefits from face-to-face communication, close follow up (reminders, newsletters), and concrete set of instructions (i..e productive assistance)
Aetiology:	Evidence based studies are violated by diverse factors and conditions due to their temporal demands and the lack of experimental control, therefore certain steps should be standardised in order to avoid leaps and drop outs
Rationale:	Good follow up, strong communication agents, administration of manual and instruction have been proven useful (i.e. Belgian study; Physicians study; section 4.3)

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REC2/d	Training is essential for the success of DRUID guidelines and support throughout the testing phase. The latter can be translated into continuous education for natural health settings
Aetiology:	Current research focuses on multifaceted interventions in order to facilitate the most effective implementation of medical guidelines but training stills holds the heaviest weight of importance
Rationale:	Participants who received training regarding the DRUID related materials showed positive change towards the implementation of DRUID guidelines in everyday practice

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Annex I: Basic Questionnaire

EVALUATION QUESTIONNAIRE Health care workers

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract No. TREN - 05-FP6TR-SO7.61320-518404-DRUID

Co-funded by the European Commission

Dear participant,

This study is conducted as part of the DRUID European project (Driving under the influence of drugs, alcohol, and medicines). Specifically, it focuses on the actual impact drugs may have on driving safety. We are interested on your opinions on the way medicines may affect driving.

The questionnaire consists of… pages and it comprises _____questions.

It will take you approximately _ minutes to complete.

Please read each question carefully and tick a box ☑ to indicate your answer. In most cases you will only have to tick one box but please read the questions carefully as sometimes you will need to tick more than one box. Answer the next question unless asked otherwise. Once you have finished please take a minute to check whether you have answered all the questions that you should have answered.

We assure you that all your answers and statements will be handled anonymously and that they will be used for scientific research purposes only.

If you have any queries about the questionnaire please do not hesitate to contact _____on _____.

☐ My participation in this questionnaire survey is voluntary (informed consent).

Thank you for your valuable participation,

Research supervisor (name) (Title and address) (Contact details)

Date:_____

ID (filled in by the researcher):

A. BACKGROUND INFORMATION

1. Gender

☐ Male ☐ Female

2. Date of birth (DD/MM/YYYY):_____

3. Country: _____

3a. Area: ☐ Urban ☐ Rural ☐ Other

4. Specialism:

☐ GP ☐ Neurologist
☐ Psychiatrist ☐ Community Pharmacist

5. Year of graduation medical school (YYYY): _____

5a. How many years are you practising as a GP/Neurologist/Psychiatrist/Pharmacist?

(Please state in full years) _____

6. Did you get any education on medicinal effects on driving skills during your studies at University?

☐ Yes ☐ No

7. If you answered "Yes" in Q6, please specify:

B. NEW TECHNOLOGIES LITERACY

1. Do you use the internet to obtain information?

☐ Yes ☐ No

2. Do you use the internet to obtain information on medicines affecting driving behaviour?

☐ Yes ☐ No

3. Have you ever used any software package / programme to obtain information on medicinal drugs effect on driving behaviour?

☐ Yes ☐ No

4. If you answered "Yes" in Q3, please specify which software packages you use:

_____
_____

5. Do you use any medical/clinical software package / programme?

☐ Yes ☐ No

6. If you answered "Yes" in Q5, please specify which software packages you use:

1. _____
2. _____
3. _____

(PRE) Please consider your current experience for completing this questionnaire.
(POST) Please consider your experience the last 6 months for completing this questionnaire.

C. ATTITUDES / AWARENESS

Please evaluate the following statements:

1. I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

2. Would you consider this (Q1) of more concern if your patient is:

- a professional driver?
  ☐ Yes ☐ No
- driving frequently?
  ☐ Yes ☐ No
- driving long distances?
  ☐ Yes ☐ No
- an “inexperienced” driver?
  ☐ Yes ☐ No
- an “experienced” driver?
  ☐ Yes ☐ No
- an elderly driver?
  ☐ Yes ☐ No
- using other CNS active drugs ?
  ☐ Yes ☐ No

3. I am willing to sacrifice some degree of efficacy by prescribing/dispensing a medicine that is less impairing to the driving skills.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

4. I feel being well aware of the effects of medicines on driving skills.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

5. It is important for me to be well-informed on medicinal effects on driving behaviour.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

6. I feel that the information I provide to patients will influence their driving behaviour.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

D. REPORTED BEHAVIOUR

Please reflect on the following statements according to your daily practice routines.

1. I ask a patient about his/her driving exposure when choosing/dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

2. I inform a patient about driving related risks when prescribing/dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

3. I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

4. I keep systematic records when I prescribe/dispense a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

5. I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

6. I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

7. I discuss medicinal drug consumption and driving related responsibility issues with the patient.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

8. How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

E. SOURCES

1. I have easy access to data and information about a medicine's effect on driving skills.

☐ Yes ☐ No

2. Please report your sources:

Professional websites ☐
Newsletters ☐
Organisations ☐
Journals ☐
Other ☐

Please specify:

---

3. Did you get any postgraduate education on medicinal effects on driving skills?

☐ Yes ☐ No

4. If you answered "Yes" in Q3, please specify:

F. ACTUAL KNOWLEDGE

Please reflect on the following statements according to your daily practice routines.
For each statement tick the one which best fits your professional opinion.

1. How much do you agree or disagree with the following statements?

Statements	Totally Disagree	Disagree	Disagree Nor Agree	Totally Agree	Don't know
Temazepam (up to 20 mg) is severely impairing driving 8 hours after intake	☐	☐	☐	☐	☐
Diazepam (regardless dose) is severely Impairing within the first 2 months of treatment	☐	☐	☐	☐	☐
Codeine (up to 20 mg) is mostly safe for drivers	☐	☐	☐	☐	☐
Fexofenadine (normal dose) is severely impairing driving	☐	☐	☐	☐	☐
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	☐	☐	☐	☐	☐
Paroxetine (up to 20 mg/day) is safe for drivers	☐	☐	☐	☐	☐

2. Physicians/pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.

☐ True ☐ False

3. If a physician informs the Driving Licensing Authority (DLA) that his/her patient is using a driving impairment medication, in order to give the DLA the possibility to perform a check-up, you believe this is:

☐ Mandatory practice ☐ Good practice ☐ No obligation ☐ Do not know

4. A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.

☐ True ☐ False

G. USER ACCEPTANCE *(PRE)*

1. If we propose to you a tool (e.g. website, cd-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for prescribing/dispensing medicines?

☐ Yes ☐ No ☐ Maybe

2. If you answered "No" or "Maybe" to Q1, what are the main reasons for your reluctance to use them?

H. USER ACCEPTANCE - CONTENT *(POST)*

1. Did you use the guidelines in order to support your communication to patients?

☐ Yes ☐ No

2. If you answered "Yes" in Q1, how often did you use the guidelines?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

3. if you answered "seldom" or "never" to Q2, what are the main reasons for your reluctance to use them?

---

4. The guidelines for prescribing/dispensing medicines that may affect driving performance were:

	Yes, very much	Quite a lot	Neutral	Not so much	No, not at all
helpful					
useful					
sufficient					

5. Did you use the fact sheets as background information in order to inform patients on medicinal drugs and driving?

☐ Yes ☐ No

6. If you answered "Yes" in Q5, how often did you use the fact sheets?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

7. The fact sheets for prescribing/dispensing medicines that may affect driving performance were:

	Yes, very much	Quite a lot	Not so much	No, not at all
helpful				
useful				
sufficient				

8. Did you think it was a problem that the facts sheets were provided in the English language?

☐ Yes ☐ No

9. Did you use the pictogram system in order to inform patients on medicinal drugs and driving?

☐ Yes ☐ No

10. If you answered "Yes" in Q5, how often did you use the fact sheets?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

11. The pictogram system for prescribing/dispensing medicines that may affect driving performance was:

	Yes, very much	Quite a lot	Not so much	No, Not at all
helpful				
useful				
sufficient				

12. Do you think that there should be any additional information that is currently missing?

☐ Yes ☐ No

13. If you answered "Yes" in Q9, please specify:

I. USER ACCEPTANCE & USABILITY –TOOL *(POST)*

Please reflect on how much the following statements represent your personal opinion. Check one of the fields accordingly.

1. I was able to find the information I asked for with no difficulty.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

2. I thought the tool was cumbersome.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

3. This tool would fit well in my working routines.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

4. If you answered "strongly disagree" or "disagree" in Q3, please explain:

---

5. Text and icons are easy to perceive.

☐ strongly disagree ☐ disagree ☐ agree ☐ strongly agree

6. If you answered "strongly disagree" or "disagree" in Q5, please explain:

---

7. Do you think that the tool should have additional options on the screen or are there any controls that are currently missing?

☐ Yes ☐ No

8. If you answered "Yes" in Q7, please specify:

J. FUTURE USE OF THE TOOL *(POST)*

1. Would you be willing to use this tool in the future?

☐ Yes ☐ No ☐ Maybe

2. If you answered "No" or "Maybe" in Q1, please explain:

---

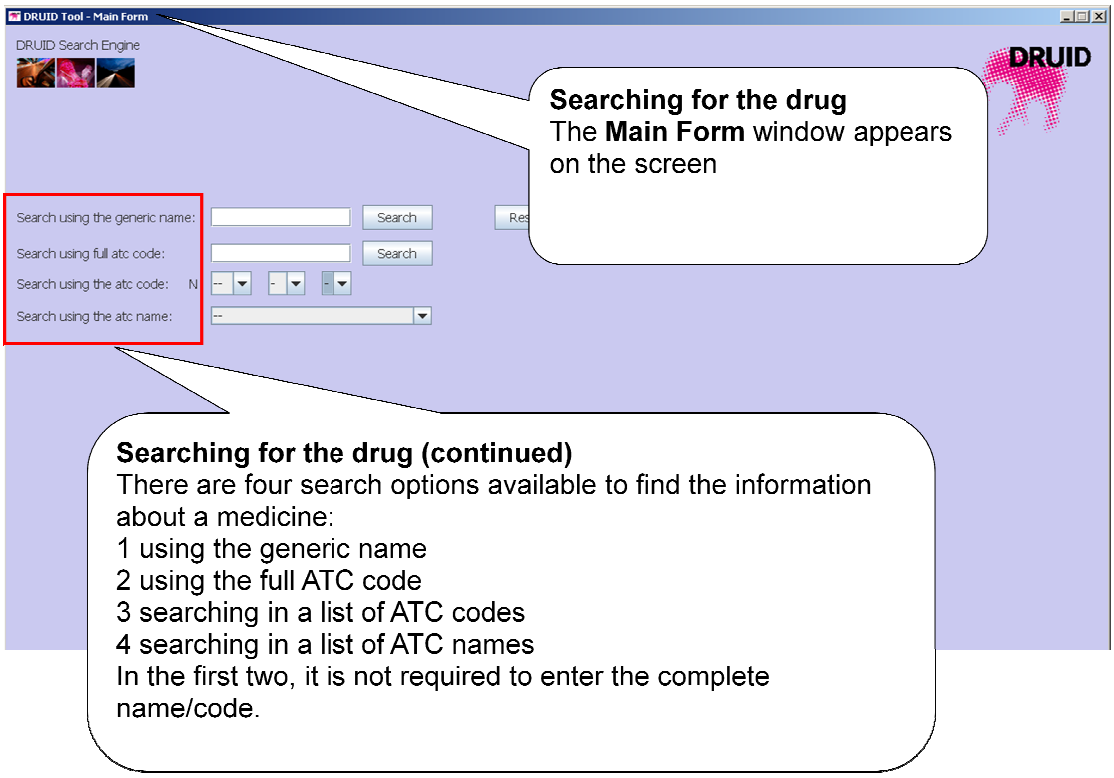
3. What would you use the tool for mostly? (Please specify):

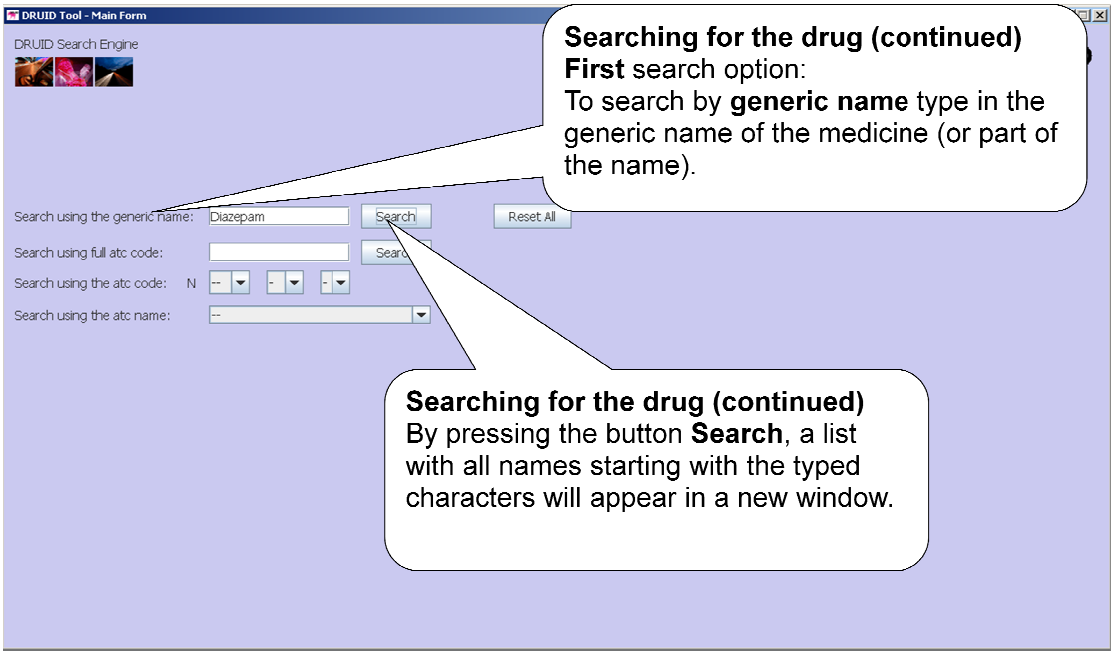
General comments
(Please provide any further comments you may have)

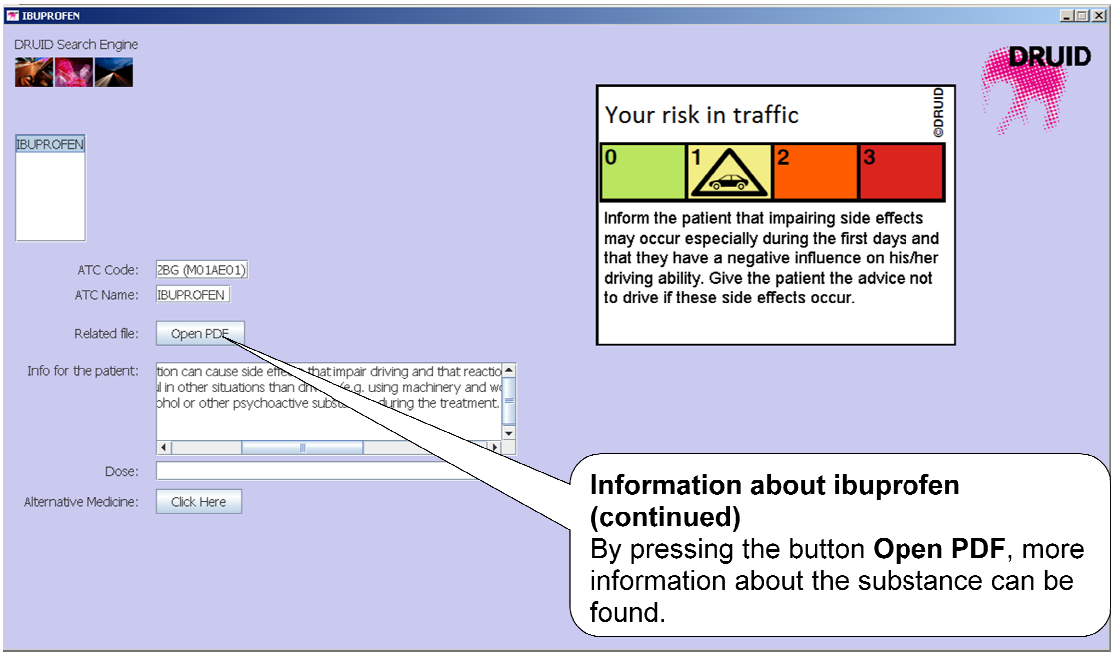
Thank you for your participation!
Please, provide your email address, in case you want to be informed about the general findings of this study

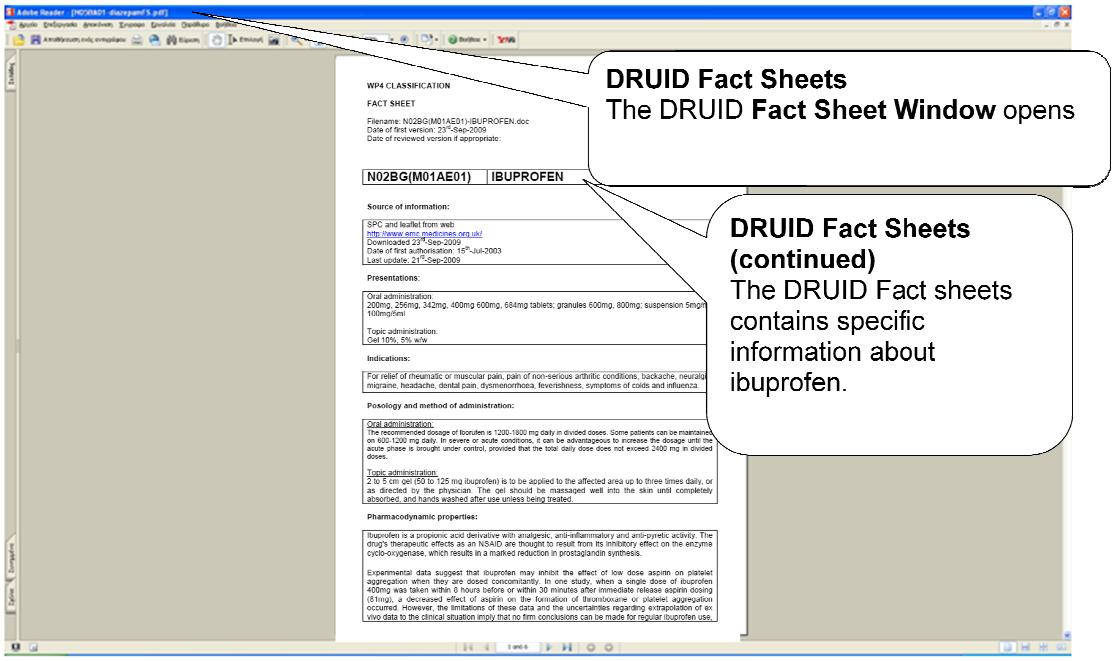
Annex II: DRUID tool snapshots

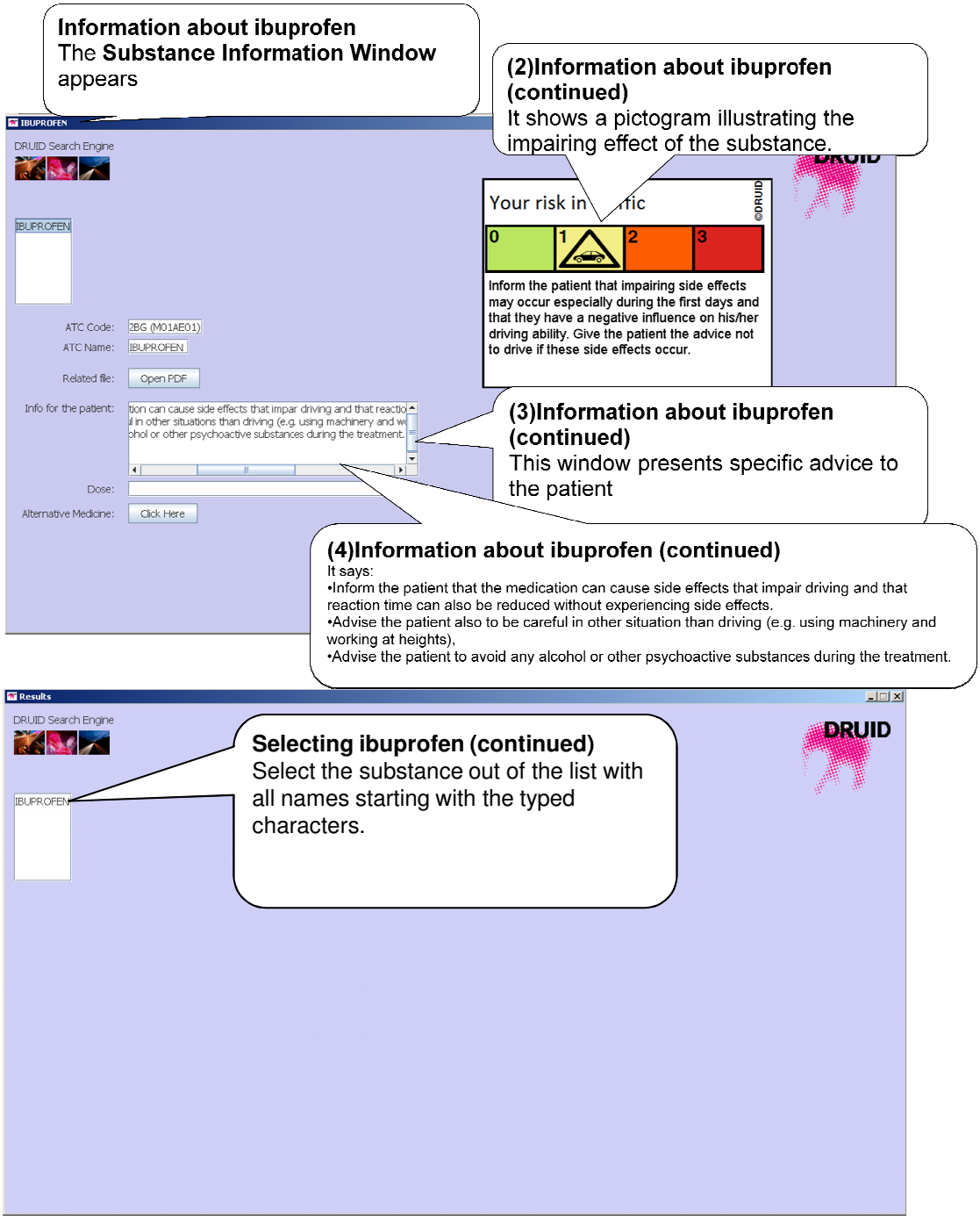
Example: Searching for a drug






IBUPROFEN
DRUID Search Engine
DRUID
IBUPROFEN
Your risk in traffic
©DRUID
0
1
2
3
Inform the patient that impairing side effects may occur especially during the first days and that they have a negative influence on his/her driving ability. Give the patient the advice not to drive if these side effects occur.
ATC Code:
2BG (M01AE01)
ATC Name:
IBUPROFEN
Related file:
Open PDF
Info for the patient:
Dose:
Alternative Medicine:
Click Here
Information about ibuprofen (continued)
By pressing the button Open PDF, more information about the substance can be found.


WP4 CLASSIFICATION
FACT SHEET
N02BG(M01AE01) IBUPROFEN
Source of information:
Presentations:
Indications:
Posology and method of administration:
Pharmacodynamic properties:
DRUID Fact Sheets
The DRUID Fact Sheet Window opens
DRUID Fact Sheets (continued)
The DRUID Fact sheets contains specific information about ibuprofen.


Information about ibuprofen
The Substance Information Window appears
(2)Information about ibuprofen (continued)
It shows a pictogram illustrating the impairing effect of the substance.
IBUPROFEN
DRUID Search Engine
IBUPROFEN
ATC Code: 2BG (M01AE01)
ATC Name: IBUPROFEN
Related file: Open PDF
Info for the patient:
Dose:
Alternative Medicine: Click Here
Your risk in
©DRUID
0
1
2
3
Inform the patient that impairing side effects may occur especially during the first days and that they have a negative influence on his/her driving ability. Give the patient the advice not to drive if these side effects occur.
(3)Information about ibuprofen (continued)
This window presents specific advice to the patient
(4)Information about ibuprofen (continued)
It says:
•Inform the patient that the medication can cause side effects that impair driving and that reaction time can also be reduced without experiencing side effects.
•Advise the patient also to be careful in other situation than driving (e.g. using machinery and working at heights),
•Advise the patient to avoid any alcohol or other psychoactive substances during the treatment.
Results
DRUID Search Engine
IBUPROFEN
DRUID
Selecting ibuprofen (continued)
Select the substance out of the list with all names starting with the typed characters.

PART B: COUNTRY REPORTS

Chapter 1: The Belgian study

1.1 Physicians Study

Authors

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List of abbreviations

ATC	Anatomical Therapeutic Chemical (ATC) classification
DRUID	Driving Under the Influence of Drugs, Alcohol and Medicines
GIT	Geneesmiddelen Informatie Tekst
GMC	General Medical Council
ICT	Information and Communication Technology
SHB	Stichting Health Base

1 Introduction

1.1 Background

Belgium has a compulsory system of health insurance with a very broad benefits package that covers almost the entire population. Social security contributions and subsidies from the federal government are the main funding sources. The compulsory health insurance is managed by the The National Institute for Health and Disability Insurance (NIHDI) which gives a prospective budget to the sickness funds to finance the health care costs of their members. Delivery of health care in Belgium is mainly private. Most physicians, whether GPs or specialists, are paid on a fee-for-service basis. The patient pays the set fee for the consultation directly to the physician, and patients are then directly reimbursed by their sickness funds.
In 2008, more than one quarter (27.6%) of the population reported having at least one long-term illness, disorder or disabling condition. From 2004 to 2008 there was an observed increase in the prevalence of chronic diseases. The growing (elderly) population in Belgium results in a higher medication consumption and more frequently consultations with GP's and other health care professionals, which has a direct influence on the social health costs. [1]

In 2009, 131 databases containing different types of health-related information were found in Belgium.[2] The actors involved in collecting these data, as well as obligations to provide information, vary from one database to another. In 2007, internet or other electronic data exchange networks were used by 73.5% of the Belgian physicians (General Practisioners (GP's) to obtain results from laboratories, compared to 39.8% in the European population (EU27), and by 13% of GP's to exchange medical data (EU27:10.3%) or administrative data (EU27: 9.7%). In Belgium, every GP who uses approved software to manage the electronic medical files of his/her patients may ask to obtain an allowance paid by the NIHDI the following year. The number of GP's receiving an allowance increases every year. The rate is higher in the Flemish region.

The first step to decrease deaths on the roads attributable to medicines is by providing GP's and pharmacists with accurate and clear guidelines with advice and information on medicines that are prone to affect driving. Secondly, introducing a uniform categorisation system, such as proposed within DRUID project, in the physicians and pharmacists' computer software is a clear and practical approach to dispense the least impairing medicines within the same therapeutical class to patients. Additionally such a grading system is a valid alternative to improve patient care, during daily practice. Considering that GP's in Belgium make use of computer software in their daily practice, including information about medicines that influence driving ability is a valuable way of giving advice to the health care provider for consulting their patients.

Another step in decreasing deaths on the road attributable to medicines is a legal step. The Belgian law not only states that a patient can be punished with criminal sanctions if he/she causes a traffic accident while using a medicine with impairing properties but also that GP's are obliged to inform the patients about the possible side effects of his/her medications on driving abilities. If not, the physician can be held partially responsible when their patient causes a traffic accident.

1.2 Aims and objectives

The object of the study was to measure the effectiveness of physicians' training on the **guidelines developed in DRUID WP7** for prescribing medicines with an influence on driving abilities, as well as the use and user acceptance of the DRUID developed prescribing support

[1] and [2] Federaal Kenniscentrum voor de Gezonheidszorg (2010) Het Belgische gezondheidsysteem in 2010. KCE report138A.

tools in which the **DRUID WP4 medicinal risk classification** system was integrated. The effectiveness was measured through the actual use rates of the integrated and stand-alone ICT support tool and in a questionnaire survey (compared to baseline measurement), after 6 months as a change in attitudes/awareness, knowledge and (reported) behaviour due to the implementation of the training.

1.3 Evaluation team

The study was organised, conducted and evaluated in close collaboration between Ghent University (UGent) and the Belgian Road Safety Institute (IBSR).

2 Methods

2.1 Research specific objectives

The following **research questions and hypotheses** were formulated:

- Do physicians' attitudes and awareness about medicines and driving change/improve after the training and intervention?
- Do physicians reported behaviour about medicines and driving change/improve after the training and intervention?
- Do physicians actual knowledge about medicines and driving improve after the training and intervention?
- Are physicians willing to accept and use the ICT prescribing (integrated/stand-alone) and paper support tools?
- Are pre-post questionnaire (socio-cognitive) changes and user acceptance rates higher in the integrated software group as compared to in the stand-alone (USB tool) support tool group?
- Are pre-post questionnaire (socio-cognitive) changes in the intervention groups (integrated/stand-alone) higher as compared to the control group?
- What is the use rate (prescribing data) of the ICT prescribing support tools (integrated/stand-alone)?
- Are there differences in the incidence of prescribed category I, II or III medicines in the ICT tools (integrated/stand-alone) use rates?

2.2 Study design

The study has a pre- and post-design and includes **2 intervention groups (training + implementation support tool) and one control group**:

- Integrated software group, in this report further referred to as **SoSoeMe group**: a group of physicians from the total group using the SoSoeme electronic medical record management software in their daily practice. The DRUID WP4 and WP7 information was integrated into the SoSoeMe software.
- Stand-alone software group, in this report further referred to as **USB group**: a group of physicians from the total group of physicians in East Flanders, who declared to be willing to participate in the study, in the intervention group. The DRUID WP4 and WP7 information was delivered through an USB stick to be installed on the physician's computer, together with a compendium including the same information
- **Control group**, a group of physicians from East Flanders, who indicated to be willing to participate in the study, either chosen to be in the control group or referred to the

control group by the research team. This group did not receive the DRUID information.

Comparison of the intervention groups allows evaluating the difference in impact and use of the DRUID WP4 and WP7 information according to the type of support tool.

Comparison with the no-intervention control group allows evaluating the impact of the DRUID information on prescribing behaviour and self-reported measures, controlled for effects outside the study scope.

Pre- and post-conditions are accounted for by a pre-questionnaire before the training and intervention phase of 6 months (for the control group: 6 months without intervention), after which the post-questionnaire was completed.

Pre-post comparisons within each group allow evaluating the impact of the DRUID WP4 and WP7 intervention.

The study design can be roughly depicted as follows:

Table 8: Activities that were performed by each group of physicians during the study period

	Group		
	SoSoeMe group	**USB group**	**Control group**
Pre-training	Pre-questionnaire	Pre-questionnaire	Pre-questionnaire
Sept 2010		**TRAINING**	_
Post-intervention (6 months after the training)	Post-questionnaire Software use data	Post-questionnaire Tool use data	Post-questionnaire

The study was approved by the **Ethics committee**, Faculty of Medicine and Health Sciences, Ghent University, Belgium on March 5, 2010 (B67020108021).

All data (questionnaires, integrated and stand-alone software) were extracted anonymously. No patient information was collected. The privacy of the patient was guaranteed throughout the whole study.

The physicians were free to refuse participation in the study. Moreover, every respondent could terminate his cooperation/participation at any time. All participants were asked to sign an informed consent form. The USB group had to sign a second informed consent provided by Health Base because Health Base information (GIT) was integrated in the USB tool. Participation to the study was on a voluntary basis. The physicians received a small monetary compensation for their participation.

2.3 Materials

2.3.1 Intervention/support tools

- **A training manual**

A training manual including the relevant DRUID WP4 and WP7 information for physicians was developed in DRUID Task 7.4.1 (D7.4.1). This manual was slightly adjusted to the specific Belgian scope. It was used as guidance when training the physicians in the USB group and handed out to them. The training manual was also handed out to the participants in the SoSoeMe group.

The training manual addressed the general background and structure of the DRUID project and more specifically of the physician study. The DRUID WP7 prescribing guidelines were explained and possible information documents for patients were overviewed. The manual furthermore familiarised the physicians with the DRUID WP4 proposed categorisation system

for medicinal effects on driving, as well as with the group-specific support tools that include the relevant information.

- **SoSoeMe integrated software**

In cooperation with SoSoeMe BVBA, a new function was introduced in the electronic medical record management SoSoeMe. The program was regularly updated.

When prescribing medicines that influence the driving abilities, the SoSoeMe information system offers support in the following ways:

- **Automatically generated warning** under the form of an icon. An icon appears to warn the physician if he or she wants to prescribe a category 1, 2 or 3 medicine.
- **Written information** about the medicine, with practical recommendations/advice concerning driving and medicines (i.e. Fact sheet and Patient letter)
- **Registration** of the number of clicks made on the icon, fact sheet and/or patient letter

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- **USB stand-alone tool**

For the stand-alone group, an USB tool was developed in DRUID by CERTH-HIT and amended to match the Belgian situation (see general part A). This tool contains comparable information as the SoSoeMe software: information for the physicians in the format of a Fact sheet (WP4) and information for the patient (GIT: patient information letters, provided by Health Base), but clearly differs from SoSoeMe as physicians have to look up the medicinal risk guidelines and information separately by themselves (no automatic pop-up and no link with the patient). Each physician was asked to install (themselves) the tool on their computer.

For the Belgian study the USB-tool described in the general part of this deliverable, was amended for following reasons:

1. Patient information letters had to be included
2. Stichting Health Base (SHB)[3] provided the information for the patient letters. Because of copyrights, Health Base texts could not be put directly on the USB-stick. Permission to put the information on a secured website was granted by means of an IP contract (UGent Tech Transfer number A09/TT/0567)

The following adjustments were made:

1. An extra button was made to link to the patient information letters
2. The information (Fact sheets and patient information letters) was put online. Links were made to PDF-files on an UGent website (http://www.druid.ugent.be/) instead of PDF-files in a directory on the C-drive of the computer.

- **Paper tool: Compendium**

For the USB group of physicians a compendium was also made. The compendium contained the fact sheets of the N-medicines developed within DRUID. The physicians were made familiar with this compendium as well as with the USB tool during the training sessions. Besides the use of the tool, the physicians were able to use the compendium to look up information on certain N01-N07 medicines.

2.3.2 Evaluation tools

Evaluation data were collected via questionnaires and through data extraction from the SoSoeMe software and USB tool use rates and characteristics.

[3] SHB maintains a database with information on all medicinal drugs in the Netherlands and Belgium intended for patients and caregivers

- **Pre- and post-questionnaire**

The evaluation questionnaire, developed within DRUID (D7.4.1), including a pre- and a similar post-part, was translated into Dutch. The translation may have generated some minor changes as compared to the original version. Furthermore, some small changes were made purposely to adapt better to the Belgian situation or for ethical reasons.

In the pre-questionnaire, the following questions were adapted or removed from the original version:

- Background information: For ethical reasons the date of birth was changed into age categories; practice area (rural/urban) was changed into number of inhabitants; the question about specialism was deleted

- New technologies familiarity: A question about how often the physician uses the Internet to obtain information was added.
- Sources: the option 'organisation' in 'please report your sources' was split up into traffic safety organisation and professional organisation.
- Actual knowledge: since temazepam is not on the Belgian market, answers on the statement regarding this medicine were not considered; the question about informing the Driving Licensing Authority was left out, because it was not applicable in Belgium.
- User acceptance: the question which type of instrument the participant would prefer (website, integrated in software, non-integrated tool, manual...) was added.

The same adjustments as were made in the post-questionnaire, and additionally:

- User acceptance - content: in questions 5-7 the term 'fact sheets' was replaced by 'patient letters'; question 8 'Was it a problem that the fact sheets were provided in English' was not applicable because the information was provided in Dutch by Stichting Health Base.

Furthermore, two extra questions were formulated in the post-questionnaire:

- Do you think that the use of the guidelines has influenced your way of prescribing medicines?
- Do you think that the use of the guidelines has influenced your choice of medication?
- Do you think that the use of the guidelines has influenced your way of communicating the information to the patients?

Both the pre- and post-questionnaire derive information on: personal and practice related background variables, familiarity with new (ICT) technologies, current sources on medicines and driving risks, attitudes and awareness, reported behaviour and actual knowledge related to prescribing medicines with potential effect on driving abilities, and user acceptance of daily practice support tools linking to driving. While identical for these areas of interest, the post-questionnaire additionally includes in-depth questions regarding user acceptance and usability of the tool(s) being used during the intervention phase. (See annex).

The three study groups filled-out the pre-questionnaire at baseline (before the training/intervention phase of 6 months): all groups filled the pre questionnaire out at home and sent it by post to the research team. The three groups filled-out the post-questionnaire after 6 months (intervention phase): all groups filled it out at home and sent it back by post to the research team.
All questionnaire data were integrated into an SPSS file.

- **Software data extraction**

The data from the integrated software SoSoeMe were automatically and anonymously extracted by SoSoeMe and provided to the research team. The data were delivered in several log files. All the data from these log files were integrated in an Excel file.

The USB group on the other hand received a step-by-step instruction plan on how to extract the data from the USB tool to the format of a log file and to mail the log file to the research team. Physicians who installed the USB tool on several computers in the practice where asked to send the log file(s) from all the different computers. The data were transferred into Excel by the research team. The USB tool data extraction included no personal identification (anonymous extraction).

Relevant SoSoeMe extracted data included: physician number, date of the search by the physician, ATC code and the DRUID category of the medicine searched for, use of fact sheet and patient letter.
Only limited data/information could be obtained from the USB tool. Relevant USB extracted data included: date and hour of the search by the physician and (part of) the substance/medicines' names they were searching for in the program.

2.4 Study procedure

2.4.1 Participant recruitment

About three-hundred-thirty (330) physicians use the SoSoeMe software. In collaboration with SoSoeMe, the participation of these physicians was asked. An email with in annex a document with extra information about the DRUID-project and the study was sent to all the physicians using SoSoeMe. The interested physicians received a package with a questionnaire, the informed consent forms, an introductory letter and an envelope. Fifteen physicians received the training/information and filled in the questionnaire for the basic measurement.

For the **USB group**, a letter was sent to all general practitioners in East Flanders (n = approximately 1600). The physicians received an introductory letter, an invitation to follow a training session, a questionnaire, an informed consent form and a return envelope by post. It was asked not to reply if they were SoSoeMe users. The aim was to include the first 40 physicians who sent back their questionnaire. Only 23 physicians signed up to participate in the USB group.

Besides the choice to follow a training session (USB group) the physicians had also the option to participate in the control group of the study. Sixty-three physicians were willing to participate in the control group. A confirmation letter of participation was only sent to 53 physicians (as mentioned in part A, the sample size calculations determined that only 31 respondents were required to be included in each group).

After sending in their questionnaire, the selected physicians (USB and control group) received a second letter that informed them that they were selected to follow a training session (for the USB group) or that they would receive a second questionnaire in 6 months (for the control group).

Table 9 indicates the flow of the study sample size: from initial participant recruitment to full study participation.

Table 9: Sample size

Respondents	SoSoeMe	USB Tool	Control Group
Total population	330*	+/- 1,600	+/- 1,600
Pre questionnaire	15	23	53**+1***
Training sessions		17	
Post questionnaire	13	10	35
Full participants**	7	10	35

*around 90% of the users updated their system and did use the DRUID-application to inform their patients
**62 physicians were interested to participate only 53 were selected
*** one physician shifted from the USB group to the control group
**** physicians who completed 2 questionnaires and sent in their log file(s).

2.4.2 Flow charts

The following flow charts depict the study procedure, from participant recruitment over study steps and follow-up actions to study finalisation.

The DRUID-functions, integrated in the **SoSoeMe** software were presented at training sessions organised by SoSoeMe. The first training was attended by the UGent research team. No extra training sessions were organised by the UGent team. For the **USB group** 2 training sessions were organised in Ghent. The physicians who could not attend the first training session were kindly invited for the second training session. Of the 22 registered physicians 10 were not able to attend a training evening. One respondent contacted the research team asking to send him all information needed to self-install the program. The other 9 respondents were asked by mail or letter whether they were still interested to participate in the DRUID study. If so a researcher would personally install the software and give information on the subject. Three physicians responded and could be included in the USB group. One respondent who attended a training session motivated his colleague to participate. Two physicians who attended a training session were excluded afterwards because of not installing the tool or incompatibility of the software.

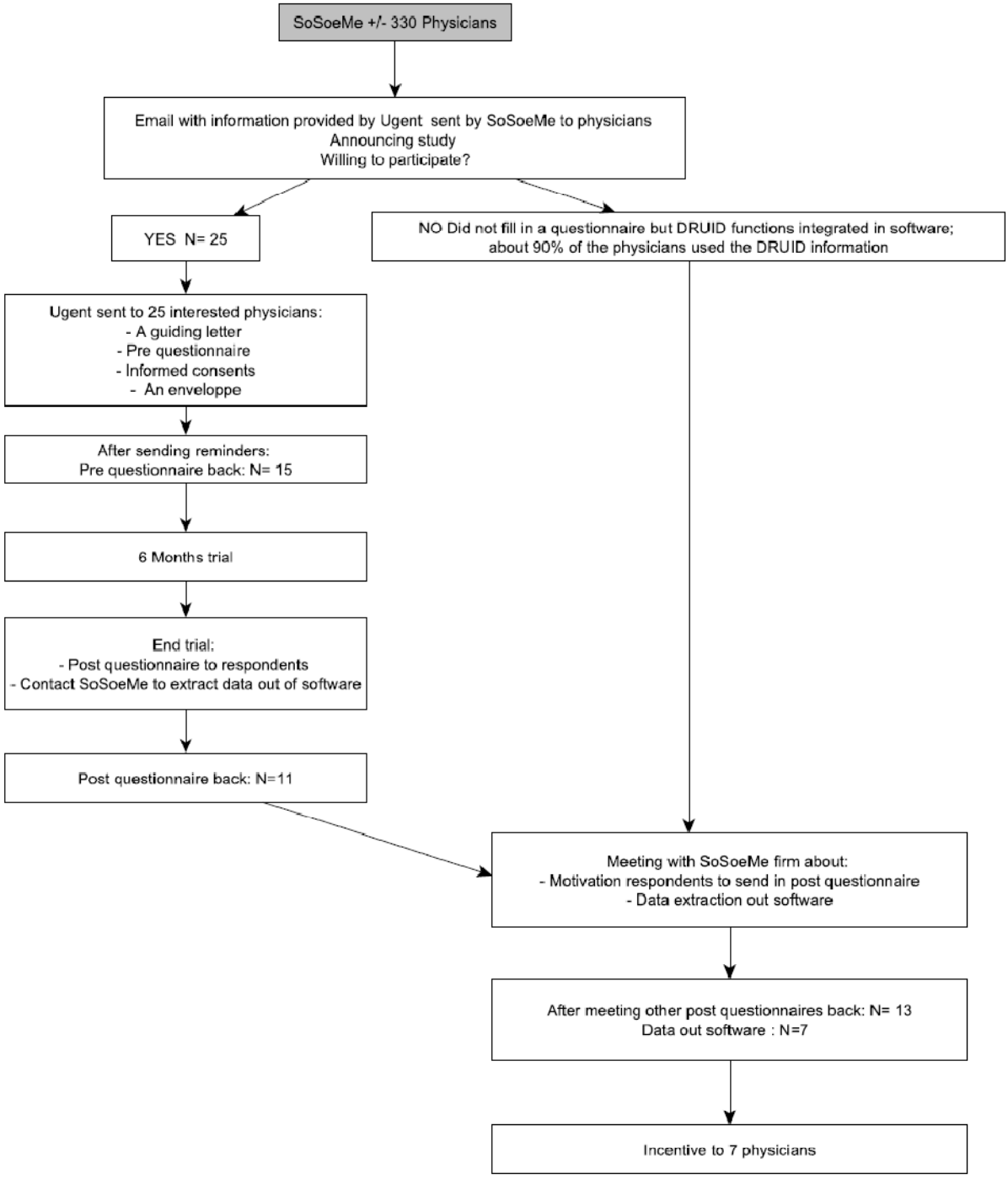
For both the Sosoeme and USB group a training manual and hand-outs of the PowerPoint showed during the training session, were made. Information on how to use the functions integrated in the SoSoeMe software and a manual on how to install and use the USB tool were developed. The step-by-step plan was integrated in the training manual. During the training sessions the physicians were informed about the DRUID project and the aim of the pharmacist and physician study. The legal aspects of driving under the influence in Belgium and the role of the physician were underlined. Furthermore, the respondents were confronted with practical situations and examples.

As depicted in the flow charts underneath, several follow-up actions were set up in order to motivate physicians for (continued) study participation and to support them in their participation.

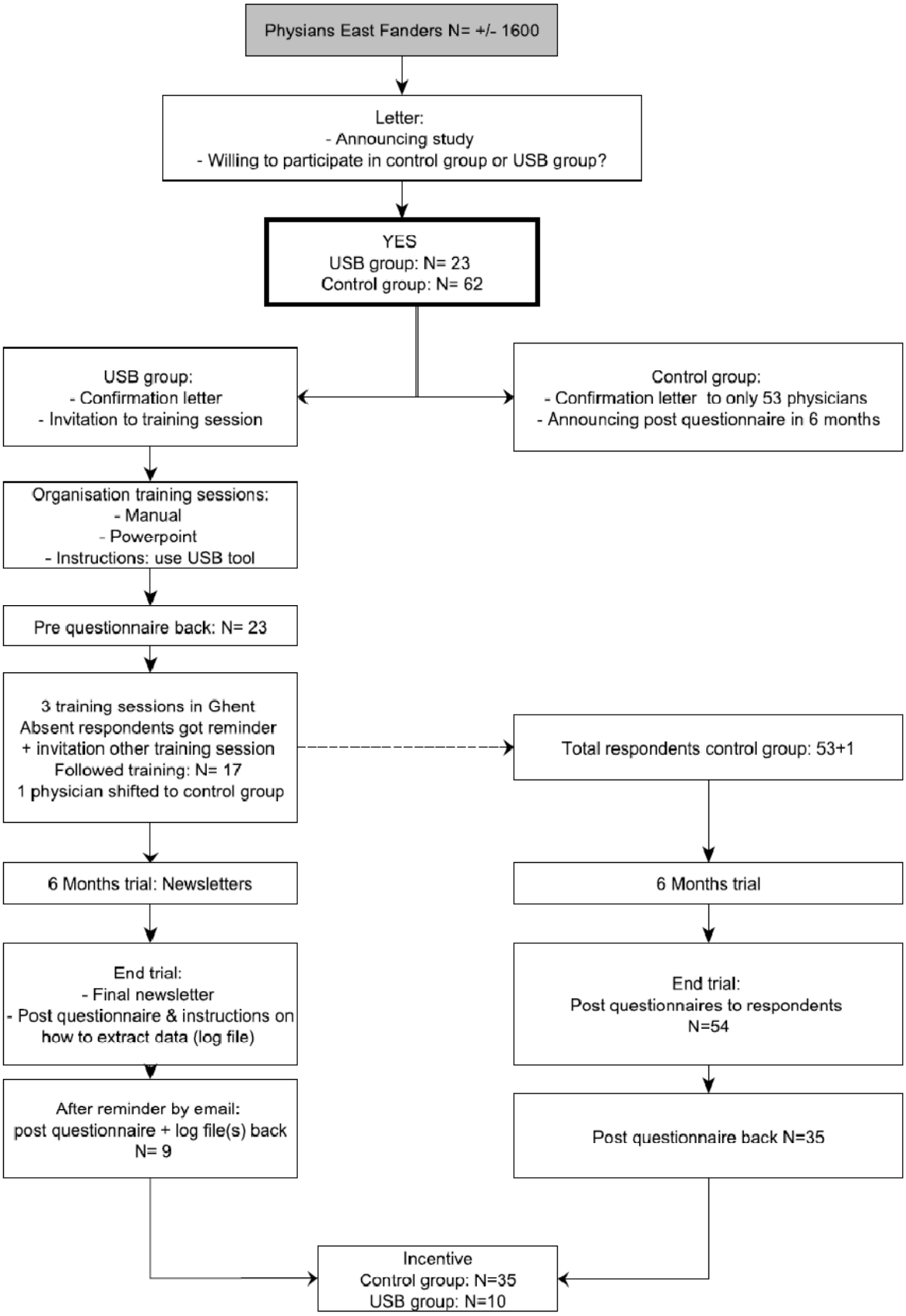
For the SoSoeMe group, it was difficult to provide a good follow-up. The research team could only communicate with the SoSoeMe respondents via the providers of the software. Due to privacy reasons the research team did not receive a list of the physicians using SoSoeMe. Because of the busy schedule and agenda of the SoSoeMe company, it became very difficult to communicate to SoSoeMe as well as to motivate or inform the respondents about the study or about the available DRUID-information.

The USB group received newsletters on a regular basis. These where a handy medium for establishing a communication with the participants. In total 3 newsletters were sent to motivate the respondents to use the program, to call in when they experienced some problems, or to inform them on the study. Furthermore, some practical cases were described or new regulations explained. Finally, the aim of the survey was underlined. The physicians were encouraged to report problems or practical remarks on the tool. The respondents could contact the research team by phone, e-mail or letter.

- **SoSoeMe group**



- **USB and control group**



2.5 Statistical analysis

SPSS version 19 (pre- and post-questionnaire data) and Microsoft Office Excel 2003 (extracted SoSoeMe/USB data) were used for the data analysis. Due to sample size restrictions and variables' scales robust non-parametric analyses were used (significance level at p≤.05; 95% confidence interval).

- **Pre-questionnaire: between-group comparisons**

For the categorical variables (background information, knowledge of new technologies, sources, user acceptance): descriptive crosstabs (within-group %), and Chi-square or Fisher's exact test to check the relationship.

For the ordinal variables composite scores[4] were calculated. For attitudes and awareness, and reported behaviour this was based on the median score. The knowledge variables were recoded into only 3 categories (don't agree, agree and don't know) and the composite score was calculated based on the sum of correct answers. Kruskal Wallis ANOVA by ranks test was used to check between-group differences and a Fisher's least significant difference (LSD) post-hoc test to locate the significant differences.

- **Within-group pre-post questionnaire change**

Pre-post significant differences were checked for attitudes and awareness, reported behaviour and knowledge, based on the Wilcoxon matched pairs - signed-rank test. For the sum composite score of knowledge paired samples t-test was used for the SoSoeMe group

- **SoSoeMe/USB data extraction**

Percentage of different click options in function of the total number of popped-up signals as a function of medicinal risk category and ATC group.

3 Results

3.1 Sample characteristics: SoSoeme (n=13), USB (n=12), Control (n=36)

Table 10: Description of the sampled population (within-group %)

		Physician groups (within-group %)			
		SoSoeMe N=13	**USB N=12**	**Control N=36**	**Total**
Gender	Male	76.9	66.7	72.2	72.1
	Female	23.1	33.3	27.8	27.9
Age*	<30 years	15.4	16.7	**0**	6.6
	30-45 years	53.8	41.7	**25**	34.4
	46-55 years	7.7	16.7	**30.6**	23
	56-65 years	23.1	25	**41.7**	34.4
	>75years	0	0	**2.8**	1.6
Inhabitants area practice	>10000	76.9	66.7	65.7	68.3
	<10000	23.1	33.3	34.3	31.7
Year of graduation from medical school	50ies	0	0	3.2	1.9
	70ies	18.2	25	32.3	27.8
	80ies	9.1	16.7	35.5	25.9

[4] A composite score combines different scores within a same category; it can be a mean, median or sum of the individual scores to provide one 'overall' category score.

	90ies	45.5	25	22.6	27.8
	2000-2009	27.3	25	6.5	14.8
	2010	0	8.3	0	1.9
Years practising as physician*	<5 year	23.1	16.7	0	8.2
	5-10 year	15.4	16.7	8.3	11.5
	11-15 year	7.7	8.3	11.1	9.8
	16-20 year	30.8	16.7	8.3	14.8
	>20 year	23.1	41.7	72.2	55.7
Education on medicinal effects on driving skills during studies at University	no	69.2	50	50	54.1
	yes	30.8	50	50	45.9

* Pearson Chi-square p≤.05 , Fisher's Exact test p≤.05

The majority of the participating physicians was male (72%), without difference between the groups (slightly less males in de USB group).

The **control group did seem to be generally older** (41.7% or the biggest group in age category 56-65) than the two other groups (biggest group in age category 30-45), especially compared to SoSoeMe participants (53.8% between 30-45). The control group even included one physician over the age of 75. None of the physicians in the control group were younger than 30.

The practicing years of the participants differed accordingly: in the **control group significantly more physicians (up to 72%) were already practicing for over 20 years** (especially compared to SoSoeMe participants with less practicing years).

Around 70% of all physicians, in all groups, had a practice in an area with more than 10,000 inhabitants (more urban).

Half of the physicians in the USB and control group mentioned to have had no education on medicinal effects on driving skills during their studies, while in the SoSoeMe group this was even 70%. Those who did receive training/education mentioned that some information on this topic was integrated in a course like "pharmacology".

3.2 Drop-outs

There were no significant differences between participants and drop-outs in the SoSoeMe, USB and Control group with regard to gender, age, number of inhabitants in the practice area, number of years from graduation or with regard to ICT familiarity.

In the **SoSoeMe group** 2 female physicians dropped out. The full participation rate was 86.7% (n=13) of the initial group.

In the **USB group** 4 physicians (2 females and 2 males) in the age group 30 to 55 dropped out of the study. The full participation rate was 75% (n=12).

Nineteen (19) physicians dropped out of the **Control group** (13 males, 6 females), from different age categories. The full participation rate was 65.5% (n=36) from the initial group.

3.3 Pre-questionnaire

The three groups were similar with regard to most pre-questionnaire parts (information sources for medicinal driving risk, pre-level attitudes and awareness, knowledge, willingness to use a prescribing support tool that takes driving risks into account). **Two significant differences were found though with regard to reported behaviour and knowledge: the SoSoeMe group at baseline indicated that they provided less detailed information when prescribing as compared to the USB and Control group. On the knowledge question on Amitriptyline the participants from the control group gave significantly**

fewer correct answers. In the following tables the questions were a significant pre post change was found were put in bold.

3.3.1 ICT familiarity

Table 11: ICT familiarity (within-group %)

		Physician groups (within-group %)			Total
		SoSoeMe N=13	USB N=12	Control N=35	
Do you use the Internet to obtain information?	no yes	7.7 92.3	0 100	8.6 91.4	6.7 93.3
Do you use the Internet to obtain information on medicines affecting driving behaviour?	no yes	75 25	75 25	71.4 28.6	72.9 27.1
If you answered "Yes" how often do you do this?	daily every week less than weekly other	25 0 50 25	0 0 66.7 33.3	10 30 40 20	11.8 17.6 47.1 23.5
Have you ever used any software package / programme to obtain information on medicinal drugs effect on driving behaviour?	No yes	83.3 16.7	83.3 16.7	80 20	81.4 18.6
Do you use any medical/clinical software package / programme in your daily practice?	no yes	1. 0 2. 100	3. 16.7 4. 83.3	5. 25.7 6. 74.3	7. 18.3 8. 81.7

The general ICT familiarity is fairly high in the whole sample when it concerns general Internet use and daily practice software use. More than 90% of all participants in all groups use the Internet to obtain general information, but only **about 25% use Internet to obtain specific information on medicines affecting driving behaviour**. About 80% of all physicians have never used any software package to obtain information on medicinal effects on driving behaviour. Besides all SoSoeMe participants, 83% of the USB and 74% of the Control group participants use a medical software package in their daily practice. Different kinds of programs were mentioned (e.g. Medidoc, Presribe, e-compendium...).

3.3.2 Sources for medicinal driving risk information

Table 12: Access to information (within-group %)

		Physician groups (within-group %)			Total group
		SoSoeMe N=13	USB N=12	Control N=36	
I have easy access to data and information about a medicine's effect on driving skills.	no	61.5	50.0	41.7	47.5
	yes	38.5	50.0	58.3	52.5
Did you get any postgraduate education on medicinal effects on driving skills?	no	100	100	94.4	96.7
	yes	0	0	5.6	3.3

Only about half of the physicians in the whole sample (52.5%) – down to just 38% in de SoSoeMe group, indicated to have easy access to data and information on the topic 'medicines and driving'. Almost no physicians had any postgraduate education on medicinal effects on driving skills.

Table 13: Source type (within-group %)

Source type:	Physician groups (within-group %)			Total group
	SoSoeMe N=13	USB N=12	Control N=36	
Professional websites	38.5	50	41.7	42.6
Newsletters	15.4	33.3	27.8	26.2
Organisations in road safety	0	0	8.3	4.9
Scientific journals	23.1	16.7	36.1	29.5

When "medicines and driving" related sources were indicated, the **most used source of information for the three groups seems to be professional websites** (42.6%), followed by scientific journals and newsletters. The package insert is furthermore mentioned as potential information source.

3.3.3 Attitudes and awareness

Table 14: Attitudes and awareness (within-group %)

		Physician groups (within-group)			Total group
		SoSoeMe N=13	USB N=12	Control N=36	
I am willing to take into account the effects of medicines on driving skills when prescribing medicines	strongly disagree	0	0	2.8	1.6
	disagree	0	0	0	0
	agree	61.5	33.3	27.8	36.1
	strongly agree	38.5	66.7	69.4	62.3
I am willing to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills.	strongly disagree	0	0	5.6	3.3
	disagree	15.4	16.7	5.6	9.8
	agree	69.2	66.7	66.7	67.2
	strongly agree	15.4	16.7	22.2	19.7
I feel being well	strongly disagree	0	8.3	2.8	3.3

aware of the effects of medicines on driving skills.	disagree	46.2	50	44.4	45.9
	agree	53.8	41.7	50.0	49.2
	strongly agree	0	0	2.8	1.6
It is important for me to be well-informed on medicinal effects on driving behaviour	strongly disagree	0	0	0	0
	disagree	0	0	0	0
	agree	61.5	50	52.8	54.1
	strongly agree	38.5	50	47.2	45.9
I feel that the information I provide to patients will influence their driving behaviour.	strongly disagree	0	8.3	0	1.6
	disagree	15.4	25	30.6	26.2
	agree	84.6	58.3	69.4	70.5
	strongly agree	0	8.3	0	1.6
Composite Score Attitudes and awareness (median)	strongly disagree (1)	0	0	0	0
	disagree (2)	0	8.3	0	1.6
	agree (3)	100	75	83.3	85.2
	strongly agree (4)	0	16.7	16.7	13.1

* Kruskal Wallis ANOVA by Ranks p≤.05

About 90**% of the physicians in all groups strongly agreed or agreed that they were willing to take into account the effects of medicines on driving skills when prescribing medicines**. Only 10-15% of the participants disagreed or even strongly disagreed to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills. **Half of the physicians**, again in all groups, **felt not being well aware of the effects of medicines on driving skills**. About 55% of the participants mentioned that it is important for them to be well informed on medicinal effects on driving behaviour. Eighty-five% of the physicians in the SoSoeMe group and 70% of the participants in the USB and control group were convinced that the information they provide to patients will influence their driving behaviour.

Table 15: Type of driver (Within-group %)

I am willing to take into account the effects of medicines on driving skills when prescribing when the patient medicines: **Would you consider this of more concern if your patient is: (YES)**	**Physician groups (within-group)**			**Total group**
	SoSoeMe N=13	**USB N=12**	**Control N=36**	
professional driver	84.6	83.3	97.2	91.8
driving frequently	92.3	75	83.3	83.6
driving long distances	92.3	83.3	86.1	86.9
inexperienced driver	61.5	66.7	74.3	70
experienced driver	38.5	50	64.7	55.9
elderly driver	100	75	88.9	88.5
using other CNS active drugs	100	83.3	97.2	95.1

More than **80% of all physicians were willing to take into account the effects** of medicines on driving skills when prescribing medicines when the patient **is a frequent driver, professional, elderly or driving long distances.** All physicians were less willing to take into account possible effects when the patient is an experienced driver.

3.3.4 Reported behaviour

Table 16: Reported behaviour (Within-group %)

	Physicians groups (within-group)			**Total group**
	SoSoeMe N=13	**USB N=12**	**Control N=36**	

I ask a patient about his/her driving exposure when prescribing a medicine (*Trend: p=.099)*	never	7.7	25	8.3	11.6
	seldom	61.5	25	13.9	26.2
	sometimes	7.7	25	44.4	32.8
	regularly	23.1	25	33.3	29.5
	always	0	0	0	0
I inform a patient about driving related risks when prescribing a medicine.	never	0	8.3	0	1.6
	seldom	7.7	8.3	5.6	6.6
	sometimes	46.2	16.7	25.0	27.9
	regularly	46.2	33.3	55.6	49.2
	always	0	33.3	13.9	14.8
I provide a patient with written information materials when prescribing a driving impairing medicine.	never	84.6	50	58.3	62.3
	seldom	15.4	41.7	22.2	24.6
	sometimes	0	8.3	11.1	8.2
	regularly	0	0	5.6	3.3
	always	0	0	2.8	1.6
I keep systematic records when I prescribe a driving impairing medicine.	never	30.8	16.7	25.0	24.6
	seldom	30.8	33.3	25.0	27.9
	sometimes	23.1	33.3	19.4	23.0
	regularly	0	8.3	16.7	11.5
	always	15.4	8.3	13.9	13.1
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine. (trend: p=.094)	never	53.8	25.0	45.7	43.3
	seldom	38.5	8.3	14.3	18.3
	sometimes	7.7	50.0	14.3	20.0
	regularly	0	8.3	22.9	15.0
	always	0	8.3	2.9	3.3
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	never	46.2	41.7	36.1	39.3
	seldom	23.1	25.0	27.8	26.2
	sometimes	23.1	25.0	22.2	23.0
	regularly	7.7	8.3	11.1	9.8
	always	0	0	2.8	1.6
I discuss medicinal drug consumption and driving related responsibility issues with the patient.	never	0	8.3	8.3	6.6
	seldom	30.8	25.0	8.3	16.4
	sometimes	53.8	16.7	36.1	36.1
	regularly	15.4	41.7	38.9	34.4
	always	0	8.3	8.3	6.6
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?*	never	7.7	8.3	5.6	6.6
	seldom	46.2	0	19.4	21.3
	sometimes	30.8	25.0	13.9	19.7
	regularly	15.4	41.7	30.6	29.5
	always	0	25.0	30.6	23.0
Composite Score Reported behaviour	never (1)	0	8.3	11.1	8.2
	seldom (2)	53.8	25.0	16.7	26.2
	sometimes (3)	38.5	25.0	41.6	37.7
	regularly (4)	7.7	33.3	27.7	24.6
	always (5)	0	8.3	2.8	3.2

* Kruskal Wallis ANOVA by Ranks – Pearson Chi-Square p≤.05

Overall, the frequencies of 'wanted' reported behaviour are rather low at baseline level (composite score: 34 % answers seldom or never to the statements). **Only one significant inter-group difference** with regards to reported behaviour was found. **The SoSoeMe group**

significantly provided less detailed information when prescribing compared to the USB and Control group (Chi-Square 8.872; p=.012). The physicians in the USB and control group asked a patient more about his/her driving exposure when prescribing a medicine than the physicians in the SoSoeMe group (trend). Half of all physicians stated that they regularly inform a patient about driving related risks when prescribing a medicine. Eleven out the 13 participants (85%) in the SoSoeMe group never provided a patient with written information materials when prescribing a driving impairing medicine. Only 2 physicians in the SoSoeMe group, 1 in the USB group and 5 in the control group always kept systematic records when prescribing a driving impairing medicine.

3.3.5 Knowledge

Table 17: Knowledge (Within-group %)

		Physician groups (within-group %)			Total group
		SoSoeMe	USB	Control	
Diazepam (regardless dose) is severely Impairing within the first 2 months of treatment	disagree	25.0	27.3	34.5	30.8
	agree (correct)	33.3	36.4	31.0	32.7
	don't know	41.7	36.4	34.5	36.5
N		12	11	29	52
Codeine (up to 20 mg) is mostly safe for drivers	disagree	91.7	58.3	71.4	72.9
	agree (correct)	8.3	8.3	8.6	8.5
	don't know	0	33.3	20	18.6
N		12	12	35	59
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	33.3	16.7	26.5	25.9
	agree	8.3	8.3	5.9	6.9
	don't know	58.3	75	67.6	67.2
N		12	12	34	58
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment *	disagree (correct)	46.2	58.3	20	33.3
	agree	15.4	8.3	25.7	20
	don't know	38.5	33.3	54.3	46.7
N		13	12	35	60
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	46.2	8.3	30.3	29.3
	agree (correct)	30.8	50	39.4	39.7
	don't know	23.1	41.7	30.3	31
N		13	12	33	58
Composite Score Knowledge (sum on 5 correct answers)	0	23.1	8.3	30.6	24.6
	1	30.8	50	30.6	34.4
	2	23.1	8.3	33.3	26.2
	3	23.1	33.3	5.6	14.8
	4	0	0	0	0
	5	0	0	0	0
N		13	12	36	61
Physicians are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	0	8.3	8.6	6.7
	true (correct)	100	91.7	91.4	93.3

N		13	12	35	60
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	9.1	8.3	2.8	5.1
	true (correct)	90.9	91.7	97.2	94.9
N		11	12	36	59
Composite Score Knowledge (total sum on 7 correct answers)	0	0	0	0	0
	1	0	8.3	5.6	4.9
	2	38.5	8.3	27.8	26.2
	3	23.1	41.7	30.6	31.1
	4	15.4	8.3	33.3	24.6
	5	23.1	33.3	2.8	13.1
	6	0	0	0	0
	7	0	0	0	0
N		13	12	36	61

*Pearson Chi-Square p≤.05

There is one **significant between-group difference at baseline level on knowledge of specific medicinal driving risks (question on Amitriptyline). The participants from the control group gave significant less correct answers than the other two groups. Eightly-five% of the respondents had less of half of the answers correct with regard to individual medicine's risk.**

In general, **increased proportions of participants in all groups answer incorrectly or failed to give any answer with regard to specific medicines' risks**: especially for Codeine (wrong: almost 75%) and don't know: 18%). Only for the question on Paroxetine most participants answered correctly (39%). **They are generally more informed about legal obligations and responsibilities** of physicians/pharmacists and patients.

3.3.6 User-acceptance

Table 18: User-acceptance (Within-group %)

		Physician groups (within-group)			Total group
		SoSoeMe N=13	USB N=12	Control N=36	
If we propose to you a tool (e.g. website, CD-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for prescribing medicines?	no	0	0	0	0
	yes	84.6	91.7	77.8	82
	Maybe	15.4	8.3	22.2	18

More than 91% of the USB respondents and over 80% of the SoSoeMe respondents stated that they are willing to use a tool to find easily information regarding medicinal drugs and driving.

About 20% were less eager to start using such a tool. The most frequent reasons for their hesitation can be linked to **fears about software user-friendliness and time pressure during the consultation**. Several physicians mentioned that the tool should be integrated,

easy to use when prescribing, have no effect on computer processes (e.g. slowing down) and cost no extra time.

More than 90% of the SoSoeMe group respondents and about 60% of the USB and control group first choice was software integrated in their own software. As second choice came out a **website** and thirdly a **stand-alone software**. 'Other' referred mostly to combinations (e.g. website + manual). Stand-alone software (e.g. CD-rom or USB) seems generally not to be preferred.

Table 19: Preference support tool (Within-group %)

Which type of support tool would you prefer ?		Physician groups (within-group)			Total group
		SoSoeMe	USB	Control	
First choice	Website	7.7	16.7	17.1	15
	Software integrated in your own software	92.3	66.7	57.1	66.7
	Stand alone software	0	8.3	0	1.7
	Manual	0	0	14.3	10
	Other	0	0	11.4	6.6
N		13	12	35	60
Second choice	**Website**	83.3	58.3	44.8	56.6
	Software integrated in your own software	8.3	16.7	6.9	9.4
	Stand alone software	0	16.7	24.1	17
	Manual	8.3	8.3	10.3	9.4
	Other	0	0	13.7	7.6
N		12	12	29	53
Third choice	Website	0	8.3	22.6	14.5
	Software integrated in your own software	0	16.7	6.5	7.3
	Stand alone software	50	33.3	35.5	38.2
	Manual	25	33.3	22.6	25.5
	Other	25	8.3	12.8	14.5
N		12	12	31	55

3.4 SoSoeme group pre-post questionnaire comparison (N=13)

Only one significant positive pre-post change after the intervention phase could be measured on the reported behaviour of SoSoeMe participants. Overall little pre-post change was found on attitudinal level. On the knowledge questions the number of incorrect or don't know answers in the post-questionnaire remained high overall.

3.4.1 Attitudes and awareness

Overall little pre-post questionnaire change was found on attitudinal level. **No significant changes were measured. A trend** change was found with regard to the question if the participants **were willing to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills** (Z= -1.667; p=.096). The participants in the SoSoeMe group were slightly more willing to prescribe a safer alternative after the trial period. Five physicians out of 13 changed their answer in positive sense. Although no significant change could be observed, overall the positive change was bigger than the negative change on 4 of the 5 questions (no change measured on one question).

Table 20: SoSoeMe group pre-post change– Attitudes and awareness

SoSoeMe group pre-post questionnaire (within-group %) (n=13)				
		Pre	**Post**	**Change**
I am willing to take into account the effects of medicines on driving skills when prescribing medicines	Strongly disagree	0	0	0
	Disagree	0	0	0
	Agree	61.5	61.5	0
	Strongly agree	38.5	38.5	0
I am willing to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills (trend: p=.096)	Strongly disagree	0	0	0
	Disagree	15.4	0	-15.4
	Agree	69.2	61.5	-7.7
	Strongly agree	15.4	38.5	23.1
I feel being well aware of the effects of medicines on driving skills.	Strongly disagree	0	0	0
	Disagree	46.2	38.5	-7.7
	Agree	53.8	61.5	7.7
	Strongly agree	0	0	0
It is important for me to be well informed on medicinal effects on driving behaviour.	Strongly disagree	0	0	0
	Disagree	0	0	0
	Agree	61.5	53.8	-7.7
	Strongly agree	38.5	46.2	7.7
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	0	0	0
	Disagree	15.4	15.4	0
	Agree	84.6	76.9	-7.7
	Strongly agree	0	7.7	7.7
Composite Score Attitudes & Awareness (median)	Strongly disagree (1)	0	0	0
	Disagree (2)	0	0	0
	Agree (3)	100	92.3	-7.7
	Strongly agree (4)	0	7.7	7.7

With regard to the question whether specific characteristics of driver-patients would make a difference, there was **no significant change compared to the baseline**. On a descriptive level, a quite large positive change was found regarding the experienced drivers. 23% of the physicians changed their answer in a positive sense, and were thus more willing to take into

account the effects of medicines on driving skills when their patient was an experienced driver.

Table 21: SoSoeMe group pre-post change – Detail attitudes and awareness

SoSoeMe group pre-post questionnaire (within-group %) (n=13)			
I am willing to take into account the effects of medicines on driving skills when prescribing medicines: (YES)	**Pre**	**Post**	**Change**
professional driver	84.6	100	15.4
driving frequently	92.3	100	7.7
driving long distances	92.3	100	7.7
inexperienced driver	61.5	69.2	7.7
experienced'driver	38.5	61.5	23
elderly driver	100	100	0
using other CNS active drugs	100	100	0

3.4.2 Reported behaviour

There wasa **significant positive change after the intervention phase of the SoSoeMe participants on 1 of the 8 reported behaviour questions**. When medication with impairing effects on driving was to be prescribed, significantly more physicians provided a patient with written information materials (Z= -2.598; p=.009). Looking at the frequencies, it is clear that for almost all reported behaviour questions there was a **good increase of the proportions of physicians in the 'regularly' and 'always' questions**.

Table 22: SoSoeMe group pre-post change – Reported behaviour

SoSoeMe group pre-post questionnaire (within-group %) (N=13)						
	Within-group %	**Never**	**Seldom**	**Sometimes**	**Regularly**	**Always**
I ask a patient about his/her driving exposure when prescribing a medicine.	Pre	7.7	61.5	7.7	23.1	0
	Post	15.4	23.1	15.4	46.2	0
	Change	7.7	-38.4	7.7	23.1	0
I inform a patient about driving related risks when prescribing a medicine.	Pre	0	7.7	46.2	46.2	0
	Post	0	7.7	30.8	53.8	7.7
	Change	0	0	-15.4	7.6	7.7
I provide a patient with written information materials when prescribing a driving impairing medicine. *	**Pre**	84.6	15.4	**0**	**0**	**0**
	Post	38.5	23.1	38.5	0	0
	Change	**-46.1**	**7.7**	**38.5**	**0**	**0**
I keep systematic records when I prescribe a driving impairing medicine.	Pre	30.8	30.8	23.1	0	15.4
	Post	15.4	30.8	7.7	23.1	23.1
	Change	-15.4	0	-15.4	23.1	7.7
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	Pre	53.8	38.5	7.7	0	0
	Post	38.5	30.8	30.8	0	0
	Change	-15.3	-7.7	23.1	0	0
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	Pre	46.2	23.1	23.1	7.7	0
	Post	15.4	53.8	30.8	0	0
	Change	-30.8	30.7	7.7	-7.7	0
I discuss medicinal drug	Pre	0	30.8	53.8	15.4	0

consumption and driving related responsibility issues with the patient.	Post	0	30.8	30.8	38.5	0
	Change	0	0	-23	23.1	0
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?	Pre	7.7	46.2	30.8	15.4	0
	Post	15.4	23.1	15.4	46.2	0
	Change	7.7	-23.1	-15.4	30.8	0
Composite Score Reported behaviour (median)	Pre	0	53.8	38.5	7.7	0
	Post	7.7	23.1	30.8	38.5	0
	Change	7.7	-30.7	-7.7	30.8	0

* Wilcoxon Signed Ranks Test Ranks p≤.05

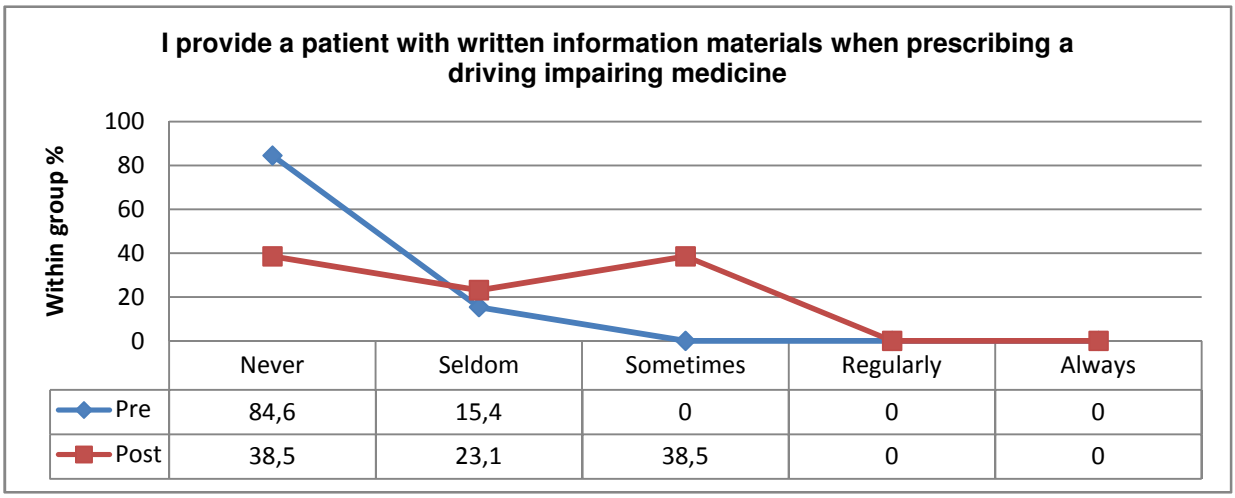


Figure 28: SoSoeMe group pre-post change- "I provide a patient with written information materials when prescribing a driving impairing medicine" (Within group %) (N=13)

3.4.3 Knowledge

The number of correct answers on the knowledge questions did not increase. For the questions on Diazepam, Amitriptyline and Paroxetine there were mainly less "don't know" answers. Several physicians changed their answer in a negative sense after the trial period when compared with the baseline (in 3 out of 5 questions). With regard to the question on Amitryptiline the biggest positive change (more correct answers) was measured. **With regard to physician/pharmacist obligations and patient responsibilities knowledge the post-answers were more or less identical to the pre-answers, which were already predominantly correct.**
Overall **the number of incorrect or don't know answers in the post-questionnaire remained high and for some questions even around 70% and more**: Codeine (92.3%), Diazepam (77%), Fexofenadine (69.2%) and Paroxetine (69.2%).

Table 23: SoSoeMe group pre-post change – Knowledge

		SoSoeMe group (within-group)			
		PRE	POST	PRE-POST difference	N
Diazepam (regardless dose) is severely impairing within the first 2 months of treatment	disagree	25	46.2	21.2	12
	agree (correct)	33.3	23.1	-10.2	
	don't know	41.7	30.8	-10.9	
Codeine (up to 20 mg) is mostly safe for drivers	disagree	91.7	84.6	-7.1	12
	agree (correct)	8.3	7.7	-0.6	

	don't know	0	7.7	7.7	
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	33.3	30.8	-2.5	12
	agree	8.3	0	-8.3	
	don't know	58.3	69.2	10.9	
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	disagree (correct)	46.2	53.8	7.6	13
	agree	15.4	15.4	0	
	don't know	38.5	30.8	-7.7	
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	46.2	61.5	15.3	13
	agree (correct)	30.8	30.8	0	
	don't know	23.1	7.7	-15.4	
Composite Score Knowledge medicine risks (sum correct answers on 5)	0	23.1	38.5	15.4	13
	1	30.8	7.7	-23.1	
	2	23.1	30.8	7.7	
	3	23.1	15.4	-7.7	
	4	0	7.7	7.7	
	5	0	0	0	
Physicians are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	0	0	0	13
	true (correct)	100	100	0	
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	9.1	7.7	-1.4	11
	true (correct)	90.9	92.3	1.4	
Composite Score Knowledge (total sum correct answers on 7)	0	0	0	0	13
	1	0	38.5	38.5	
	2	38.5	15.4	-23.1	
	3	23.1	23.1	0	
	4	15.4	15.4	0	
	5	23.1	7.7	-15.4	
	6	0	0	0	
	7	0	0	0	

Wilcoxon Signed Ranks Test Ranks p≥.05

SoSoeMe Physicians **did not give significantly more correct answers** in the post-questionnaire as compared to the pre-questionnaire.

Table 24: SoSoeMe group pre-post change – Knowledge composite score

Knowledge Composite Scores (mean sum correct answers)			
	PRE	**POST**	**Change (mean)**
CS specific medicinal risks (sum on 5) - Mean (SD)*	1.46	1.46	0
CS overall Knowledge (sum on 7) - Mean (SD)*	3.23	3.38	0.2

* Paired samples t-test p≥0.05

3.5 USB group pre-post questionnaire comparison (n=12)

There was no significant pre-post change on the attitude and awareness, reported behaviour and knowledge questions for the physicians in the USB group. **However** two **trends were measured on the reported behaviour question if they provided a patient with written information materials and if they discussed medicinal drug consumption and driving related responsibility issues with the patient.**

3.5.1 Attitudes and awareness

Also for this group little pre-post questionnaire change was found on attitudinal level. **There was no significant pre-post change on the attitude and awareness questions.** Although no significant positive pre-post change was found**, on all questions the positive change was bigger than the negative change. Several physicians changed their answer from 'agree' into 'strongly agree'** on the question if they are willing to take into account the effect of medicines on driving skills when prescribing medicines, if they felt aware of the potential effect of medicines on driving and if they felt that the information they provided to the patient will have an influence on his/her driving behaviour.

Table 25: USB group pre-post change – Attitudes and awareness

USB group pre-post questionnaire (within-group %)					
		Pre	**Post**	**Change**	**N**
I am willing to take into account the effects of medicines on driving skills when prescribing medicines	Strongly disagree	0	0	0	10
	Disagree	0	0	0	
	Agree	33.3	30	-3.3	
	Strongly agree	66.7	70	3.3	
I am willing to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills.	Strongly disagree	0	0	0	11
	Disagree	16.7	0	-16.7	
	Agree	66.7	90.0	23.3	
	Strongly agree	16.7	10	-6.7	
I feel being well aware of the effects of medicines on driving skills.	Strongly disagree	8.3	0	-8.3	11
	Disagree	50	54.5	4.5	
	Agree	41.7	36.4	-5.3	
	Strongly agree	0	9.1	9.1	
It is important for me to be well informed on medicinal effects on driving behaviour.	Strongly disagree	0	0	0	11
	Disagree	0	0	0	
	Agree	50	45.5	-4.5	
	Strongly agree	50	54.5	4.5	
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	8.3	0	-8.3	11
	Disagree	25	18.2	-6.8	
	Agree	58.3	72.7	14.4	
	Strongly agree	8.3	9.1	0.8	
Composite Score Attitudes & Awareness (median)	Strongly disagree (1)	0	0	0	11
	Disagree (2)	8.3	0	-8.3	
	Agree (3)	75	81.8	6.8	
	Strongly agree (4)	16.7	18.2	1.5	

Wilcoxon Signed Ranks Test Ranks p≥.05

With regard **to the question whether specific traffic participation relevant characteristics of patients** would make a difference in considering effects of medicines on driving skills, **no significant changes compared to the baseline measurement were found**. However rather

positive pre-post changes in the within-group frequency (%) were found especially when their patient was an inexperienced driver, an experienced driver of using other CNS active drugs.

Table 26: USB group pre-post change – Detail attitudes and awareness

USB group pre-post questionnaire (within-group %)				
I am willing to take into account the effects of medicines on driving skills when prescribing medicines: (YES)	**Pre**	**Post**	**Change**	**N**
professional driver	83.3	90	6.7	10
driving frequently	75	100	5	10
driving long distances	83.3	90	6.7	10
inexperienced driver	66.7	100	33.3	10
experienced'driver	50	66.7	16.7	9
elderly driver	75	90	15	10
using other CNS active drugs	83.3	100	16.7	10

3.5.2 Reported behaviour

No significant positive change after the training and the intervention phase of USB participants on the behaviour questions was found. However **two trends were measured on the question about providing a patient with written information materials (Z=-1.890;p=.059) and discussing medicinal drug consumption and driving related responsibility issues with the patient (Z=-1.667;p=.096)**. Several physicians changed their answer from 'never' into 'seldom' on the question regarding the written information materials. Better results were found on the question whether the physicians discussed he topic 'drugs and driving'" with the patient, 7 physicians out of 13 stated to discuss this topic regularly with their patients.

Table 27: USB group pre-post change – Reported behaviour

USB group pre-post questionnaire (within-group %) (n=11)						
	Within-group %	**Never**	**Seldom**	**Sometimes**	**Regularly**	**Always**
I ask a patient about his/her driving exposure when prescribing a medicine.	Pre	25	25	25	25	0
	Post	18.2	27.3	0	54.5	0
	Change	-6.8	2.3	-25	29.5	0
I inform a patient about driving related risks when prescribing a medicine.	Pre	8.3	8.3	16.7	33.3	33.3
	Post	9.1	0	9.1	72.7	9.1
	Change	0.8	-8.3	-7.6	39.4	-24.2
I provide a patient with written information materials when prescribing a driving impairing medicine (trend: p=.059)	Pre	50	41.7	8.3	0	0
	Post	27.3	54.5	9.1	9.1	0
	Change	*-22.7*	*12.8*	*0.8*	*9.0*	*0*
I keep systematic records when I prescribe a driving impairing medicine.	Pre	16.7	33.3	33.3	8.3	8.3
	Post	18.2	27.3	9.1	36.4	9.1
	Change	1.5	-6	-24.2	28.1	0.8
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	Pre	25	8.3	50	8.3	8.3
	Post	18.2	18.2	36.4	27.3	0
	Change	-6.8	9.9	-13.6	19	-8.3

I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	Pre	41.7	25	25	8.3	0
	Post	45.5	9.1	45.5	0	0
	Change	3.8	-15.9	20.5	-8.3	0
I discuss medicinal drug consumption and driving related responsibility issues with the patient (trend: p=.096)	Pre	8.3	25	16.7	41.7	8.3
	Post	9.1	0	18.2	63.6	9.1
	Change	*0.8*	*-25*	*1.5*	*21.9*	*0.8*
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?	Pre	8.3	0	25	41.7	25
	Post	0	9.1	45.5	36.4	9.1
	Change	-8.3	9.1	20.5	-5.3	-15.9
Composite Score Reported behaviour (median)	Pre	8.3	25	25	33.3	8.3
	Post	9.1	9.1	18.2	63.7	0
	Change	0.8	-15.9	-6.8	30.4	-8.3

Wilcoxon Signed Ranks Test Ranks p≥.05

3.5.3 Knowledge

No significant positive change (more correct answers) was found on the knowledge questions. Negative pre post changes (less correct answers) were found on the questions on Amitriptyline and Paroxetine. A possible explanation for the negative change in answers could be that the physicians were more aware about potential risks of medicines on driving after the training and intervention period, and thus more careful in their estimation of potential risk of medicines on the driving abilities. A trend was observed on the question on Diazepam (Z=-1.732;p=.083). About 30% of the physicians gave more correct answers after the intervention. **On the question on the physician/pharmacists responsibilities and patient responsibilities knowledge the post-answers were more or less identical to the pre-answers, which were already predominantly correct.** Looking at both composite score on the knowledge, 5 out 11 physicians scored more correct answers compared to the baseline.

Table 28: USB group pre-post change – Knowledge

		USB group (within-group)			
		PRE	POST	PRE-POST difference	N
Diazepam (regardless dose) is severely impairing within the first 2 months of treatment (trend: p=.083)	disagree	27.3	22.2	*-5.1*	*9*
	agree (correct)	36.4	77.8	*44.4*	
	don't know	36.4	0	*-36.4*	
Codeine (up to 20 mg) is mostly safe for drivers	disagree	58.3	72.7	6.7	11
	agree (correct)	8.3	18.2	9.9	
	don't know	33.3	9.1	-24.2	
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	16.7	18.2	1.5	11
	agree	8.3	0	-8.3	
	don't know	75	81.8	6.8	
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	disagree (correct)	58.3	54.5	-3.8	11
	agree	8.3	27.3	19	
	don't know	33.3	18.2	-15.1	
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	8.3	36.4	28.1	11
	agree (correct)	50	36.4	-13.6	
	don't know	41.7	27.3	-14.4	
Composite Score Knowledge medicine risks (sum correct answers on 5)	0	8.3	18.2	9.9	11
	1	50	9.1	-40.9	
	2	8.3	45.5	37.2	
	3	33.3	18.2	-15.1	
	4	0	9.1	9.1	
	5	0	0	0	
Physicians are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	8.3	9.1	0.8	11
	true (correct)	91.7	90.9	-0.8	
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	8.3	0	-8.3	11
	true (correct)	91.7	100	8.3	
Composite Score Knowledge	0	0	0	0	11

(total sum correct answers on 7)	1	8.3	0	-8.3	
	2	8.3	18.2	9.9	
	3	41.7	18.2	-23.5	
	4	8.3	36.4	28.1	
	5	33.3	18.2	-15.1	
	6	0	9.1	9.1	
	7	0	0	0	

Wilcoxon Signed Ranks Test Ranks p≥.05

Table 29: USB group pre-post change – Knowledge composite score

Knowledge Composite Scores (mean sum correct answers)			
	PRE	**POST**	**Change (mean)**
CS specific medicinal risks (sum on 5) - Mean (SD)*	1.7	1.9	0.2
CS overall Knowledge (sum on 7) - Mean (SD)*	3.5	3.8	0.3

* Paired samples t-test p≥0.05

3.6 Control group pre-post questionnaire comparison (n=36)

There were no significant changes on the awareness and attitude, reported behaviour questions for the physicians in the control group. For the knowledge question on Amitriptyline and both composite scores a significant positive pre-post change was found.

3.6.1 Attitudes and awareness

There were **no significant changes** on the awareness and attitude questions for the physicians in the control group. **The largest part of the physicians** (69% up to 97%) **remained at the same agreement level as in the pre-questionnaire**, which is conform the expected results for the control group. The participants felt less aware of the effects of medicines on driving skills compared to the baseline measurement.

Table 30: Control group pre-post change – Attitudes and awareness

Control group pre-post questionnaire (within-group %)					
		Pre	**Post**	**Change**	**N**
I am willing to take into account the effects of medicines on driving skills when prescribing medicines	Strongly disagree	2.8	2.8	0	36
	Disagree	0	0	0	
	Agree	27.8	36.1	8.3	
	Strongly agree	69.4	61.1	-8.3	
I am willing to sacrifice some degree of efficacy by prescribing a medicine that is less impairing to the driving skills.	Strongly disagree	5.6	0	-5.6	35
	Disagree	5.6	8.6	3	
	Agree	66.7	68.6	1.9	
	Strongly agree	22.2	22.9	0.7	
I feel being well aware of the effects of medicines on driving skills.	Strongly disagree	2.8	0	-2.8	36
	Disagree	44.4	58.3	13.9	
	Agree	50	41.7	-8.3	
	Strongly agree	2.8	0	-2.8	
It is important for me to be well-informed on medicinal effects on driving behaviour.	Strongly disagree	0	0	0	36
	Disagree	0	0	0	
	Agree	52.8	58.3	5.5	
	Strongly agree	47.2	41.7	-5.5	
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	0	0	0	36
	Disagree	30.6	13.9	-16.7	
	Agree	69.4	86.1	16.7	
	Strongly agree	0	0	0	
Composite Score Attitudes & Awareness (median)	Strongly disagree (1)	0	0	0	36
	Disagree (2)	0	0	0	
	Agree (3)	83.3	88.9	5.6	
	Strongly agree (4)	16.7	11.1	-5.6	

Wilcoxon Signed Ranks Test Ranks p≥.05

Looking at the questions about the characteristics of the patient it became clear that **the majority of the physicians stayed at the same agreement level**.

Table 31: Control group pre-post change – Detail attitudes and awareness

Control group pre-post questionnaire (within-group %)				
I am willing to take into account the effects of medicines on driving skills when prescribing medicines: (YES)	Pre	Post	Change	N
professional driver	97.2	91.7	-5.5	36
driving frequently	83.3	80.6	-2.7	36
driving long distances	86.1	86.1	0	36
inexperienced driver	74.3	75	0.7	35
experienced'driver	64.7	62.9	-1.8	33
elderly driver	88.9	88.9	0	36
using other CNS active drugs	97.2	100	2.8	36

3.6.2 Reported behaviour

There were **no significant changes** of the reported behaviour of the physicians in the control group. Compared to the baseline measurement, the participants stated less to ask a patient about his/her driving exposure (-11.1% 'sometimes; -5.5 % 'regularly'). On the questions if they kept systematic records when advising a patient on possible effects of the medicines and if they kept record of the patient's traffic participation, about respectively 40-30% of the physicians changed their answers in a positive sense ('regularly –'always' answers). **A big part of the participants did not change their answer compared to the pre-questionnaire** (31%-58%).

Table 32: Control group pre-post change – Reported behaviour

Control group pre-post questionnaire (within-group %)							
	Within-group %	Never	Seldom	Sometimes	Regularly	Always	N
I ask a patient about his/her driving exposure when prescribing a medicine.	Pre	8.3	13.9	44.4	33.3	0	3
	Post	8.3	30.6	33.3	27.8	0	
	Change	0	16.7	-11.1	-5.5	0	
I inform a patient about driving related risks when prescribing a medicine.	Pre	0	5.6	25	55.6	13.9	3
	Post	0	5.6	22.2	69.4	2.8	
	Change	0	0	-2.8	13.8	-11.1	
I provide a patient with written information materials when prescribing a driving impairing medicine.	Pre	58.3	22.2	11.1	5.6	2.8	3
	Post	61.1	22.2	8.6	5.6	2.8	
	Change	2.8	0	-2.5	0	0	
I keep systematic records when I prescribe a driving impairing medicine.	Pre	25	25	19.4	16.7	13.9	3
	Post	19.4	25	22.2	13.9	19.4	
	Change	-5.6	0	2.8	-2.8	5.5	
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	Pre	45.7	14.3	14.3	22.9	2.9	3
	Post	22.2	36.1	25	11.1	5.6	
	Change	-23.5	21.8	10.7	-11.8	2.7	
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	Pre	36.1	27.8	22.2	11.1	2.8	3
	Post	38.9	19.4	27.8	13.9	0	
	Change	2.8	-8.4	5.6	2.8	-2.8	
I discuss medicinal drug consumption and driving related responsibility	Pre	8.3	8.3	36.1	38.9	8.3	3
	Post	0	13.9	30.6	50	5.6	

issues with the patient.	Change	-8.3	5.6	-5.5	11.1	-2.7	
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?	Pre	5.6	19.4	13.9	30.6	30.6	3
	Post	0	19.4	30.6	33.3	16.7	
	Change	-5.6	0	16.7	2.7	-13.9	
Composite Score Reported behaviour (median) *	Pre	11.1	16.7	41.6	27.7	2.8	3
	Post	2.8	25	38.9	30.5	2.8	
	Change	-8.3	8.3	-2.7	2.8	0	

Wilcoxon Signed Ranks Test Ranks p≥.05

3.6.3 Knowledge

For the knowledge questions **significant changes were observed for the question on Amitriptyline (Z= -2.530; p=.011) and the two composite scores (Z=-2.639;p=.008 & Z=-2756;p=.006).** Taking a closer look at the question on Amitripyline, 26% of the physicians gave more correct answers (9 physicians out of 35). The majority of the physicians (71%) remained at the same knowledge level (25 physicians out of 35).

A decrease in knowledge was found when calculating the composite scores. In the pre questionnaire 94.5% of the physicians had a score of 2/5 questions correct (composite score knowledge individual medicine risks) compared to 72.2% in the post questionnaire. In the pre questionnaire 64% of the participants had a score of 3/7 questions correct (composite score knowledge total) compared to 41.7% of the participants in the post questionnaire.

On the question on codeine and fexofenadine a positive change (more correct answers) was found. Only 7 physicians (of the 36) gave the correct answer on the codeine question and 12 physicians gave the correct answer on the paroxetine question. **We can conclude that the majority of the participants gave wrong or incorrect answers on the knowledge questions. No big pre-post changes were found on the questions regarding legal obligations and patient responsibilities.**

Table 33: Control group pre-post change – Knowledge

		Control group (within-group)			
		PRE	POST	PRE-POST difference	N
Diazepam (regardless dose) is severly impairing within the first 2 months of treatment	disagree	34.5	32.4	-2.1	29
	agree (correct)	31	35.3	4.3	
	don't know	34.5	32.4	-2.1	
Codeine (up to 20 mg) is mostly safe for drivers	disagree	71.4	63.9	-7.5	35
	agree (correct)	8.6	19.4	10.8	
	don't know	20	16.7	-3.3	
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	26.5	33.3	6.8	34
	agree	5.9	13.9	8	
	don't know	67.6	52.8	-14.8	
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment *	disagree (correct)	20	41.7	21.7	35
	agree	25.7	36.1	10.4	
	don't know	54.3	22.2	-32.1	
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	30.3	22.2	-8.1	33
	agree (correct)	39.4	38.9	-0.5	
	don't know	30.3	38.9	8.6	
Composite Score Knowledge medicine risks (sum correct	0	30.6	19.4	-11.2	36
	1	30.6	30.6	0	
	2	33.3	22.2	-11.1	

answers on 5)*	3	5.6	22.2	16.6		
	4	0	2.8	2.8		
	5	0	2.8	2.8		
Physicians are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	8.6	2.8	-5.8	35	
	true (correct)	91.4	97.2	5.8		
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	2.8	5.7	2.9	35	
	true (correct)	97.2	94.3	-2.9		
Composite Score Knowledge (total sum correct answers on 7)*	0	0	2.8	2.8	36	
	1	5.6	0	-5.6		
	2	27.8	16.7	-11.1		
	3	30.6	36.1	5.5		
	4	33.3	16.7	-16.6		
	5	2.8	22.2	19.4		
	6	0	2.8	2.8		
	7	0	2.8	2.8		

* Wilcoxon Signed Ranks Test Ranks p≤.05

Table 34: Control group pre-post change – Knowledge composite score

Knowledge Composite Scores (mean sum correct answers)			
	PRE	**POST**	**Change (mean)**
CS specific medicinal risks (sum on 5) - Mean (SD)*	1.14	1.67	0.53
CS overall Knowledge (sum on 7) - Mean (SD)*	3	3.56	0.56

* Paired samples t-test p≤0.05

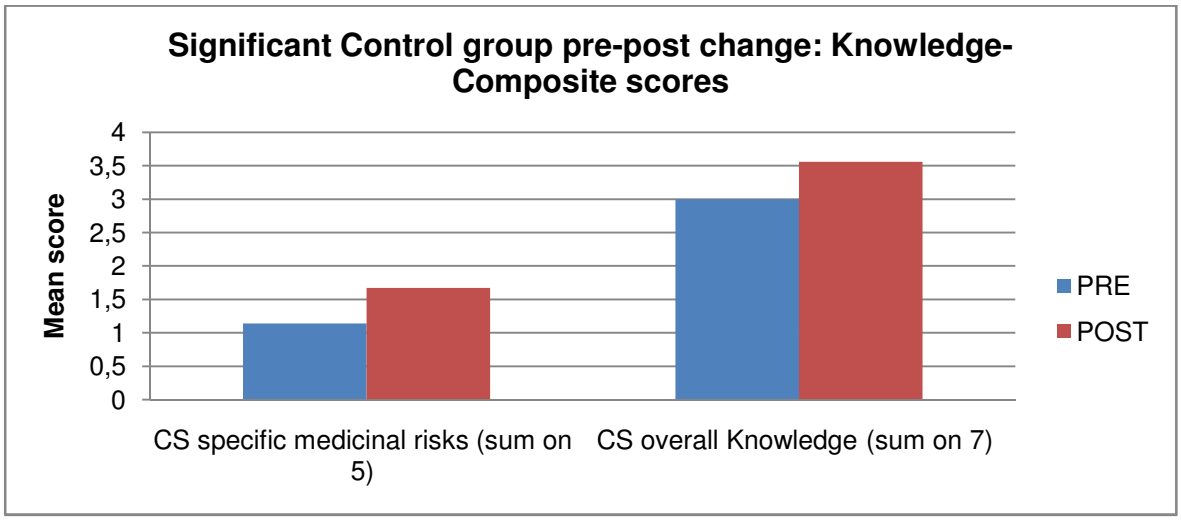


Figure 29: Significant Control group pre-post change – Knowledge Composite Scores (within group%)

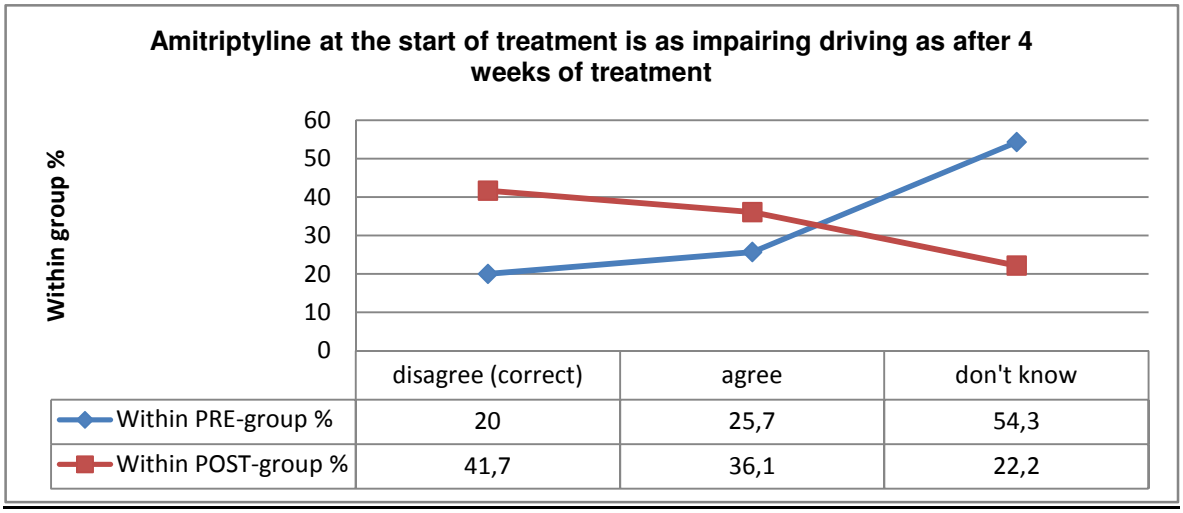


Figure 30: Control group- pre-post change: "Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment".

3.7 SoSoeMe group software data

Only limited data was retrieved from the SoSoeMe software. When the physician wanted to prescribe a N-medicine a pictogram appeared in the software to warn the physician about the potential risk of that medicine on driving. After clicking on the pictogram the physician had the option to open a fact sheet and/or a patient letter. The participants had also the possibility to print this fact sheet and/or patient letter. Consequently after the physician had clicked on the pictogram, the number of clicks to open a fact sheet and/or patient letter were registered (see deliverable 7.4.1).

In total the research team received data from **only 7 physicians**. Between 26th of March 2010 (first click registered) and 28th of February 2011 (last click registered) **111 clicks were made** on the pictogram in the SoSoeMe software. The number of clicks was not equally divided between the 7 physicians (see table below). About 58% of the clicks were made by two physicians (physician 2&7). When taking a closer look to the data, it became clear that sometimes several physicians worked within one practice. The data from physician 2 and physician 7 represent the use of the software by 5 physicians (physician 2: a practice with 3 physicians; physician 7: a practice with 2 physicians).

Table 35: SoSoeMe software data (n= 111)

Distribution by 'clicks' (within group%)		Distribution by risk category (%)	
Physician 1	15.3	Category 1	18.9
Physician 2	23.4	Category 2	35.1
Physician 3	2.7	Category 3	45.9
Physician 4	1.8		
Physician 5	5.4		
Physician 6	16.2		
Physician 7	35.1		

Of the 111 clicks on the pictogram the physicians clicked only 11 times on the fact sheet button. **On the other hand, the patient letter was viewed 103 times**. Whether the patient letter was printed could not be retrieved from the data. The physicians consulted the DRUID information the most when prescribing **Anxiolytics** or **Antidepressants**.

Table 36: SoSoeMe software data: Distribution by ATC code

Distribution by ATC code (absolute numbers)	Fact sheet		Patient letter	
	Yes	No	Yes	No

N01-- Anesthetics	1	0	0	1
N02 – Analgesics	2	14	14	1
N03 – Anti-epileptics	1	3	4	1
N04 - Antiparkinson	0	1	0	0
N05A – Antipsychotics	0	4	4	0
N05B – Anxiolytics	**3**	25	**26**	2
N05C – Hypnotics &sedatives	**1**	14	**15**	0
N06A – Antidepressants	**2**	29	**29**	2
N06B – Psychostimulants	0	0	0	0
N06C – Psycholeptics/ psychanaleptics in combination	0	4	4	0
N06D – Antidementia medicines	0	2	2	0
N07B – Drugs used in addictive disorders	0	1	1	0
N07C- Antivertigo preparations	1	3	3	1
Total	11	100	103	8

3.8 SoSoeMe user-acceptance

Table 37: SoSoeMe group post-questionnaire – User acceptance

		SoSoeMe group (within-group %) (n=13)		
		Guidelines	**Fact sheet**	**Pictogram**
Did you use … in order to support your communication to patients?	Yes	84.6	53.8	92.3
	No	15.4	46.2	7.7
If you answered "Yes", how often did you use the …?	Always	0	0	7.7
	Regularly	16.7	12.5	53.8
	Sometimes	66.7	37.5	15.4
	Seldom	8.3	50.0	15.4
	Never	8.3	0	0
	Unknown	0	0	7.7
The … for prescribing medicines that may affect driving performance were: helpful	Yes, very much	61.5	30.8	100
	Quite a lot	30.8	61.5	0
	Not so much	0	0	0
	No way	0	0	0
	Unknown	7.7	7.7	0
The … for prescribing medicines that may affect driving performance were: useful	Yes, very much	38.5	0	84.6
	Quite a lot	38.5	46.2	15.4
	Not so much	15.4	46.2	0
	No way	0	0	0
	Unknown	7.7	7.7	0
The … for prescribing medicines that may affect driving performance were: sufficient	Yes, very much	53.8	30.8	38.5
	Quite a lot	30.8	61.5	61.5
	Not so much	7.7	0	0

	No way	0	0	0
	Unknown	7.7	7.7	0
Did you think it was a problem that the fact sheets were provided in the English language?	No	/	53.8	/
	Yes	/	30.8	/
	Unknown	/	15.4	/

More than **80% used the guidelines in their communication to the patients**, of which 66% only sometimes. Only two physicians mentioned why they did not use the guidelines: their patient was not a driver and time pressure. About **60% found the prescribing guidelines very helpful. Around 80% found the guidelines very or quite a lot useful and sufficient. Only 50% of the participants used the fact sheets**. About half of the physicians who did use the fact sheets use them seldom. Despite the low use of the factsheets, the participants scored the facts sheets as very helpful (61.5%- yes very much), useful (46.2% -quite a lot) and sufficient (61.5% -quite a lot). **The pictogram system was used by almost every SoSoeMe participant (92.3%).** 61.5% of the physicians used the system regularly or always. Every physician found the pictograms helpful, 84.6% found them very useful and 60.5% found the pictograms quite sufficient. Overall it can be stated that the pictogram was found useful to draw attention but not sufficient. When more information was needed the guidelines were used.

Table 38: SoSoeMe group Post questionnaire - Guidelines

		SoSoeMe group (within-group %) (n= 13)
Do you think that the guidelines have changed your manner/way to prescribe medication?	Yes, very much	0
	Quite a lot	61.5
	Neutral	15.4
	Not so much	15.4
	No way	7.7
Do you think that the guidelines have changed your manner/way to inform the patient?	Yes, very much	0
	Quite a lot	76.9
	Neutral	23.1
	Not so much	0
	No way	0
Do you think that the guidelines have changed your choice of medication	Yes, very much	0
	Quite a lot	53.8
	Neutral	15.4
	Not so much	23.1
	No way	7.7

About 60% of the SoSoeMe physicians stated that the guidelines had changed the manner they prescribed medication quite a lot. **Even 77% of the participants think that the provided guidelines changed their way to inform a patient quite a lot**. Only half of the physicians mentioned an influence of the guidelines on their choice of medication.

Table 39: SoSoeMe group Post questionnaire - User friendliness

		SoSoeMe group (within-group %) (n=13)
I was able to find the information I asked for with no difficulty.	Strongly disagree	0
	Disagree	0
	Agree	69.2
	Strongly agree	30.8
I thought the tool was	Strongly disagree	30.8

cumbersome.	Disagree	69.2
	Agree	0
	Strongly agree	0
This tool would fit well in my working routines.	Strongly disagree	0
	Disagree	0
	Agree	46.2
	Strongly agree	53.8
Text and icons are easy to perceive.	Strongly disagree	0
	Disagree	0
	Agree	46.2
	Strongly agree	53.8
Do you think that the tool should have additional options on the screen or are there any controls that are currently missing?	Yes	23.1
	No	76.9
Would you be willing to use this tool in the future	Yes	84.6
	No	0
	Maybe	7.7
	Unknown	7.7

Every physician (strongly) agreed that they could find the information without difficulties, that the tool would fit well in their working routines and that the texts and icons were easy to perceive. Every physician disagreed with the statement that the tool was cumbersome. 85% of the participants was willing to use this tool in the future. The two physicians (15.4%) who mentioned that the tool should have additional options liked **more thorough information on side effects or less vague advice**. These are also the reasons why these physicians did not want to use the tool in the future. On the question for what the physicians would use the tool mostly, they mentioned that the tool could help them to remind to inform the patient about possible side effects as well as provide them with the information to inform/advise the patient.

3.9 USB group software data

Only limited data could be extracted from the USB tool (see the annex from Part A). Only date and hour on which the physician searched for a medicine (used the tool) and what the physician typed in (the brand name or the generic name of the medicine, ATC code, partial brand or generic names...) was recorded and consequently extracted by the physicians in the format of a log file. The research team further completed the data by including a specific ATC code (e.g. N05BA01), a grouped ATC code (e.g. N05B-cat3) a category (1-3) and an ATC name (e.g. Anxiolytics-cat3).

The physicians that used the USB tool (N=10) made only **182 clicks** in the USB program between the time period 8th of September 2010 and 3th of March 2011 (a bit less than 6 months). The distribution of the number/proportion of clicks was not equally divided between the 10 physicians. **Half of the total number of clicks was made by three physicians** (see table below).

The most frequent medicines searched for were **Lorazepam (8.7% – cat.3), Diazepam (7.7% - cat. 3), Tramadol (7.1% – cat. 3), Tetrazepam (6.0%- ATC code M[5]) and Alprazolam (5.5% - cat. 3).**

A risk category could be linked to 182 clicks'. No category could be linked if:

[5] Tetrazepam has ATC code: M03BX07, and thus not included in the USB program. The physician had no 'hit'.

- the medicine searched for was not in the database or no N-medicine (only N-medicines were integrated into the USB tool) (25 clicks)
- if the physicians only searched on a grouped ATC code (11 clicks)
- the medicine was not available in Belgium (5 clicks)
- invalid entry in tool (e.g. physicians typed 'test') (3 clicks)

About **70% of the physicians' clicks searched for a medicine of category 3 in the tool**. When leaving out the missings/unknowns, 40% of the clicks were made for a medicine of the ATC group N05B (Anxiolytics) and N05C (Hypnotics and sedatives).

Table 40: USB group: Description data log files (within-group %) (n=182)

Distribution by 'clicks' (within group%)		**Distribution by risk category (%)**		**Distribution by ATC code**	
Physician 1	5.5	Category	7.2	N02 – Anesthetics	13.0
Physician 2	3.8	1	24.6	N03 – Anti-epileptics	5.1
Physician 3	10.4	Category	68.1	N05A – Antipsychotics	8.0
Physician 4	0.5	2		**N05B – Anxiolytics**	29.7
Physician 5	7.7	Category		**N05C – Hypnotics &sedatives**	21.0
Physician 6	15.9	3		**N06A – Antidepressants**	18.1
Physician 7	18.1			N06B – Psychostimulants	0
Physician 8	5.5			N06C – Psycholeptics/ psychanaleptics in combination	0.7
Physician 9	17.0				
Physician 10	15.4			N07B – Drugs used in addictive disorders	4.3

3.10 USB group- User acceptance

When a physician opens the program on the USB tool he/she can type in the generic name or ATC code of the medicine he/she wants to prescribe. The physician had the option to search in a list of ATC codes or ATC names. After pushing the search button a window appeared where the physician had the option to choose from a lists of medicines matching his/her search. Next a 'medication information window' opened with the DRUID pictogram as well as the options to open a fact sheet, patient letter or an alternative medicine (see annex in Part A).

Table 41: USB group post questionnaire – User acceptance

		USB group (within-group %) (n=11)		
		Guidelines	**Fact sheet**	**Pictogram**
Did you use … in order to support your communication to patients?	Yes	90.9	81.8	36.4
	No	9.1	18.2	54.5
If you answered "Yes", how often did you use the …?	Always	0	0	0
	Regularly	18.2	11.1	22.2
	Sometimes	54.5	55.6	11.1
	Seldom	18.2	33.3	22.2
	Never	0	0	11.1
	Unknown	9.1	0	33.3
The … for prescribing medicines that may affect driving performance were: helpful	Yes, very much	90.9	63.6	27.3
	Quite a lot	9.1	18.2	36.4
	Not so much	0	0	27.3

	No way	0	0	0
	Unknown	0	18.2	9.1
The … for prescribing medicines that may affect driving performance were: useful	Yes, very much	36.4	18.2	27.3
	Quite a lot	18.2	45.5	27.3
	Not so much	27.3	9.1	36.4
	No way	0	0	0
	Unknown	18.2	27.3	9.1
The … for prescribing medicines that may affect driving performance were: sufficient	Yes, very much	9.1	36.4	27.3
	Quite a lot	72.7	54.5	27.3
	Not so much	9.1	0	36.4
	No way	0	0	0
	Unknown	9.1	9.1	9.1

91% of the Physicians in the USB group stated to have used the guidelines, of which half only sometimes used the guidelines. The physicians who mentioned not to have used the guidelines gave as reason the fact that the tool was: not integrated in their daily used software and by consequence was too time consuming. **90% found the guidelines very helpful. 82% used the factsheets and only 36.4 used the pictogram system. Despite the low use of the pictogram system half of the physicians found the pictograms (very) helpful, useful and sufficient.** The fact sheets were even higher scored: 81% found them very much up to quite a lot helpful and 63% found them very much up to quite a lot useful. Every physician found the fact sheets (very) sufficient.

Table 42: USB group Post questionnaire - Guidelines

		USB group (within-group %) (n=11)
Do you think that the guidelines have changed your manner/way to prescribe medication?	Yes, very much	0
	Quite a lot	36.4
	Neutral	45.5
	Not so much	18.2
	No way	0
Do you think that the guidelines have changed your manner/way to inform the patient?	Yes, very much	18.2
	Quite a lot	27.3
	Neutral	36.4
	Not so much	18.2
	No way	0
Do you think that the guidelines have changed your choice of medication?	Yes, very much	9.1
	Quite a lot	45.5
	Neutral	36.4
	Not so much	9.1
	No way	0

Only about 35% of the physicians mentioned that the guidelines have changed their manner of prescribing medication. More physicians stated that the guidelines have changed their manner to inform the patient (45.5% quite a lot – very much) and their choice of medication (54.6% quite a lot – very much).

Table 43: USB group Post questionnaire - User friendliness

		USB group (within-group %) (n=11)	
		USB stick	**Manual**
I was able to find the information I asked for with no difficulty.	Strongly disagree	9.1	0
	Disagree	18.2	0
	Agree	63.6	30
	Strongly agree	9.1	20
	Unknown	0	50
I thought the USB stick/manual was cumbersome.	Strongly disagree	9.1	10
	Disagree	54.5	30
	Agree	18.2	10
	Strongly agree	18.2	0
	Unknown	0	50
This USB-stick/manual would fit well in my working routines.	Strongly disagree	9.1	0
	Disagree	18.2	10
	Agree	63.6	30
	Strongly agree	9.1	10
	Unknown	0	50
Text and icons are easy to perceive.	Strongly disagree	0	0
	Disagree	0	0
	Agree	81.8	40
	Strongly agree	18.2	10
	Unknown	0	50
Do you think that the USB- stick should have additional options on the screen or are there any controls that are currently missing?	Yes	27.3	11.1
	No	72.7	44.4
	Unknown	0	44.4
Would you be willing to use this USB stick in the future	Yes	63.6	50
	No	9.1	10
	Maybe	27.3	10
	Unknown	0	30

About 73% of the physicians (strongly) agreed that they were able to find the information without difficulties and that the USB stick would fit well in their working routines. All participants agreed that the text and icons are easy to perceive. Four physicians stated that there should be two additional options to the USB tool: **the categorisation of other medicines, the possibility to search on brand names, more safer alternatives, the possibility to easily print the fact sheets, a 'match' of information mentioned in the fact sheets and the Belgian situation and the possibility to integrate the tool into the daily used software**. Only one physician mentioned why he/she was not willing to use the tool in the future: there was no possibility to make a connection with the daily used prescribing software. On the question for what they would use the USB tool the physicians answered that they mainly would use the information to advise the patient (e.g. showing the pictogram).

There were quite a lot of missing data regarding the user acceptance questions on the manual. **5 out of 11 physicians were willing to use the manual in the future.** They would use the tool for advising especially professional drivers, the search for brand names and to search to which risk category a medicine belongs. About half of the physicians agreed that the manual would fit in their daily practice and that the texts and icons are easily to perceive. Only one physician stated to miss information in the manual namely information in Dutch.

3.11 Control group software data and user-acceptance

About 80% of the participants (29 of the 36 physicians) in the control group mentioned in the post questionnaire to be willing to use a tool in prescribing medicines. A small decrease in 'maybe' answers was found.

Table 44: Control group pre-post change - User acceptance (Within-group %)

		Control group (Within-group %) (n=36)		
		PRE	**POST**	**Change**
If we propose to you a tool (e.g. website, CD-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for prescribing medicines?	no	0	2.8	2.8
	yes	77.8	80.6	2.8
	Maybe	22.2	13.9	-8.3
	Unknown	0	2.8	2.8

No big changes regarding the type of support tool the physicians in the control group preferred was noticed. First choice was still software integrated in their own software, a small increase of preference (1.5%) was measured. The second choice was a website (increase of 2.4%). A change in third choice was found. In the pre questionnaire the third preference was stand-alone software (35.5%). In the post questionnaire the physicians preferred rather a manual (27.8%) than stand alone software (19.4%).

Table 45: Control group pre-post change: Preference support tool (Within-group %)

	Which type of support tool would you prefer?	**Physician groups (within-group %) (n=36)**		
		PRE	**POST**	**Change**
First choice	Website	17.1	19.4	2.3
	Software integrated in your own software	54.1	55.6	1.5
	Stand alone software	0	0	0
	Manual	14.3	19.4	5.1
	Not filled	0	2.8	2.8
	Other	11.4	2.8	-8.6
Second choice	**Website**	44.8	47.2	2.4
	Software integrated in your own software	6.9	11.1	4.2
	Stand alone software	24.1	11.1	-13
	Manual	10.3	11.1	0.7
	Not filled	0	13.9	13.9
	Other	13.7	5.6	-8.1
Third choice	Website	22.6	19.4	-3.2
	Software integrated in your own software	6.5	2.8	-3.7
	Stand alone software	**35.5**	19.4	-16.1
	Manual	22.6	**27.8**	5.2
	Not filled	0	19.4	19.4

	Other	12.8	11.2	-1.6

4 Discussion

4.1 Main study results

Personal and practice related sample characteristics. From the analyses regarding sample characteristics it became **clear that except for the characteristic 'the years practicing as a physician' the three groups (SoSoeMe; USB and Control group) did not differ significantly regarding personal/practice related background variables**. There were no significant differences between participants and drop-outs in the SoSoeMe, USB and Control group with regard to gender, age, number of inhabitants in the practice area, number of years from graduation of with regard to ICT familiarity**.**

Pre questionnaire. The three groups (SoSoeMe, USB and control group) were similar with regard to most pre-questionnaire parts. Two significant differences were found with regard to one knowledge question (Amitripthyline) and one reported behaviour question (on how frequently the physicians provided information when prescribing medicines with impairing effects on driving performance)**.** It can be stated that the participants in the present study (in all groups) had **a high ICT familiarity**. Despite the high use of the Internet and use of medical software programs only half of the physicians stated to have easy access to data and information on the topic 'medicines and driving'. Only 25% used the Internet to obtain information on medicines affecting driving behaviour. Overall the physicians liked **being well informed on the topic drugged driving and the potential role they can play** in providing information on the potential risk of medicines to the patient. **Remarkably, half of the physicians in all groups felt not being well aware of the effects of medicines on driving skills**. This can be (partially) due to the low access to relevant information and the fact that they didn't receive it during their education. Contrary to the positive attitude, rather low frequencies of 'wanted' reported behaviour were found (composite score: 34.40 % answers seldom or never to the statements). The SoSoeMe group significantly provided less detailed information when prescribing compared to the USB and Control group. In **general a low knowledge on the topic 'medicines and driving' was measured**. The physicians are more informed about legal obligations and responsibilities of physicians/pharmacists and patients.

Pre-post questionnaire comparison. When comparing the three groups on the pre-post questionnaires changes of the composite scores on attitudes & awareness, reported behaviour and knowledge regarding medicinal driving risk, several conclusions can be drawn (see table below).

Table 46: Total group overview of pre-post changes: Composite scores

	Composite Scores SoSoeMe group			Composite Scores USB group			Composite Scores control group		
	PRE	POST	Change	PRE	POST	Change	PRE	POST	Change
Attitudes & awareness									
Strongly disagree	0	0	**0**	0	0	**0**	0	0	0
Disagree	0	0	**0**	8.3	0	**-8.3**	0	0	0
Agree	100	92.3	**-7.7**	75	81.8	**6.8**	83.3	88.9	5.6
Strongly agree	0	7.7	**7.7**	16.7	18.2	**1.5**	16.7	11.1	-5.6
Reported behaviour									
Never	0	7.7	**7.7**	8.3	9.1	**0.8**	11.1	2.8	**-8.3**
Seldom	53.8	23.1	**-30.7**	25	9.1	**-15.9**	16.7	25	**8.3**
Sometimes	38.5	30.8	**-7.7**	25	18.2	**-6.8**	41.6	38.9	**-2.7**
Regularly	7.7	38.5	**30.8**	33.3	63.7	**30.4**	27.7	30.5	**2.8**
Always	0	0	**0**	8.3	0	**-8.3**	2.8	2.8	**0**
Knowledge medicine risk									
0	23.1	38.5	**15.4**	8.3	18.2	**9.9**	30.6	19.4	**-11.2***

1	30.8	7.7	**-23.1**	50	9.1	**-40.9**	30.6	30.6	**0**
2	23.1	30.8	**7.7**	8.3	45.5	**37.2**	33.3	22.2	**-11.1***
3	23.1	15.4	**-7.7**	33.3	18.2	**-15.1**	5.6	22.2	**16.6***
4	0	7.7	**7.7**	0	9.1	**9.1**	0	2.8	**2.8***
5	0	0	**0**	0	0	**0**	0	2.8	**2.8***
General knowledge									
0	0	0	**0**	0	0	**0**	0	2.8	**2.8***
1	0	38.5	**38.5**	8.3	0	**-8.3**	5.6	0	**-5.6***
2	38.5	15.4	**-23.1**	8.3	18.2	**9.9**	27.8	16.7	**-11.1***
3	23.1	23.1	**0**	41.7	18.2	**-23.5**	30.6	36.1	**5.5***
4	15.4	15.4	**0**	8.3	36.4	**28.1**	33.3	16.7	**-16.6***
5	23.1	7.7	**-15.4**	33.3	18.2	**-15.1**	2.8	22.2	**19.4***
6	0	0	**0**	0	9.1	**9.1**	0	2.8	**2.8***
7	0	0	**0**	0	0	**0**	0	2.8	**2.8***

Significant pre-post changes at composite score level were only found in the Control group: this group gave more wrong answers on the knowledge questions. Furthermore, taking a look at the number of significant pre-post changes on individual statements or questions, the SoSoeMe group had only 1 significant positive change (on a total of 20 statements/questions), the control group had also one significant positive change on the knowledge questions. For the USB group no significant pre-post changes were found.

Little pre-post questionnaire change was found on attitudinal level for the SoSoeMe, USB and control group. No significant pre-post change on the attitude and awareness questions for all three groups was found. It can be noted that for the SoSoeMe and USB group the overall positive change was bigger than the negative. In the control group the largest part of the physicians (>69%) remained at the same agreement level as in the pre-questionnaire, which is conform the expected results for the control group. The conclusion can be made that the **agreement level in the pre questionnaire was already high.** More than 53% of the physicians indicated to agree or strongly agreed with the statements. When leaving out the question 'I feel being well aware of the effects of medicines on driving skills' the percentage even raised to 67%. **Overall, the physicians included in the study had a positive attitude and awareness on the topic 'medicines & driving' but felt insecure about their knowledge on the potential risk of medicines on driving.** This result is conform the remarks made by the participants during the training sessions. Several physicians mentioned that the motivation to participate in the study was that they wanted to increase their knowledge on the topic.

Only for the SoSoeMe group a significant pre-post change was found with regard to the reported behaviour questions. The SoSoeMe participants provided the patient significantly more with written information materials after the trial period. The remark should be made that only the USB group had a training and not the SoSoeMe group. Due to the fact that the SoSoeMe group did not receive a training, smaller pre-post changes in reported behaviour were expected for this group. The questions on keeping systematic record of the patient's traffic participation, if the patient was a driver and when prescribing a impairing medicine, were topics where quite a debate was raised during the training sessions of the USB participants. When looking at the post questionnaire answers on these questions from the participants of the SoSoeMe group and the USB group, the trend was found that the USB group stated to keep more often (more regularly) record of abovementioned information than the SoSoeMe users. This is a clear training effect/influence.
T**wo positive pre post change trends were found for the USB group** on the questions if the physicians provided a patient with written information materials (p=.59) and if the discussed medicinal drug consumption and driving related responsibility issues with the patient. However not significant, it can be said that a positive change in reported behaviour was measured after the training/ trial period. As expected, a large part of the participants in the control group did not change their answer on the behaviour questions in the post questionnaire.

No significant pre-post changes were found with regard to the knowledge questions in the SoSoeMe group and the USB group. The physicians in the control group scored better (gave more correct answers) in the pre-questionnaire compared to the post questionnaire. In the pre questionnaire 64% of the participants had a score of 3/7 questions correct (composite score knowledge total) compared to 41.7% of the participants in the post questionnaire. A decrease in knowledge was measured after the trial period. A possible explanation could be that the physicians were more motivated to fill in the pre questionnaire and paid more attention to the questions.

Objective data and user acceptance. Looking at the data regarding the **user acceptance**, several differences between the SoSoeMe group and USB group were found. The SoSoeMe group mentioned a much bigger influence of the provided prescribing support tool on their manner to prescribe or to inform patients than the USB group. Due to the fact that the information was integrated and a pop up automatically appeared on their screen, the physicians were 'forced' to pay attention to possible effects of the medicine they want to prescribe. It seems that such a little 'push' is necessary to realize a change in behaviour.

Table 47: Summary- User acceptance

	SoSoeMe group (within-group %) (n=11)	**USB group (within-group %) (n=36)**
Yes, very much/ Quit a lot' answers		
Do you think that the guidelines have changed your manner/way to prescribe medication?	61.5	36.4
Do you think that the guidelines have changed your manner/way to inform the patient?	76.9	45.5
Do you think that the guidelines have changed your choice of medication?	53.8	54.6
USE (yes)		
Guidelines	84.6	90.9
Fact sheets	53.8	81.8
Pictograms	92.3	36.4

The physicians that used the USB tool made only **182 clicks** in the USB program during the trial period. **Half of the total number of clicks was made by three physicians**. The most frequent medicines searched for were category 3 medicines (e.g. Lorazepam, Diazepam & Tramadol). Most searched for ATC groups were Anxiolytics and Hypnotics and sedatives. Also the data from the SoSoeMe software was quite limited. In total 111 clicks where made on the pictogram, of which 58% was made by two physician practices. **The physicians have a clear preference for the patient letter instead of the fact sheet.** The medicines most searched for were also category 3 medicines. As mentioned above, the registered data out SoSoeMe is just the tip of the iceberg. From the software provider the remark was made that about 90% of their members use the information. The motivation to actually send in the data in the format of a query was too much of a hassle which resulted in a low response.

4.2 Study limitations, challenges and solutions

No link between questionnaire and software data. The study design initially took care that each participant had a unique DRUID identification number in order to link questionnaire data to tool data (SoSoeMe or USB tool). After the six months trial it became clear though that it was impossible to determine how many physicians exactly used the DRUID functions in the SoSoeMe or USB software. This was due to the fact that many of the participants work in practices with several physicians using the same computer, and thus using the support software tool.

Sample restrictions. There was only a small number of participating physicians, especially in the USB and SoSoeMe group,.

Shortened USB intervention phase. Due to some problems regarding the development of the USB tool the intervention period (6 months) had to be shortened in order not to delay the study. This may have had an influence on the measured effect of the DRUID information/guidelines on the questionnaire and tool use data.

Motivated study participants. It has to be kept in mind that our population was already very interested in the topic medicines and driving; their participation was voluntary. All physicians mentioned at baseline that they already knew something about the topic but that they wanted to expand this knowledge. This may have led to smaller changes in reported pre-post measures during this study.

Low use of the USB support tool. Due the low use of the provided prescribing support tools it became difficult to measure an effect on attitude & awareness, reported behaviour and knowledge of the physicians. However the promising results of the present study can be a starting point for future research.

Besides these study limitations, several challenges had to be overcome by the research team during the course of the study

Table 48: Study limitations, challenges and solutions

Challenge	Offered solution
An email was sent to all users by SoSoeMe to inform them about the study. One of the users of the software SoSoeme was the President of **the General Medical Council (GMC) of East Flanders**. By the end of March the president notified that all physicians had to ask permission at the GMC of East Flanders to participate in the study. Asking for an **extra approval** would mean that the drop out would be very high.	*The UGent team tried to inform and explain the GMC the aim of the physicians study. At the beginning of June we received permission to proceed. The study was delayed for more than two months*
Like explained above the research team had **no direct communication with the SoSoeMe respondents**. In addition, there was a difficult contact with the software providers due to their busy schedule. The software version had to be updated by the SoSoeMe users to be able to use the DRUID-functions. That **update was not performed by all physicians using SoSoeMe** for several reasons (purchase of new version, no real advantages, happy with older version,…). Because of the lack of direct contact several physicians dropped out of the study. Some because they did not receive crucial information, for example the need to install a special program to see the DRUID information in their software, others because they simply forgot to update the software. It can be presumed that the lack of follow up had a negative influence on the non response rate.	*A lot of efforts (e.g. phone calls, emails on a regular base) were made to keep the communication going.*
The SoSoeMe company was not eager on the idea to organise separate training sessions. The	*The research team developed information folders (with a introductory letter, questionnaire,*

physician study was introduced in the normal SoSoeMe training sessions. The disadvantage of having **no specific DRUID training** was that **the possible respondents did not receive a lot of information about the DRUID-project or the physician study**. It became very difficult to motivate the physicians to sign up to participate in our study	*informed consent and return envelope) for the physicians that were interested to participate in the study. SoSoeMe was encouraged to inform their members by email about the study.*
Before organising the training sessions for the USB group the research team had to wait for the finalisation of the USB-Tool. In the months April, May and June the research team **experienced a lot of problems when installing the program on different computers** (e.g. program was not found, PDF's could not be opened, the tool did not run correctly on Windows Vista or on a Windows 64-bit). The provided USB-tool **caused several installation but also user problems**. Sometimes a wrong directory was linked to a certain medication, what caused that the physician did not receive the needed information. Due to these kinds of problems and the delay in finishing the USB-tool, the trial period for some physicians was shorter than originally foreseen (6 months).	*The USB tool was tested on several computers by the research team and later modified to match the most current operating systems installed on the pharmacy computers*
It turned out that **the sessions were scheduled too early in the evening**. Some physicians did not make it to the training sessions	*SoSoeMe informed the research team about other training sessions organised by professional organisations for physicians. Still corrective measurements were needed to include more respondents. The research team personally installed the program for some physicians.*
Several physicians made the remark that **the manual could be easily brought when doing house** calls. The physicians did warn that there would be an **underestimation of the possible impact** of the tool/information. The physicians were more eager to look medication up in the manual than using the USB-tool.	*The research team took this remark into account when analysing the data from the USB support tool.*
Most of the participants **did not know the ATC codes** of medicines but only the brand and generic names. When developing a tool, search options should be based on the brand and generic name and not only on ATC codes.	*More information on the ATC codes of medicines was provided during the training sessions. Besides the use of the manual to search for corresponding ATC codes was enhanced.*
Sometimes **different advices were given in the DRUID Fact Sheets than in the patient letters provided by Health Base**. Several participants remarked that they missed concrete, detailed information and recommendations. Often the physicians found the advice too vague.	*During the training sessions attention was put on the fact that an advice should be tailor-made, so a certain flexibility should be foreseen.*

There was **difficulty to motivate** the physicians to use the USB tool. The physicians warned the research team that they do not have the time to open several programs during consultation.	*During the training sessions the speaker and the research team tried to motivate the physicians by e.g. providing a step by step manual on how to install en use thee USB tool. Besides the possibility of making a shortcut on the computer desktop to easily open the USB program was mentioned. During the study newsletters were developed to keep the participants informed and motivated*
Several physicians had **difficulties when installing the USB tool.**	*Shortly after the training session a newsletter was sent to the participants in order to detect installation problems early in the study. Several physicians needed and received help with the installation (by phone, by email or in person).*

Main recommendations for future field studies with physician deal with: have good intermediaries or contact persons, using informative and supporting newsletters, inform and if necessary ask for permission of the (General) Medical Counsels in the area you want to perform a study. Having good contact persons help to establish a good communication with the respondents you want to reach. The use of newsletters turned out to be a very handy and useful tool in contacting the respondents directly.

4.3 Overal conclusions and recommendations

In conclusion it can be stated that few significant pre-post changes in attitude & awareness, reported behaviour and knowledge were found for any of the three groups.

- The importance of a good follow up

We did expect, conform with the results from the pharmacist study, to find more (significant) positive changes for the SoSoeMe group. A possible explanation could be the lack of contact between the research team and the participants. This group had no training and received no newsletters during the trial period. Also no follow up (e.g. when some problems raised when updating the software) could be foreseen. At the start of the study this group was not very eager to fill in questionnaires but they did want to use the information integrated in SoSoeme. After the trial period the conclusion could be made that about 90% of the physicians that used SoSoeMe had used the information on a quite regular base. Their feedback was very positive and all physicians wanted a continuation of the DRUID information into their daily used software. Therefore the lack of positive change found in attitude, behaviour and knowledge should be nuanced and it is very plausible that the found results are an underestimation of the real impact of the study.

- A manual: a useful tool

The lack of (significant) pre post changes in the **USB group** could be explained by the low use of the USB tool. From the data analyses of the log files it became clear that few physicians had used the tool, not even on a sporadic base. Some physicians warned that the registered searches in the usb program was an underestimation of the real impact of the study. Several participants mentioned that after looking up a medicine, they remember the advice given by the DRUID information. For the next patient they do not need to look up the medicine again, giving a underrepresentation of the use of the guidelines. Contrary to the low use of the USB tool, several physicians mentioned to have used the manual very often. Most physicians did prefer a manual above the software.

- Willingness to use a prescribing support tool

- When looking at the user acceptance data and the objective data, the conclusion can be made that **the physicians are willing to use a prescribing support tool when this tool is integrated in their daily used software, asks no extra efforts or time to update, is easy to use and contains practical information. The physicians underlined the need for more information on the topic 'medicines and driving'. This information should not only be made available to physicians but also be integrated in the patient leaflet or on the medicine box.**Suggestions with regard to the DRUID prescribing guidelines and the prescribing support tools:

Following the participants' feedback and remarks, several suggestions and recommendations for improvement of the DRUID prescribing guidelines and precribing support tool(s) can be given:

With regard to the DRUID prescribing guidelines:

- The physician recommend to focus on first prescriptions/ first use of a medicine
- The respondents mentioned that the guidelines should not only focus on people that participate in daily traffic but also users of heavy machinery or seniors (higher risk to fall)
- The categorisation of other and new medicines

With regard to the delivery support tool(s):

- The information should be integrated in the software and updated automatically
- A combination of tools, ideally integrated software and a manual would be much appreciated
- In case of search functions: the respondents would like to have the possibility to search on brand names and/or generic names and/or ATC codes
- Safer alternatives have to be formulated if possible
- The physicians would like to have the possibility to easily print the fact sheets or information for the patient.
- The provided information in the fact sheets should 'match' the Belgian situation in order to be useful to Belgian patients.
- The physicians underlined that the information included in the tool should be in Dutch. Especially patient information leaflets.

- Further lessons learnt

Further lessons learnt, remarks and recommendations should be considered in future physicians' delivery support implementation plans:

- ✓ Almost all physicians preferred to start informing and advising patients about the possible influence on the driving ability of certain medication at the start of therapy. Advising patients who already use a medicine for years to change medication is very difficult. Several physicians made the remark that the DRUID advice, patient letter and categorization are suitable for and applicable on patients who do not use medication on a regular base. But what to do with patients that build a tolerance for certain substances?
- ✓ Most of the physicians did not know that they could be (partially) legally responsible when not informing a patient about possible side effects and effects on the driving ability. The physicians who did know about the law had already a system developed. After informing the patient about the effects of the prescribed medicine, the patient had to sign a paper acknowledging that they received information. Some physicians warned that signing a form of informed consent would violate the patient-doctor relationship. Other respondents asked if there was a standard document available to use in their daily practice. Besides an extra document, several physicians put a note in the electronic medical file of a patient when they have given certain information.

- ✓ The importance of therapy compliance was underlined by all physicians. Some physicians preferred that for example a depressed patient used his or her medication even if this had a possible effect on the driving ability over not using their medicines at all.
- ✓ When getting to know the fact sheets and the USB-tool a lot of participants found the provided USB-tool useful. However it would be even more useful when the functions would be integrated in their daily used software.
- ✓ Most of the respondents explained that they cannot forbid the patient to drive. The physicians were only willing to warn a patient.
- ✓ All physicians were willing to prescribed an alternative if possible. According to the respondents an alternative is possible for some medicines but not for all. The medical record of the patient has also to be kept in mind when exploring the possibly to prescribe a safer alternative.
- ✓ Informing the patient about the topic 'driving and medicines' was experienced as difficult. Certainly when informing older people.
- ✓ Most of the physicians underlined that a change in knowledge and attitude of the physicians is possible when physicians are regularly confronted with the possible dangers of certain medications. The developed tools help to remind as well as confront the physician about the possible influences of medicines on the driving ability.
- ✓ The respondents wanted to extend the target group: the target group should not only be people that participate in daily traffic but also users of heavy machinery or seniors (higher risk of falling).
- ✓ The participants advised the research team to integrate the provided information and/or categorization on the patient information leaflet. Many patients use 'old' medication, medication that was once prescribed. These patients will not remember the information on the possible negative effects given from their physician.
- ✓ The physicians regretted the absence of medico-pharmaceutical consultation structures or meetings where local physicians and pharmacists can assemble and discuss certain topics. The remark was made that the communication and collaboration between physicians and pharmacists would be easier when both health care workers know each other personally. It has to be noted that several attempts are presently made to bring pharmacists and physicians in closer collaboration.
- ✓ After the trial period SoSoeMe let us know that out of the 330 SoSoeMe users, around 300 had updated their software version. Almost all of them used the pictogram and the fact sheets/ patient letters to inform their patients. The response of the users was very good, they liked the new application. This shows that an implementation of information about influence of medicines on driving is very warmly received.

5 Acknowledgements

The research team would like to thank all physicians involved in the study. A special thanks to Ms. Ingrid Vergult and Mr. Paul Van Hove from the SoSoeMe-company. We would also like to thank Ms Hilka Wolschrijn who gave the courses to the participants from the USB group.

6 Annex

6.1 Newsletter – USB October 2010

Nieuwsbrief DRUID-onderzoek

Oktober 2010

Vooreerst hartelijk dank voor uw interesse in het DRUID-onderzoek! Vanaf heden mag u regelmatig een nieuwsbrief over het DRUID-onderzoek in uw emailbox verwachten.

In deze nieuwsbrief vindt u informatie over:
- Het DRUID-Onderzoek
- Categorieën (handig lijstje)
- Welke informatie kan u terugvinden in de tool?
- Belangrijke aandachtspunten
- Adviezen
- Installeren en gebruiken tool gelukt?/problemen? **Gelieve uw problemen te melden!**

Categorieën

- **Categorie 3:** Mogelijk ernstig of potentieel gevaarlijk effect op de rijgeschiktheid.
- **Categorie 2:** Mogelijk matig negatief effect op de rijgeschiktheid.
- **Categorie 1:** Mogelijk licht negatief effect op de rijgeschiktheid.
- **Categorie 0**: Effect op rijgeschiktheid onwaarschijnlijk of verondersteld veilig.

OPGELET!

⇨ Start behandeling en in standaarddosering.
⇨ Classificatie zegt niet alles:
- Hypnotica allemaal 3, maar effect neemt in de loop van de uren af.
- Chronische medicatie, men raakt soms aan effect gewend (niet bij alle middelen!).

Welke informatie kan u terugvinden?

Van alle CNS-middelen (ATC-code N):
- Pictogram met categorie
- Fact sheets (wetenschappelijke informatie)
- Patiëntenbrieven
- Rijveiliger alternatieven

Belangrijke aandachtspunten

- Gedifferentieerde adviezen op te zoeken met de DRUID-tool
- Rijveiliger alternatieven
- Verkeersveiligheid: er is een rol voor de arts!

Adviezen

- Vraag naar verkeersdeelname
- Vraag naar motivatie voor de behandeling
- Geef aan niet te combineren met alcohol of drugs
- Waarschuw voor bijwerkingen, zoals sufheid en slaperigheid.
- Opvolgconsultatie: Vraag naar ervaringen.
- Geef ook specifieke adviezen per middel:

Druid-onderzoek

Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor **'Driving under the influence of drugs, alcohol and medicines'**

Onderzoeksvraag?

In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wat wordt gemeten?

De mate waarin u de USB tool gebruikt & Uw kennis en houding ten aanzien van het onderwerp Medicatie en Rijden.

Uw rol?

- Deelnemen aan een trainingsavond;
- Invullen van een enquête (voormeting);
- De USB tool installeren;
- Zes maanden deze tool gebruiken;

Na deze periode

- De gebruiksdata van de voorbije zes maanden anoniem opsturen naar de onderzoekers(logfile);
- Een tweede enquête invullen (nameting).

Doelstelling?

Patiënten kunnen informeren over:
- De invloed van medicatie op de rijgeschiktheid

Vragen?
Ervaart u (nog) problemen bij de installatie of bij het gebruik van de USB-tool?
druid@ugent.be

Informatie?
www.druid-project.eu

Categorieën tranquillizers, hypnotica en antidepressiva

Behalve de tranquillizers, hypnotica en antidepressiva staan er op onderstaande lijst ook enkele andere veel gebruikte rijgevaarlijke middelen en enkele medicijnen met dezelfde ATC, maar met andere dan bovengenoemde toepassingen.

De categorie geeft het **acute effect** weer in de **gebruikelijke dosering**. Dus het effect in de paar uur na inname van een eenmalige dosis of het effect aan het begin van een chronisch gebruik.
De categorie zegt **niet** alles over het te geven **advies** om wel of niet te rijden en/of na hoeveel tijd men weer mag rijden. Dat advies staat onder andere in de Geneesmiddel Informatie Tekst (GIT).

Lijstje van meest voorkomende middelen:

Alprazolam *(Xanax)*	3
Amitriptyline *(Redomex)*	3
Bromazepam *(Lexotan)*	3
Citalopram *(Cipramil)*	2
Clorazepaat *(Tranxene)*	2
Codeïne	2
Diazepam *(Valium)*	3
Dosulepine *(Prohtiaden)*	3
Escitalopram *(Sipralexa)*	1
Flunitrazepam *(Rohypnol)*	3
Flurazepam *(Staurodorm)*	3
Lorazepam *(Temesta, Serenase)*	3
Mirtazapine *(Remergon)*	3
Oxazepam *(Tranquo)*	3
Paroxetine *(Seroxat)*	1
Sertraline *(Serlain)*	2
Trazodon *(Trazolan, Nestrolan)*	3
Venlafaxine *(Efexor)*	1
Zolpidem *(Stilnoct)*	3

6.2 Newsletter USB- January 2011

Nieuwsbrief DRUID-onderzoek

Januari 2011

Vooreerst wenst het Gentse DRUID team U een boeiend 2011!

In deze tweede nieuwsbrief vindt u informatie over:
- Het DRUID-Onderzoek
- Wettelijke aspecten: Voorbeeld uit de actualiteit
- Welke informatie kan u terugvinden in de tool?
- Weetje: Testen pijnpatiënten positief?
- Contact van apothekers met arts
- Belangrijkste aandachtpunten
- **Uw mening!?**

Druid-onderzoek

Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor '**Driving under the influence of drugs, alcohol and medicines**'

Onderzoeksvraag?

In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wettelijke aspecten : Voorbeeld uit de actualiteit

Arts en chauffeur schuldig aan dodelijk ongeval

02/11/10

De Dendermondse strafrechter heeft een 53-jarige arts uit Erpe-Mere veroordeeld tot een gevangenisstraf van acht maanden met uitstel en 2.750 euro boete met uitstel wegens schuldig verzuim. De 49-jarige patiënt van de arts, die onder invloed van een overdosis medicijnen een bromfietser doodreed, kreeg dezelfde straf en een jaar rijverbod.

Op 12 november 2007 ondernam Paul C. uit Erpe-Mere een poging om zelfmoord te plegen en slikte een overdosis pillen. Vlak na de inname van de medicijnen bedacht hij zich echter en trommelde hij zijn arts op om hem te helpen. Die stuurde hem naar de spoedafdeling van het Aalsterse ziekenhuis om daar zijn maag te laten leegpompen. Paul C., onder invloed van de geslikte geneesmiddelen, viel tijdens de rit evenwel in slaap en reed bromfietser Koen Van Damme dood.

De chauffeur werd gedagvaard wegens het sturen onder invloed en het veroorzaken van een dodelijk ongeval. Ook de arts van de man werd gedagvaard wegens schuldig verzuim. De rechter tilde erg zwaar aan de feiten en verweet de arts dat hij zijn patiënt aan zijn lot had overgelaten en hem niet zelf naar het ziekenhuis gebracht had, of minstens gewacht had tot de ziekenwagen er was. (belga/lpb)

Gepubliceerd in 'De Morgen'

Weetje

Testen pijnpatiënten die morfine nemen positief bij de nieuwe speekseltest?

Morfine wordt opgespoord door de speekseltest. Bij pijnpatiënten zal morfine gedetecteerd worden. De behandelende arts kan patiënten met een morfinepomp rijgeschikt verklaren. Hierbij houdt de arts rekening met de gewenning die kan optreden, therapietrouw alsook het feit dat de dosis automatisch toegediend wordt (en men dus niet kan overdoseren). Wettelijk gezien is het de arts van CARA die het attest van rijgeschiktheid moet afleveren.

Welke informatie kan u terugvinden?

Van alle CNS-middelen (ATC-code N):
- Pictogram met categorie
- Uitgifte-begeleidings-teksten
- Patiëntenbrieven
- Rijveiliger alternatieven

Contact van apothekers met arts
- Informeren over de invloed op rijgeschiktheid
- Rijveiligere alternatieven aanreiken bij categorie 2-of3-middelen
- Adviseren een lagere dosering of ander doseerpatroon voor te schrijven
- Terugrapportage ervaringen patiënt

Belangrijkste aandachtpunten
- Gedifferentieerde adviezen opzoeken met de DRUID- tool
- Rijveiligere alternatieven (ook bij OTC)
- Verkeersveiligheid: er is een rol voor de arts!

Uw mening?

Ervaart u (nog) problemen bij het gebruik van de USB-tool? Heeft u opmerkingen/bemerkingen ivm gebruik van de USB-tool?

⇨ druid@ugent.be

Informatie?

www.druid-project.eu

6.3 USB group - February 2011

Nieuwsbrief DRUID-onderzoek

Februari 2011

Via deze nieuwsbrief willen wij u graag op de hoogte brengen van het einde van de artsenstudie waaraan u deelneemt. Binnenkort zal u een tweede vragenlijst en een informed consent van de stichting Health Base toegestuurd krijgen. Zoals aangegeven op de trainingsavond zal naast data uit de vragenlijsten ook data verwerkt worden met betrekking tot het gebruik van de usb-tool. Wij verzoeken u dan ook vriendelijk om deze data, na het ontvangen van de vragenlijst, via email door te sturen naar het DRUID- onderzoeksteam. Om deze overdracht te ondersteunen sturen wij u korte instructies toe. Deze instructies kan u ook reeds terugvinden in voorliggende nieuwsbrief.

In deze laatste nieuwsbrief vindt u informatie over:
- Wat krijgt u toegestuurd... en wat stuurt u terug?
- Het ophalen van de data... Hoe?
- Wat nu?
- Deadline
- Uw mening!?

Het ophalen van de data... Hoe?

Verzenden van de logfile

Gelieve hieronder een beschrijving te vinden van de logfile die uw zoekopdrachten van deze 6 maand proefperiode heeft bijgehouden.

Deze logfile is een kladblokbestand en bevindt zich in een submap van C:\ DRUID_physicians_tool.

Stap 1: ga naar 'mijn computer' en dubbelklik op de C-schijf ('lokaal station C' of 'OS (C)')
Stap 2: ga naar 'DRUID_pharmacists_tool'
Stap 3: open de map 'RUN_DRUID_TL'
Stap 4: open de map 'resources'
Stap 5: klik met de rechtermuisknop op 'logfile' en selecteer 'naam wijzigen'
Stap 6: hernoem het bestand naar logfile_12_XXXX*
Stap 7: verstuur dit kladblokbestand naar druid@ugent.be

Wanneer U de tool op verschillende computers heeft gebruikt, doorloopt U deze stappen per PC en vult U de logfile-namen aan met a,b,c,…
Bv: logfile_12_xxxx_a
logfile_12_xxxx_b
…..

**12-xxxx is uw persoonlijk druid nummer en zal reeds ingevuld staan op uw persoonlijke brief die u toegestuurd zal krijgen met de tweede vragenlijst.*

Indien u hieromtrent vragen heeft, of problemen ondervindt, aarzel niet om ons te contacteren!

Wat krijgt u toegestuurd...

- ✓ Een begeleidende brief
- ✓ Een tweede vragenlijst
- ✓ Een informed consent van de stichting Health Base
- ✓ Een stappenplan hoe de data van de usb-tool op te halen (zie kader links)
- ✓ Een terugstuurenveloppe

... en wat stuurt u terug?

Met de terugstuurenveloppe:
- ✓ 2 de vragenlijst
- ✓ Informed consent stichting Health Base

Via email (druid@ugent.be):
- ✓ Log-file(s) Indien u de usb-tool hebt geïnstalleerd op verschillende computers zal u meerdere logfiles moeten versturen

!! Deadline 4 maart 2011 !!

Wat nu?

Na het ontvangen van uw vragenlijst, informed consent alsook uw logfile(s) sturen wij u de beloofde waardebon ter waarde van 100€ zo snel mogelijk toe!

De resultaten van deze bevraging worden in de tweede helft van 2011 gepubliceerd op de DRUID-website: www.druid-project.eu

Uw mening?
Heeft u opmerkingen/bemerkingen ivm gebruik van de USB- tool of andere?

⇨ druid@ugent.be

6.4 Pre questionnaire

VRAGENLIJST VOOR ARTSEN

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract Nr: TREN - 05-FP6TR-SO7.61320-518404-DRUID

Beste deelnemer,

Deze studie is een onderdeel van het Europese project DRUID ("Driving under the influence of drugs, alcohol and medicines", http://www.druid-project.eu). We zijn hierbij geïnteresseerd in uw mening over de invloed van geneesmiddelen op de rijvaardigheid.

Lees iedere vraag grondig en kruis het gepaste antwoordvakje ☑ aan. Bij de meeste vragen hoeft U slechts één vakje aan te duiden maar lees a.u.b. alle vragen zorgvuldig aangezien soms meer dan één vakje aangeduid moet worden.

We garanderen U dat al uw antwoorden anoniem behandeld zullen worden en dat deze enkel voor wetenschappelijke doeleinden gebruikt zullen worden.

Indien U nog meer vragen hebt, aarzel dan niet om het DRUID-team te contacteren via druid@ugent.be of 09 332 67 33.

☐ Mijn deelname aan deze vragenlijst is vrijwillig.
(informed consent).

Bedankt voor uw medewerking,

Prof. dr. Alain Verstraete
UZ Gent
Polikliniek 8, 2de verdieping
De Pintelaan 185
9000 Gent

Bedankt voor uw medewerking!

Datum:_____

A. ACHTERGROND INFORMATIE

1. Geslacht

☐ Man ☐ Vrouw

2. Leeftijd

☐ < 30 jaar
☐ 30 – 45 jaar
☐ 46 – 55 jaar
☐ 56 – 65 jaar
☐ 66 – 75 jaar
☐ > 75 jaar

3. Aantal inwoners gemeente praktijk

☐ > 10000
☐ <10,000

4. Jaar van afstuderen (JJJJ): _____

5a. Hoeveel jaar staat U reeds in de praktijk als arts?

☐ < 5 jaar
☐ 5 – 10 jaar
☐ 11 – 15 jaar
☐ 16– 20 jaar
☐ > 20 jaar

5. Is de invloed van geneesmiddelen op de rijvaardigheid tijdens uw universitaire opleiding aan bod gekomen?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, specificeer a.u.b:

_____

_____

B. KENNIS VAN NIEUWE TECHNOLOGIE

1. Gebruikt U het internet om informatie op te zoeken?

☐ Ja ☐ Nee

2. Gebruikt U het internet om informatie op te zoeken over de invloed van geneesmiddelen op de rijvaardigheid?

☐ Ja ☐ Nee

3. Indien U "Ja" antwoordde op vraag 2, hoe vaak doet U dit?

☐ Dagelijks ☐ Wekelijks ☐ Maandelijks ☐ 1x per jaar

4. Hebt U ooit software gebruikt om informatie op te zoeken over het effect van geneesmiddelen op de rijvaardigheid?

☐ Ja ☐ Nee

5. Indien U 'Ja' antwoordde op vraag 4, om welke software ging dit?

1. _____
2. _____
3. _____
4. _____
5. _____

6. Gebruikt U software om geneesmiddelen voor te schrijven in uw dagelijkse praktijk?

☐ Ja ☐ Nee

7. Indien U "Ja" antwoordde op vraag 6, om welke software gaat dit?

1. _____
2. _____
3. _____
4. _____
5.

C. ATTITUDES EN BEWUSTZIJN

Evalueer de volgende stellingen a.u.b:

1. Ik ben bereid het effect op de rijvaardigheid in overweging te nemen bij het voorschrijven van een medicijn.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Zou U dit (vraag 1) belangrijker vinden indien uw patiënt: (gelieve alle vragen te beantwoorden)

- een professionele bestuurder is? ☐ Ja ☐ Nee
- frequent rijdt? ☐ Ja ☐ Nee
- lange afstanden aflegt? ☐ Ja ☐ Nee
- een "onervaren" bestuurder is? ☐ Ja ☐ Nee
- een "ervaren" bestuurder is? ☐ Ja ☐ Nee
- een oudere bestuurder is? ☐ Ja ☐ Nee
- nog andere psychoactieve middelen neemt? ☐ Ja ☐ Nee

3. Ik ben bereid om een bepaalde mate van efficiëntie van een geneesmiddel op te offeren indien een alternatief geneesmiddel minder invloed heeft op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4. Ik ben goed op de hoogte van de effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

5. Het is voor mij belangrijk dat ik goed geïnformeerd blijf over effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Ik denk dat de informatie die ik geef aan mijn patiënten hun rijgedrag zal beïnvloeden.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

D. GEDRAG

Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen a.u.b.

1. Ik vraag mijn patiënt naar zijn/haar rijgedrag wanneer ik een geneesmiddel kies om voor te schrijven.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

2. Ik informeer een patiënt mondeling over risico's op de rijvaardigheid wanneer ik een geneesmiddel voorschrijf.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

3. Ik geef een patient geschreven informatie mee als ik een geneesmiddel met invloed op de rijvaardigheid voorschrijf.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

4. Ik neem systematisch nota van het voorschrijven van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

5. Ik neem systematisch nota van mijn adviezen aan een patiënt over de omstandigheden (wanneer, hoe) waarbinnen rijden mogelijk is bij gebruik van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

6. Ik neem nota van de verkeersdeelname van een patiënt (bvb. hoe vaak hij/zij naar het werk rijdt met de wagen)

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

7. Ik bespreek geneesmiddelengebruik en verantwoordelijkheid bij verkeersdeelname met de patiënt.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

8. Hoe vaak verstrekt U meestal gedetailleerde informatie aan een patiënt wanneer U een rijgevaarlijk geneesmiddel voorschrijft?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

E. BRONNEN

1. Ik heb gemakkelijk toegang tot data en informatie over het effect van een geneesmiddel op de rijvaardigheid.

☐ Ja ☐ Nee

2. Vermeld a.u.b. uw bronnen:

☐ Professionele websites
☐ Nieuwsbrieven
☐ (Verkeersveiligheids)organisaties/ Bercepsverenigingen
☐ Wetenschappelijke tijdschriften
☐ Andere (specificeer: _____)

3. Heeft U een postgraduaatsopleiding gekregen waarin de invloed van geneesmiddelen op de rijvaardigheid aan bod kwam?

☐ Ja ☐ Nee

4. Indien U "Ja" antwoordde op vraag 3, specificeer a.u.b:

_____

_____

_____

F. KENNIS

Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen a.u.b.
Duid telkens aan welk antwoord het best aansluit bij uw professionele inschatting.

1. In welke mate bent U het eens of oneens met onderstaande stellingen?

Stelling	Totaal oneens	Oneens	Noch eens noch oneens	Totaal eens	Weet niet
Temazepam (tot 20 mg) heeft een sterk negatieve invloed op de rijvaardigheid 8 uur na inname.	☐	☐	☐	☐	☐
Diazepam (onafhankelijk van dosis) heeft een sterk negatieve invloed op de rijvaardigheid tot 2 maanden na het begin van de behandeling.	☐	☐	☐	☐	☐
Codeïne (tot 20 mg) is meestal veilig voor bestuurders.	☐	☐	☐	☐	☐
Fexofenadine (in normale dosis) heeft een sterk negatieve invloed op de rijvaardigheid.	☐	☐	☐	☐	☐
Amitriptyline bij het begin van een behandeling heeft evenveel negatieve invloed op de rijvaardigheid als 4 weken na de start van de behandeling.	☐	☐	☐	☐	☐
Paroxetine (tot 20 mg/dag) is veilig voor bestuurders	☐	☐	☐	☐	☐

2. Artsen zijn verplicht om hun patiënten in te lichten over de mogelijke effecten van hun geneesmiddel op de rijvaardigheid.

☐ Waar ☐ Niet waar

3. Een patiënt kan aansprakelijk gesteld worden indien hij/zij een ongeval heeft veroorzaakt terwijl een potentieel rijgevaarlijk geneesmiddel gebruikt werd en de arts hem geadviseerd had om niet te rijden.

☐ Waar ☐ Niet waar

G. AANVAARDING DOOR GEBRUIKER

1. Indien we U een ondersteunend instrument (cfr. Vraag 2) zouden voorstellen dat U toelaat om informatie te vinden over geneesmiddelen en de rijvaardigheid, zou U bereid zijn dit te gebruiken bij het voorschrijven?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" geantwoord hebt op vraag 1, wat zijn de belangrijkste redenen om dit ondersteunend instrument (misschien) niet te gebruiken?

_____
_____
_____

3. Naar welk type instrument zou uw voorkeur gaan: gelieve in rangorde 1 tot 3 uw voorkeur weer te geven waarbij 1 uw meest geprefereerde vorm aanduidt.

	1	2	3
Website			
Software geïntegreerd in eigen programma			
Aparte digitale informatie (bvb. USB-stick, CD-ROM)			
Handboek			
Andere (specificeer a.u.b:_____)			

Bijkomende opmerkingen
(Gelieve hieronder alle eventuele bijkomende opmerkingen en aanbevelingen te vermelden)
_____
_____
_____

6.5 Post Questionnaire

VRAGENLIJST VOOR ARTSEN

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract Nr: TREN - 05-FP6TR-SO7.61320-518404-DRUID

Beste deelnemer,

Deze studie is een onderdeel van het Europese project DRUID ("Driving under the influence of drugs, alcohol and medicines", http://www.druid-project.eu). We zijn hierbij geïnteresseerd in uw mening over de invloed van geneesmiddelen op de rijvaardigheid.

Lees iedere vraag grondig en kruis het gepaste antwoordvakje ☑ aan. Bij de meeste vragen hoeft U slechts één vakje aan te duiden maar lees a.u.b. alle vragen zorgvuldig aangezien soms meer dan één vakje aangeduid moet worden.

We garanderen U dat al uw antwoorden anoniem behandeld zullen worden en dat deze enkel voor wetenschappelijke doeleinden gebruikt zullen worden.

Indien U nog meer vragen hebt, aarzel dan niet om het DRUID-team te contacteren via druid@ugent.be of 09 332 67 33.

☐ Mijn deelname aan deze vragenlijst is vrijwillig.
(informed consent).

Bedankt voor uw medewerking,

Prof. dr. Alain Verstraete
UZ Gent
Polikliniek 8, 2de verdieping
De Pintelaan 185
9000 Gent

Bedankt voor uw medewerking!

Geef hieronder uw e-mail adres op indien U op de hoogte wil gebracht worden van de algemene resultaten van deze studie.

E-mail: _____

Datum:_____

A. ACHTERGROND INFORMATIE

1. Geslacht

☐ Man ☐ Vrouw

2. Leeftijd

☐ < 30 jaar
☐ 30 – 45 jaar
☐ 46 – 55 jaar
☐ 56 – 65 jaar
☐ 66 – 75 jaar
☐ > 75 jaar

3. Aantal inwoners gemeente praktijk

☐ > 10000
☐ <10,000

4. Jaar van afstuderen (JJJJ): _____

5a. Hoeveel jaar staat U reeds in de praktijk als arts?

☐ < 5 jaar
☐ 5 – 10 jaar
☐ 11 – 15 jaar
☐ 16– 20 jaar
☐ > 20 jaar

5. Is de invloed van geneesmiddelen op de rijvaardigheid tijdens uw universitaire opleiding aan bod gekomen?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, specificeer a.u.b:

_____

_____

B. KENNIS VAN NIEUWE TECHNOLOGIE

1. Gebruikt U het internet om informatie op te zoeken?

☐ Ja ☐ Nee

2. Gebruikt U het internet om informatie op te zoeken over de invloed van geneesmiddelen op de rijvaardigheid?

☐ Ja ☐ Nee

3. Indien U "Ja" antwoordde op vraag 2, hoe vaak doet U dit?

☐ Dagelijks ☐ Wekelijks ☐ Maandelijks ☐ 1x per jaar

4. Hebt U ooit software gebruikt om informatie op te zoeken over het effect van geneesmiddelen op de rijvaardigheid?

☐ Ja ☐ Nee

5. Indien U 'Ja' antwoordde op vraag 4, om welke software ging dit?

1. _____
2. _____
3. _____
4. _____
5. _____

6. Gebruikt U software om geneesmiddelen voor te schrijven in uw dagelijkse praktijk?

☐ Ja ☐ Nee

7. Indien U "Ja" antwoordde op vraag 6, om welke software gaat dit?

1. _____
2. _____
3. _____
4. _____
5. _____

C. ATTITUDES EN BEWUSTZIJN

Evalueer de volgende stellingen a.u.b:

1. Ik ben bereid het effect op de rijvaardigheid in overweging te nemen bij het voorschrijven van een medicijn.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Zou U dit (vraag 1) belangrijker vinden indien uw patiënt: (gelieve alle vragen te beantwoorden)

- een professionele bestuurder is? ☐ Ja ☐ Nee
- frequent rijdt? ☐ Ja ☐ Nee
- lange afstanden aflegt? ☐ Ja ☐ Nee
- een "onervaren" bestuurder is? ☐ Ja ☐ Nee
- een "ervaren" bestuurder is? ☐ Ja ☐ Nee
- een oudere bestuurder is? ☐ Ja ☐ Nee
- nog andere psychoactieve middelen neemt? ☐ Ja ☐ Nee

3. Ik ben bereid om een bepaalde mate van efficiëntie van een geneesmiddel op te offeren indien een alternatief geneesmiddel minder invloed heeft op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4. Ik ben goed op de hoogte van de effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

5. Het is voor mij belangrijk dat ik goed geïnformeerd blijf over effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Ik denk dat de informatie die ik geef aan mijn patiënten hun rijgedrag zal beïnvloeden.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

D. GEDRAG

Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen a.u.b.

1. Ik vraag mijn patiënt naar zijn/haar rijgedrag wanneer ik een geneesmiddel kies om voor te schrijven.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

2. Ik informeer een patiënt mondeling over risico's op de rijvaardigheid wanneer ik een geneesmiddel voorschrijf.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

3. Ik geef een patiënt geschreven informatie mee als ik een geneesmiddel met invloed op de rijvaardigheid voorschrijf.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

4. Ik neem systematisch nota van het voorschrijven van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

5. Ik neem systematisch nota van mijn adviezen aan een patiënt over de omstandigheden (wanneer, hoe) waarbinnen rijden mogelijk is bij gebruik van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

6. Ik neem nota van de verkeersdeelname van een patiënt (bvb. hoe vaak hij/zij naar het werk rijdt met de wagen)

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

7. Ik bespreek geneesmiddelengebruik en verantwoordelijkheid bij verkeersdeelname met de patiënt.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

8. Hoe vaak verstrekt U meestal gedetailleerde informatie aan een patiënt wanneer U een rijgevaarlijk geneesmiddel voorschrijft?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

E. BRONNEN

1. Ik heb gemakkelijk toegang tot data en informatie over het effect van een geneesmiddel op de rijvaardigheid.

☐ Ja ☐ Nee

2. Vermeld a.u.b. uw bronnen:

☐ Professionele websites
☐ Nieuwsbrieven
☐ (Verkeersveiligheids)organisaties/ Beroepsverenigingen
☐ Wetenschappelijke tijdschriften
☐ Andere (specificeer: _____)

3. Heeft U een postgraduaatsopleiding gekregen waarin de invloed van geneesmiddelen op de rijvaardigheid aan bod kwam?

☐ Ja ☐ Nee

4. Indien U "Ja" antwoordde op vraag 3, specificeer a.u.b:

_____
_____
_____

F. KENNIS

Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen a.u.b.
Duid telkens aan welk antwoord het best aansluit bij uw professionele inschatting.

1. In welke mate bent U het eens of oneens met onderstaande stellingen?

Stelling	Totaal oneens	Oneens	Noch eens noch oneens	Totaal eens	Weet niet
Temazepam (tot 20 mg) heeft een sterk negatieve invloed op de rijvaardigheid 8 uur na inname.	☐	☐	☐	☐	☐
Diazepam (onafhankelijk van dosis) heeft een sterk negatieve invloed op de rijvaardigheid tot 2 maanden na het begin van de behandeling.	☐	☐	☐	☐	☐
Codeïne (tot 20 mg) is meestal veilig voor bestuurders. Fexofenadine (in normale dosis) heeft een sterk negatieve invloed op de rijvaardigheid.	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
Amitriptyline bij het begin van een behandeling heeft evenveel negatieve invloed op de rijvaardigheid als 4 weken na de start van de behandeling.	☐	☐	☐	☐	☐
Paroxetine (tot 20 mg/dag) is veilig voor bestuurders	☐	☐	☐	☐	☐

2. Artsen zijn verplicht om hun patiënten in te lichten over de mogelijke effecten van hun geneesmiddel op de rijvaardigheid.

☐ Waar ☐ Niet waar

3. Een patiënt kan aansprakelijk gesteld worden indien hij/zij een ongeval heeft veroorzaakt terwijl een potentieel rijgevaarlijk geneesmiddel gebruikt werd en de arts hem geadviseerd had om niet te rijden.

☐ Waar ☐ Niet waar

G. AANVAARDING DOOR GEBRUIKER - INHOUD

Evalueer volgende stellingen op basis van uw 6 maanden ervaring met de aangeboden hulpmiddelen (software of USB-stick en handboek)

1. Hebt U de aangeboden richtlijnen gebruikt ter ondersteuning van uw communicatie naar de patiënt toe?

☐ Ja ☐ Nee

2. Indien U "Ja" antwoordde op vraag 1, hoe vaak gebruikte U de richtlijnen?

☐ altijd ☐ vaak ☐ soms ☐ zelden ☐ nooit

3. Indien U 'zelden' of 'nooit' antwoordde op vraag 2, wat zijn de belangrijkste redenen van uw weerstand om de richtlijnen te gebruiken?

---

4. De aangeboden richtlijnen voor het voorschrijven van potentieel rijgevaarlijke medicijnen zijn:

	Ja, heel erg	Tamelijk	Minder	Nee, helemaal niet
Nuttig				
Bruikbaar				
Toereikend				

5.Gebruikte U de gedetailleerde fact sheets van de geneesmiddelen als achtergrondinformatie om uw patiënt te informeren over geneesmiddelen en rijvaardigheid?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, hoe vaak gebruikte U de fact sheets ?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

7. De fact sheets per geneesmiddel met mogelijk rijgevaarlijk effect zijn:

	Ja, heel erg	Tamelijk	Minder	Nee, helemaal niet
Nuttig				
Bruikbaar				
Toereikend				

8. Vond U het een probleem dat de fact sheets enkel in het Engels beschikbaar waren?

☐ Ja ☐ Nee

9. Gebruikte U het pictogramsysteem om uw patiënt te informeren over geneesmiddelen en rijvaardigheid?

☐ Ja ☐ Nee

10. Indien U "Ja" antwoordde op vraag 9, hoe vaak gebruikte U het pictogramsysteem?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

11. Het pictogramsysteem voor het voorschrijven van **geneesmiddel met mogelijk rijgevaarlijk effect is:**

	Ja, heel erg	**Tamelijk**	**Minder**	**Nee, helemaal niet**
Nuttig				
Bruikbaar				
Toereikend				

12. Vindt U dat er extra informatie moet toegevoegd worden die nu nog ontbreekt?

☐ Ja ☐ Nee

13. Indien U "Ja" antwoordde op vraag 12, specificeer a.u.b:

_____
_____
_____

14. Denkt U dat de richtlijnen **uw manier van voorschrijven** beïnvloed hebben?

Ja, heel erg ☐ ☐ ☐ ☐ ☐ Nee, totaal niet

15. Denkt U dat de richtlijnen **uw keuze van medicatie** beïnvloed hebben?

Ja, heel erg ☐ ☐ ☐ ☐ ☐ Nee, totaal niet

16. Denkt U dat de richtlijnen **uw manier van informatie** geven aan patiënten beïnvloed hebben?

Ja, heel erg ☐ ☐ ☐ ☐ ☐ Nee, totaal niet

H. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID - SOFTWARE (indien u de USB-stick en het handboek gebruikte, ga naar vraag I en J)

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan.

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van de software omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. Deze software zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:

---

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

---

7. Vindt U dat de software nog extra opties moet hebben op het scherm of dat bepaalde functies momenteel ontbreken?
☐ Ja ☐ Nee

8. Indien U "Ja" antwoordde op vraag 7, specificeer a.u.b:

I. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID – USB-STICK (indien u de software gebruikte, ga naar vraag K)

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van de USB-stick omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. I let gebruik van deze USB-stick zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:

---

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

---

7. Vindt U dat de USB-stick nog extra opties moet hebben of dat bepaalde functies momenteel ontbreken?
☐ Ja ☐ Nee

8. Indien U 'Ja' antwoordde op vraag 7, specificeer a.u.b:

J. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID – HANDBOEK

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan.

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van het handboek omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. Het gebruik van het handboek zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:

---

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

_____
_____
_____

7. Vindt U dat het handboek nog extra informatie moet bevatten?

☐ Ja ☐ Nee

8. Indien U 'Ja' antwoordde op vraag 7, specificeer a.u.b:
_____
_____
_____

K. GEBRUIK VAN DE SOFTWARE IN DE TOEKOMST (Indien u de USB-stick en het handboek gebruikte, ga naar vraag L en M)

1. Zou U deze software willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:
_____
_____
_____

3. Waarvoor zou U de software het meest gebruiken? (specificeer a.u.b.)
_____
_____
_____

L. GEBRUIK VAN DE USB-STICK IN DE TOEKOMST

1. Zou U deze USB-stick willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:
_____
_____
_____

3. Waarvoor zou U de USE-stick het meest gebruiken? (specificeer a.u.b.)
_____
_____

M. GEBRUIK VAN HET HANDBOEK IN DE TOEKOMST

1. Zou U dit handboek willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:

_____
_____
_____

3. Waarvoor zou U het handboek het meest gebruiken? (specificeer a.u.b.)
_____
_____
_____

Bijkomende opmerkingen
(Gelieve hieronder alle eventuele bijkomende opmerkingen en aanbevelingen te vermelden)
_____
_____
_____

1.2 Pharmacists Study

Please refer to this report as follows:

Legrand, S.A., Boets S., Meesmann, U., Van der Linden, T. & Verstraete, A. (2011). Belgian country report on the implementation, evaluation and new technologies of practice guidelines and information materials for pharmacists. Section of EU Project DRUID D7.4.2.

Research team:

UGent:	**IBSR:**
Sara-Ann Legrand,	Sofie Boets
Trudy Van der Linden	Uta Meesmann
Alain Verstraete	Mark Tant

Table of Contents

List of abbreviations

ATC	Anatomical Therapeutic Chemical (ATC) classification
DRUID	Driving Under the Influence of Drugs, Alcohol and Medicines
EUB	First-time dispensing counselling (Eerste Uitgifte Begeleiding)
EUC	First-time dispensing check (Eerste Uitgifte Controle)
GIT	Written patient information (Geneesmiddelen Informatie Tekst)
ICT	Information and Communication Technology
IP contract	Intellectual Property contract
TUB	Second-time dispensing counselling (Tweede Uitgifte Begeleiding)

1 Introduction

1.1 Background

Medicines that affect the fitness to drive are provided with a package information leaflet for the patient. The information in the package information leaflet usually does not always provide proper advice to the user on his/her participation in traffic. However health care professionals, such as physicians and pharmacists, are expected to provide this information at the time of prescription or dispensing of a medicine.

In the past few years pharmacists play a much more central role in providing patients with information when delivering a medicine. Since April 2010, a new system of remuneration for pharmacists has come into force. The objective of this new system is to reinforce the intellectual role of the pharmacist and to partly disconnect the pharmacists' remuneration from the drug price. Dispensing guidelines and a categorisation system, as developed by DRUID, integrated in their dispensing software can help the pharmacists to comply with their role and allow them to provide more concrete information to the patient.

In the Netherlands, since October 2008, the Dutch government funded the development of and ICT–oriented support in dispensing practices (there is no specific ICT-oriented support for physicians). Based on that assignment, Health Base Foundation has developed additional information pertaining to the categorisation system as a support to counselling patients while dispensing a medicine. In Belgium one company (ESCAPO) uses the information provided by the Health Base Foundation as input for their dispensing support tool: ViaNova. Apart from the software ViaNova different other dispensing software tools/databases are available in Belgium (e.g., (Delphi care, Sofie (Farm@doc)), Omegasoft, Pharmawin, Aegate, Farmad twin, Officinall…) In contrast with the ViaNova software, specific information on the possible influence of a medicine on the driving abilities is not available in most of the other software systems.

1.2 Aims and objectives

The object of the study was to measure the effectiveness of pharmacist training on the **dispensing guidelines** for medicines with an influence on driving abilities, as well as the use and user acceptance of the dispensing support tools in which the **medicinal risk classification** system was integrated. The effectiveness was measured through the actual use rates of the integrated and stand-alone ICT support tool and in a questionnaire survey (compared to baseline measurement), after 6 months as a change in attitudes/awareness, knowledge and (reported) behaviour due to the implementation of the training.

1.3 Evaluation team

The study was organised, conducted and evaluated in close collaboration between Ghent University (UGent) and the Belgian Road Safety Institute (IBSR).

2 Methods

2.1 Research specific objectives

The following **research questions and hypotheses** were formulated:

- Do pharmacists' attitudes and awareness about medicines and driving change/improve after the training and intervention?
- Do pharmacists' reported behaviour about medicines and driving change/improve after the training and intervention?
- Do pharmacists' actual knowledge about medicines and driving improve after the training and intervention?

- Are pharmacists willing to accept and use the ICT dispensing (integrated/stand-alone) and paper support tools?

- Are pre-post questionnaire (socio-cognitive) changes and user acceptance rates higher in the integrated software group as compared to in the stand-alone (USB tool) support tool group?

- Are pre-post questionnaire (socio-cognitive) changes in the intervention groups (integrated/stand-alone) higher as compared to the control group?

- What is the use rate (dispensing data) of the ICT dispensing support tools (integrated/stand-alone)?

- Are there differences in the incidence of dispensed category I, II or III medicines in the ICT tools (integrated/stand-alone) use rates?

2.2 Study design

The study has a pre- and post-design and includes **2 intervention groups (training + implementation support tool) and one control group**:

- Integrated software group, in this report further referred to as **ViaNova group**: a group of pharmacists using the ViaNova dispensing system in their daily practice. The DRUID WP4 and WP7 information was integrated into the ViaNova software.

- Stand-alone software group, in this report further referred to as **USB group**: a group of pharmacists in East Flanders, , in the intervention group. The DRUID information was delivered through an USB stick to be installed on the pharmacists' computer. The program on the USB stick had access to an internet-site were all DRUID information was posted.

- **Control group**, a group of pharmacists from East Flanders, either chosen to be in the control group or by the research team referred to the control group. This group did not receive the DRUID information.

Comparison of the intervention groups allows evaluating the difference in impact and use of the DRUID WP4 and WP7 information according to the type of support tool.

Comparison with the no-intervention control group allows evaluating the impact of the DRUID information on dispensing behaviour and self-reported measures, controlled for effects outside the study scope.

Pre- and post-conditions are accounted for by a pre-questionnaire before the training and intervention phase of 6 months (for the control group: 6 months without intervention), after which the post-questionnaire was asked to be filled-out.

Pre-post comparisons within each group allow evaluating the impact of the DRUID WP4 and WP7 intervention.

The study design can be roughly depicted as follows:

Table 49: Activities that were performed bye ach Group of pharmacists during the study period.

	Group		
	ViaNova group	**USB group**	**Control group**
Pre-training		Pre-questionnaire	Pre-questionnaire
April 2010 (ViaNova) **Sept 2010 (USB)**	Pre-questionnaire + **TRAINING**	**TRAINING**	–
Post-intervention **(6 months after the**	Post-questionnaire Software use data	Post-questionnaire Tool use data	Post-questionnaire

training)			

The study was approved by the **Ethics committee**, Faculty of Medicine and Health Sciences, University Ghent, Belgium on the 5th of March 2010 (B67020108020).

All data (questionnaires, integrated and stand-alone software) were extracted anonymously. No patient information was collected. The privacy of the patient was guaranteed throughout the whole study.

The pharmacists were free to refuse participation in the study. Moreover, every respondent could terminate their cooperation/participation at any time. All participants were asked to sign an informed consent. The USB group had to sign a second informed consent provided by Health Base because Health Base information (GIT) was integrated in the USB tool.

2.3 Materials

2.3.1 Intervention/support tools

- **Training manual**

A training manual including the relevant DRUID WP4 and WP7 information for pharmacists was developed in DRUID Task 7.4.1 (D7.4.1). This manual was slightly adjusted to the specific Belgian context. It was used as guidance when training the pharmacists in the ViaNova and USB group and handed out to them.

The training manual addressed the general background and structure of the DRUID project and more specifically of the pharmacist study. The DRUID WP7 dispensing guidelines were explained and possible information documents for patients were reviewed. The manual furthermore familiarised the pharmacists with the DRUID WP4 proposed categorization system for medicinal effects on driving, as well as with the group-specific support tools that include the relevant information.

- **ViaNova integrated software**

Before the official start of the pharmacist study, several meetings were held with software company ESCAPO (provider of the pharmacy information system ViaNova) in order to make agreements on the activation of signals regarding the influence of medicines on driving abilities and how to start up the DRUID study with the integrated ViaNova group.

It was decided that software including the relevant information could be introduced into the system ViaNova, with the aim of supporting the delivery of medicines and contributing to the education on medication with an influence on driving ability.

More information on the ViaNova support software for dispensing potential driving-risky medicines can be found in D7.4.1 and D7.2.2.

After activation of the DRUID functions by the pharmacists, ViaNova offered support in three manners when dispensing medicines that can influence the driving abilities: (a) *Medication safety* contains a first delivery control (e.g. a warning that driving (for a certain period) is not allowed). If possible, a safer alternative is proposed. (b) *Medication accompaniment* includes a first and second dispensing counselling. In the first dispensing counselling advice for safer driving is given. The second dispensing counselling is a continued accompaniment, where the pharmacist for example is requested to ask about any possible side-effects. (c) *Patient information* refers to practical and understandable information available in the ViaNova software that can be provided to the patient. Furthermore a warning label can be printed to affix on the medication box. Possible advice on this label is for example: ‘This medicine can influence your responsiveness’ or ‘Be careful when using alcoholic beverages’.

Practically, when delivering medicines that influence the driving abilities, the ViaNova information system offers support in the following ways:

1. **EUC signal:** A 'first delivery control signal' appears only at the first delivery of medicines when: driving a car is not allowed (generally category 3) and when safer alternatives are available.

2. **EUB signal:** the 'first delivery accompaniment signal' includes the information (concerning driving and medicines) to be told to the patient at a first delivery.

3. **TUB signal:** the 'second delivery accompaniment signal': includes the information and possible questions for conversation with the patient at a second delivery.

4. **GIT: written information** on the medicine, with practical recommendations/advices concerning driving and medicines, which can be printed out for the patient.

5. **Automatically generated warning:** these warnings are brief messages that attract the attention on a possible influence of the medication on the driving abilities. These recommendations and warnings can be affixed on a package as a label.

6. **Registration** of the automatic signals and how they are dealt with (which of these activities have been used for the patient).

- **USB stand-alone tool**

For the stand-alone group, an USB tool was developed in DRUID by CERTH-HIT and amended to match the Belgian situation. This tool contains comparable information as the ViaNova software: information for the pharmacists in the format of a Fact sheet or first delivery text and information for the patient (GIT: patient information letters) for the N-medicines: N01-N07) provided by Health Base), but clearly differs from ViaNova as pharmacists have to look up the medicinal risk guidelines and information separately by themselves (no automatic pop-up and no link with the patient). Each pharmacist was asked to install (themselves) the tool on their computer.

For the Belgian study the USB tool described in the general part of this deliverable, was amended for following reasons:

1. Patient information letters had to be included

2. Stichting Health Base (SHB) provided the information texts used in this study. Because of copyrights, Health Base texts could not be put directly on the USB-stick. Permission to load the information on a secured website was granted by means of an IP contract (UGent Tech Transfer number A09/TT/0567)

The following adjustments in the USB tool were made:

1. An extra button was made to make the link to the patient information letters

2. The information (Delivery accompaniments and patient information letters) was put online. The links leading to the information were created to pdf-files on an UGent website (http:/www..druid.ugent.be/) instead of PDF-files in a directory on the C-drive of the computer.

2.3.2 *Evaluation tools*

Evaluation data were collected via questionnaires and through data extractions from the ViaNova software and USB tool use rates and characteristics.

- **Pre- and post-questionnaire**

The evaluation questionnaire, developed within DRUID (D7.4.1), including a pre- and a similar post-part, was translated into Dutch for the Belgian pharmacist study. The translation may have generated some minor changes as compared to the original version. Furthermore, some small changes were made purposely to adapt better to the Belgian situation or for ethical reasons.

With regard to the pre-questionnaire, the following questions were adapted or removed from the original version:

- Background information: for ethical reasons date of birth was changed into age categories; practice area (rural/urban) was changed into number of inhabitants.
- New technologies familiarity: a question about how often the pharmacist uses the internet to obtain information was added.
- Sources: the option 'organisation' in 'please report your sources' was split up into traffic safety organisation and professional organisation.
- Actual knowledge: since temazepam is not on the Belgian market, answers on the statement regarding this medicine were not considered; the question about informing the Driving Licensing Authority was left out because this is not applicable in Belgium.
- User acceptance: the question which type of instrument the participant would prefer (website, integrated in software, non-integrated tool, manual...) was added.

The same adjustments as were made in the post-questionnaire, and additionally:

- User acceptance - content: in questions 5-7 the term 'fact sheets' was replaced by 'patient letters'; question 8 'Was it a problem that the fact sheets were provided in English' was not applicable because the information was provided in Dutch by Stichting Health Base, and therefore removed.

Furthermore, two extra questions were formulated in the post-questionnaire:

- Do you think that the use of the guidelines has influenced your way of delivering medicines?
- Do you think that the use of the guidelines has influenced your way of communicating the information to the patients?

Both the pre- and post-questionnaire derive information on: personal and practice related background variables, familiarity with new (ICT) technologies, current sources on medicines and driving risks, attitudes and awareness, reported behaviour and actual knowledge related to dispensing medicines with potential effect on driving abilities, and user acceptance of daily practice support tools linking to driving. While identical for these areas of interest, the post-questionnaire additionally includes in-depth questions regarding user acceptance and usability of the tool(s) being used during the intervention phase. (See annex 5).

The three study groups filled-out the pre-questionnaire at baseline (before the training/intervention phase of 6 months): the ViaNova group filled it out just before the training session started; the USB and control group filled it out at home and sent it by mail to the research team. The three groups filled-out the post-questionnaire after 6 months (intervention phase): all groups filled it out at home and sent it back by post to the research team.

All questionnaire data were integrated into an SPSS file.

- **ViaNova and USB data extraction**

The data from the integrated software ViaNova were automatically and anonymously extracted by ESCAPO and provided to the research team. The data were delivered in an Excel file.

The USB group on the other hand received a step by step instruction plan on how to extract the data from the USB tool in the format of a log file and to mail the log file to the research team. Pharmacists who installed the USB tool on several computers in the pharmacy where asked to send the log file(s) from all the different computers. The data were transferred into Excel by the research team. The USB tool data extraction included no personal identification (anonymous extraction).

Relevant ViaNova extracted data included: information regarding EUC, EUB and TUB: the number of EUB/TUB/EUC signals, the ATC code and how the signal was handled: discussed/not discussed; cancelled delivery, gave GIT to patient, discussed side effects, ignore (signal will return)

Relevant USB extracted data included: Only limited data/information could be obtained out the USB tool: date and hour of the search by the pharmacists and (part of) the substance/medicines they were searching for in the program.

2.4 Study procedure

2.4.1 Participant recruitment

About hundred Flemish pharmacists use the **ViaNova** software system in their daily practice. In collaboration with ESCAPO, participation was asked for through an internal email. In the original study design it was foreseen to include 40 pharmacists, but because of the high enthusiasm and big response, the decision was made to include all pharmacists who wanted to participate. In the end, 90 pharmacists (90% of all ViaNova users) registered to follow a DRUID training session. After the 6 months trial it became clear that 70 pharmacists used the DRUID functions integrated in ViaNova on a regular base. Only those 70 pharmacists received a second questionnaire, 68 of them sent it back. Only the pharmacists who sent in the second questionnaire and the log file(s) were included in the study. After receiving the last questionnaire and the log file(s), a gift voucher was sent to the respondents by mail.

With regard to the **USB and control group**, a letter was sent to all pharmacists of East Flanders (636 in total), including general study information, an invitation to follow a training session, the pre-questionnaire, an informed consent form and a return envelope. They were asked not to reply if they are ViaNova users. They were asked for their participation either in the USB group (select a training session date and send back the signed informed consent) or in the control group (fill-out and send back the pre-questionnaire and signed informed consent). They could thus self-select the group of participation (USB or control), although the letter also indicated that only the first 30 respondents would be considered for following a training course (USB group) or would be selected for the control group.

The aim was to select 31 pharmacists for the USB group, but only 18 volunteered. On the other hand, 24 pharmacists wanted to be included in the control group; and another three who first registered for the USB group were added later as they were not able to attend a training session.

After sending back their pre-questionnaire, the selected pharmacists in the USB and control group received a second letter that informed them that they were selected to follow a training session (USB group) or that they will receive a second questionnaire in 6 months (control group).

Table 50 indicates the flow of the study sample size: from initial participant recruitment to full study participation.

Table 50: Sample size

	Pharmacist group		
Respondents	**ViaNova**	**USB**	**control**
Total population	+/- 100	636	
Pre-questionnaire	84	18	24+3*

Training sessions	90	15	
Post-questionnaire	68	12	21
Full participants[6]	**68**	**12**	**21**

* three absent USB group respondents in the training were switched to the control group

2.4.2 Flow charts

The following flow charts depict the study procedure, from participant recruitment over study steps and follow-up actions to study finalisation.

For the **ViaNova group** of pharmacists 3 training sessions were organised in close collaboration with ESCAPO. The pharmacists were asked to fill in the questionnaire before the training session started in order to avoid invalid data/information.

For **USB group** 2 training sessions were organized in Ghent. Pharmacists registered for the first training session who could not attend, were kindly invited for the second training session. For both groups a training manual and hand-outs of the Powerpoint presentation showed during the training session, were made. ESCAPO made a step by step plan how to activate and use the functions integrated in their software. Also for the USB group a manual on how to install and use the USB-tool was developed. During the training sessions the pharmacists were informed about the DRUID project and the aim of the pharmacist and physician study. The legal aspects of driving under the influence in Belgium and the role of pharmacists were underlined. Furthermore, the pharmacists were confronted with practical situations and examples.

As also depicted in the flow charts, several follow-up actions were set up in order to motivate pharmacists for (continued) study participation and to support them in their participation.

Newsletters were sent on a regular base to the ViaNova and USB group. The ones for the ViaNova group were designed in collaboration with ESCAPO, who distributed them to their customers. In total, 3 newsletters were sent to the all ViaNova users (see annex 1). By sending the newsletters to all users of ViaNova, every pharmacist was informed about the (progress of) the study. Several pharmacists who did not participate in the study did activate the DRUID functions.

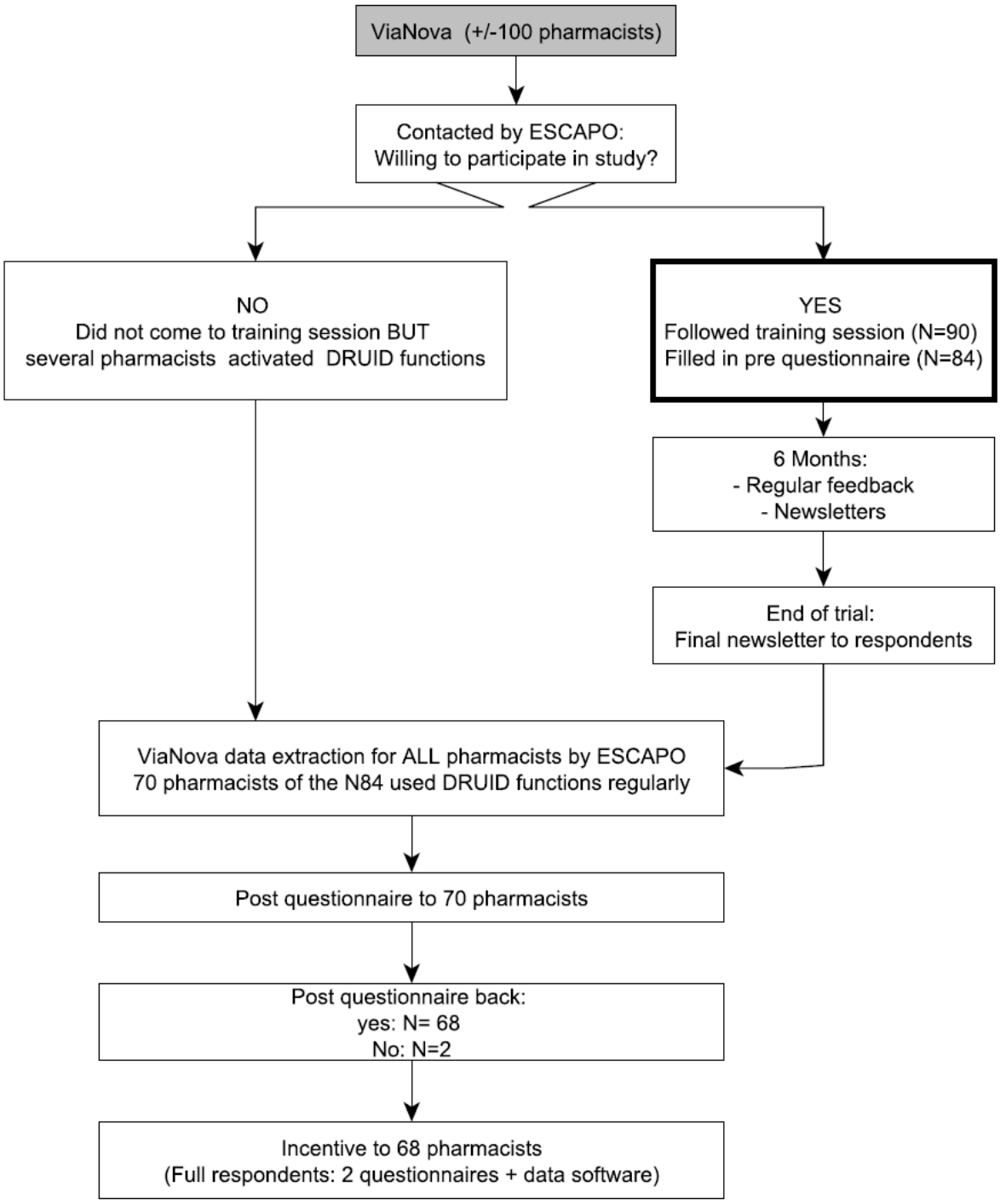
The USB group received newsletters by email from the Ghent University research team. Shortly after the training a first newsletter was already sent to the participants. Based on the reactions to this newsletter, it became clear that several pharmacists still experienced problems in installing the USB tool on the personal computer. Corrective **supportive measures** had to be taken, and problems could finally be solved by means of email, telephone calls, or personal intervention.. In total 3 newsletters were sent throughout the USB study (see annex 2). They mainly aimed at motivating the participants to use the tool and to ask for help when they experienced problems, but also at informing them on the study. Furthermore, some practical case studies were described or new legal regulations explained. Finally the aim of the survey was underlined.

After 'full' participation an **incentive** was received. Due to the high number of participants, the ViaNova group received a gift voucher value of 60 euro (instead of 100 euro). The USB group received a gift voucher of 100 euro and the control group of 25 euro.

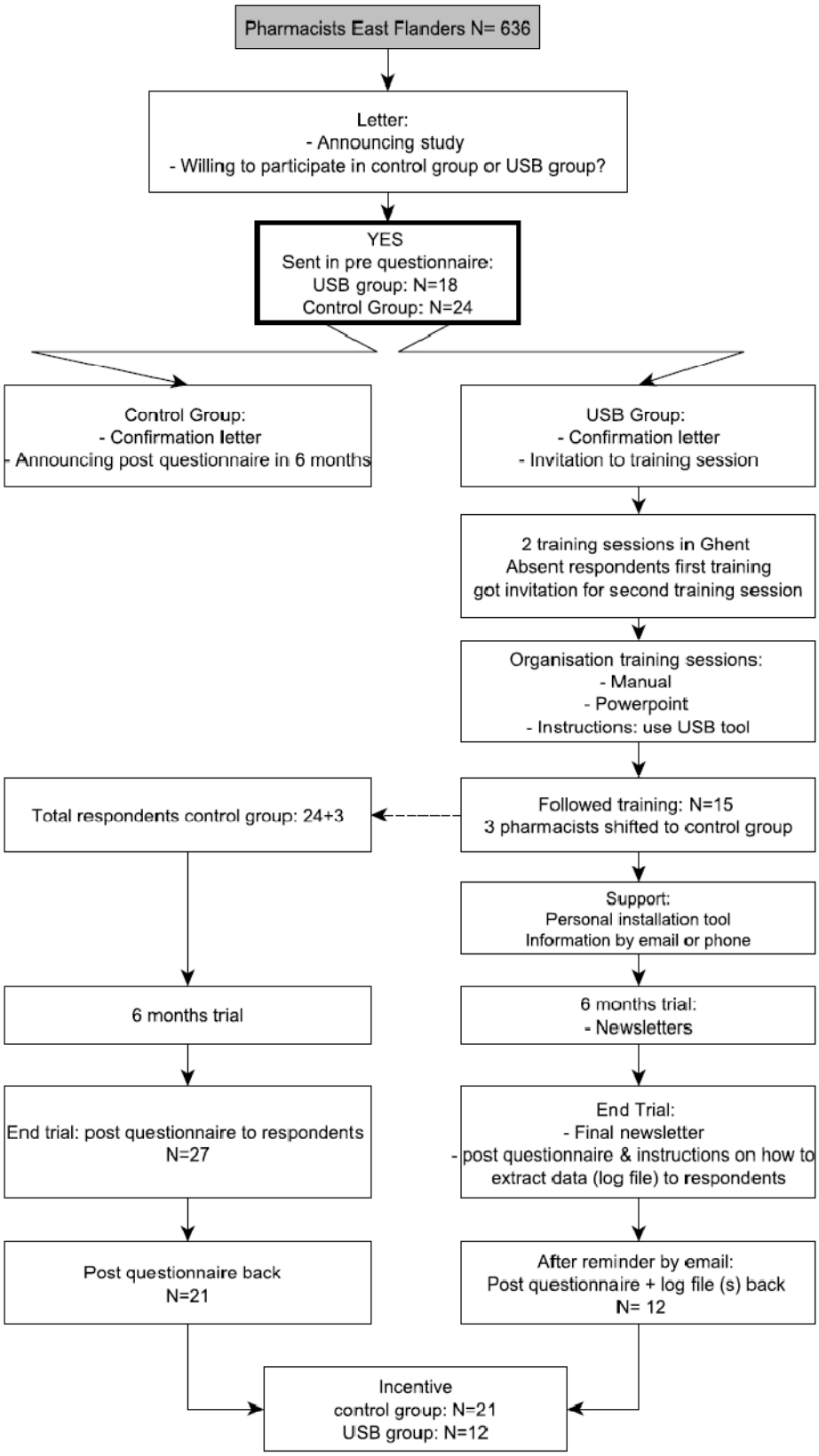
Furthermore, other **sensitising and dissemination actions** in support of the study were set up. A banner was developed for the ViaNova group, which was shown on flat screens in the pharmacist practices using the ViaNova system (see annex 3). An interview was published in the magazine 'Visie', a paper of Christian Health Insurance and a short radio interview was broadcasted. The study was also presented in September 2010 on the first Belgian pharmaceutical care symposium (see poster in annex 4)

[6] Full participants: intervention respondents from which the two questionnaires (pre- and post-) and software data extraction were received; this does not count for the control group.

- **ViaNova group**



- **USB and control group**



2.5 Statistical analysis

SPSS version 19 (pre- and post-questionnaire data) and Microsoft Office Excel 2003 (extracted ViaNova/USB data) were used for the data analysis. Due to sample size restrictions and variable scales robust non-parametric analyses were used (significance level at p≤.05; 95% confidence interval).

- **Pre-questionnaire: between-group comparisons**

For the categorical variables (background information, knowledge of new technologies, sources, user acceptance): descriptive crosstabs (within-group %), and Chi-square or Fisher's exact test to check the relationship.

For the ordinal variables composite scores[7] were calculated. For attitudes and awareness, and reported behaviour this was based on the median score. The knowledge variables were recoded into only 3 categories (don't agree, agree and don't know) and the composite score was calculated based on the sum of correct answers. Kruskal Wallis ANOVA by ranks test was used to check between-group differences, and a Fisher's least significant difference (LSD) post-hoc test to locate the significant differences.

- **Within-group pre-post questionnaire change**

Pre-post significant differences were checked for attitudes and awareness, reported behaviour and knowledge, based on the Wilcoxon matched pairs - signed-rank test. For the sum composite score of knowledge paired samples t-test was used for the ViaNova group (sample size restrictions in the other groups).

- **ViaNova/USB data extraction**

Percentage of different click options in function of the total number of popped-up signals (EUB and TUB, EUC), as a function of medicinal risk category and ATC group.

3 Results

3.1 Sample characteristics: ViaNova (n = 68), USB (n = 12), Control (n = 20)

For the description of the study population only 'full' respondents were included. Full respondents were respondents from whom the research team received the two (pre-post) questionnaires. The total study population includes: 68 participants in the ViaNova group, 12 in the USB group and 20 in the control group (total N=100).

In Table 51 within-group distributions are shown for gender, age, inhabitants in the practice area, year of graduation from University, years practising as pharmacists and whether pharmacists had any education on medicinal effects on driving skills during their studies at University.

Except for the number of inhabitants in the practice area (a measure of more rural versus more urban practice area) the three groups did not differ significantly regarding personal/practice related background variables.

With regard to the **gender** distribution, 60% or more of the participants in the ViaNova and Control group was female, while the majority in the USB group was male (almost 60%). 45% of all participants had an **age** ranging between 30 and 45; this is the biggest portion in each group (42.60%-Vianova; 66.70%-USB group; 40%-Control group). Second most involved participant age group was 46 to 55 years. While none of the participants in the USB group was aged below 30 or above 55, these were smaller groups in the ViaNova and Control group. Taking gender into account, more than 50% of the females were aged between 30 and

[7] A composite score combines different scores within a same category; it can be a mean, median or sum of the individual scores to provide one 'overall' category score.

45, while this was more equally distributed between the age of 30 and 65 in the male pharmacists.

About 70% of the pharmacists (in all groups) were **practising** for more than 10 years. There was no significant group-difference with regard to the **graduation year** or decade of the participating pharmacists. This varied between 1965 and 2009 (mean/median 1989), with most graduating in the 80ies (32%) and 90ies (30%). Part of the ViaNova and Control group graduated in the earlier years, compared to none in the USB group. Most respondents in all groups clearly indicated not to have had any **specific education** regarding possible effects of medicines on the driving abilities. Those who did mention education underlined that the information was given as 'side information', and that this information was often vague and superficial.

Table 51: Description study participants (within-group %)

		Pharmacist groups (within-group %)			
		ViaNova N=68	**USB N= 12**	**Control n=20**	**Total**
Gender	Male	33.8	58.3	40	38
	Female	66.2	41.7	60	62
Age	<30 years	10.3	0	20	11
	30-45 years	42.6	66.7	40	45
	46-55 years	29.4	33.3	25	29
	56-65 years	17.6	0	15	15
Inhabitants area practice*	**>10000**	**89.2***	**41.7**	**55**	**76.3**
	<10000	**10.8***	**58.3**	**45**	**23.7**
Year of graduation medical school	60ies	1.5	0	0	1
	70ies	22.1	0	20	19
	80ies	32.4	41.7	25	32
	90ies	27.9	33.3	35	30
	≥2000	16.2	25	20	18
Years practising as pharmacist	<5 year	10.4	0	10	9.1
	5-10 year	6	25	10	9.1
	11-15 year	14.9	25	15	16.2
	16-20 year	16.4	16.7	35	20.2
	>20 year	52.2	33.3	30	45.5
Education on medicinal effects on driving skills during studies at University	no	82.1	83.3	68.4	79.6
	yes	17.9	16.7	31.6	20.4

* Pearson Chi-Square p≤.05

With regard to inhabitants in the area of the practice, **ViaNova group pharmacists seemed to have their practice significantly more often in more populated (more urbanised) areas (>10,000 inhabitants)** while the spreading of more or less populated locations was more equal in the other groups.

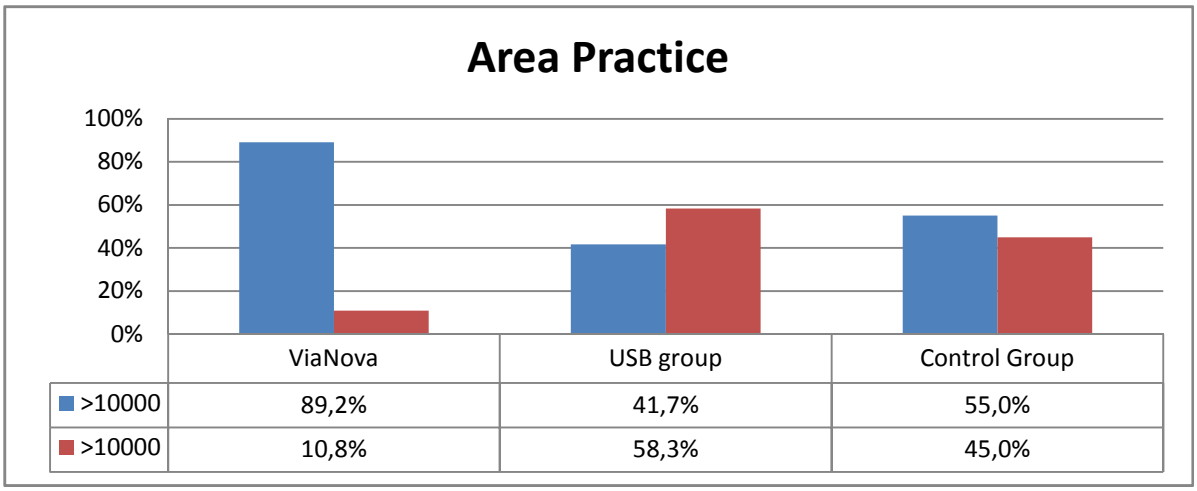


Figure 31: Inter-group difference: Inhabitants in area of practice (within-group %) (p<.000)

3.2 Drop-outs

There were no significant differences between participants and drop-outs in the USB and Control group with regard to personal/practice related background variables and ICT familiarity. With regard to the ViaNova group though, the dropped-out group seemed to be relatively more often younger (below 30), with less practicing years and more often working in a rural setting.

In the **ViaNova group** 16 pharmacists dropped out (13 females, 3 males; from different age categories but none above 55 years). The full participation rate was 80.95% . There seem to be some differences between participants and drop-outs regarding age, number of inhabitants in the practice area and number of years from graduation. The dropped-out group had an increased relative number of below 30 year old participants (43.8% of drop-out group), no pharmacists from the oldest age groups dropped out. Connected to younger age, also the number of years in practice differs, with a relative high number of less than 5 working years in the drop-out group. Quite similar relative numbers of pharmacists in rural-urban areas dropped out, although taking the initial low rural area numbers into account, proportionally more rurally located pharmacists dropped out. There were no indications of differences with regard to ICT familiarity.

In the **USB group** 3 female pharmacists within the age group 30 to 45 dropped out of the study. The full participation rate was 80%. No significant group differences between participants versus drop-outs were found regarding gender, age, number of inhabitants in the practice area, number of years from graduation of with regard to ICT familiarity.

Five pharmacists dropped out of the **Control group** (3 males, 2 females), from different age categories but none within the 46-55 years group. The full participation rate was 80%. No significant differences between participants versus drop-outs were found regarding personal background variables or ICT familiarity.

3.3 Pre-questionnaire: Vianova (n=68), USB (n=12), Control (n=20)

The three groups were similar with regard to most pre-questionnaire parts (used sources for medicinal driving risk information, pre-level attitudes, awareness and knowledge, willingness to use a dispensing support tool that takes driving risks into account). **Some differences were found though with regard to ICT familiarity (1) and reported behaviour (2).** A small difference related to familiarity with software to find medicinal risk information (less in the Control group). More differences were found though with regard to pre-level reported behaviour: the USB and Control group less often provided written information to patients than the ViaNova group, and ViaNova respondents less often kept record of patients'

traffic participation than Control group respondents. **On the level of the relevant socio-cognitive-behavioural composite scores, the three groups were equivalent.**

3.3.1 General ICT literacy and familiarity with medicinal ICT

Table 52: Medicinal ICT familiarity (within-group %)

		Pharmacist groups (within-group %)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
Do you use the internet to obtain information?	no	3	8.3	5	4
	yes	97	91.7	95	96
Do you use the internet to obtain information on medicines affecting driving behaviour?	no	83.6	75	75	80.8
	yes	16.4	25	25	19.2
If you answered 'Yes' how often do you do this?	*daily*	0	0	0	0
	every week	0	0	20	5.3
	less than weekly	90.9	66.7	60	78.9
	other	9.1	33.3	20	15.8
Have you ever used any software package / programme to obtain information on medicinal drugs effect on driving behaviour? *	**no**	**43.9**	**41.7**	**75***	**50**
	yes	**56.1**	**58.3**	**25***	**50**
Do you use any medical/clinical software package / programme in your daily practice?	no	4.6	0	10	5.2
	yes	95.4	100	90	94.8

*Pearson Chi-Square p≤.05

In general, almost all participants had a high ICT familiarity when it concerns the general use of **internet** (96% of the total group) and the use of **daily support software** in their practice (94.8%).

Searching medicinal driving related risks through software was indicated by about half of the respondents in the ViaNova and USB group, while 75% of the Control group indicated never to have used that ($Chi^2 = 6.303$; p=.043). Searching such risks **via Internet** was done far less frequently in all groups (more than 3/4th).

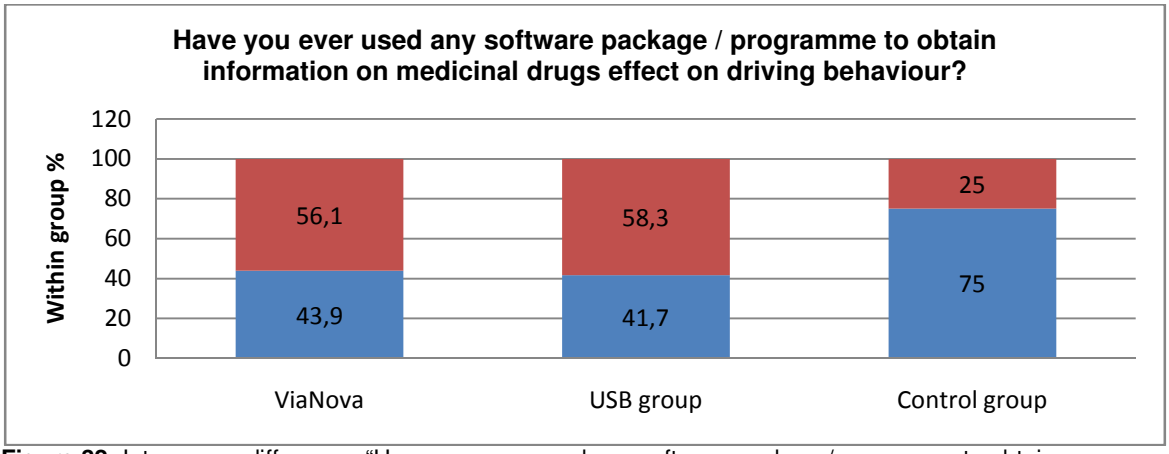


Figure 32: Inter-group difference: "Have you ever used any software package/programme to obtain information on medicinal drugs effects on driving behaviour?". (within-group %)

The mentioned software packages for obtaining medicinal driving related risks, included just the ViaNova software (+ 1 Omegasoft) for the ViaNova group, while the other groups referred to national pharmaceutical organisations (BCFI, APB), scientific databases (Delphi care, Sofie (Farm@doc)), software tools/providers (Omegasoft, Pharmawin (Omegasoft), Aegate, Farmad twin, Officinall, or websites (www.geneesmiddeleninhetverkeer.nl).

In each group the use of medical/clinical software for daily practice was well established (>90%). Mentioned packages/programmes were, besides mainly ViaNova in de ViaNova group (in order of frequency): Delphi (care), Farmad (Twin), Corilus, pharmawin, Officinall, Internet / Google, BCFI, aegate, Corilus, Sofie, RIZIV, website beroepsvereniging KLAV, APB, Pletmedicatel Escapo, Kinget & vragen, Phenix, Sabco new.

3.3.2 Sources for medicinal driving risk information

Some questions asked the pharmacists if they had easy access to information or data about the possible effect of medicines on driving abilities, and if so, which type of source they consulted.

More than 70% of the pharmacists in every group declared to have easy **access to information** or data. None of the pharmacists indicated to have followed any **postgraduate education** including effects of medicines on driving skills.

Table 53: Access to information (within-group %)

		Pharmacist groups (within-group %)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
I have easy access to data and information about a medicine's effect on driving skills.	no	17.9	25	30	21.2
	yes	82.1	75	70	78.8
Did you get any postgraduate education on medicinal effects on driving skills?	no	100	100	100	100
	yes	0	0	0	0

The most consulted information and data **sources** were professional websites (45% of the total group), followed by scientific journals (39%). ViaNova participants (35.3%) seemed to consult professional websites significantly less than the USB (75%) and Control group (60%). Furthermore, 30% of the Control group enquired newsletters, which is much more than ViaNova participants (4.4%).

Table 54: Source type (within-group %)

Source type crossed:	Pharmacist groups (within-group %)			Within total group %
	ViaNova N=68	USB N=12	Control N=20	
Professional websites *	**35.3***	75	60	45
Newsletters *	**4.4***	16.7	**30***	11
Organisations in road safety	0	0	0	0
Organisations in my profession	14.7	16.7	30	18
Scientific journals	32.4	58.3	50	39

* Pearson Chi-Square p≤.05; Fisher's Exact Test p≤.05

Other mentioned sources were: pharmacist software (e.g. ViaNova, Delphi), GIT texts, Informatorium Medicamentorum, Internet, BCFI, databases on professional websites, and the package leaflet.

3.3.3 Attitudes and awareness

There were **no significant inter-group differences with regard to attitudes and awareness** on (the relevance of considering) medicinal risks for driving. Overall, the participating **pharmacists already generally had rather positive attitudes** towards this topic at baseline level (composite score indicates that 91% of the whole group agrees or strongly agrees with the statements; looking at the individual statements more than 3/4th of whole sample (strongly) agreed with 4 of the 5 statements); only their feeling of being well aware of medicinal risk effects was more differentiated (54% (strongly) disagreeing). 99% of all participants even indicated that it is very important to be informed on this topic. These results indicate a lack of and need for information.

Table 55: Attitudes and awareness (within-group %)

		Pharmacist groups (within-group %)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	strongly disagree	1.5	0	0	1
	disagree	27.3	16.7	20	24.5
	agree	66.7	75	80	70.4
	strongly agree	4.5	8.3	0	4.1
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	strongly disagree	0	0	0	0
	disagree	19.7	0	25	18.4
	agree	75.8	100	70	77.6
	strongly agree	4.5	0	5	4.1
I feel being well aware of the effects of medicines on driving skills.	strongly disagree	5.9	0	0	4
	disagree	45.6	66.7	55	50
	agree	47.1	33.3	45	45
	strongly agree	1.5	0	0	1
It is important for me to be well-informed on medicinal effects on driving behaviour (trend)	strongly disagree	0	0	0	0
	disagree	0	8.3	0	1
	agree	66.2	50	57.9	62.6
	strongly agree	33.8	41.7	42.1	36.4
I feel that the	strongly disagree	0	0	0	0

information I provide to patients will influence their driving behaviour.	disagree agree strongly agree	20.6 73.5 5.9	25 66.7 8.3	20 70 10	21 72 7
Composite Score Attitudes and awareness (median)	strongly disagree (1) disagree (2) agree (3) strongly agree (4)	0 10.3 86.8 2.90	0 8.3 91.7 0	0 5 90 5	0 9 88 3

* Kruskal Wallis ANOVA by Ranks p≤.05

With regard to the question whether they would take medicinal driving risks more into account **in** function of the **type of patient-driver**, the vast majority (more than 90%) said they do in case a patient is using other CNS active medicines or is a professional driver; also high numbers of pharmacists (more than 80%) said they do when patients drive frequently or long distances. A further 79.4% of the total group would take it more into account for elderly drivers. Lower relevance was found for inexperienced (66%) and especially for experienced (41%) drivers. The three groups did not differ with regard to this matter.

Table 56: Detail attitudes & awareness: Take into account possible effects of medicines on driving skills depending on the type of driver (within-group %)

I am willing to take into account the effects of medicines on driving skills when dispensing medicines: **Would you consider this of more concern if your patient is: (YES)**	**Pharmacist groups (within-group %)**			**Within total group %**
	ViaNova N=68	**USB N=12**	**Control N=20**	
Professional driver	94	91.7	95	93.9
Driving frequently	84.6	91.7	95	87.6
Driving long distances	89.4	91.7	90	89.8
Inexperienced driver	63.5	66.7	75	66.3
Experienced driver	41.3	33.3	45	41.1
Elderly driver	80	75	80	79.4
Using other CNS active drugs	95.5	100	90	94.9

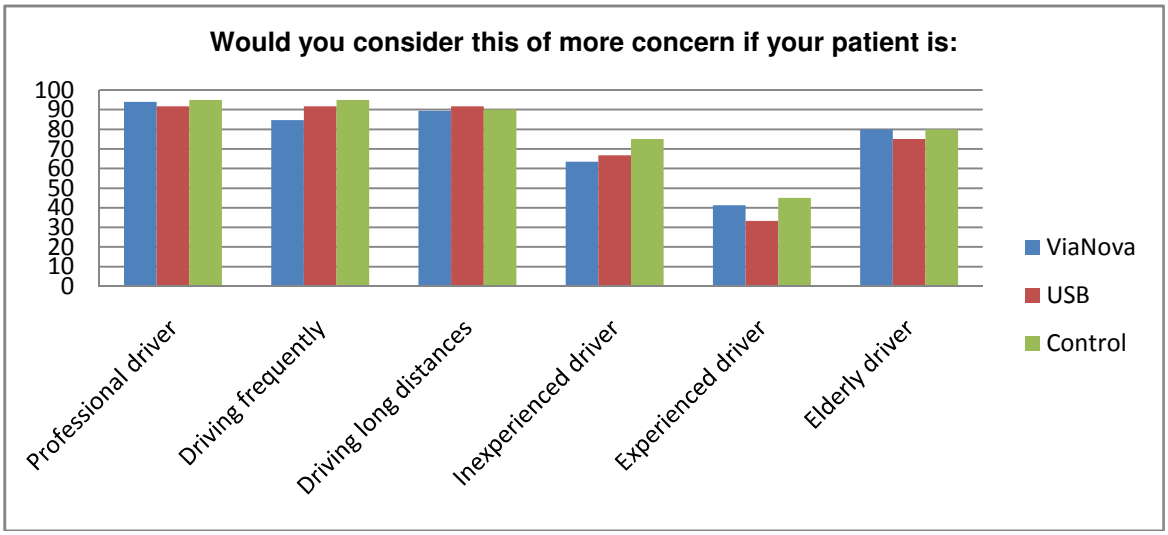


Figure 33: Inter-group difference: Take into account possible effects of medicines on driving skills depending on the type of driver (within-group %)

3.3.4 Reported behaviour

Overall, the frequencies of 'wanted' reported behaviour were rather low at baseline level (composite score: 61% answers seldom or never to the statements). Most frequently reported behaviour dealt with informing patients about driving related risks (91% did this at least sometimes); on the opposite, keeping any kind of record related to driving was a very rare event (most say never). Asking about driving exposure, discussing responsibility issues and providing detailed risk information was mostly reported to take place seldom to sometimes.

The groups differed significantly on two of the 'reported behaviour' statements (Kruskal Wallis; LSD). The **USB and Control group indicated significantly less often than the ViaNova group to provide written information materials when dispensing a driving impairing medicine** (Chi^2 = 11,869; p=0.003); the clear majority (>80%) in the first groups said they never or seldom do this, while 45% of the ViaNova group stated they at least sometimes did this. Furthermore, **ViaNova participants indicated less often than the Control group that they kept record of a patient's traffic participation** (Chi-Square 7,126; p=.028); although the vast majority in all groups indicated never to do this, a slightly larger proportion in the Control group (35%) indicated to do this seldom/sometimes.

Table 57: Reported behaviour (within-group %)

		Pharmacist groups (within-group)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
I ask a patient about his/her driving exposure when dispensing a medicine.	never	16.2	16.7	10	15
	seldom	32.4	33.3	35	33
	sometimes	45.6	33.3	25	40
	regularly	5.9	16.7	30	12
	always	0	0	0	0
I inform a patient about driving related risks when dispensing a medicine.	never	0	0	0	0
	seldom	7.4	8.3	15	9
	sometimes	38.2	33.3	45	39
	regularly	47.1	58.3	35	46
	always	7.4	0	5	6
I provide a patient with written information materials when dispensing a driving impairing medicine. *	never	**19.1**	33.3	60	29
	seldom	**35.3**	50	20	34
	sometimes	**27.9**	16.7	15	24
	regularly	**17.6**	0	5	13
	always	**0**	0	0	0
I keep systematic records when I dispense a driving impairing medicine.	never	65.2	50	70	64.3
	seldom	18.2	25	20	19.4
	sometimes	7.6	25	5	9.2
	regularly	6.1	0	0	4.1
	always	3	0	5	3.1
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	never	70.6	41.7	65	66
	seldom	16.2	50	20	21
	sometimes	8.8	8.3	10	9
	regular	4.4	0	0	3
	always	0	0	5	1
I keep a record of the patient's traffic participation (e.g. how often he/she drives to	never	**89.7**	83.3	**65**	84
	seldom	**10.3**	8.3	**30**	14
	sometimes	**0**	8.3	**5**	2
	regularly	**0**	0	**0**	0

work). *	always	**0**	0	**0**	0
I discuss medicinal drug consumption and driving related responsibility issues with the patient.	never	13.2	0	10	11
	seldom	32.4	50	45	37
	sometimes	35.3	50	25	35
	regularly	19.1	0	20	17
	always	0	0	0	0
How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving performance?	never	5.9	0	10	6
	seldom	30.9	16.7	35	30
	sometimes	41.2	58.3	30	41
	regularly	20.6	25	15	20
	always	1.5	0	10	3
Composite Score Reported behaviour (median)	never (1)	13.2	8.3	20	14
	seldom (2)	48.5	41.6	45	47
	sometimes (3)	32.4	50	25	33
	regularly (4)	5.9	0	10	6
	always (5)	0	0	0	0

* Kruskal Wallis ANOVA by Ranks p≤.05

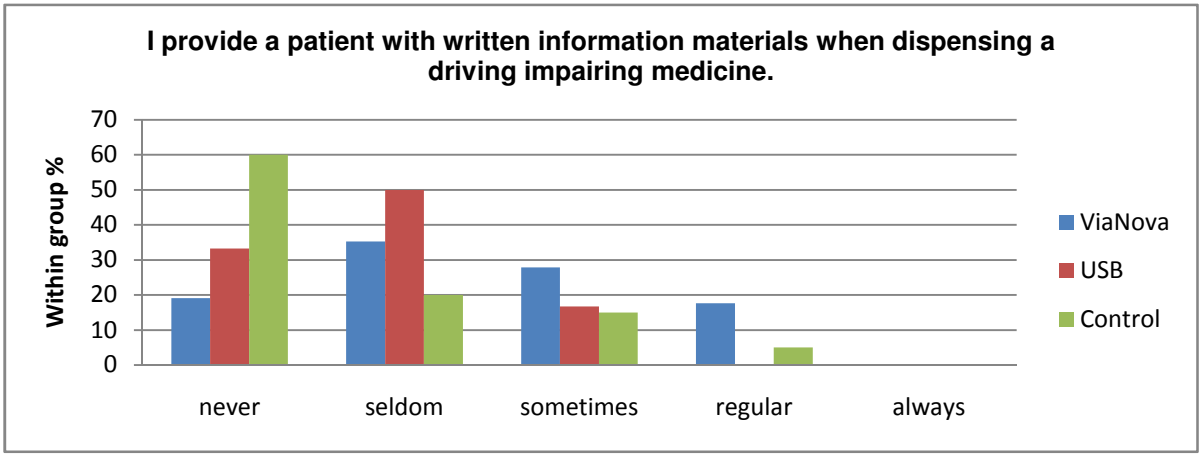


Figure 34: Inter-group difference: "I provide a patient with written information materials when dispensing a driving impairing medicine" (within-group %)

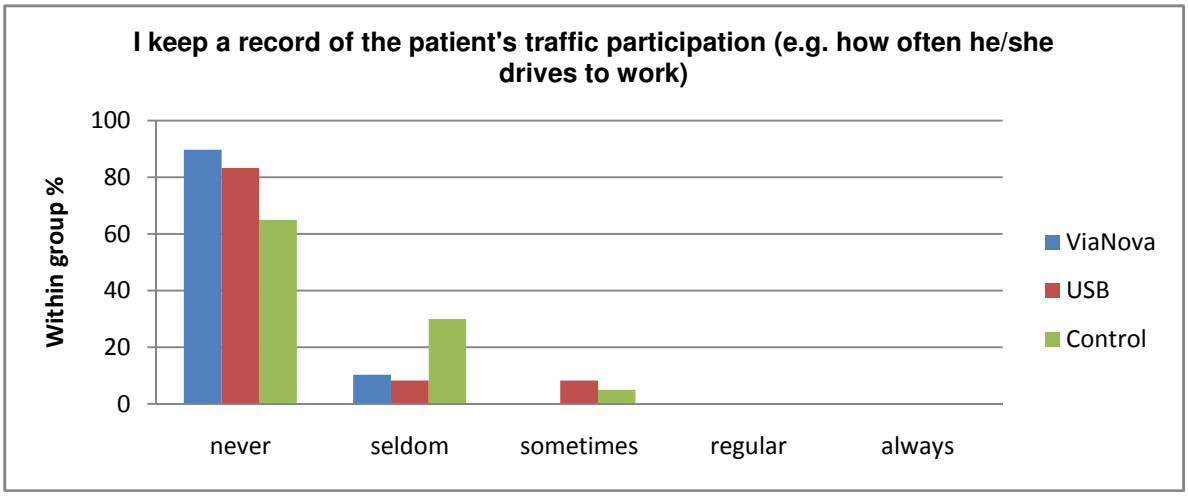


Figure 35: Inter-group difference: "I keep a record of the patient's traffic participation" (within-group %)

3.3.5 Knowledge

There were **no significant between-group differences at baseline level on knowledge of specific medicinal driving risks, and neither to related legal aspects and responsibilities**. The biggest respondent portion (75%) did not reach half of the total correct answers sum score with regard to individual medicine's risk.

In general, **increased proportions of participants in all groups answered incorrectly or failed to give any answer with regard to specific medicines' risks**: especially for Diazepam (wrong: almost 50%, and don't know: 1/3rd), Codeine (43% wrong – except for the Control group where most were correct), and Amitriptyline (most don't know). Only for the question on Fexofenadine most participants answered correctly, as well as – to a lesser extent – on Paroxetine.

They were generally more informed about legal obligations and responsibilities of physicians/pharmacists and patients.

Table 58: Knowledge (within-group %)

		Pharmacist groups (within-group %)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
Diazepam (regardless of dose) is severely Impairing within the first 2 months of treatment	disagree	46.3	41.7	65	49.5
	agree (correct)	16.4	33.3	10	17.2
	don't know	37.3	25	25	33.3
Codeine (up to 20 mg) is mostly safe for drivers	disagree	44.1	50	35	43
	agree (correct)	33.8	25	60	38
	don't know	22.1	25	5	19
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	64.6	60	60	63.2
	agree	10.80	0	10	9.5
	don't know	24.6	40	30	27.4
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	disagree (correct)	34.3	25	35	33.3
	agree	22.4	33.3	25	24.2
	don't know	43.3	41.7	40	42.4
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	26.5	16.7	20	24
	agree (correct)	38.2	50	45	41
	don't know	35.3	33.3	35	35
Composite Score - knowledge medicine risks (sum correct answers on 5)	0	10.3	8.3	5	9
	1	25	33.3	15	24
	2	41.2	33.3	50	42
	3	17.6	16.7	25	19
	4	5.9	8.3	5	6
	5	0	0	0	0
Pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	23.9	8.3	10	19.2
	true (correct)	76.1	91.7	90	80.8
A patient can be	false	27.7	25	25	26.8

punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	true (correct)	72.3	75	75	73.2
Composite Score – general knowledge (sum correct answers on 7)	0	4.4	0	0	3
	1	8.8	8.3	0	7
	2	13.2	16.7	10	13
	3	22.1	16.7	25	22
	4	35.3	41.7	45	38
	5	11.8	8.3	20	13
	6	4.4	8.3	0	4
	7	0	0	0	0

* Kruskal Wallis ANOVA by Ranks p≤.05

3.3.6 User-acceptance

Table 59: User-acceptance (within-group %)

		Pharmacist groups (within-group %)			Within total group %
		ViaNova N=68	USB N=12	Control N=20	
If we propose to you a tool (e.g. website, cd-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for dispensing medicines?	no	0	0	5	1
	yes	94.1	75	70	87
	Maybe	5.9	25	25	12

More than 90% of the ViaNova respondents and over 70% of the respondents from the USB and Control group stated that they were willing to use a tool to easily find information regarding medicinal drugs and driving.

About 25% were less eager to start using such a tool. The most frequent reasons for their hesitation can be linked to **fears about software user-friendliness**. Several pharmacists mentioned that the tool should be integrated, easy to use when dispensing, have no effect on computer processes (e.g. slowing down) and cost no extra time.

The respondents were asked about their preferred support tool. The possible options were website, integrated software, stand-alone software or other. More than 90% of the ViaNova and USB group respondents and 70% of the control group **first choice was software integrated** in their own software. **As main second choice came out a website, and thirdly, a manual**. 'Other' tools referred mostly to combinations (primarily: integrated software + manual or website, but also e.g. website + manual). **Stand-alone software (e.g. cd-rom or USB) seemed generally not to be a preferred tool.**

Table 60: Preference support tool (within-group %)

Which type of support tool would you prefer ?	Pharmacist groups (within-group %)			Within total group %
	ViaNova N=68	USB N=12	Control N=20	

First choice	Website	0	0	5	1
	Software integrated in your own software	94.1	91.7	70	89
	Stand alone software	0	0	0	0
	Manual	1.5	8.3	5	3
	Other	4.4	0	20	7
Second choice	**Website**	48.5	58.3	55	51
	Software integrated in your own software	1.5	0	5	2
	Stand alone software	8.8	16.7	15	11
	Manual	16.2	8.3	20	16
	Not filled	5.9	8.3	5	6
	Other	19.2	8.3	0	14
Third choice	Website	16.2	25	15	17
	Software integrated in your own software	0	0	5	1
	Stand alone software	29.4	25	30	29
	Manual	38.2	33.3	15	33
	Not filled	2.9	0	0	2
	Other	13.2	16.7	35	18

3.4 ViaNova group pre-post questionnaire comparison

There were several significant positive pre-post changes after the training/intervention phase of ViaNova participants: mainly on reported behaviour (7 of the 8 statements), then on knowledge related to detailed medicine risk (2 of the 7 questions) and on the one statement measuring awareness of medicinal effects on driving. The behaviour and knowledge composite scores increased significantly in the post-measurement.

3.4.1 Attitudes and awareness

Overall, little pre-post questionnaire change was found on attitudinal level: for all statements the majority remained at the same agreement level as in the pre-questionnaire (Composite score indicates a status-quo for 76.12% of respondents). In case of changes though, the positive change was bigger than the negative change on 4 of the 5 statements; with regard to the willingness to take into account medicinal risk effects when dispensing the proportion of strongly agreeing doubled, but the disagreeing part also increased. The fact that less striking changes were found here is also related to the already rather high pre-level agreement (most already agreed with the statements before the intervention).

There was **only one significant positive pre-post change** after the training/intervention phase of ViaNova participants, namely on **'I feel being well aware of the effects of medicines on driving skills'** (Z= -1.980; p=.048): 25.4% of the pharmacists changed their answer in the positive sense, although 63% remained at the initial agreement level. 8.1% of the pharmacists additionally agreed or strongly agreed to feel aware in the post-questionnaire; but, overall, a **quite high percentage (43.3%) still disagreed**.

While the portion of positively 'agreeing' ViaNova pharmacists was clearly highest for most attitudinal statements, this still remained less obvious for their feeling of awareness and their willingness to take medicinal driving risks into account when dispensing.

Table 61: ViaNova group pre-post questionnaire comparison – attitudes and awareness

ViaNova group pre-post questionnaire (within-group %)					
		Pre	**Post**	**Change**	**N**

I am willing to take into account the effects of medicines on driving skills when dispensing medicines	Strongly disagree	1.5	0	-1.5	65
	Disagree	27.3	32.8	5.5	
	Agree	66.7	58.2	-8.5	
	Strongly agree	4.5	9	4.5	
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	Strongly disagree	0	1.5	1.5	66
	Disagree	19.7	11.8	-7.9	
	Agree	75.8	80.9	5.1	
	Strongly agree	4.5	5.9	1.4	
I feel being well aware of the effects of medicines on driving skills. *	**Strongly disagree**	**5.9**	**0**	**-5.9**	**67**
	Disagree	**45.6**	**43.3**	**-2.3**	
	Agree	**47.1**	**52.2**	**5.1**	
	Strongly agree	**1.5**	**4.5**	**3**	
It is important for me to be well-informed on medicinal effects on driving behaviour.	Strongly disagree	0	1 5	1.5	68
	Disagree	0	0	0	
	Agree	66.2	57.4	-8.8	
	Strongly agree	33.8	41.2	7.4	
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	0	0	0	67
	Disagree	20.6	11.9	-8.7	
	Agree	73.5	77.6	4.1	
	Strongly agree	5.9	10.4	4.5	
Composite Score attitudes & awareness (median)	Strongly disagree (1)	0	0	0	68
	Disagree (2)	10.3	11.8	1.5	
	Agree (3)	86.8	83.9	-2.9	
	Strongly agree (4)	2.9	4.4	1.5	

* Wilcoxon Signed Ranks Test p≤.05

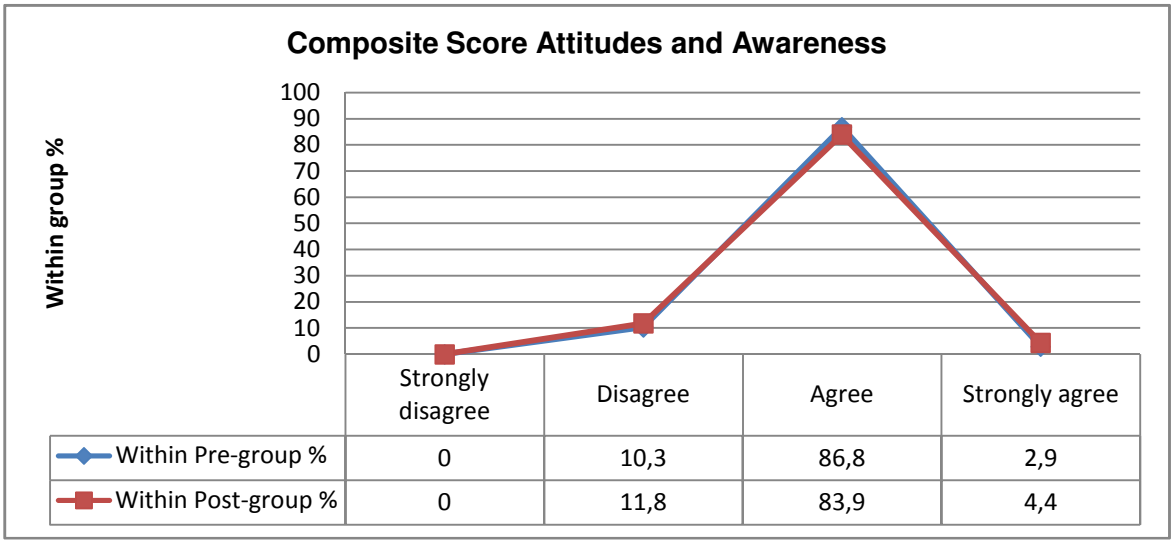


Figure 36: ViaNova group pre-post change – Composite Score attitudes & awareness (median) (within-group %)

With regard to the question whether **specific characteristics of driver-patients** would make a difference, the Wilcoxon test showed no significant changes (most status-quo answers) as compared to the baseline measurement that indicated already a rather high general concern for most groups. For the groups that initially were of a bit less concern in the pre-questionnaire (inexperienced and mainly experienced driver), there was an increase in concern up to almost 5%. the concern for elderly drivers also slightly increased.

Table 62: ViaNova group pre-post change –Detail attitudes & awareness: Take into account possible effects of medicines on driving skills depending on the type of driver (within-group %)

ViaNova group pre-post questionnaire (within-group %)			
I am willing to take into account the effects of medicines on driving skills when dispensing medicines: (YES)	**Pre**	**Post**	**Change**
professional driver	94.0	92.6	-1.4
driving frequently	84.6	85.3	0.7
driving long distances	89.4	88.2	-1.2
inexperienced driver	63.5	67.2	3.7
experienced driver	41.3	45.5	4.2
elderly driver	80.0	83.8	3.8
using other CNS active drugs	95.5	91.2	-4.3

3.4.2 Reported behaviour

There was a **significant positive change after the training and intervention phase of ViaNova participants on 7 of the 8 reported behaviour questions and on the behaviour composite score** (Z=-6.143; p<.001). When medication with impairing effects on driving was to be dispensed, significantly more pharmacists reported in the post-questionnaire to ask patients about their patients' driving experience (Z= -5,207; p<.001), to inform patients about the driving related risks (Z= -5.443; p<.001) and to discuss the medication consumption and driving related responsibilities (Z=-5.231; p<.001). After the intervention more pharmacists also indicated to provide more frequently detailed information on impairing effects of medication (Z= -5.733; p<.001), and to keep records when dispensing such medicines (Z= -4.611; p<.001), when giving advice to patients (Z= -5.198, p<.001), and about patients' traffic participation (Z= -3.589; p<.001).

Looking at the frequencies, it is clear that **for all reported (wished) behaviour questions there was a good increase of the proportion of pharmacists in the 'sometimes', 'regular' and 'always' answers**.

Table 63: ViaNova group pre-post change – reported behaviour

ViaNova group pre-post questionnaire (within-group %)							
	Within-group %	**Never**	**Seldom**	**Sometimes**	**Regularly**	**Always**	**N**
I ask a patient about his/her driving exposure when dispensing a medicine. *	**Pre**	13.1	32.1	46.4	7.1	1.2	68
	Post	4.4	11.8	39.7	39.7	4.4	
	Change	**-8.7**	**-20.3**	**-6.7**	**32.6**	**3.2**	
I inform a patient about driving related risks when dispensing a medicine. *	**Pre**	0	6	33.3	47.6	13.1	68
	Post	0	0	4.4	69.1	26.5	
	Change	**0**	**-6**	**-28.9**	**21.5**	**13.4**	
I provide a patient with written information materials when dispensing a driving impairing medicine.	**Pre**	19.1	35.3	27.9	17.6	0	68
	Post	16.2	32.4	38.2	11.8	1.5	
	Change	-2.9	-2.9	10.3	-5.8	1.5	
I keep systematic records when I dispense a driving impairing medicine. *	**Pre**	60.7	19	6	7.1	4.8	68
	Post	23.5	23.5	11.8	8.8	30.9	
	Change	**-37.2**	**4.5**	**5.8**	**1.7**	**26.1**	

I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine. *	**Pre**	64.3	14.3	13.1	6	2.4	67
	Post	25	17.6	26.5	11.8	17.6	
	Change	**-39.3**	**3.3**	**13.4**	**5.8**	**15.2**	
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work). *	**Pre**	89.3	9.5	1.2	0	0	68
	Post	66.2	20.6	8.8	2.9	1.5	
	Change	**-23.1**	**11.1**	**7.6**	**2.9**	**1.5**	
I discuss medicinal drug consumption and driving related responsibility issues with the patient. *	**Pre**	10.7	28.6	33.3	25	2.4	67
	Post	1.5	13.2	29.4	41.2	13.2	
	Change	**-9.2**	**-15.4**	**-3.9**	**16.2**	**10.8**	
How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving performance? *	**Pre**	4.8	25	44	20.2	6	68
	Post	0	5.9	25	50	19.1	
	Change	**-4.8**	**-19.1**	**-19**	**29.8**	**13.1**	
Composite Score Reported behaviour (median) *	**Pre**	13.2	48.5	32.4	5.9	0	68
	Post	1.5	10.3	48.5	32.3	7.3	
	Change	**-11.7**	**-38.2**	**16.1**	**26.4**	**7.3**	

* Wilcoxon Signed Ranks Test p≤.05

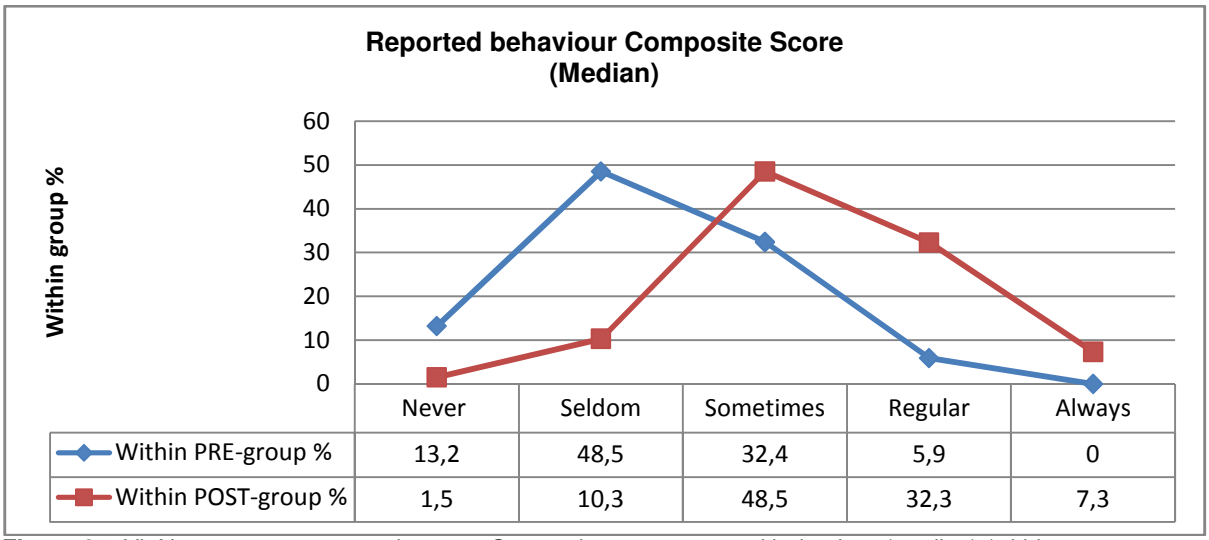


Figure 37: ViaNova group pre-post change – Composite score reported behaviour (median) (within-group %)

The proportion informing patients regularly or always about risks increased up to almost the maximum (95.6%). Furthermore, most group majority shifts were made from pre-level 'seldom to sometimes' answers to post-level 'sometimes to regular' level (asking about driving exposure, discussing responsibilities, frequency of detailed informing).
With regard to record keeping when dispensing risky medicines or when giving driving related advise, this seemed to be clearly more often done – up to even 30.9% saying they always do – but also still quite large portions indicated never or seldom to do this.
Although there was a change in the positive sense, still 86.8% of the pharmacists indicated never or seldom to note patients' traffic participation information.

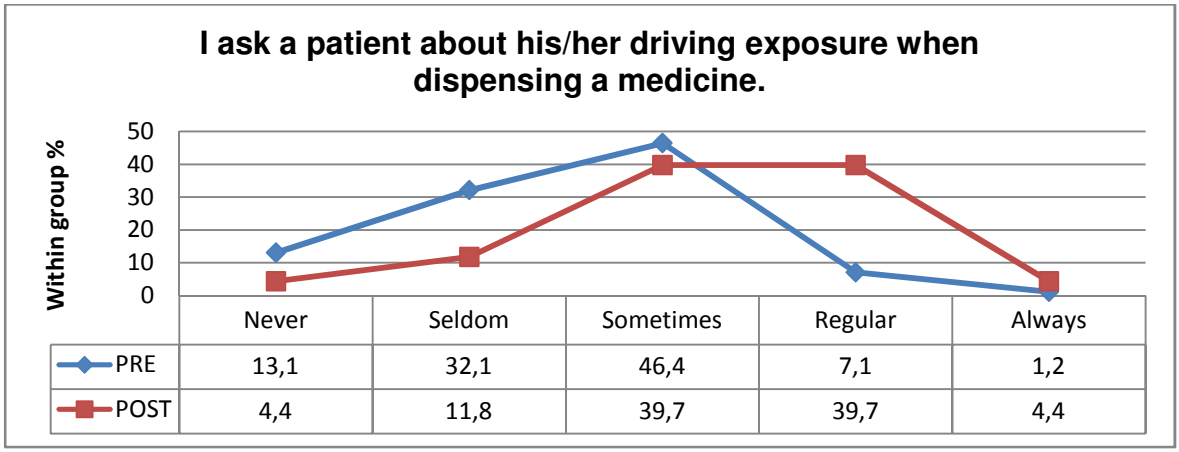


Figure 38: ViaNova group pre-post change –" I ask a patient about his/her driving exposure when dispensing a medicine" (within-group %)

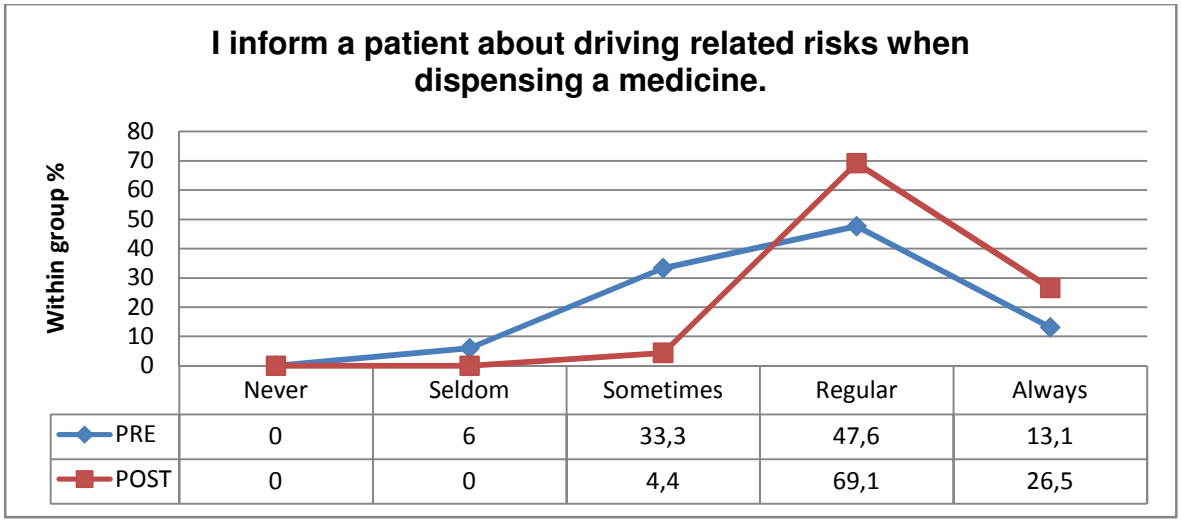


Figure 39: ViaNova group pre-post change – "I inform a patient about driving related risks when dispensing a medicine" (within-group %)

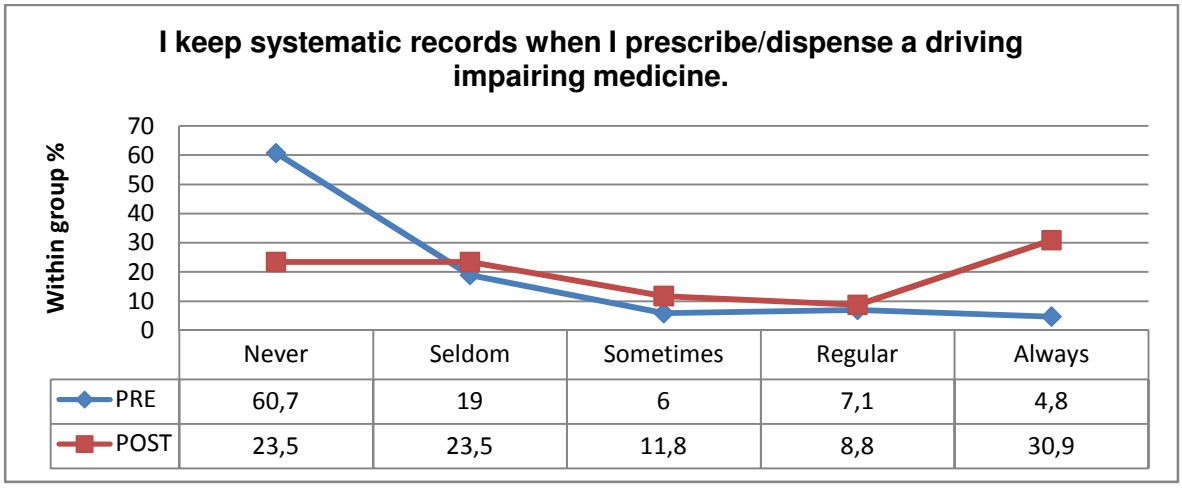


Figure 40: ViaNova group pre-post change – "I keep systematic records when I dispense a driving impairing medicine" (within-group %)

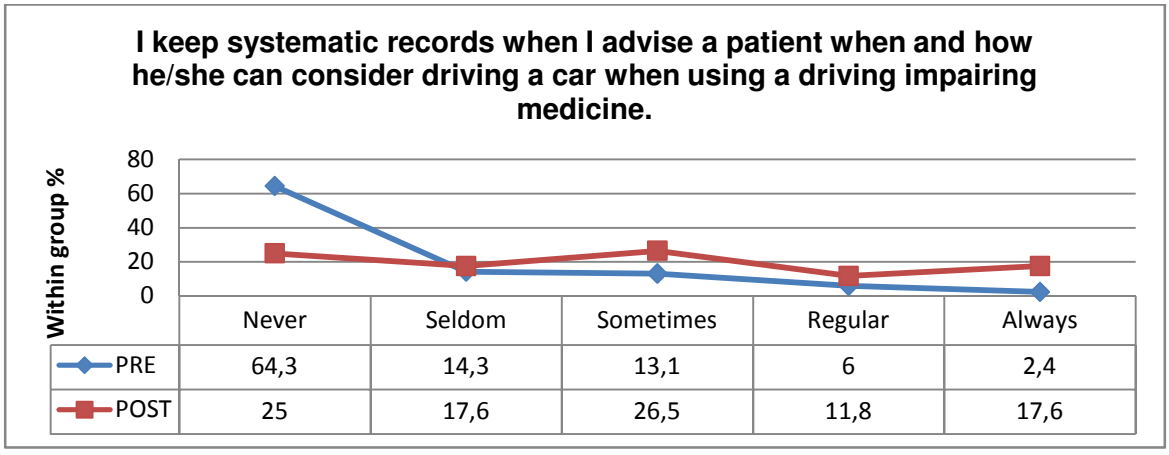


Figure 41: ViaNova group pre-post change – "I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine" (within-group %)

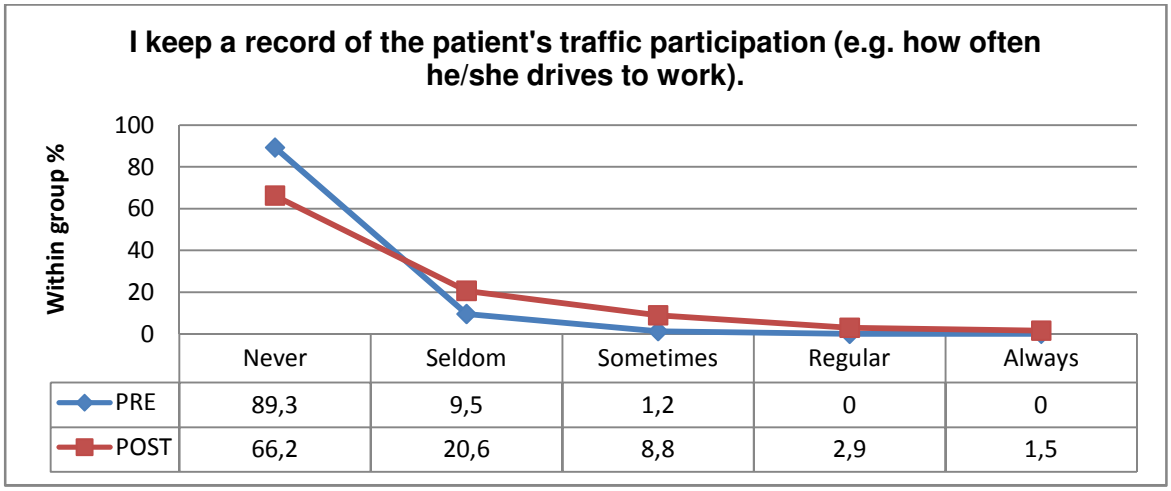


Figure 42: ViaNova group pre-post change – "I keep a record of the patient's traffic participation (e.g. how often he/she drives to work)" (within-group %)

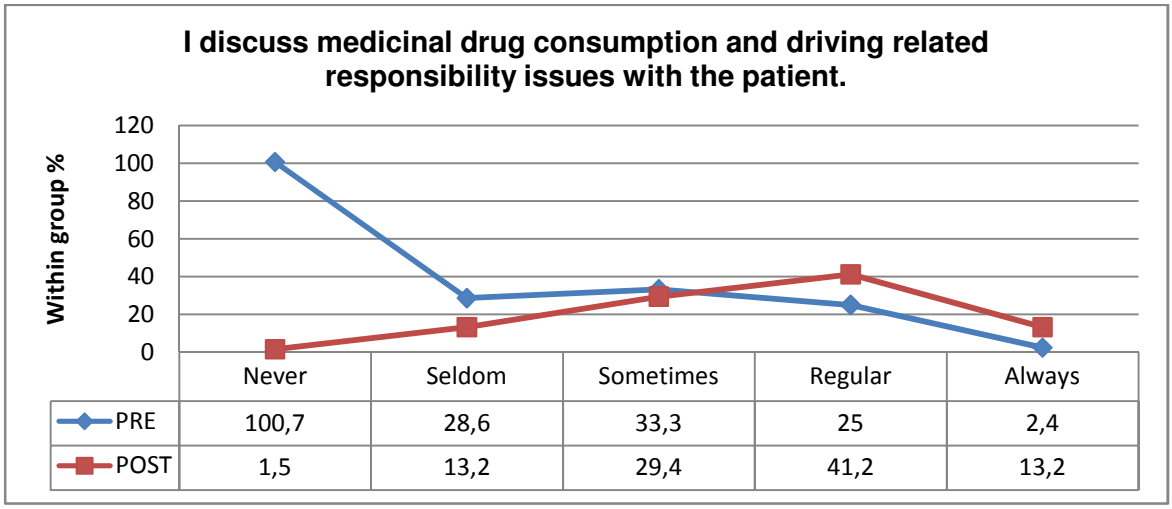


Figure 43: ViaNova group pre-post change –" I discuss medicinal drug consumption and driving related responsibility issues with the patient" (within-group %)

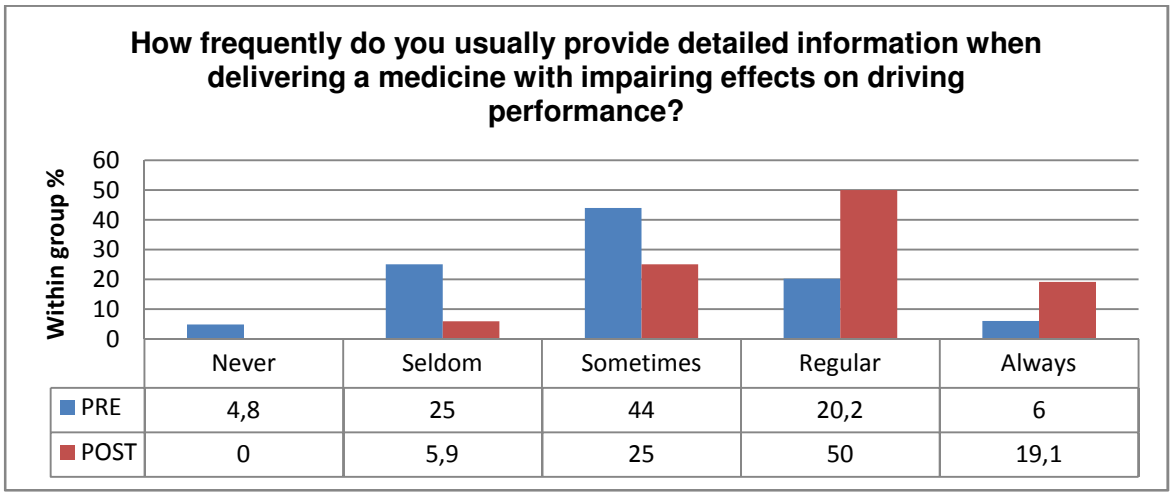


Figure 44: ViaNova group pre-post change – "How frequently do you usually provide detailed information when delivering a medicine with impairing effects on driving performance" (within-group %)

3.4.3 Knowledge

Significant positive changes (more correct answers) were found on two knowledge questions related to risk of individual medicines, **and on the composite scores** (on 5 – focussing on individual medicinal risks – and on 7 – total score –): **Diazepam** (Z= -2.200; p= .028) and **Amitriptyline** (Z= -2.744; p= .006). For both questions there were mainly fewer 'don't know' answers; this shift was actually also the case in all medicinal risk related questions. For the question on Diazepam though, still more than half of the pharmacists answered incorrectly in the post-questionnaire. With regard to the question on Amitryptiline almost 60% was correct afterwards.

There was also a trend pre-post positive change for the question on Codeine (Z= -1.859; p=.063): 33.8% of the ViaNova pharmacists gave more correct answers after the intervention, coming up to 50% of the group being correct.

Although the pre-post change direction was mainly as expected, except for the Paroxetine question (more incorrect post-answers), **the number of incorrect or don't know answers in the post-questionnaire remained overall quite high and for some questions even more than the majority**: Paroxetine (70%), Diazepam (67%), Codeine (50%), Amitriptyline (40%) and Fexofenadine (34%).

Table 64: ViaNova group pre-post change – Knowledge

		Pharmacist groups (within-group)			
		PRE	POST	PRE-POST difference	N
Diazepam (regardless of dose) is severely impairing within the first 2 months of treatment *	disagree	46.3	52.2	**5.9**	**66**
	agree (correct)	16.4	32.8	**16.4**	
	don't know	37.3	14.9	**-22.4**	
Codeine (up to 20 mg) is mostly safe for drivers (trend)	disagree	44.1	35.3	-8.8	68
	agree (correct)	33.8	50	16.2	
	don't know	22.1	14.7	-7.4	
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	64.6	66.2	1.6	68
	agree	10.8	10.3	-0.5	
	don't know	24.6	23.5	-1.1	
Amitriptyline at the	disagree (correct)	34.3	59.7	**25.4**	**66**

start of treatment is as impairing driving as after 4 weeks of treatment *	agree	22.4	28.4	**6**	
	don't know	43.3	11.9	**-31.4**	
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	26.5	41.8	15.3	67
	agree (correct)	38.2	29.9	-8.30	
	don't know	35.3	28.4	-6.9	
Composite Score - knowledge medicine risks (correct answers on 5) *	0	10.3	10.3	**0**	67
	1	25	20.6	**-4.4**	
	2	41.2	17.6	**-23.6**	
	3	17.6	27.9	**10.3**	
	4	5.9	20.6	**14.7**	
	5	0	2.9	**2.9**	
Pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	23.9	23.5	-0.4	67
	true (correct)	76.1	76.5	0.4	
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	27.7	15.6	-12.1	61
	true (correct)	72.3	84.40	12.1	
Composite Score – general knowledge (correct answers on 7) *	0	4.4	0	**-4.4**	66
	1	8.8	4.4	**-4.4**	
	2	13.2	13.2	**0**	
	3	22.1	23.5	**1.4**	
	4	35.3	20.6	**-14.7**	
	5	11.8	23.5	**11.7**	
	6	4.4	11.8	**7.4**	
	7	0	2.9	**2.9**	

* Wilcoxon Signed Ranks Testp≤.05

ViaNova pharmacists gave significantly more correct answers in the post-questionnaire as compared to the pre-questionnaire: with regard to specific medicines' risk level (t= -2.600; p=.011) (Z= -2.511; p=.012) as well as overall, including judicial obligations and responsibilities (t= -2.934; p= .005) (Z= -2.763; p= .006). **With regard to physician/pharmacist obligations and patient responsibilities knowledge the post-answers were more or less identical to the pre-answers, which were already predominantly correct.**

Table 65: ViaNova group pre-post change – Knowledge composite score

Knowledge Composite Scores (mean sum correct answers)			
	PRE	**POST**	**Change (mean)**
CS specific medicinal risks (sum on 5) - Mean (SD)*	1.84 (1.031)	2.37 (1.37)	0.53
CS overall Knowledge (sum on 7) - Mean (SD)*	3.28 (1.434)	3.93 (1.469)	0.65

* Paired samples t-test p≤0.05

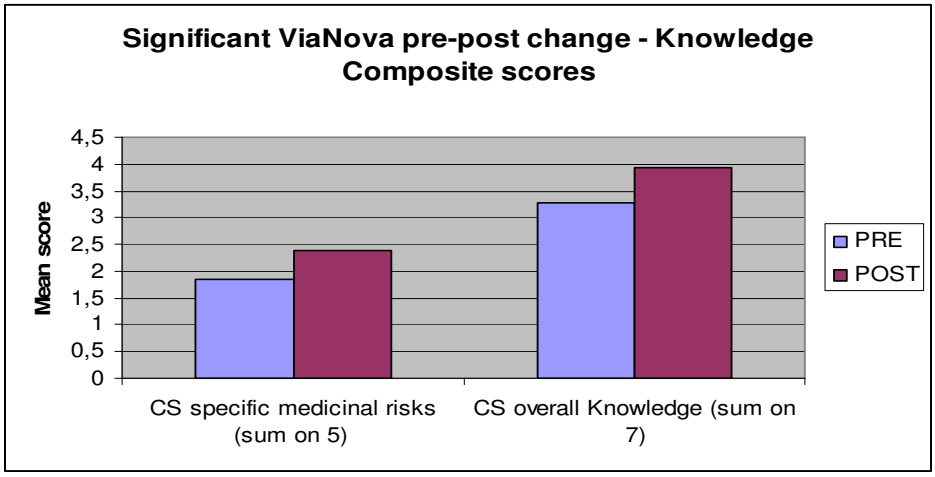
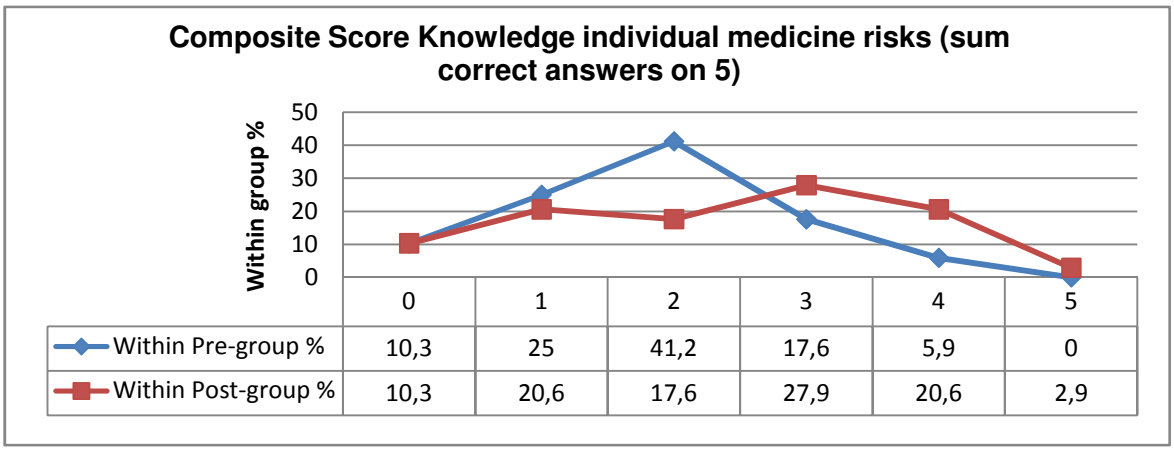
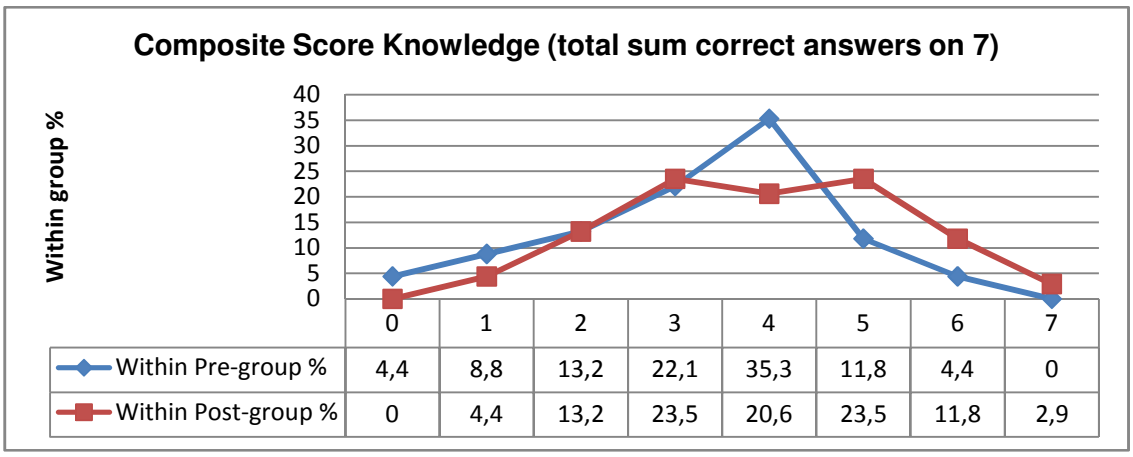


Figure 45: ViaNova group pre-post change – Knowledge Composite Scores (within-group %)



	0	1	2	3	4	5
Within Pre-group %	10,3	25	41,2	17,6	5,9	0
Within Post-group %	10,3	20,6	17,6	27,9	20,6	2,9

Figure 46: ViaNova group pre-post change – Composite Score individual medicine risks knowledge (median) (within-group %)



	0	1	2	3	4	5	6	7
Within Pre-group %	4,4	8,8	13,2	22,1	35,3	11,8	4,4	0
Within Post-group %	0	4,4	13,2	23,5	20,6	23,5	11,8	2,9

Figure 47: ViaNova group pre-post change – Composite score: Total knowledge (median) (within-group %).

3.5 USB group pre-post questionnaire comparison (N12)

There were two significant positive pre-post changes after the training/intervention phase of the USB participants: on one statement regarding reported behaviour ('I discuss medicinal drug consumption and driving related responsibility issues with the patient') and on one of the knowledge questions related to the risk of individual medicines (Amitriptyline question). There were no significant positive changes in the attitude and awareness questions.

3.5.1 Attitudes and awareness

There were **no significant changes** after the training and intervention phase of the USB group participants in the attitude and awareness questions.

The most pre-post positive effect was measured for the question 'I feel being well aware of the effects of medicines on driving skills': 25% changed their answer in the positive sense, however still 50% still disagreed with this statement, making this the only statement where a high number of USB group pharmacists disagreed on. **Except for the awareness statement, all attitudinal statements were generally positively self-assessed by the clear majority.**

The biggest part of the pharmacists (66% up to 91%) remained at the same level for all questions regarding attitudes and awareness. Generally there was little difference in the pre- versus post-condition on the level of awareness and attitude (Composite Score: 91.7% no change).

Table 66: USB group pre-post change – attitudes and awareness

USB group pre-post questionnaire (within-group %) (n=12)				
		Pre	**Post**	**Change**
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	Strongly disagree	0	0	0
	Disagree	16.7	8.3	-8.4
	Agree	75	91.7	16.7
	Strongly agree	8.3	0	-8.3
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	Strongly disagree	0	0	0
	Disagree	0	0	0
	Agree	100	91.7	-8.3
	Strongly agree	0	8.3	8.3
I feel being well aware of the effects of medicines on driving skills.	Strongly disagree	0	0	0
	Disagree	66.7	50	-16.7
	Agree	33.3	50	16.7
	Strongly agree	0	0	0
It is important for me to be well-informed on medicinal effects on driving behaviour.	Strongly disagree	0	0	0
	Disagree	8.3	0	-8.3
	Agree	50	50	0
	Strongly agree	41.7	50	8.3
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	0	0	0
	Disagree	25	16.7	-8.3
	Agree	66.7	75	8.3
	Strongly agree	8.3	8.3	0
Composite Score attitudes & awareness (median)	Strongly disagree (1)	0	0	0
	Disagree (2)	8.3	0	-8.3
	Agree (3)	91.7	100	8.3
	Strongly agree (4)	0	0	0

With regard to the question whether specific traffic participation relevant characteristics of patients would make a difference in considering effects of medicines on driving skills, no

significant changes compared to the baseline measurement were found. The rather negative pre-post changes in the within-group frequency (%) the table below should not be interpreted as less concern for specific driver-patient characteristics, but rather should be seen against the scope of the general question whether they would be willing to take medicinal effects on driving into account when dispensing, which increased (from 75%) up to 91.3% of the total USB group agreeing with this (so regardless of the type of patient).

Table 67: USB group pre-post change – Detail attitudes & awareness: Take into account possible effects of medicines on driving skills depending on the type of driver (within-group %)

USB group pre-post questionnaire (within-group %) (n=12)			
I am willing to take into account the effects of medicines on driving skills when dispensing medicines: (YES)	**Pre**	**Post**	**Change**
professional driver	91.7	91.7	0
driving frequently	91.7	75	-16.7
driving long distances	91.7	90.9	-0.8
inexperienced driver	66.7	58.3	-8.4
experienced'driver	33.3	36.4	3.1
elderly driver	75	66.7	-8.3
using other CNS active drugs	100	83.3	-16.7

3.5.2 Reported behaviour

One significant positive change after the training and the intervention phase of the USB group participants was found within the reported behaviour questions**:** 50% of the pharmacists changed their answer in a positive sense on the question whether they **discuss medicinal drug consumption and driving related responsibility issues with the patient** (Z= -2.333; p=.02). This is now stated to be done at least sometimes (50%) to regularly (25%), while at pre-level this was 50-50% seldom-sometimes.

Table 68: USB pre-post change – Reported behaviour

USB group pre-post questionnaire (within-group %) (n=12)						
	Within-group %	**Never**	**Seldom**	**Sometimes**	**Regularly**	**Always**
I ask a patient about his/her driving exposure when dispensing a medicine.	Pre	16.7	33.3	33.3	16.7	0
	Post	0	25	50	25	0
	Change	-16.7	-8.3	16.7	8.3	0
I inform a patient about driving related risks when dispensing a medicine.	Pre	0	8.3	33.3	58.3	0
	Post	0	16.7	8.3	75	0
	Change	0	8.4	-25	16.7	0
I provide a patient with written information materials when dispensing a driving impairing medicine.	Pre	33.3	50	16.7	0	0
	Post	33.3	41.7	16.7	8.3	0
	Change	0	-8.3	0	8.3	0
I keep systematic records when I dispense a driving impairing medicine.	Pre	50	25	25	0	0
	Post	58.3	33.3	8.3	0	0
	Change	8.3	8.3	-16.7	0	0
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	Pre	41.7	50	8.3	0	0
	Post	41.7	41.7	16.7	0	0
	Change	0	-8.3	8.4	0	0
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	Pre	83.3	8.3	8.3	0	0
	Post	83.3	16.7	0	0	0
	Change	0	8.4	-8.3	0	0

I discuss medicinal drug consumption and driving related responsibility issues with the patient. *	**Pre** **Post** **Change**	**0** **0** **0**	**50** **16.7** **-33.3**	**50** **58.3** **8.3**	**0** **25** **25**	**0** **0** **0**
How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving performance?	Pre Post Change	0 0 0	16.7 25 8.3	58.3 50 -8.3	25 25 0	0 0 0
Composite Score Reported behaviour (median)	Pre Post Change	8.3 0 -8.3	41.6 33.4 -8.2	50 50 0	0 16.7 16.7	0 0 0

* Wilcoxon Signed Ranks Test p≤.05

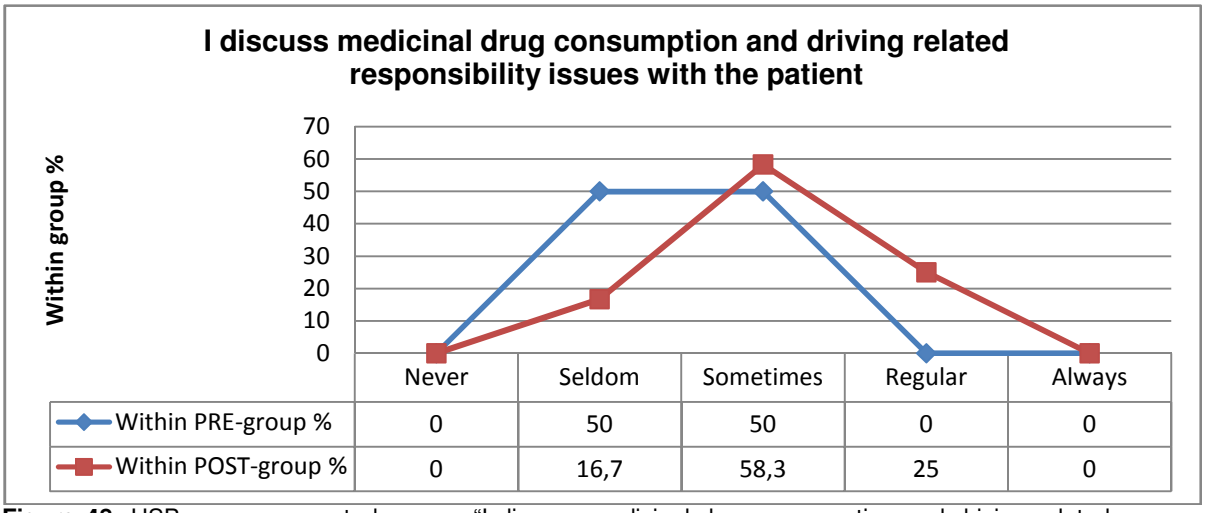


Figure 48: USB group pre-post change – "I discuss medicinal drug consumption and driving related responsibility issues with the patient" (within-group %)

Looking at the overall composite score the frequencies indicate a **clear pre-post increase of pharmacists in the USB group towards more regularly (wanted) reported behaviour; nevertheless the biggest portion remained at the 'sometimes' level, followed by 'seldom' answer categories.**

Clearly more often reported (from 'seldom' to 'regularly') behaviour statements were related to asking a patient about his/her driving exposure, informing a patient about driving related risks, discussing driving related responsibility issues, and frequency of providing detailed information. Rather seldom to never were the reports on providing written information materials and the (systematic) record keeping.

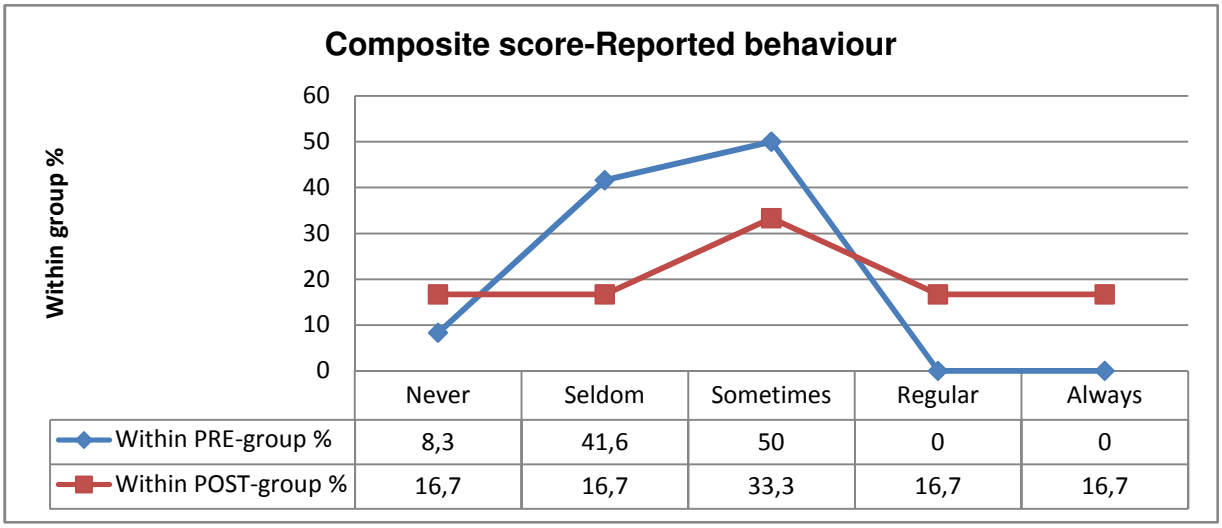


Figure 49: USB group pre-post change – Composite score Reported behaviour (median) (within group %)

3.5.3 Knowledge

One significant positive change (more correct answers) was found on the knowledge questions related to risk of individual medicines: **Amitriptyline** (Z=-2.00; p=.046). On this question there were fewer 'don't know' answers (-25%) and an increase of 33% answering correctly. Almost 60% (compared to 25%) answered correctly in the post-questionnaire.

Just on a descriptive level, some negative pre-post changes (less correct answers) were found: on the Diazepam and Paroxetine risk questions. Although this is not a significant change anyway, a possible explanation could be that the pharmacists were more aware about potential risks of medicines on driving after the training and intervention period, and thus more careful in their estimation of potential risk of medicines on the driving abilities. However, one of the most frequently searched for substance in the provided USB tool was Diazepam (see part on log file data), so more correct answers for this substance was expected though.

There was also another unexpected trend pre-post change for the question with regard to the health care obligations to inform patients on medicinal driving risks (Z=-1.732; p=.083): about 25% of the USB group participants gave more wrong answers after the intervention. On the other hand, an extra 16% of the pharmacist gave a correct answer regarding patient responsibilities after the intervention period.

Table 69: USB group pre-post change – Knowledge

		Pharmacist groups (within-group %)			
		Pre	Post	Change	N
Diazepam (regardless dose) is severely impairing within the first 2 months of treatment	disagree	41.7	33.3	-8.4	12
	agree (correct)	33.3	16.7	-16.6	
	don't know	25	50	25	
Codeine (up to 20 mg) is mostly safe for drivers	disagree	50	50	0	12
	agree (correct)	25	33.3	8	
	don't know	25	16.7	-8.3	
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	60	72.7	12.7	9
	agree	0	0	0	
	don't know	40	27.3	-12.7	
Amitriptyline at the start of	**disagree (correct)**	**25**	**58.3**	**33.3**	**12**
	agree	**33.3**	**25**	**-8.3**	

treatment is as impairing driving as after 4 weeks of treatment *	**don't know**	**41.7**	**16.7**	**-25**	
Paroxetine (up to 20 mg/day) is safe for drivers	disagree	16.7	41.7	25	12
	agree (correct)	50	25	-25	
	don't know	33.3	33.3	0	
Composite Score Knowledge individual medicine risks (sum correct answers on 5)	0	8.3	0	-8.3	12
	1	33.3	33.3	0	
	2	33.3	33.3	0	
	3	16.7	33.3	16.6	
	4	8.3	0	-8.3	
	5	0	0	0	
Pharmacists are obliged to inform the patients about the possible side-effects of his/her medications on driving abilities. (trend P=.083)	*false*	*8.3*	*33.3*	*25*	*12*
	true (correct)	*91.7*	*66.7*	*-25*	
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	25	8.3	-16.7	12
	true (correct)	75	91.7	16.7	
Composite Score Knowledge (total sum correct answers on 7)	0	0	0	0	12
	1	8.3	0	-8.3	
	2	16.7	16.7	0	
	3	16.7	33.3	16.6	
	4	41.7	25	-16.7	
	5	8.3	25.0	16.7	
	6	8.3	0	-8.3	
	7	0	0	0	

* Wilcoxon Signed Ranks Test p≤.05

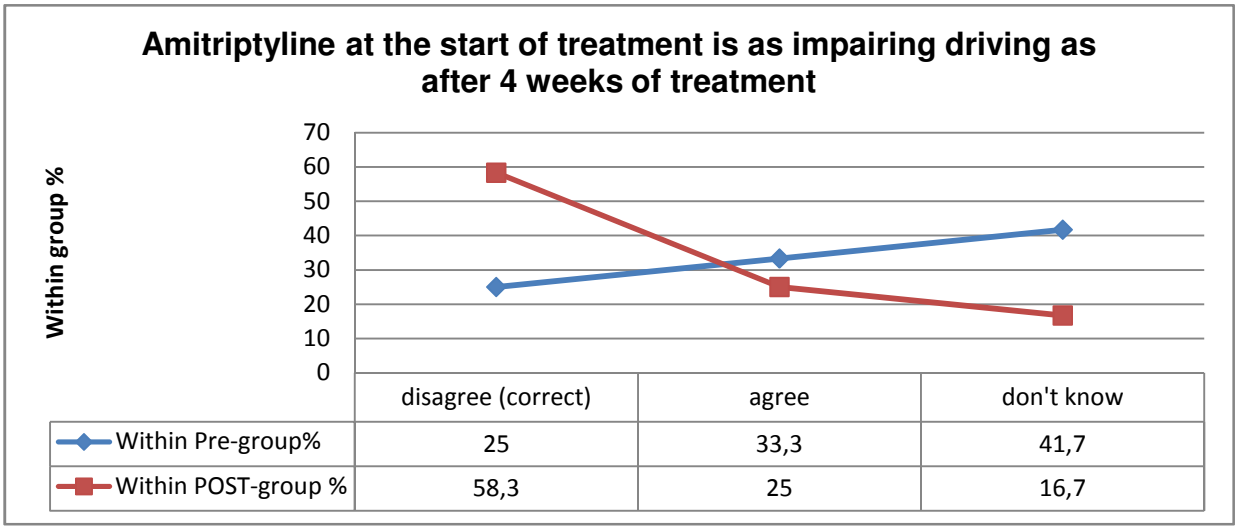


Figure 50: USB group pre-post change – "Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment" (within-group %)

Looking at the composite score on the knowledge questions related to risk of individual medicines, 66.6% of the pharmacists did not answer half of the questions correctly (score 1 or 2 on 5); 99.9% scored maximum 3 on 5. The overall composite score (sum on 7) shows that only 50% of the participants gave a correct answer on at least 4 of the 7 questions.

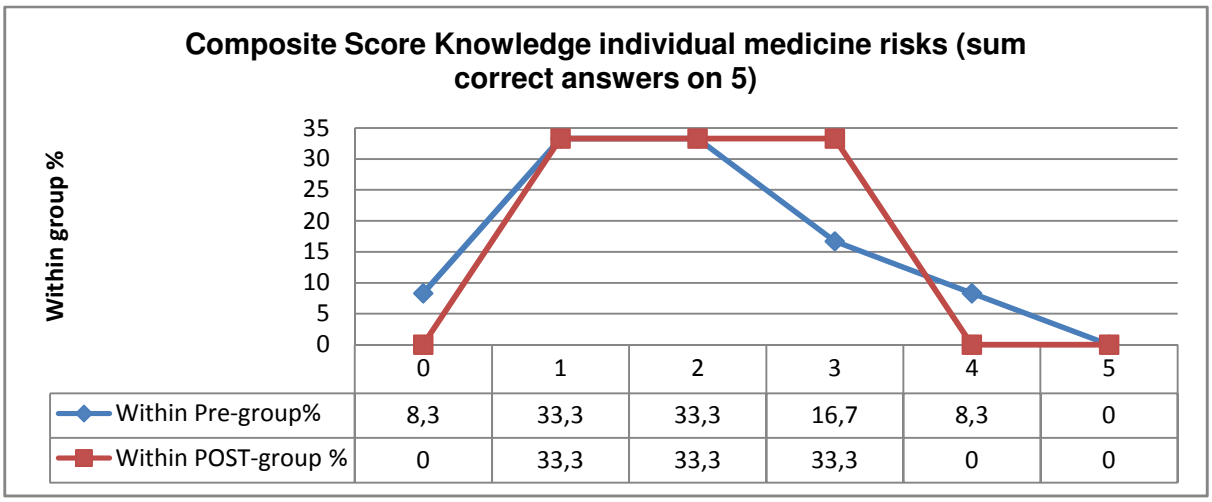


Figure 51: USB group pre-post change – Composite score on individual medicine risks knowledge (median) (within-group %)

3.6 Control group pre-post questionnaire comparison (N 20)

There were no significant pre-post changes on the awareness and attitudes, reported behaviour or knowledge questions for the pharmacists in the control group.

3.6.1 Attitudes and awareness

There were **no significant changes** on the awareness and attitudes questions for the pharmacists in the control group. The largest part of the pharmacists (65% up to 90%) remained at the same agreement level as in the pre-questionnaire, which is conform the expected results for the control group. Looking at the frequencies, the participants especially kept feeling less aware of the effects of medicines on driving skills; furthermore, still about a third answered less positively with regard to willingness to take into account the effects of medicines on driving skills or scarifying some degree of efficacy by dispensing a medicine that is less impairing.

Table 70: Control group pre-post change - Attitudes and awareness

Control group pre-post questionnaire (within-group %)					
		Pre	**Post**	**Change**	**N**
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	Strongly disagree	0	0	0	20
	Disagree	20	30	10	
	Agree	80	65	-15	
	Strongly agree	0	5	5	
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	Strongly disagree	0	5	5	20
	Disagree	25	25	0	
	Agree	70	60	-10	
	Strongly agree	5	10	5	
I feel being well aware of the effects of medicines on driving skills.	Strongly disagree	0	0	0	20
	Disagree	55	65	10	
	Agree	45	35	-10	
	Strongly agree	0	0	0	
It is important for me to be well-informed on medicinal effects on driving behaviour.	Strongly disagree	0	0	0	19
	Disagree	0	0	0	
	Agree	57.9	60	2.1	
	Strongly agree	42.1	40	-2.1	
I feel that the information I provide to patients will influence their driving behaviour.	Strongly disagree	0	0	0	20
	Disagree	20	15	-5	
	Agree	70	85	15	
	Strongly agree	10	0	-10	
Composite Score attitudes & awareness (median)	Strongly disagree (1)	0	0	0	20
	Disagree (2)	5	15	10	
	Agree (3)	90	85	-5	
	Strongly agree (4)	5	0	-5	

* Wilcoxon Signed Ranks Test p≤.05

With regard to the questions about the characteristics of the patient a small increase in willingness to take medicinal driving risks into account was observed in case of a patient being a professional driver, driving frequently or driving long distances (see table below). The vast majority of the pharmacists stayed at the same agreement level regarding all types of patient-drivers (generally at a high to very high willingness level, except for experienced drivers, only 44.4%).

Table 71: Control group pre-post change – Detail attitudes & awareness: Take into account possible effects of medicines on driving skills depending on the type of driver (within-group %)

Control group pre-post questionnaire (within-group %) (n=20)			
I am willing to take into account the effects of medicines on driving skills when dispensing medicines: (YES)	**Pre**	**Post**	**Change**
professional driver	95	100	5
driving frequently	95	100	5
driving long distances	90	95	5
inexperienced driver	75	63.2	-11.8
experienced'driver	45	44.4	-0.6
elderly driver	80	72.2	-7.8
using other CNS active drugs	90	89.50	-0.5

Looking at the composite score on attitudes and awareness, it is clear that no big pre-post changes in answers of the participants in the control group was measured (see figure below).

3.6.2 Reported behaviour

There were **no significant changes** of the reported behaviour of the pharmacists in the control group. For the question **'I inform a patient about driving related risks when dispensing a medicine' a positive pre-post trend was observed** though (Wilcoxon Z=-1.941; p=.052). 40% of the pharmacists (8 of the 20 participants) changed their answer in the positive sense. In total, 20% of the pharmacists additionally answered to inform patients regularly or always (up to 60% in total now) about driving related risks when dispensing medicines compared to the pre-questionnaire (see Table 71). The positive change in answers could be (partially) explained by the fact that the pharmacists in the control group were inclined to give 'social acceptable answers' or gained some awareness for this topic by just being included in the study.

Table 72: Control group pre-post change – Reported behaviour

Control group pre-post questionnaire (within-group %) (n=20)						
	Within-group %	**Never**	**Seldom**	**Sometimes**	**Regular**	**Always**
I ask a patient about his/her driving exposure when dispensing a medicine.	**Pre**	10	35	25	30	0
	Post	10	25	40	20	5
	Change	0	-10	15	-10	5
I inform a patient about driving related risks when dispensing a medicine. (trend p=.052)	***Pre***	*0*	*15*	*45*	*35*	*5*
	Post	*0*	*10*	*30*	*45*	*15*
	Change	*0*	*-5*	*-15*	*10*	*10*
I provide a patient with written information materials when dispensing a driving impairing medicine.	**Pre**	60	20	15	5	0
	Post	40	35	20	5	0
	Change	-20	15	5	0	0
I keep systematic records when I dispense a driving impairing medicine.	**Pre**	70	20	5	0	5
	Post	75	15	0	5	5
	Change	5	-5	-5	5	0
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	**Pre**	65	20	10	0	5
	Post	55	35	0	10	0
	Change	-10	15	-10	10	-5
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	**Pre**	65	30	5	0	0
	Post	75	20	5	0	0
	Change	-10	10	0	0	0
I discuss medicinal drug consumption and driving related responsibility issues with the patient.	**Pre**	10	45	25	20	0
	Post	5	40	15	40	0
	Change	-5	-5	-10	20	0
How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving performance?	**Pre**	10	35	30	15	10
	Post	0	35	30	25	10
	Change	-10	0	0	10	0
Composite Score Reported	**Pre**	20	45	25	10	0

behaviour (median)	**Post**	15	50	25	10	0
	Change	-5	5	0	0	0

* Wilcoxon Signed Ranks Test p≤.05

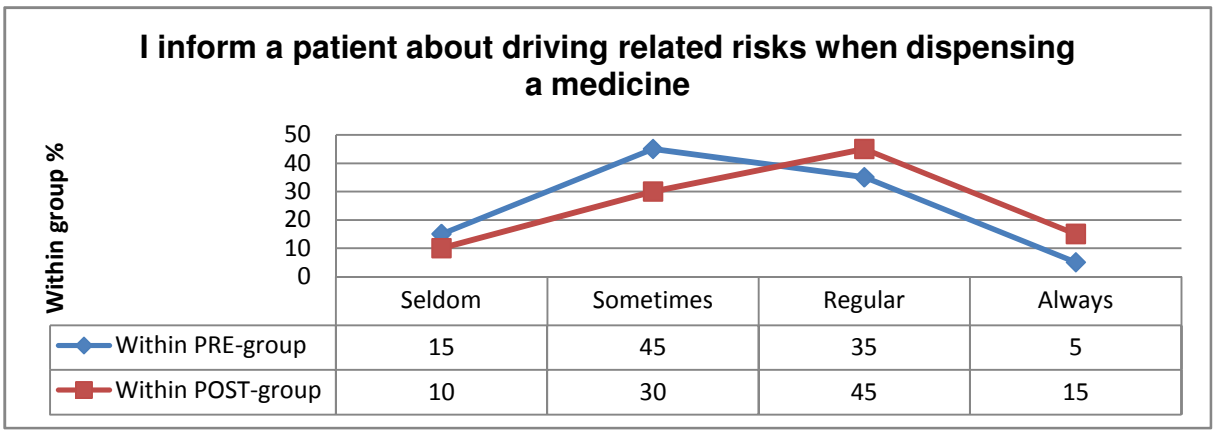


Figure 52: Control group pre-post change –" I inform a patient about driving related risks when dispensing a medicine" (trend)

Considering the composite score an almost equal number of pharmacists changed their answer in a positive or negative sense or did not change their answer (about 30).

3.6.3 _*Knowledge*

Also for the knowledge questions **no significant changes** were observed.

On the questions regarding Diazepam and Paroxetine additionally 25% of the pharmacists in the control group answered correctly compared to the pre-questionnaire. **For the Diazepam question even a positive pre-post trend was measured** (Z=-1.890; p=.059). **Overall the number of incorrect or don't know questions are quite high**. With regard to the questions on physician/pharmacists obligations and patient responsibilities, no big change was noticed.

Table 73: Control group pre-post change – Knowledge questions

		Pharmacist groups (within-group %) (n=19)		
		Pre	**Post**	**Change**
Diazepam (regardless of dose) is severely impairing within the first 2 months of treatment (trend p=.059)	disagree	65	38.9	-26.1
	agree (correct)	10	38.9	28.9
	don't know	25	22.2	-2.8
Codeine (up to 20 mg) is mostly safe for drivers	disagree	35	36.8	1.8
	agree (correct)	60	52.6	-7.4
	don't know	5	10.5	5.5
Fexofenadine (normal dose) is severely impairing driving	disagree (correct)	60	68.4	8.4
	agree	10	5.3	-4.7
	don't know	30	26.3	-3.7
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	disagree (correct)	35	47.4	12.4
	agree	25	21.1	-3.9
	don't know	40	31.6	-8.4
Paroxetine (up to 20 mg/day) is safe for	disagree	20	21.1	1.1
	agree (correct)	45	68.4	23.4

drivers	don't know	35	10.5	-24.5
Composite Score Knowledge individual medicine risks (sum correct answers on 5)	0	5	10.5	5.5
	1	15	10.5	-4.5
	2	50	15.8	-34.2
	3	25	31.6	6.6
	4	5	21.1	16.1
	5	0	10.5	10.5
Pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	false	10	10.5	0.5
	true (correct)	90	89.5	-0.5
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive	false	25	21.1	-3.9
	true (correct)	75	78.9	3.9
Composite Score Knowledge (total sum correct answers on 7)	0	0	0	0
	1	0	0	0
	2	10	15.8	5.8
	3	25	15.8	-9.2
	4	45	10.5	-34.5
	5	20	31.6	11.6
	6	0	21.1	21.1
	7	0	5.3	5.3

* Wilcoxon Signed Ranks Test p≤.05

3.7 ViaNova software extraction and user acceptance

Like explained above the information on medicines and driving was integrated in ViaNova. When an impairing substance is dispensed, ViaNova gave a warning sign in the form of a First dispensing Control signal (EUC) when the pharmacists wanted to deliver a medicine category 3 (not exclusively; sometimes category 2) or when a safer alternative existed. When going further in dispensing the impairing substance a first and second delivery accompaniment signal appeared. The first delivery accompaniment signal (**EUB signal**) included the information (concerning driving and medicines) to be told to the patient at a first delivery. The second delivery accompaniment signal **(TUB signal**) included the information and possible questions for conversation with the patient at a second delivery. Besides that, the pharmacists had the possibility to print out written information on the medicine for the patient (**GIT**). Finally a **pictogram** was integrated in the pop-up of the GIT in ViaNova.

3.7.1 EUB Signals

When the EUB signal appeared the pharmacist had several options to go further in dispensing a medicine: ‘continue’ (the signal will appear again later on); ‘wrong’ EUB signal, ‘GIT’ information for the patient’, ‘discussed’, ‘side-effects discussed’, ‘not discussed’ or ‘cancellation’ of delivery. In table 26 the registered EUB signals and the opted clicks are divided by medicinal risk category.

In general, **in about 89% of the popped-up EUB signals the option 'side-effects discussed' was clicked, and this for all risk categories of medicines (1 to 3).** There were no clear differences in click options used as a basis of the medicinal risk categories, except for a small effect regarding the provision of the GIT (patient information leaflet): a GIT was less given in case of risk category 1 (0.3%), as compared to risk category 2 (3.9%) or 3 (3.5%); and also a small effect regarding cancellation of the (medicine) delivery: more often for risk category 1 (1.2%).

Table 74: ViaNova group - EUB signals divided by risk category

EUB signals divided by risk category				
	Risk category 1 11.223 (12.8%)	**Risk category 2** 40.644 (46.5%)	**Risk category 3** 35.522 (40.6%)	**Total** 87.389 (100%)
Continue	858 (7.6%)	3,135 (7.7%)	2,713 (7.5%)	6,706 (7.6%)
GIT for patient	398 (0.3%)	1,589 (3.9%)	1,240 (3.5%)	3,227 (3.6%)
Wrong EUB signal	0	0	0	0
EUB discussed	9,883 (88.1%)	35,655 (87.7%)	31,278 (88.1%)	76,816 (87.9%)
EUB/side-effects discussed	**10,007 (89.3%)**	**36,327 (89.4%)**	**31,699 (89.2%)**	**78,033 (89.2%)**
EUB not discussed	0	0	0	0
Cancel delivery	143 (1.2%)	310 (0.8%)	295 (0.8%)	747 (0.8%)

60.5% of the EUB pop-ups considered 6 ATC categories: N02 Analgesics cat3 (17.9%), N05C Hypnotics and sedatives cat3 (11.2%), N05B Anxiolytics cat3 (10.5%), N02 Analgesics cat2 (7.3%), R05 Cough and cold preparations cat2 (6.9%), and N06A Antidepressants cat1 (6.8%).

Looking at the proportions of 'discussed' clicks as a basis of the ATC type, there were no clear differences for the relevant N02-N07, R01, R05-06 and S categories: on average in 90% (SD 3.3) of the cases (EUB pop-up), the pharmacists clicked the 'discussed' option (either specifically side-effects or in general), with a min/max of 85.8/100%.

3.7.2 TUB

In general, **in about 99% of the popped-up TUB signals the option 'discussed' was clicked, and this counted for the three risk categories of medicines (1 to 3).** There were no clear differences in the distribution of the different click options as a basis of the medicinal risk categories. The only options that were clicked after a TUB signal were either 'discussed (in general or specifically side-effects)' and 'GIT'.

Table 75: ViaNova group - TUB signals divided by risk category

TUB signals divided by risk category					
	Risk category 1 4747 (12.8%)	**Risk category 2** 14293 (38.6%)	**Risk category 3** 17610 (47.6%)	**Risk category 2/3** 351 (0.9%)	**Total** 37001 (100%)
Continue	0	0	0	0	0
GIT for patient	93 (1.6%)	272 (1.9%)	307 (1.7%)	6 (1.7%)	678 (1.8%)
Wrong TUB signal	0	0	0	0	0

TUB discussed	**4721 (99.5%)**	**14071 (98.4%)**	**17399 (98.8%)**	**345 (98.3%)**	**36536 (98.7%)**
TUB/side-effects discussed	997 (21.0%)	2751 (19.2%)	3311 (18.8%)	74 (21.1%)	7133 (19.3%)
TUB not discussed	0	0	0	0	0
Cancel delivery	0	0	0	0	0

3.7.3 EUC

The majority of the EUC signals were for medicines of risk category 3, which was expected. **About 96% of the EUC signals (risk category 2 or 3) where discussed with the patient**. A small minority cancelled the delivery (about 0.5%). No big differences were noticed in the way the EUC signal was handled between risk category 2 and risk category 3 medicines.

Table 76: ViaNova group - EUC signals divided by risk category

EUC signals divided by risk category			
	Risk category 2 25602 (38.2%)	**Risk category 3** 41447 (61.8%)	**Total** 67049 (100%)
Continue	762 (3%)	1475 (3.6%)	2237 (3.3%)
EUC discussed	**24703 (96.5%)**	**39688 (95.8%)**	**64391 (96%)**
Cancel delivery	137 (0.5%)	284 (0.7%)	421 (0.6%)

3.7.4 ViaNova group: user-acceptance

Table 77: ViaNova group post-questionnaire – User acceptance

		ViaNova group (within-group %) (n=68)		
		Guidelines	**Fact sheet**	**Pictogram**
Did you use … in order to support your communication to patients?	Yes	**95.60**	10.30	22.10
	No	4.40	**88.20**	**76.50**
If you answered 'Yes', how often did you use the …?	Always	**15.70**	0	14.30
	Regularly	**69.20**	28.60	50
	Sometimes	12.30	57.10	28.60
	Seldom	3.10	14.30	0
	Never	0	0	7.10
The … for dispensing medicines that may affect driving performance were: **helpful**	Yes, very much	**66.20**	2.90	16.20
	Quite a lot	**26.50**	19.10	14.70
	Not so much	1.50	10.30	5.90
	No way	0	0	1.50
	Unknown	5.90	67.60	61.80
The … for dispensing medicines that may affect driving performance were:	Yes, very much	**48.50**	4.40	16.20
	Quite a lot	**41.20**	14.70	17.60

useful	Not so much	5.90	16.20	4.40
	No way	0	0	1.50
	Unknown	4.40	64.70	60.30
The … for dispensing medicines that may affect driving performance were: **sufficient**	Yes, very much	**44.10**	5.90	13.20
	Quite a lot	**41.2**	14.70	19.10
	Not so much	1.50	11.80	4.40
	No way	0	0	1.50
	Unknown	13.20	67.70	61.80

95% of the ViaNova pharmacists indicate to have used the guidelines in their communication to the patients, of which 84% at least regularly. Those pharmacists who did not use the guidelines mentioned that they did not always find the time to use them in their communication to the patient. About **98% of the ViaNova participants found the dispensing guidelines helpful and also the clear majority (>80%) found them useful and sufficient**.

The fact sheets and pictogram were used much less. Only 10% of the participants indicated to have used the fact sheets. The pictogram was used a little bit more often (22%). Of the ones that have used the pictogram, almost 65% indicated to have done so at least regularly. The pictogram system was also rated higher ('yes very much') than the fact sheets on helpfulness (16.2%), usefulness (16.2%) and sufficiency (13.2%).

Table 78: ViaNova group post-questionnaire: Guidelines

		ViaNova group (within-group %) (n=68)
Do you think that the guidelines have changed your manner/way to dispense medication?	Yes, very much	5.90
	Quite a lot	**47.10**
	Neutral	32.40
	Not so much	8.80
	No way	1.50
	Unknown	4.40
Do you think that the guidelines have changed your manner/way to inform the patient?	Yes, very much	14.70
	Quite a lot	**45.60**
	Neutral	26.50
	Not so much	8.80
	No way	0
	Unknown	4.40

More than half of the ViaNova pharmacists stated that the guidelines have changed the manner they dispensed medication. 60% of the participants think that the provided guidelines changed quite a lot up to very much their way to inform a patient.

Table 79: ViaNova group post-questionnaire: ViaNova software User friendliness

		ViaNova group (within-group %) (n=68)
I was able to find the information I asked for with no difficulty.	Strongly disagree	0
	Disagree	0
	Agree	**67.7**
	Strongly agree	21.5
	Unknown	10.8
I thought the tool was cumbersome.	Strongly disagree	27.2
	Disagree	**58.5**
	Agree	1.5
	Strongly agree	0
	Unknown	12.3

This tool would fit well in my working routines.	Strongly disagree	0
	Disagree	0
	Agree	**61.5**
	Strongly agree	26.2
	Unknown	12.3
Text and icons are easy to perceive.	Strongly disagree	0
	Disagree	0
	Agree	**68.8**
	Strongly agree	18.8
	Unknown	12.5
Do you think that the tool should have additional options on the screen or are there any controls that are currently missing?	Yes	7.7
	No	**80**
	Unknown	12.3
Would you be willing to use this tool in the future	Yes	**80**
	No	1.5
	Maybe	1.5
	Unknown	16.9

About 90% of the pharmacists (strongly) agreed that they could find the information without difficulties, that the tool would fit well in their working routines (87.7%) and that the texts and icons were easy to perceive (87.6%). Five of the 68 pharmacists mentioned that the tool should have additional options like more thorough information on side-effects or less vague advice. **80% of the ViaNova pharmacists want to use the tool in the future.**

3.8 USB - log files and user acceptance

3.8.1 USB- Log files

Only limited data could be extracted from the USB tool. Only 'date' and 'hour' on which the pharmacists searched for a medicine (used the tool) and what the pharmacists typed in (the brand name or the generic name of the medicine, ATC code, partial brand or generic names...) were recorded and consequently extracted by the pharmacists in the format of a log file. The research team further completed the data by including a specific ATC code (e.g. N05BA01), a grouped ATC code (e.g. N05B-cat3), a category (1-3) and an ATC name (e.g. Anxiolytics-cat3).

The pharmacists that used the USB tool (N=12) made in total 527 searches (clicks) in the USB program between the time period 10th of September 2010 and 3th of March 2011 (a bit less than 6 months). The distribution of the amount/proportion of searches was not equally divided between the 12 pharmacists: **only two pharmacists were responsible for about 40% of the clicks** (see table 32). Taken all data together, only 1 click/search was made every four days (527 clicks on 180 days * N12).

The five medicines most frequently searched for were all of risk category 3: Tetrazepam (8%), Diazepam (6.2%), Lorazepam (6.2%), Alprazolam (5.1%) and Zolpidem (4.4%).

A risk category could be linked to 400 'clicks'. No category could be linked if:

- the medicine searched for was not in the database (only N-medicines were integrated into the USB tool) (102 searches)
- the medicine was not available in Belgium (11 searches)
- invalid entry in tool (e.g. pharmacists typed 'test') (7 searches)
- the letters entered in the tool were too short to identify a medicine (3 searches)
- if the pharmacist only searched on a grouped ATC code (2 searches)
- a typing error occurred (1 searches)
- entry of brand name with different ATC codes (1 searches)

Several pharmacists made typing errors when searching and using the USB tool (4.4%). The research team tried to link a category if possible (only for 1 case of the 23 no category could be matched to the medicine that was searched for). **About 70% of the pharmacists' searches concerned a category 3 medicine**. Sixty of the clicks of the 527 searches were made for an anxiolytics or aHypnotic/sedative.

Table 80: USB group - Description data log files (within-group %) (n=400)

Distribution by 'clicks'		**Distribution by risk category**	
Pharmacist 1	**19.0**	Category 1	9.8
Pharmacist 2	9.9	Category 2	17.0
Pharmacist 3	5.1	Category 3	**73.2**
Pharmacist 4	3.6	**Distribution by ATC group**	
Pharmacist 5	3.0	N02 – Anesthetics	2.3
Pharmacist 6	11.2	N03 – Anti-epileptics	2.3
Pharmacist 7	8.6	N05A – Antipsychotics	4.8
Pharmacist 8	4.4	**N05B – Anxiolytics**	**41.4**
Pharmacist 9	**22.0**	**N05C – Hypnotics &sedatives**	**21.2**
Pharmacist 10	9.0	**N06A – Antidepressants**	**26**.0
Pharmacist 11	3.8	N06B – Psychostimulants	1.0
Pharmacist 12	0.8	N06C – Psycholeptics/ psychanaleptics in combination	0.3
		N07B – Drugs used in addictive disorders	0.8

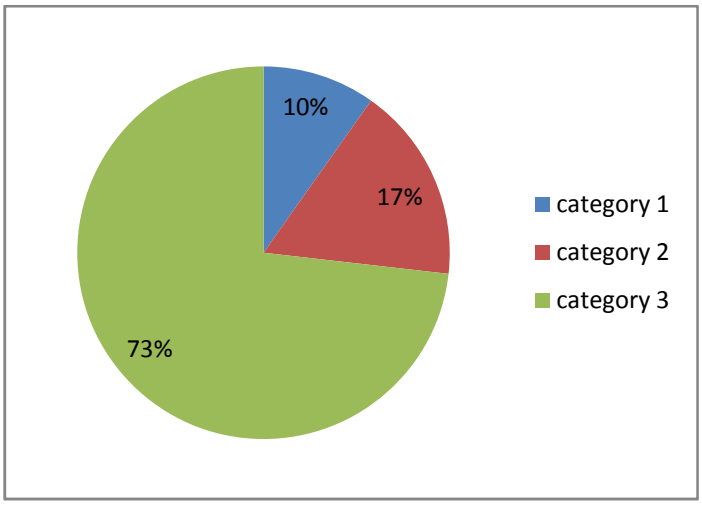


Figure 53: USB tool search distribution by medicinal risk category

3.8.2 USB group: user acceptance

Table 81: USB group post-questionnaire – User acceptance

		USB group (within-group %) (n=12)		
		Guidelines	**Fact sheet**	**Pictogram**
Did you use … in order to support your communication to patients?	**Yes**	**91.7**	33.3	41.7
	No	8.3	66.7	58.3
If you answered 'Yes', how	**Always**	8.3	40	20

often did you use the …?	**Regularly**	16.7	20	20
	Sometimes	25	0	40
	Seldom	50	40	20
	Never	0	0	0
The … for dispensing medicines that may affect driving performance were: **helpful**	**Yes, very much**	**50**	33.3	50
	Quite a lot	41.7	33.3	16.7
	Not so much	8.3	16.7	16.7
	No way	0	0	0
	Unknown	0	16.7	16.7
The … for dispensing medicines that may affect driving performance were: **useful**	**Yes, very much**	33.3	25	41.7
	Quite a lot	**50**	16.7	25
	Not so much	16.7	33.3	8.3
	No way	0	0	0
	Unknown	0	25	25
The … for dispensing medicines that may affect driving performance were: **sufficient**	**Yes, very much**	**41.7**	25	33.3
	Quite a lot	33.3	25	16.7
	Not so much	16.7	25	25
	No way	8.3	0	0
	Unknown	0	25	25

91% of the pharmacists in the USB group stated to have used the guidelines (but rather seldom). The pharmacists who mentioned not to have used them gave as reason the fact that the tool is: 'too time consuming, not easy to use and contained too vague information'. They stated that **they would have used the tool more often if it would have been integrated in their daily used software**. The provided guidelines are considered helpful, useful and sufficient by a clear majority; the fact sheets were considered helpful but less useful and sufficient; while the pictogram was considered helpful and useful (>50%) but slightly less sufficient.

Table 82: USB group post-questionnaire: Guidelines

		USB group (within-group %) (n=12)
Do you think that the guidelines have changed your manner/way to dispense medication?	Yes, very much	16.7
	Quite a lot	33.3
	Neutral	33.3
	Not so much	16.7
	No way	0
Do you think that the guidelines have changed your manner/way to inform the patient?	Yes, very much	8.3
	Quite a lot	**66.7**
	Neutral	8.3
	Not so much	16.7
	No way	0

Half of the pharmacists indicate that the guidelines have changed their manner of dispensing medication (other half is neutral or negative). **More than 70% thinks that the guidelines have changed their way of informing the patient**.

Table 83: USB group post-questionnaire: USB tool User friendliness

USB tool User friendliness		**USB group (within-group %) (n=12)**
I was able to find the information I asked for with no difficulty.	Strongly disagree Disagree Agree Strongly agree	8.3 16.7 **58.3** 16.7
I thought the USB stick was cumbersome.	Strongly disagree Disagree Agree Strongly agree	16.7 25.0 33.3 25.0
This USB-stick would fit well in my working routines.	Strongly disagree Disagree Agree Strongly agree	25.0 25.0 41.7 8.3
Text and icons are easy to perceive.	Strongly disagree Disagree Agree Strongly agree	0.0 8.3 **83.3** 8.3
Do you think that the USB- stick should have additional options on the screen or are there any controls that are currently missing?	Yes No	16.7 **83.3**
Would you be willing to use this USB stick in the future	Yes No Maybe Unknown	50.0 25.0 8.3 16.7

The **feelings of user-friendliness of the USB tool are rather mixed.** The USB group was only clear on the fact that text and icons are easy to perceive (>90%) and to a lesser extent that the information was easily found (74%). On the other hand, the proportions were rather mixed (50-50%) on the statements that the tool is cumbersome or would fit well in the working routines, as well as on the question if they would use the tool in the future.

The main reason for doubts about the tool fitting well in their daily routine was that it could not be integrated into their pharmacy software. Only one pharmacist found the text and icons not easy to perceive. Two pharmacists stated that there should be two additional options to the USB tool: **the possibility to search on brand names and the possibility to integrate the tool into the daily used software**. Four of the 12 pharmacists were explicitly not willing to use the USB tool in the future because there was no integration into their software and using the tool took too much time. On the question in which circumstances they would use the USB tool pharmacists answered that they would focus on first prescriptions.

3.8.3 Control group – User acceptance

Seventy percent of the participants in the control group still mentioned in the post-questionnaire to be willing to use a support tool in dispensing potentially risky medicines for driving (no change compared to pre-questionnaire). A small increase in 'maybe' (from 'no') answers was found.

Table 84: Control group pre-post change - User acceptance (Within-group %)

	Control group (within-group %) (n=20)

		Pre	Post	Change
If we propose to you a tool (e.g. website, cd-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for dispensing medicines?	no	5	0	-5
	yes	70	70	0
	Maybe	25	30	5

There were no big changes regarding the type of support tool they preferred.

4 Discussion

4.1 Main study results

Personal and practice related sample characteristics. From the analyses regarding sample characteristics it became clear that except for the number of inhabitants in the practice area (a measure of more rural versus more urban practice area) the three groups (ViaNova, USB and Control group) did not differ significantly regarding personal or practice related background variables. Furthermore there were no significant differences between participants and drop-outs in the USB and Control group with regard to personal/practice related background variables and ICT familiarity. The **ViaNova dropped-out group seemed to be relatively more often younger (below 30), with less practicing years and more often working in a rural setting**.

Pre-questionnaire. The three groups were quite similar with regard to pre-level ICT familiarity, attitudes, awareness, reported behaviour and knowledge. Some differences were found though with regard to ICT familiarity (1) and reported behaviour (2). A small difference related to familiarity with software to find medicinal risk information (less in the Control group). More differences were found though with regard to pre-level reported behaviour: the USB and Control group provided at base level already less often written information to patients compared to the ViaNova group, and ViaNova participants less often kept record of patients' traffic participation than Control group respondents. It can be stated that the participants in the present study (in all groups) had a **high general ICT familiarity** and indicated a **high access to information** (on the potential effect of medicines on driving). Despite the high access to information the participants did report a **lack and need for information,** and there seemed to be a **low knowledge on medicinal driving risk specifics**. The pharmacists had **positive attitudes** towards the importance of being well informed on the topic medicinal driving risks and on the potential role they can play in providing information on the potential risk of medicines to the patient. Contrary to the positive attitudes, **low frequencies of reported behaviour that considers medicinal driving risks'** were found prior to the training/intervention in all groups (61% answered 'seldom' to 'never' on the statements). With regard to user acceptance of possible dispensing support tools, more than **90% of the ViaNova respondents and over 70% of the respondents from the USB and Control group stated that they would be willing to use a dispensing support tool** to easily find information regarding medicinal drugs and driving. The most frequent reasons for any hesitation though was linked to fears about software user-friendliness (it should be integrated, easy to use, no effect on other computer processes and time-efficient). The **clear first choice tool was software integrated in the proper software**, second choice was a website, and third a manual; stand-alone software (like cd-rom or USB stick) seemed generally not to be preferred.

Pre-post questionnaire comparison. When comparing the three groups on the pre-post questionnaire changes of the composite scores on attitudes & awareness, reported behaviour and knowledge regarding medicinal driving risk, several conclusions can be drawn (see Table 85).

Table 85: Total group overview of pre-post changes: Composite scores

	Composite scores ViaNova group			Composite scores USB group			Composite scores Control group		
	Pre	**Post**	**Change**	**Pre**	**Post**	**Change**	**Pre**	**Post**	**Change**
Attitudes & awareness									
Strongly disagree	0	0	**0**	0	0	**0**	0	0	**0**
Disagree	10.3	11.8	**1.5**	8.3	0	**-8.3**	5	15	**10**
Agree	86.8	83.9	**-2.9**	91.7	100	**8.3**	90	85	**-5**
Strongly agree	2.9	4.4	**1.5**	0	0	**0**	5	0	**-5**
Reported behaviour									
Never	13.2	1.5	**-11.7***	8.3	0	**-8.3**	20	15	**-5**
Seldom	48.5	10.3	**-38.2***	41.6	33.4	**-8.2**	45	50	**5**
Sometimes	32.4	48.5	**16.1***	50	50	**0**	25	25	**0**
Regular	5.9	32.3	**26.4***	0	16.7	**16.7**	10	10	**0**
Always	0	7.3	**7.3***	0	0	**0**	0	0	**0**
Knowledge specific medicinal risks (sum on 5)									
0	10.3	10.3	**0***	8.3	0	**-8.3**	5	10.5	**5.5**
1	25	20.6	**-4.4***	33.3	33.3	**0**	15	10.5	**-4.5**
2	41.2	17.6	**-23.6***	33.3	33.3	**0**	50	15.8	**-34.2**
3	17.6	27.9	**10.3***	16.7	33.3	**16.6**	25	31.6	**6.6**
4	5.9	20.6	**14.7***	8.3	0	**-8.3**	5	21.1	**16.1**
5	0	2.9	**2.9***	0	0	**0**	0	10.5	**10.5**
Knowledge general (sum on 7)									
0	4.4	0	**-4.4***	0	0	**0**	0	0	**0**
1	8.8	4.4	**-4.4***	8.3	0	**-8.3**	0	0	**0**
2	13.2	13.2	**0***	16.7	16.7	**0**	10	15.8	**5.8**
3	22.1	23.5	**1.4***	16.7	33.3	**16.6**	25	15.8	**-9.2**
4	35.3	20.6	**-14.7***	41.7	25	**-16.7**	45	10.5	**-34.5**
5	11.8	23.5	**11.7***	8.3	25.0	**16.7**	20	31.6	**11.6**
6	4.4	11.8	**7.4***	8.3	0	**-8.3**	0	21.1	**21.1**
7	0	2.9	**2.9***	0	0	**0**	0	5.3	**5.3**

Significant pre-post changes at composite score level were only found in the ViaNova group: this group significantly increased in reported medicinal risk considering behaviour and in medicinal risk specific knowledge level. Furthermore, the **ViaNova group had in total 10 significant positive changes (on a total of 20 statements/questions), compared to just 2 in the USB group and none in the Control group as expected.**

Table 86: Total group overview of number of significant pre-post questionnaire changes: individual statements/questions

Number of significant pre-post changes				
		Pharmacist group		
	Total statements / questions	**ViaNova N=68**	**USB N=12**	**Control N=20**
Attitudes & awareness	**5**	1	0	0
Reported behaviour	**8**	7	1	0
Knowledge	**7**	2	1	0

Little pre-post questionnaire change are generally found on pharmacists' attitudinal and awareness level. The majority of the pharmacists in all groups remained at the same agreement level as in the pre-questionnaire. Only one significant positive pre-post change was measured in the **ViaNova** group ('I feel being well-aware of the effects of medicines on driving skills: 25% of the pharmacists changed their answer in the positive sense). No significant positive changes were found for the **USB and Control group** (see Table 86).

Very good results are found on the pre-post reported behaviour comparison of the integrated software group. A significant positive change after the training and intervention phase of **ViaNova** participants was found on 7 of the 8 reported behaviour questions. The proportion of pharmacists informing patients regularly or always about risks increased up to almost the maximum. Only one significant positive change was found within the **USB group**: the participants discussed medicinal drug consumption and driving related responsibility issues with the patient more often. For the **Control group** no change could be recorded. A big positive change in reported behaviour was found for the ViaNova group: 33.7% changed their answer in the better sense (regularly and always), followed by the USB group: 16.7%. No change was registered for the control group, conform the expected results.

Rather limited pre-post change was generally found on knowledge of individual medicinal risks on driving; this knowledge remained generally at a low level. The best results were found in the **ViaNova** group: significant increase in mean sum score in the post-questionnaire (from 1.84 on 5 (SD 1.031) to 2.37 on 5 (SD 1.37)) and 28% changed towards a sum score of at least 3 on 5. The number of incorrect and don't know answers in the post-questionnaire remained overall quite high though and for some questions even more than the majority. Besides the significant change in the composite score, a significant positive change was found on two knowledge questions related to risk of individual medicines: question on Diazepam – but still more than half of the pharmacists answered incorrectly – and Amitriptyline – 60% correct –). Only one significant positive change was found in the **USB group** (question on Amitriptyline). Still about half of the pharmacists answered incorrectly or did not know the answer in the post-questionnaire. No significant changes were found on the knowledge questions in the **Control group.** In general, the remark can be made that the correctness of some answers on the knowledge questions is arbitrary. Especially the question on Diazepam can evoke some discussion. Some studies did show that no severely impairing impact of Diazepam after just one month could be measured (the 'correct' answer in the questionnaire was that Diazepam was still heavily impairing after two months). Interpretation of the knowledge results needs thus to be done with caution due to questionnaire limitations (arbitrary answers, 'mismatch' of information in the provided study material (general information) and in the questions (referring to details like time periods, dosage). In addition, the questionnaire was developed within WP7 and has not been used before for similar research (i.e. not validated). **The basic knowledge on legal physicians/pharmacists obligations and patient responsibilities is generally good, already at baseline.** Therefore, little pre-post changes are found on this aspect

ViaNova software data and user acceptance. The software extracted data of the ViaNova participants indicate that **in about 89% of the popped-up EUB signals the option 'side-effects discussed' was clicked,** and this for the three risk categories of medicines. There were no clear differences in the number of clicks on 'discussed' in function of the ATC group. Also the option of printing patient information (GIT) was used on a regular basis. One difference in dispensing the GIT to the patient was noted: a GIT was less given to a patient when dispensing a risk category 1 (0.3%) medicine as compared to a risk category 2 (3.9%) or 3 medicine (3.5%). Similar results were found for the TUB and EUC signals. This high use of the DRUID functions integrated in their pharmacy software suggests a positive attitude of the ViaNova pharmacists. When interpreting this high percentage the reader should keep in mind **though** that the pharmacist was **more or less obliged** to click on 'EUB discussed' or 'gave GIT to patient' or 'side effects discussed' to go further with dispensing a medicine (so to leave the EUB signal). If the pharmacists chose 'continue' the EUB signal would appear again in a later phase of dispensing.

In correspondence to the observed behavioural data, the rates of user acceptance of the guidelines and of the integrated software user friendliness are high. The majority found the dispensing guidelines helpful, useful and sufficient. On the other hand, there was a very low use of the fact sheets and the pictogram system (10-20%). A remark regarding the pictograms should be made: several pharmacists did not understand this question very well, and pointed out that they did not know where to find these pictograms and/or if they used them in the software. Also the term 'fact sheet' was not well understood by the participants. This low use of the of the fact sheets and pictogram can be explained by the fact that no specific attention was paid to this information during the training sessions. The pictogram is

rather small and can be easily 'looked over'. Furthermore the term 'fact sheet' was not used in ViaNova, there is a big possibility that most pharmacists did read the text/fact sheet but did not mentioned this in the questionnaire. The user acceptance responses for these two sources thus need to be interpreted with care, as probably the terms were not clear (confusing) for the respondents. Looking at the ViaNova extracted data, the conclusion can be made that the fact sheets and pictograms were consulted on a regular base.

More than half of the ViaNova pharmacists stated that the guidelines have changed the manner they dispensed medication, and 60% of the participants think that the provided guidelines changed quite a lot up to very much their way to inform a patient. Up to 90% of the pharmacists (strongly) agreed that they could find the information without difficulties and that the tool would fit well in their working routines. Also the texts and icons were easy to perceive. **Some pharmacists mentioned that the tool should have additional options like more thorough information on side-effects or less vague advice**. **80% of the participants express their willingness to use the tool in the future.**

USB tool data and user acceptance. When analysing the USB tool extracted data the conclusion was made that **most of the pharmacists seldom used the provided program**. Furthermore, most searches were made on the day of the installation of the tool and some days after the participants received an email to send in their log files. The most frequent medicines searched for were category 3 medicines (e.g. Tetrazepam, Diazepam and Lorazepam). $1/4^{th}$ of the clicks could not be linked to a risk category due to typing errors or invalid entry of substances in the tool. When looking at the answers to the questions of user acceptance some explanation of the low use of the USB tool could be found. The pharmacists mentioned that the USB tool was **too time consuming, not easy to use and contained too vague information**. They stated that they would have used the tool more often if it was integrated in their daily used software. **Besides the integration in their daily used software, the pharmacists also recommend the possibility to search on brand names**. Pharmacists who were willing to use (an adapted/optimised) USB tool, would only use it in cases of first prescription.

4.2 Study limitations, challenges and solutions

No link between questionnaire and software data. The study design initially took care that each participant had a unique DRUID identification number in order to link questionnaire data to tool data (ViaNova or USB tool). After the six months trial it became clear though that it was impossible to determine how many pharmacists exactly used the DRUID functions in the ViaNova or USB software. This was due to the fact that many of the participants work in pharmacies with several pharmacists using the same computer, and thus using the support software tool.

Shortened USB intervention phase. Due to some problems regarding the development of the USB tool the intervention period (6 months) had to be shortened in order not to delay the study. This may have had an influence on the measured effect of the DRUID information/guidelines on the questionnaire and tool use data.

Motivated study participants. It has to be kept in mind that our population was already very interested in the topic medicines and driving; their participation was based on own willingness. All pharmacists mentioned at baseline that they already knew something about the topic but that they wanted to expand this knowledge. This may have led to smaller changes in reported pre-post measures during this study.

Sample restrictions. There was only a small number of participating pharmacists, especially in the USB and Control group.

Age of study participants. 66% of the study population was older than 46 years. A possible influence of the older population is noted regarding ICT knowledge. Younger pharmacists found it less hard to install the USB tool. It is not unlikely that the older pharmacists were less inclined to use the USB tool when experiencing problems in installation or use, which resulted in a low amount of data that could be collected.

Besides these study limitations, several challenges had to be overcome by the research team during the course of the study:

Table 87: Study limitations, challenges and solutions

Challenge	Offered solution
There was difficulty to motivate the pharmacists to activate the functions in the integrated software ViaNova and to keep using them properly.	*During the training session the speaker and ESCAPO (ViaNova provider) tried to motivate the pharmacists by e.g. providing a step-by-step manual on how to use and activate the DRUID functions. During the study newsletters were produced to keep the participants informed and motivated.*
For the non-integrated group of pharmacists it became very difficult to plan the training sessions. It turned out that the sessions were scheduled too early in the evening. Secondly it had to be taken into account that the courses did not overlap with other courses organised by professional organisations for pharmacists.	*Several pharmacists were consulted on the closing hours of the pharmacies in East Flanders. ESCAPO provided the research team with information regarding other training sessions organised by professional organisations for pharmacists.*
During the training sessions it became clear that the ICT knowledge of the participating pharmacist was rather low with regard to installing a new program on their computer (USB tool).	*Several pharmacists needed and obtained help with the installation (by phone, by email or in person). Shortly after the training session a newsletter was sent to the respondents in order to detect installation problems early in the study.*
Besides the delay of the USB tool the research team also experienced a lot of other problems regarding the USB-program, for example sometimes files were not correctly uploaded in the program, the tool did not run on windows Vista or on a Windows 64-bit, etc. Due to these kinds of problems and the delay in finishing the USB-tool, the trial period for some pharmacists was shorter than originally foreseen (6 months).	*The USB tool was tested on several computers by the research team and later modified to match the most current operating systems installed on the pharmacy computers.*
Several pharmacists were worried about the compatibility between their own software and the USB tool. Some pharmacists refused to install the tool unless the research team could guarantee that no problems would appear.	*After contacting several software companies, the message could be sent to all partners that the tool could be installed without any problems or risk of incompatibility.*
Most of the respondents made clear that more than one computer is used in a pharmacy.	*The respondents were motivated to install the USB tool / program on every computer present at the pharmacy. After the six months trial it was underlined to send back all log file(s) from all computers where the program was installed on.*
Almost every pharmacist present at the training sessions preferred a tool integrated into their daily used software. According to the pharmacists, having several programs open on the computer when helping patients is a waste of time. The new DRUID-functions or information should be integrated in the software used in daily practice.	*During the training session the study design and the importance of a non-integrated software (USB) group was explained. The possibility of making a shortcut on the computer desktop to easily open the USB program was mentioned.*
Most of the pharmacists did not know the ATC codes of medicines (only generic and brand names). The question whether it was	*More information on the ATC codes of medicines was provided during the training session.*

also possible to integrate brand names was often mentioned. This should be kept in mind when developing new programs/software.	
In the end, the aim of including 31 pharmacists in the non-integrated group could not be fulfilled. Few pharmacists were willing to follow a training session and use a new tool/program.	*After every training session, absent pharmacists were invited by letter to the next training session. In this way several pharmacists could be motivated to follow a training session anyway.*
Several pharmacists warned that the therapy compliance can be threatened when one informs the patients about the negative influence of certain medication on the driving ability. The respondents were not willing to give the DRUID information to patients who already used a medicine for years.	*During the training sessions it was explained to focus on first prescriptions.*
The pharmacists mentioned during the training sessions that there is a difficult collaboration between pharmacists and physicians. Almost none of the participants was prepared to make a phone call to a physician when a safer alternative should be proposed to the patient. All participants, especially more experienced pharmacists had some negative experiences in trying to realise a cooperation with the physicians in their region.	*The research team published information about the DRUID project and the physician/pharmacist study on the internal website of the physician of the region 'Tongeren', where a training session was held.*

Main recommendations for future field studies with pharmacists deal with: having good intermediaries or contact persons, using informative and supporting newsletters for participants. During the study it became clear that having intermediaries or contact persons (e.g. contact persons within ESCAPO) has a very positive influence on the response rate, follow-up and outcome of the study. These contact persons help establish a good communication with the respondents as well as motivate them to participate actively in the study. The use of newsletters turned out to be a very handy and useful tool in contacting the respondents directly. It became furthermore clear that the subpopulation of pharmacists is overly asked to participate in studies. The DRUID study was carefully planned by ESCAPO in order to avoid overlap between several studies, which would have a negative influence on the participation rate.

Table 88. Problems encountered

Problems encountered
✓ Difficult to motivate pharmacists (certainly the non-integrated group) ✓ Difficult to plan a training session (hours) ✓ ICT knowledge low (difficulties installing USB-Tool) ✓ Difficult to finalise the USB-tool, delay study ✓ Clear preference for integrated information in the daily used software ✓ Compatibility software and usb-tool ✓ (almost) No knowledge of the ATC codes ✓ Installation of usb-tool on several computers: no control on who and how many pharmacists used the tool ✓ Low number of respondents in the non integrated software group (USB) ✓ Therapy compliance threatened ✓ Difficult collaboration between pharmacists and physicians: There is a lack of structures or organisations where physicians and pharmacists can collaborate.

4.3 Overall conclusion and recommendations

- Most positive outcome with integrated software

As could be expected, most and highest self-reported topic-favorable (medicinal effects on driving) changes were found in the integrated ViaNova software group, as compared to far less in the stand-alone USB group and none in the Control group. Most positive changes were found on specific reported behaviour, on which the pharmacists were trained. Almost no change on attitudinal level for none of the three groups was observed, which can be related to an already rather a priori good attitude towards the topic medicinal driving risks of the participating pharmacists. One could say that the pharmacists who participated in this study firmly underline the importance of being well informed and aware of the possible risks of medicines on driving. In other words their positive attitude was a motivation to take part in the present study. Although the training and 6 months trial increased some awareness for risks of medicines for driving (also related to fine-tuned knowledge about specific medicines' risks), more effort still seems to be required in order to further help pharmacists increase their awareness and knowledge.

The DRUID dispensing guidelines were overall very well accepted and liked. What stands out most strikingly from all results is the importance of having a support system integrated in the daily dispensing software in order to be effectively used.

- Lack of information on the topic 'medicines and driving'

Almost every pharmacist involved in present study (all groups) underlined the importance of being informed on the potential risk of medicines on driving. Yet, the participants reported a lack of information on this topic. The majority is willing to use a tool in their daily practice, as long as it is integrated into their daily software, updated automatically, easy to use, focus on first deliveries, cost- and time-efficient, contain concrete & detailed information and if possible safer alternatives.

- Suggestions with regard to the DRUID dispensing guidelines and the delivery support tools:

Following the participants' feedback and remarks, several suggestions and recommendations for improvement of the DRUID dispensing guidelines and dispensing support tool(s) can be given.

With regard to the DRUID dispensing guidelines:

- ✓ Guidelines have to be uniform
- ✓ The provided information has to be detailed
- ✓ Safer alternatives have to be formulated if possible
- ✓ The proposed DRUID categorisation should be recognised and approved on European level
- ✓ New medicines have to be classified
- ✓ The pharmacists recommend focusing only on the first prescriptions. Patients who already use certain medication for several years will not agree to use another (safer) medication then the one they are used to.

With regard to the dispensing support tool(s):

- ✓ The information integrated in the software should be updated automatically
- ✓ Besides the information integrated in the software, a manual or instructions folder has to be available to facilitate the information transition on other pharmacists or assistant pharmacists in the pharmacy
- ✓ A combination of tools, ideally integrated software + a manual or a website, would be much appreciated
- ✓ In case of a search function: the respondents would like to have the possibility to search on brand and generic name of a medicine; after typing two letters several

suggestions of medication have to appear (several pharmacists misspelled the brand/generic name which did not gave a match in the tool)
- ✓ All the information of the USB tool has to be integrated in the daily used software. When this information is available it should be made compatible with all existing software packages used by the pharmacists in the region/country

- Further lessons learnt

The following should be considered in future pharmacists' dispensing support implementation plans:

- ✓ Besides the need for safer alternatives there is a need for concrete and detailed advice in the package leaflet or on the medicine box.
- ✓ Most of the pharmacists mentioned that they cannot forbid patients to drive or to use heavy machinery when using medication that can cause impaired driving. They can only underline the danger of driving under the influence of the prescribed medication.
- ✓ The pharmacists noted that informing family members, who come and collect the prescribed medication, can be difficult. A lot of information is lost when the communication was not directly with the patient.
- ✓ Some pharmacists were worried about the fact if the pharmacy assistants were not enough trained to give advice about the influence of medication on the driving abilities.
- ✓ Due to the difficult cooperation between physicians and pharmacists it is recommended, according to the participants, to inform all physicians in the region/province about the study. Raising the awareness of the physicians will augment the chance to realize a real change in behaviour of the pharmacists.
- ✓ The pharmacists recognise that they have an important role in advising the patient. Certainly because of the fact that a lot of patients go to different physicians to receive prescriptions for several types of medication. The pharmacist can advise the patient not to combine certain medicines or to not drive for X hours. For this, the pharmacists want to point out the importance of good safer alternatives.
- ✓ Pharmacists mentioned that patients were grateful for the advice and warnings. The communication with the patient turned out to be easier than expected.
- ✓ Every patient understands that driving under the influence of alcohol is very dangerous. In practice, it is useful to compare the influence of certain medication with the influence of alcohol. Using such a comparison makes the communication with the patients and the information transmission smoother and more apprehensible.
- ✓ The participating pharmacists were surprised by the number of patients who don't participate in daily traffic.
- ✓ Several pharmacists did not know that a classification of medicines was yet available.
- ✓ Most of the pharmacists made clear that not enough attention is paid to the topic 'driving under the influence of medicines'.
- ✓ Several participants expressed their worries on being (partially) legally responsible when a patient has a traffic accident.
- ✓ A lot of delivery software programs are currently being used by pharmacists. Until today no classification of medications is included in the software. The DRUID classification and the accompanying pictogram is a benefit according the respondents. These pictograms should not only be integrated in the software but also put on the medicine boxes and patient information leaflet. A proposal of the participants was to build in a function in their software that makes it possible to print stickers with the pictogram.
- ✓ During the training sessions the participants underlined the importance of a training manual or hand-outs. In most pharmacies several pharmacists/assistants/students are employed. In order to inform all co-workers a manual should be available.
- ✓ Several pharmacists made the remark that sometimes a pop-up in the software warned for an influence on the driving ability while the medication was prescribed to infants and little children (e.g. Toplexil). Some pharmacists proposed to link an age category to the medicine.

5 Acknowledgements

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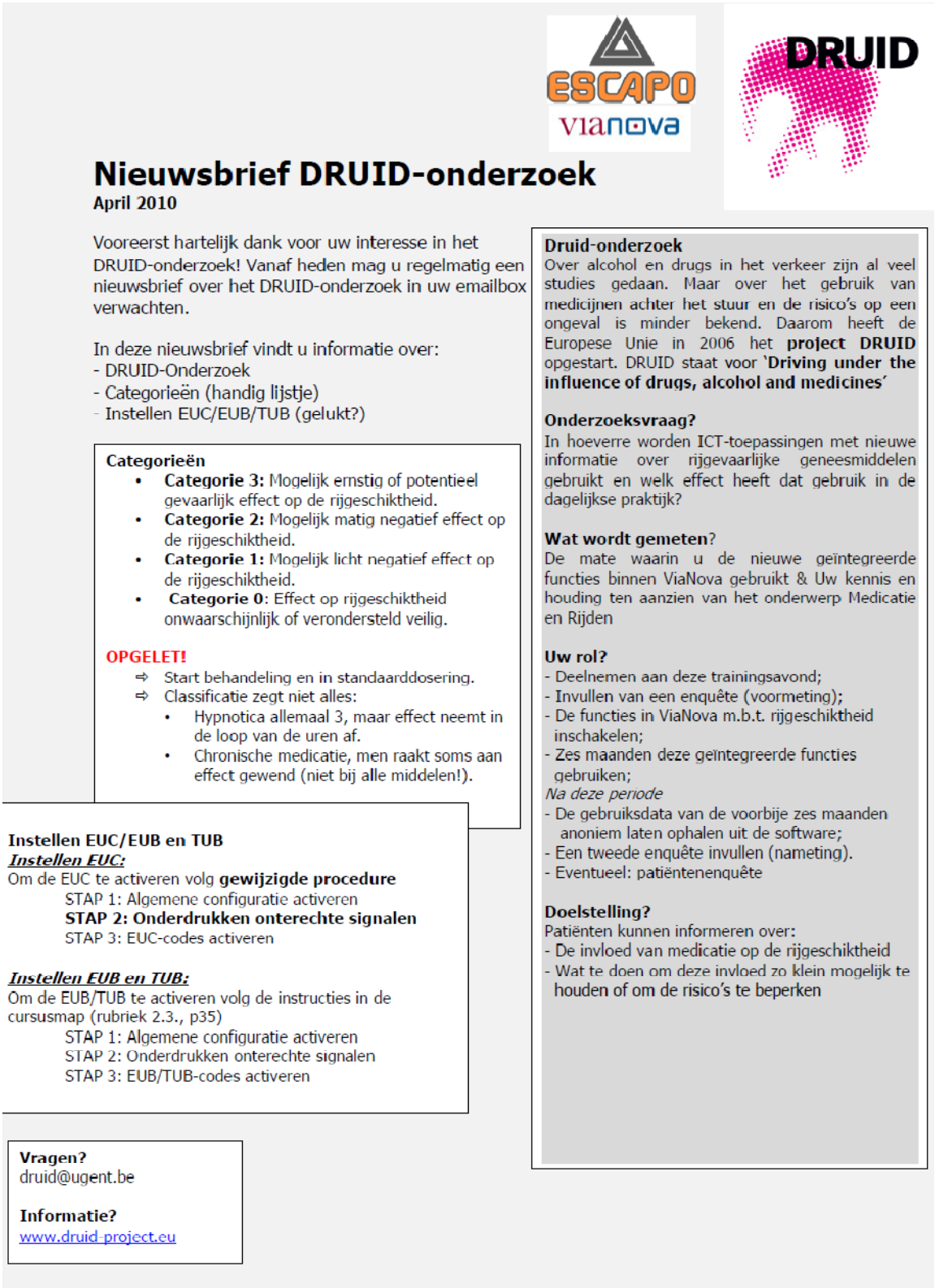
6 Annex

6.1 Annex 1: Newsletters ViaNova

6.1.1 Newsletter ViaNova - April 2010



Nieuwsbrief DRUID-onderzoek
April 2010

Vooreerst hartelijk dank voor uw interesse in het DRUID-onderzoek! Vanaf heden mag u regelmatig een nieuwsbrief over het DRUID-onderzoek in uw emailbox verwachten.

In deze nieuwsbrief vindt u informatie over:
- DRUID-Onderzoek
- Categorieën (handig lijstje)
- Instellen EUC/EUB/TUB (gelukt?)

Categorieën
- **Categorie 3:** Mogelijk ernstig of potentieel gevaarlijk effect op de rijgeschiktheid.
- **Categorie 2:** Mogelijk matig negatief effect op de rijgeschiktheid.
- **Categorie 1:** Mogelijk licht negatief effect op de rijgeschiktheid.
- **Categorie 0**: Effect op rijgeschiktheid onwaarschijnlijk of verondersteld veilig.

OPGELET!
⇨ Start behandeling en in standaarddosering.
⇨ Classificatie zegt niet alles:
- Hypnotica allemaal 3, maar effect neemt in de loop van de uren af.
- Chronische medicatie, men raakt soms aan effect gewend (niet bij alle middelen!).

Instellen EUC/EUB en TUB
Instellen EUC:
Om de EUC te activeren volg **gewijzigde procedure**
STAP 1: Algemene configuratie activeren
STAP 2: Onderdrukken onterechte signalen
STAP 3: EUC-codes activeren

Instellen EUB en TUB:
Om de EUB/TUB te activeren volg de instructies in de cursusmap (rubriek 2.3., p35)
STAP 1: Algemene configuratie activeren
STAP 2: Onderdrukken onterechte signalen
STAP 3: EUB/TUB-codes activeren

Vragen?
druid@ugent.be

Informatie?
www.druid-project.eu

Druid-onderzoek
Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor **'Driving under the influence of drugs, alcohol and medicines'**

Onderzoeksvraag?
In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wat wordt gemeten?
De mate waarin u de nieuwe geïntegreerde functies binnen ViaNova gebruikt & Uw kennis en houding ten aanzien van het onderwerp Medicatie en Rijden

Uw rol?
- Deelnemen aan deze trainingsavond;
- Invullen van een enquête (voormeting);
- De functies in ViaNova m.b.t. rijgeschiktheid inschakelen;
- Zes maanden deze geïntegreerde functies gebruiken;

Na deze periode
- De gebruiksdata van de voorbije zes maanden anoniem laten ophalen uit de software;
- Een tweede enquête invullen (nameting).
- Eventueel: patiëntenenquête

Doelstelling?
Patiënten kunnen informeren over:
- De invloed van medicatie op de rijgeschiktheid
- Wat te doen om deze invloed zo klein mogelijk te houden of om de risico's te beperken

Categorieën tranquillizers, hypnotica en antidepressiva

Behalve de tranquillizers, hypnotica en antidepressiva staan er op onderstaande lijst ook enkele andere veel gebruikte rijgevaarlijke middelen en enkele medicijnen met dezelfde ATC, maar met andere dan bovengenoemde toepassingen.

De categorie geeft het **acute effect** weer in de **gebruikelijke dosering**. Dus het effect in de paar uur na inname van een eenmalige dosis of het effect aan het begin van een chronisch gebruik.
De categorie zegt **niet** alles over het te geven **advies** om wel of niet te rijden en/of na hoeveel tijd men weer mag rijden. Dat advies staat onder andere in de Geneesmiddel Informatie Tekst (GIT) en op de Eerste Uitgifte Begeleidingssignalen (EUB).

Lijstje van meest voorkomende middelen:

Alprazolam	3
Amitriptyline	3
Bromazepam	3
Citalopram	2
Clorazepaat	2
Codeïne	2
Diazepam	3
Dosulepine	3
Escitalopram	1
Flunitrazepam	3
Flurazepam	3
Lorazepam	3
Mirtazapine	3
Oxazepam	3
Paroxetine	1
Sertraline	2
Trazodon	3
Venlafaxine	1
Zolpidem	3

6.1.2 Newsletter ViaNova - June 2010

Nieuwsbrief DRUID-onderzoek

Juni 2010

Enkele maanden terug besloot u deel te nemen aan het DRUID-Onderzoek. In navolging op de nieuwsbrief die u mocht ontvangen in april sturen we een korte up-date toe met wat meer informatie over:

- Het DRUID - Onderzoek
- **Opgepast: Bijkomende codes te activeren!!!**
- Casus
- Waarschuwingsniveau's patiënten
- Mogelijke adviezen
- Richtlijnen voor afleveren

Bijkomende codes te activeren (cfr onderstaande lijst)

EUB Nummers: 2020 & 2021

TUB Nummer: 2022

Druid onderzoek

Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor '**Driving under the influence of drugs, alcohol and medicines**'

Onderzoeksvraag?

In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Casus

Een patiënt heeft veel last van lage rugpijn, in het bijzonder tijdens autorijden. Hij gebruikt occasioneel Tramadol druppels in situaties waar hij pijn verwacht, ondermeer ... bij autorijden!
De patiënt geeft zelf aan dat autorijden inderdaad lastiger is door de medicatie, maar ja ... niet autorijden is geen optie ...bestaat er een andere oplossing ?

Samen met de patiënt zoek je naar mogelijke oplossingen zoals:

- Inname van andere pijnstillers als NSAIDs, paracetamol op momenten van autorijden;
- Andere werktijden waardoor de patiënt buiten spits naar het werk kan rijden en daardoor minder lang in de auto moet zitten;
- Gebruik van een steunkussen om in auto te gebruiken;
- Een doorverwijzing naar een multidisciplinair pijncentrum.

Waarschuwingsniveaus voor de patiënt

Categorie 1 (licht effect)
Rij alleen als u de relevante informatie over het effect op de rijgeschiktheid op de bijsluiter gelezen heeft.

Categorie 2 (matig effect)
Rij niet zonder het inwinnen van advies van een arts/apotheker. Lees de relevante sectie op de bijsluiter met betrekking tot het effect op het rijden, alvorens u de arts of apotheker consulteert.

Categorie 3 (ernstig/gevaarlijk effect)
Rij niet. Win na enige behandelingsduur medisch advies in met betrekking tot de voorwaarden en mogelijkheden om opnieuw te rijden.

Mogelijke adviezen

- Alleen autorijden als u geen last heeft van bijwerkingen die de rijgeschiktheid kunnen beïnvloeden.
- Niet autorijden tot x uur na inname.
- Niet autorijden de eerste x dagen/weken dat u dit medicijn gebruikt.
- Niet autorijden zolang u dit medicijn gebruikt.

Richtlijnen voor afleveren

1. Rijdt de patiënt auto? Ander gemotoriseerd voertuig?
2. Gebruikt patiënt andere psychotrope middelen? Is lever- of nierfunctie aangetast? Oudere? Dan groter effect.
3. Bepaal effect van het middel (duur, mate)?
4. Zijn er manieren om zo min mogelijk last te hebben? Bijvoorbeeld voor de nacht slikken?
5. Adviseer de patiënt: wanneer innemen, wel geen autorijden, wel/geen alcohol/drugs.

Vragen?

druid@ugent.be

Informatie?

www.druid-project.eu

Bijkomende codes activeren voor het DRUID-project

STAP 1: onderdrukken onterechte signalen
Hoofdmenu – WIES – onderdrukken onterechte EU-signalen – "JA"!

STAP 2: EUB/TUB-codes activeren
Hoofdmenu – WIES – Configuratie – EUB-codes.
Zet onderstaande EUB-nummers ivm rijvaardigheid op "JA"

EUB-nummer	Schermtekst	Argumentatie
2020	*Rijv: 1e week NIET rijden, daarna niet bij bijw.	Voor clomipramine, fluvoxamine, maprotiline en nortriptiline is EUB-nummer 1456 vervangen door EUB-nummer 2020. Het geheugensteuntje blijft ongewijzigd, maar de achtergrondinfo is vereenvoudigd. Het advies om dit middel 's avonds in te nemen bij optreden van slaperigheid is enkel nog opgenomen in de achtergrondinfo horend bij de rubriek gebruik van dit EUB-signaal en niet meer bij de rubriek rijvaardigheid. EUB-nummer 1456 blijft behouden voor citalopram, sertraline, imipramine en duloxetine.
2021	*Rijv: 1e week NIET rijden, daarna niet bij bijw.	Voor bupropion is EUB-nummer 1456 vervangen door EUB-nummer 2021. Het geheugensteuntje blijft hetzelfde, maar de achtergrondinfo is gewijzigd. Het advies om dit middel eventueel 's avonds in te nemen is geschrapt omdat dit middel slapeloosheid kan veroorzaken en daarom bij voorkeur 's morgens ingenomen wordt.

Hoofdmenu – WIES – Configuratie – TUB-codes.
Zet onderstaande TUB-nummers ivm rijvaardigheid op "JA"

TUB-nummer	Schermtekst	Argumentatie
2022	Rijv: Nog bijw die reactievermogen beinvloeden?	Hiervoor verwijzen we naar de argumentatie bij EUB-nummer 2021.

Opmerking:

Waarom is aan amitriptyline tabletten met onmiddellijke en vertraagde vrijstelling een andere EUB-nummer gekoppeld betreffende de rijvaardigheid?
➔ Aan Redomex tabletten is EUB-nr 1458 gekoppeld (rijv: > 75 mg/dg NIET rijden, 75mg of minder).
➔ Aan Redomex diffucaps is EUB-nr 1460 gekoppeld (rijv: > 50 mg/dg mga NIET rijden, 50mg of minder).
Dit onderscheid is gebaseerd op informatie uit het Farmacotherapeutisch Kompas waarin aangegeven wordt dat 50 mg/dag van een tablet met vertraagde vrijstelling ongeveer overeenkomt met 3x 25 mg/dag van een tablet met onmiddellijke vrijstelling.

6.1.3 Newsletter ViaNova - October 2010

Nieuwsbrief DRUID-onderzoek

Oktober 2010

Enkele maanden terug besloot u deel te nemen aan het DRUID-Onderzoek. Vandaag wensen wij u met deze nieuwsbrief op de hoogte te brengen van het einde van de testperiode van zes maanden. Wij gaan dan ook spoedig aan de slag met de verwerking van uw gegevens. Graag willen wij u reeds danken voor uw medewerking!

In deze nieuwsbrief vindt u informatie over:
- Het DRUID - Onderzoek
- Stand van zaken en **wat NU**?
- Weetje: Symposium
- Eerste resultaten
- **BELANGRIJK** bericht ons over: uw mening, ervaringen, leuke/belangrijke/typerende casussen,...

Druid onderzoek

Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor '**Driving under the influence of drugs, alcohol and medicines'.**

Onderzoeksvraag?

In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wat wordt gemeten?

De mate waarin u de nieuwe geïntegreerde functies binnen ViaNova gebruikt & uw kennis en houding ten aanzien van het onderwerp Medicatie en Rijden.

Doelstelling?

Patiënten kunnen informeren over:
- De invloed van medicatie op de rijgeschiktheid
- Wat te doen om deze invloed zo klein mogelijk te houden of om de risico's te beperken

Stand van zaken
- U nam deel aan een trainingsavond in april
- U vulde de 1ste vragenlijst in
- U schakelde de functies in ViaNova m.b.t. rijgeschiktheid in
- U gebruikte zes maanden deze geïntegreerde functies

Wat nu?
- De gebruiksdata van de voorbije zes maanden zullen anoniem worden opgehaald uit de software door ESCAPO
- **Een tweede enquête invullen (nameting)**

U zal de tweede vragenlijst ontvangen via ESCAPO!
Na het ontvangen van de tweede vragenlijst kunnen wij aan de slag met het verwerken van zowel de data uit de 1ste vragenlijst alsook de data uit de 2de vragenlijst. Eerste resultaten worden verwacht begin volgend jaar en zullen in een nieuwsbrief en/of een editie van "Blikvanger" voorgesteld worden.

Weetje

Het DRUID onderzoek en de apothekerstudie werd voorgesteld op het '**First Belgian Pharmaceutical Care Symposium**' - 18 september 2010 te Brussel.

OPGELET!

Ook al is de testfase van 6 maanden verstreken, u kan de ingeschakelde signalen verder gebruiken en de opgedane ervaring verder uitbouwen. Zo wordt farmaceutische zorg voor patiënten voelbaar en uitgebreid.

Eerste resultaten

-Verschillende apothekers gaven aan dat de communicatie in verband met rijgevaarlijke geneesmiddelen met patiënten beter verliep dan dat ze op voorhand hadden ingeschat.
-De meeste apothekers leggen geen verbod van rijvaardigheid op maar waarschuwen er wel voor. De meeste patiënten appreciëren dit advies en reageren heel positief en begrijpend.
-Het vergelijken van het effect van sommige geneesmiddelen met het effect van alcohol is een handige tool bij het adviseren en voorlichten van de patiënt.
-Verschillende patiënten hebben te kennen gegeven dat ze niet met de auto rijden.
-Communicatie met derden die medicatie komen halen verloopt soms moeilijker.
-Een waarschuwingssignaal over een rijgevaarlijk geneesmiddel kan voor de patiënt de aanleiding zijn om op verhaal te komen en vragen te stellen. Voor de apotheker is dit signaal de opstap om de patiënt beter te begeleiden bij het gebruik van geneesmiddelen.

Belangrijk!
- Graag hadden we **uw mening** gehoord over de studie alsook over de beschikbare informatie (m.b.t. het effect van een geneesmiddel op de rijvaardigheid) in uw ViaNova software.
- Wat zijn volgens u de **voordelen en nadelen** van informatie geïntegreerd in uw software?
- Hoe verliep uw **communicatie** met en **voorlichting** van de patiënt?
- Heeft u terugkerende **problemen** vastgesteld?

⇨ **Meld het ons : druid@ugent.be**

Informatie?
www.druid-project.eu

6.2 Annex 2: Newsletters- Non integrated software group (USB-tool)

6.2.1 Newsletter USB– October 2010

Nieuwsbrief DRUID-onderzoek

Oktober 2010

Vooreerst hartelijk dank voor uw interesse in het DRUID-onderzoek! Vanaf heden mag u regelmatig een nieuwsbrief over het DRUID-onderzoek in uw emailbox verwachten.
In deze nieuwsbrief vindt u informatie over:
- Het DRUID-Onderzoek
- Categorieën (handig lijstje)
- Welke informatie kan u terugvinden in de tool?
- Richtlijnen voor afleveren
- Adviezen
- Installeren en gebruiken tool gelukt?/problemen? **Gelieve uw problemen te melden!**

Categorieën

- **Categorie 3:** Mogelijk ernstig of potentieel gevaarlijk effect op de rijgeschiktheid.
- **Categorie 2:** Mogelijk matig negatief effect op de rijgeschiktheid.
- **Categorie 1:** Mogelijk licht negatief effect op de rijgeschiktheid.
- **Categorie 0**: Effect op rijgeschiktheid onwaarschijnlijk of verondersteld veilig.

OPGELET!

⇨ Start behandeling en in standaarddosering.
⇨ Classificatie zegt niet alles:
- Hypnotica allemaal 3, maar effect neemt in de loop van de uren af.
- Chronische medicatie, men raakt soms aan effect gewend (niet bij alle middelen!).

Welke informatie kan u terugvinden?

Van alle CNS-middelen (ATC-code N):
- Pictogram met categorie
- Uitgifte-begeleidings-teksten
- Patiëntenbrieven
- Rijveiliger alternatieven

Richtlijnen voor afleveren

1. Rijdt de patiënt auto? Ander gemotoriseerd voertuig?
2. Gebruikt patiënt andere psychotrope middelen? Is lever- of nierfunctie aangetast? Oudere? Dan groter effect.
3. Bepaal effect van het middel (duur, mate)?
4. Zijn er manieren om zo min mogelijk last te hebben? Bijvoorbeeld voor de nacht slikken?
5. Adviseer de patiënt: wanneer innemen, wel geen autorijden, wel/geen alcohol/drugs.

Adviezen

- Vraag naar verkeersdeelname
- Vraag naar motivatie voor de behandeling
- Geef aan niet te combineren met alcohol of drugs
- Waarschuw voor bijwerkingen, zoals sufheid en slaperigheid.
- Tweede uitgifte: Vraag naar ervaringen.
- Geef ook specifieke adviezen per middel

Druid-onderzoek

Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor **'Driving under the influence of drugs, alcohol and medicines'**

Onderzoeksvraag?

In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wat wordt gemeten?

De mate waarin u de USB tool gebruikt & Uw kennis en houding ten aanzien van het onderwerp Medicatie en Rijden

Uw rol?

- Deelnemen aan een trainingsavond;
- Invullen van een enquête (voormeting);
- De USB tool installeren;
- Zes maanden deze tool gebruiken;

Na deze periode

- De gebruiksdata van de voorbije zes maanden anoniem opsturen naar de onderzoekers(logfile);
- Een tweede enquête invullen (nameting).

Doelstelling?

Patiënten kunnen informeren over:
- De invloed van medicatie op de rijgeschiktheid
- Wat te doen om deze invloed zo klein mogelijk te houden of om de risico's te beperken

De **DRUID-tool** kunnen gebruiken t.b.v.:
- Voorlichting aan de patiënt,
- Bewaking op verkeersdeelname
- Registratie van de handelingen.

Vragen?
Ervaart u (nog) problemen bij de installatie of bij het gebruik van de USB-tool?

druid@ugent.be

Informatie?
www.druid-project.eu

Categorieën tranquillizers, hypnotica en antidepressiva

Behalve de tranquillizers, hypnotica en antidepressiva staan er op onderstaande lijst ook enkele andere veel gebruikte rijgevaarlijke middelen en enkele medicijnen met dezelfde ATC, maar met andere dan bovengenoemde toepassingen.

De categorie geeft het **acute effect** weer in de **gebruikelijke dosering**. Dus het effect in de paar uur na inname van een eenmalige dosis of het effect aan het begin van een chronisch gebruik.
De categorie zegt **niet** alles over het te geven **advies** om wel of niet te rijden en/of na hoeveel tijd men weer mag rijden. Dat advies staat onder andere in de Geneesmiddel Informatie Tekst (GIT).

Lijstje van meest voorkomende middelen:

Alprazolam *(Xanax)*	3
Amitriptyline *(Redomex)*	3
Bromazepam *(Lexotan)*	3
Citalopram *(Cipramil)*	2
Clorazepaat *(Tranxene)*	2
Codeïne	2
Diazepam *(Valium)*	3
Dosulepine *(Prohtiaden)*	3
Escitalopram *(Sipralexa)*	**1**
Flunitrazepam *(Rohypnol)*	3
Flurazepam *(Staurodorm)*	3
Lorazepam *(Temesta, Serenase)*	3
Mirtazapine *(Remergon)*	3
Oxazepam *(Tranquo)*	3
Paroxetine *(Seroxat)*	**1**
Sertraline *(Serlain)*	2
Trazodon *(Trazolan, Nestrolan)*	3
Venlafaxine *(Efexor)*	**1**
Zolpidem *(Stilnoct)*	3

6.2.2 Newsletter USB- January 2011

Nieuwsbrief DRUID-onderzoek

Januari 2011

Vooreerst wenst het Gentse DRUID team u een boeiend 2011!

In deze tweede nieuwsbrief vindt u informatie over:
- Het DRUID-Onderzoek
- Welke informatie kan u terugvinden in de tool?
- Wettelijke aspecten: Voorbeeld uit de actualiteit
- Weetje: Testen pijnpatiënten positief?
- Belangrijkse aandachtpunten
- **Uw mening!?**

Druid-onderzoek
Over alcohol en drugs in het verkeer zijn al veel studies gedaan. Maar over het gebruik van medicijnen achter het stuur en de risico's op een ongeval is minder bekend. Daarom heeft de Europese Unie in 2006 het **project DRUID** opgestart. DRUID staat voor '**Driving under the influence of drugs, alcohol and medicines**'

Onderzoeksvraag?
In hoeverre worden ICT-toepassingen met nieuwe informatie over rijgevaarlijke geneesmiddelen gebruikt en welk effect heeft dat gebruik in de dagelijkse praktijk?

Wettelijke aspecten : Voorbeeld uit de actualiteit

Arts en chauffeur schuldig aan dodelijk ongeval

02/11/10

De Dendermondse strafrechter heeft een 53-jarige arts uit Erpe-Mere veroordeeld tot een gevangenisstraf van acht maanden met uitstel en 2.750 euro boete met uitstel wegens schuldig verzuim. De 49-jarige patiënt van de arts, die onder invloed van een overdosis medicijnen een bromfietser doodreed, kreeg dezelfde straf en een jaar rijverbod.

Op 12 november 2007 ondernam Paul C. uit Erpe-Mere een poging om zelfmoord te plegen en slikte een overdosis pillen. Vlak na de inname van de medicijnen bedacht hij zich echter en trommelde hij zijn arts op om hem te helpen. Die stuurde hem naar de spoedafdeling van het Aalsterse ziekenhuis om daar zijn maag te laten leegpompen. Paul C., onder invloed van de geslikte geneesmiddelen, viel tijdens de rit evenwel in slaap en reed bromfietser Koen Van Damme dood.

De chauffeur werd gedagvaard wegens het sturen onder invloed en het veroorzaken van een dodelijk ongeval. Ook de arts van de man werd gedagvaard wegens schuldig verzuim. De rechter tilde erg zwaar aan de feiten en verweet de arts dat hij zijn patiënt aan zijn lot had overgelaten en hem niet zelf naar het ziekenhuis gebracht had, of minstens gewacht had tot de ziekenwagen er was. (belga/lpb)

Gepubliceerd in 'De Morgen'

Weetje
Testen pijnpatiënten die morfine nemen positief bij de nieuwe speekseltest?

Morfine wordt opgespoord door de speekseltest. Bij pijnpatiënten zal morfine gedetecteerd worden. De behandelende arts kan patiënten met een morfinepomp rijgeschikt verklaren. Hierbij houdt de arts rekening met de gewenning die kan optreden, therapietrouw alsook het feit dat de dosis automatisch toegediend wordt (en men dus niet kan overdoseren). Wettelijk gezien is het de arts van CARA die het attest van rijgeschiktheid moet afleveren.

Welke informatie kan u terugvinden?
Van alle CNS-middelen (ATC-code N):
- Pictogram met categorie
- Uitgifte-begeleidings-teksten
- Patiëntenbrieven
- Rijveiliger alternatieven

Belangrijkste aandachtpunten
- Gedifferentieerde adviezen opzoeken met de DRUID- tool
- Rijveiligere alternatieven (ook bij OTC)
- Bij contact met patiënt (en ook met arts): refereer naar nieuwe inzichten, denk mee
- Verkeersveiligheid: er is een rol voor de apotheker!

Uw mening?
Ervaart u (nog) problemen bij het gebruik van de USB-tool?
Heeft u opmerkingen/bemerkingen ivm gebruik van de USB- tool?

⇨ druid@ugent.be

Informatie?
www.druid-project.eu

6.2.3 Newsletter USB - February 2011

Nieuwsbrief DRUID-onderzoek

Februari 2011

Via deze nieuwsbrief willen wij u graag op de hoogte brengen van het einde van de apothekerstudie waaraan u deelneemt. Binnenkort zal u een tweede vragenlijst en een informed consent van de stichting Health Base toegestuurd krijgen. Zoals aangegeven op de trainingsavond zal naast data uit de vragenlijsten ook data verwerkt worden met betrekking tot het gebruik van de usb-tool. Wij verzoeken u dan ook vriendelijk om deze data, na het ontvangen van de vragenlijst, via email door te sturen naar het DRUID- onderzoeksteam. Om deze overdracht te ondersteunen sturen wij u korte instructies toe. Deze instructies kan u ook reeds terugvinden in voorliggende nieuwsbrief.

In deze laatste nieuwsbrief vindt u informatie over:
- Wat krijgt u toegestuurd... en wat stuurt u terug?
- Het ophalen van de data... Hoe?
- Wat nu?
- Deadline
- Uw mening!?

Het ophalen van de data... Hoe?

Verzenden van uw data (de logfile)

Gelieve hieronder een beschrijving te vinden van de logfile die uw zoekopdrachten van deze 6 maand proefperiode heeft bijgehouden.

Deze logfile is een kladblokbestand en bevindt zich in een submap van C:\ DRUID_pharmacists_tool.

Stap 1: ga naar 'mijn computer' en dubbelklik op de C-schijf ('lokaal station C' of 'OS (C)')
Stap 2: ga naar 'DRUID_pharmacists_tool'
Stap 3: open de map 'RUN_DRUID_TL'
Stap 4: open de map 'resources'
Stap 5: klik met de rechtermuisknop op 'logfile' en selecteer 'naam wijzigen'
Stap 6: hernoem het bestand naar logfile_**22_XXXX***
Stap 7: verstuur dit kladblokbestand naar druid@ugent.be

Wanneer U de tool op verschillende computers heeft gebruikt, doorloopt U deze stappen per PC en vult U de logfile-namen aan met a,b,c,…
Bv: logfile_22_xxxx_a
logfile_22_xxxx_b
…..

**22-xxxx is uw persoonlijk druid nummer en zal reeds ingevuld staan op uw persoonlijke brief die u toegestuurd zal krijgen met de tweede vragenlijst.*

Indien u hieromtrent vragen heeft, of problemen ondervindt, aarzel niet om ons te contacteren!

Wat krijgt u toegestuurd...

- ✓ Een begeleidende brief
- ✓ Een tweede vragenlijst
- ✓ Een informed consent van de stichting Health Base
- ✓ Een stappenplan hoe de data van de usb-tool op te halen (zie kader links)
- ✓ Een terugstuurenveloppe

... en wat stuurt u terug?

Met de terugstuurenveloppe:
- ✓ Uw tweede vragenlijst
- ✓ Informed consent stichting Health Base

Via email (druid@ugent.be):
- ✓ Uw Log-file(s). Indien u de usb-tool hebt geïnstalleerd op verschillende computers zal u meerdere logfiles moeten versturen.

!! Deadline 4 maart 2011 !!

Wat nu?

Na het ontvangen van uw vragenlijst, informed consent alsook uw logfile(s) sturen wij u de beloofde waardebon ter waarde van 100€ zo snel mogelijk toe!

De resultaten van deze bevraging worden in de tweede helft van 2011 gepubliceerd op de DRUID-website: www.druid-project.eu

Uw mening?
Heeft u opmerkingen/bemerkingen ivm gebruik van de USB- tool of andere?

⇨ druid@ugent.be

Annex 3: Banner shown on flat screens – pharmacists ViaNova

Annex 4: First Belgian pharmaceutical care symposium – Poster (18/9/2010)

Effect van ondersteunende richtlijnen en instrumenten op houding van apothekers bij aflevering van rijgevaarlijke geneesmiddelen

Trudy Van der Linden[a], Sara-Ann Legrand[a], Chantal Leirs[b], Anneleen Janssen[b], Alain Verstraete[a]

[a] Universiteit Gent, Vakgroep Klinische biologie, microbiologie en immunologie, De Pintelaan 185, Gent
[b] Escapo cv, Antwerpsesteenweg 263, Mechelen

Inleiding:

DRUID (Driving Under the Influence of Drugs,alcohol and medicines) is een Europees onderzoeksproject waarin onder meer studies worden uitgevoerd over het effect van geneesmiddelen op de rijvaardigheid. Er werden richtlijnen voor apothekers voor het afleveren van mogelijk rijgevaarlijke geneesmiddelen ontwikkeld alsook een classificatiesysteem dat aanduidt in welke mate een geneesmiddel invloed heeft op de rijvaardigheid. Deze richtlijnen en classificatiesysteem worden geïmplementeerd binnen bestaande software om ze in de praktijk te gebruiken om patiënten beter te informeren over de mogelijke risico's.

Doelstelling:

Het doel van de studie is om de impact van het gebruik van de richtlijnen en het classificatiesysteem te meten in de dagelijkse praktijk. De impact wordt op twee manieren gemeten: vanuit de geïntegreerde software zullen anonieme data geëxtraheerd worden en verandering van kennis en attitude zal geanalyseerd worden via enquêtes.

Methode:

84 apothekers die gebruik maken van de VlaNova software waren geïnteresseerd in de studie. Aan deze groep wordt gevraagd om:

- De functies m.b.t. rijvaardigheid (eerste uitgiftesignalen: EUC (eerste uitgifte controle) en EUB (eerste uitgifte begeleiding) te activeren in Vlanova
- Deel te nemen aan een trainingsavond over de invloed van geneesmiddelen op de rijvaardigheid.
- Een enquête in te vullen.
- Zes maand de geïntegreerde functies m.b.t. rijvaardigheid te gebruiken.
- Na deze periode de gegevens anoniem te laten ophalen uit de software.
- Na deze periode een tweede enquête in te vullen

Er werden een uitgebreide handleiding en nieuwsbrieven opgemaakt om de apothekers zo goed mogelijk te ondersteunen en te blijven motiveren. Om het publiek attent te maken op het thema 'medicatie en rijden' werd een wachtverzachter (zie fig1) gemaakt die in de apotheken te zien was. Ook verscheen er een artikel in een mutualiteitskrant[1] en was een kort interview te horen op de Oost-Vlaamse radio.

Resultaten:

De basismeting aan de hand van de eerste vragenlijst is reeds gebeurd. De gegevens zijn ingevoerd in een statistisch programma (PASW).
Een eerste beschrijving van de populatie aangaande geslacht en leeftijd is te zien in tabel 1. De leeftijdscategorie 30-45j is het meest vertegenwoordigd. De verhouding man/vrouw is 30/70. Bij de vrouwelijke deelnemers ligt het hoogste percentage in de leeftijdsgroep 30-45j, bij de mannelijke vrijwilligers is dit de groep 56-65j. ¼ van de deelnemers heeft meer dan 10 jaar ervaring, met het hoogste percentage in de groep 20+. 18% van de deelnemers geeft aan tijdens hun studies les te hebben gehad over de invloed van geneesmiddelen op de rijvaardigheid, zij het meestal oppervlakkig en summier.
53.6% gebruikt de teksten in VlaNova om informatie over dit thema op te zoeken.
60% informeert de patiënt altijd of op regelmatige basis.
66.7% vindt effecten op de rijvaardigheid een belangrijke factor in hun beslissing om een medicijn af te leveren. Dit percentage is het hoogst wanneer het een professionele bestuurder betreft, of iemand die andere psychoactieve middelen gebruikt, en het laagst wanneer de patiënt een ervaren bestuurder blijkt. Figuur 2 toont de verdeling van deze factor voor het soort bestuurder.

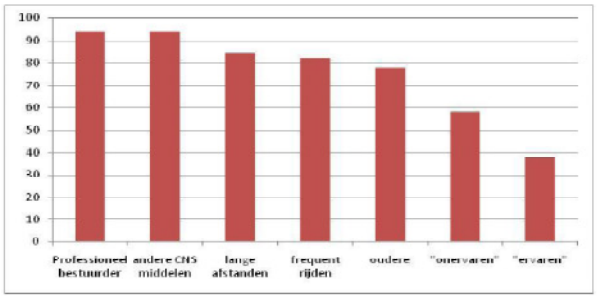
Figuur 1: 'Wachtverzachter' die in de apotheek aandacht vraagt omtrent het thema 'Medicatie en Rijden'

Naast het invullen van een vragenlijst werd gevraagd aan de deelnemers om de functies in verband met de rijvaardigheid in VlaNova in te schakelen. De 6 maand proefperiode wordt afgesloten door middel van het versturen van de tweede enquête. Dit wordt voorzien in de periode oktober-november 2010.

Verdere analyse resultaten worden verwacht in het voorjaar van 2011.

Tabel 1: kruistabel geslacht – leeftijdscategorieën van de deelnemende populatie

		Geslacht		Totaal
		Man	Vrouw	
Leeftijdsgroepen	< 30 j	2 (8,0%)	12 (20,3%)	14 (16,7%)
	30 - 45 j	7 (28,0%)	27 (45,8%)	34 (40,5%)
	46 - 55 j	6 (24,0%)	18 (30,5%)	24 (28,6%)
	56 – 65 j	10 (40%)	2 (3,4%)	12 (14,3%)
Totaal		25 (100%)	59 (100%)	84 (100%)



Figuur 2: percentage van apothekers die de effecten op de rijvaardigheid een belangrijke factor vinden in hun beslissing om een medicijn af te leveren wanneer het bepaalde patiënten betreft: een professioneel bestuurder, persoon die andere psychoactieve stoffen neemt, die lange afstanden aflegt, frequent rijdt, een oudere bestuurder is, onervaren of ervaren is.

Discussie:

De focus ligt op de eerste uitgiftebegeleiding bij nieuwe voorschriften, in eerste instantie wordt enkel bij eerste uitgifte op deze problematiek gewezen. Dit omdat de apothekers aangaven dat het aankaarten van de mogelijke effecten van een geneesmiddel op de rijvaardigheid vooral nut heeft bij de opstart daar vele middelen dan een probleem geven. Ook in de GIT (geneesmiddelen informatie tekst) die aan de patiënt kan meegegeven worden, kan steeds de rubriek rijvaardigheid bekeken worden.
De apothekers willen niet in het vaarwater van artsen komen en vinden een samenwerking omtrent dit thema niet vanzelfsprekend. Om tegemoet te komen aan hun vraag om artsen van dit studiedesign in te lichten, werd informatie geplaatst op een website van artsen van een deelnemende regio. Tevens werd het DRUID-onderzoek kort toegelicht in 'De artsenkrant'.

Conclusie:

Met een goede, wetenschappelijk onderbouwde classificatie moeten artsen en apothekers in de toekomst in staat zijn de patiënt optimaal in te lichten. De talrijke opkomst bij de trainingsavonden geeft aan dat er vanuit de apothekersgroep grote belangstelling is voor een implementatie van een systeem dat ze kunnen gebruiken om de patiënt begrijpelijke informatie mee te geven.

[1] CM Visie nummer 11 16 april 2010, p5. http://www.acv-online.be/images/visie_nr11_dd1604new_tcm9-219607.pdf

Meer informatie omtrent DRUID kan u vinden op www.druid-project.eu of druid@ugent.be
Website escapo: www.escapo.be

Disclaimer: This abstract has been produced under the project "Driving Under the Influence of Drugs, Alcohol and Medicines" (DRUID) financed by the European Commission within the framework of the EU 6th Framework Program. This abstract reflects only the author's view. The European Community is not liable for any use that may be made of the information contained therein.

Annex 5: Questionnaires

Baseline questionnaire

VRAGENLIJST VOOR APOTHEKERS

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract Nr: TREN - 05-FP6TR-SO7.61320-518404-DRUID

Beste deelnemer,

Deze studie is een onderdeel van het Europese project DRUID (Driving under the influence of drugs, alcohol and medicines). We zijn hierbij geïnteresseerd in uw mening over de invloed van geneesmiddelen op de rijvaardigheid.

Lees iedere vraag grondig en kruis het gepaste antwoordvakje ☑ aan. Bij de meeste vragen hoeft U slechts één vakje aan te duiden maar lees aub alle vragen zorgvuldig aangezien soms meer dan één vakje aangeduid moet worden.

We garanderen U dat al uw antwoorden anoniem behandeld zullen worden en dat deze enkel voor wetenschappelijke doeleinden gebruikt zullen worden.

Indien U nog meer vragen hebt, aarzel dan niet om het DRUID-team te contacteren via druid@ugent.be of 09 332 67 33.

☐ Mijn deelname aan deze vragenlijst is vrijwillig.
(informed consent).

Bedankt voor uw medewerking,

Prof. dr. Alain Verstraete
UZ Gent
Polikliniek 8, 2de verdieping
De Pintelaan 185
9000 Gent

Bedankt voor uw medewerking!

Datum:_____

A. ACHTERGROND INFORMATIE

1. Geslacht

☐ Man ☐ Vrouw

2. Leeftijd

☐ < 30 jaar
☐ 30 – 45 jaar
☐ 46 – 55 jaar
☐ 56 – 65 jaar
☐ 66 – 75 jaar
☐ > 75 jaar

3. Aantal inwoners gemeente praktijk

☐ > 10000
☐ <10,000

4. Jaar van afstuderen (JJJJ): _____

4a. Hoeveel jaar staat U reeds in de praktijk als apotheker ?

☐ < 5 jaar
☐ 5 – 10 jaar
☐ 11 – 15 jaar
☐ 16 – 20 jaar
☐ > 20 jaar

5. Kreeg U een tijdens uw studies aan de universiteit les over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, specificeer aub: _____

_____

B. KENNIS VAN NIEUWE TECHNOLOGIEËN

1. Gebruikt U het internet om informatie op te zoeken ?

☐ Ja ☐ Nee

2. Gebruikt U het internet om informatie op te zoeken over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

3. Indien U 'Ja' antwoordde op vraag 2, hoe vaak doet U dit ?

☐ Dagelijks ☐ Wekelijks ☐ Minder dan wekelijks ☐ Anders (specificeer: _____)

4. Heeft U ooit software gebruikt om informatie op te zoeken over het effect van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

5. Indien U 'Ja' antwoordde op vraag 4, om welke software ging dit ?

1. _____
2. _____
3. _____
4. _____
5. _____

6. Gebruikt U software om geneesmiddelen af te leveren in uw dagelijkse praktijk ?

☐ Ja ☐ Nee

7. Indien U 'Ja' antwoordde op vraag 6, om welke software gaat dit ?

1. _____
2. _____
3. _____
4. _____
5. _____

C. ATTITUDES EN BEWUSTZIJN

Evalueer aub de volgende stellingen:

1. Effecten op de rijvaardigheid zijn een belangrijke factor in mijn beslissing om een medicijn af te leveren.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Zou U dit (vraag 1) belangrijker vinden indien uw patiënt: (gelieve alle vragen te beantwoorden)

- een professionele bestuurder is? ☐ Ja ☐ Nee
- frequent rijdt? ☐ Ja ☐ Nee
- lange afstanden aflegt? ☐ Ja ☐ Nee
- een "onervaren" bestuurder is? ☐ Ja ☐ Nee
- een "ervaren" bestuurder is? ☐ Ja ☐ Nee
- een oudere bestuurder is? ☐ Ja ☐ Nee
- nog andere psychoactieve middelen neemt? ☐ Ja ☐ Nee

3. Ik ben bereid (in gevallen van *over the counter* medicatie) om een bepaalde mate van efficiënte van het geneesmiddel op te offeren indien het alternatieve geneesmiddel minder invloed heeft op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4. Ik voel me goed op de hoogte van de effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

5. Het is voor mij belangrijk dat ik goed geïnformeerd blijf over effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Ik denk dat het geven van informatie aan mijn patiënten hun beslissing om wel of niet te rijden beïnvloedt.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

D. GEDRAG

1. Ik vraag mijn patiënt naar zijn rijgedrag wanneer ik een geneesmiddel kies om af te leveren

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

2. Ik informeer een patiënt mondeling over risico's op de rijvaardigheid wanneer ik een geneesmiddel aflever.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

3. Ik geef een patiënt geschreven informatie mee als ik een geneesmiddel aflever met een invloed op de rijvaardigheid.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

4. Ik hou systematisch bij wanneer ik een rijgevaarlijk geneesmiddel aflever.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

5. Ik hou systematisch bij welk adviezen ik geef aan een patiënt als ik weet dat hij/zij mogelijks een auto zal besturen bij gebruik van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

6. Ik hou de verkeersdeelname van een patiënt bij (bvb. Hoe vaak hij/zij naar het werk gaat met de auto)

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

7. Ik praat over geneesmiddelengebruik en verantwoordelijkheid bij verkeersdeelname met de patiënt.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

8. Hoe vaak verstrekt U gedetailleerde informatie aan de patiënt wanneer U een rijgevaarlijk geneesmiddel aflevert ?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

E. BRONNEN

1. Ik heb gemakkelijk toegang tot data en informatie over het effect van een geneesmiddel op de rijvaardigheid.

☐ Ja ☐ Nee

2. Vermeld aub uw bronnen:

☐ Professionele websites
☐ Nieuwsbrieven
☐ Verkeersveiligheidsorganisaties
☐ Beroepsverenigingen
☐ Wetenschappelijke tijdschriften
☐ Andere (specifieer: _____)

3. Heeft U een postgraduaatsopleiding gekregen over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

4. Indien U "Ja" antwoordde op vraag 3, specificeer aub :

F. KENNIS

1. Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen. Duid telkens aan welk antwoord het best aansluit bij uw professionele inschatting.

Stelling	Totaal oneens	Oneens	Noch eens noch oneens	Totaal eens	Weet niet
Temazepam (tot 20 mg) heeft een sterk negatieve invloed op de rijvaardigheid 8 uur na inname.	☐	☐	☐	☐	☐
Diazepam (onafhankelijk van dosis) heeft een sterk negatieve invloed op de rijvaardigheid tot 2 maanden na het begin van de behandeling.	☐	☐	☐	☐	☐
Codeïne (tot 20 mg) is meestal veilig voor bestuurders.	☐	☐	☐	☐	☐
Fexofenadine (in normale dosis) heeft een sterk negatieve invloed op de rijvaardigheid.	☐	☐	☐	☐	☐
Amitriptyline bij het begin van een behandeling heeft evenveel negatieve invloed op de rijvaardigheid als 4 weken na de start van de behandeling.	☐	☐	☐	☐	☐
Paroxetine (tot 20 mg/dag) is veilig voor bestuurders	☐	☐	☐	☐	☐

2. Apothekers zijn verplicht om hun patiënten in te lichten over de mogelijke effecten van hun geneesmiddel op de rijvaardigheid.

☐ Waar ☐ Niet waar

3. Een patiënt kan aansprakelijk gesteld worden indien hij/zij een ongeval veroorzaakt en een potentieel rijgevaarlijk geneesmiddel neemt en nadat de dokter/apotheker hem geadviseerd heeft om niet te rijden.

☐ Waar ☐ Niet waar

G. AANVAARDING DOOR GEBRUIKER

1. Indien we U een software voorstellen die U toelaat om informatie te vinden over geneesmiddelen en de rijvaardigheid, zou U bereid zijn om deze te gebruiken ?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" geantwoord hebt op vraag 1, wat zijn de belangrijkste redenen om deze software (misschien) niet te gebruiken ?

_____

_____

3. Naar welk type instrument zou uw voorkeur gaan: gelieve in rangorde 1 tot 3 uw voorkeur weer te geven waarbij 1 uw meest geprefereerde vorm aanduidt.

	1	2	3
Website			
Software geintegreerd in eigen programma			
Aparte digitale informatie (bvb. USB-stick, CD-ROM)			
Handboek			
Andere (specificeer a.u.b:_____)			

Bijkomende opmerkingen
(Gelieve hieronder alle eventuele bijkomende opmerkingen en aanbevelingen te vermelden)

Second Questionnaire

VRAGENLIJST VOOR APOTHEKERS

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract Nr: TREN - 05-FP6TR-SO7.61320-518404-DRUID

Beste deelnemer,

Deze studie is een onderdeel van het Europese project DRUID (Driving under the influence of drugs, alcohol and medicines). We zijn hierbij geïnteresseerd in uw mening over de invloed van geneesmiddelen op de rijvaardigheid.

Lees iedere vraag grondig en kruis het gepaste antwoordvakje ☑ aan. Bij de meeste vragen hoeft U slechts één vakje aan te duiden maar lees aub alle vragen zorgvuldig aangezien soms meer dan één vakje aangeduid moet worden.

We garanderen U dat al uw antwoorden anoniem behandeld zullen worden en dat deze enkel voor wetenschappelijke doeleinden gebruikt zullen worden.

Indien U nog meer vragen hebt, aarzel dan niet om het DRUID-team te contacteren via druid@ugent.be of 09 332 67 33.

☐ Mijn deelname aan deze vragenlijst is vrijwillig.
(informed consent).

Bedankt voor uw medewerking,

Prof. dr. Alain Verstraete
UZ Gent
Polikliniek 8, 2de verdieping
De Pintelaan 185
9000 Gent

Bedankt voor uw medewerking!

Datum:_____

A. ACHTERGROND INFORMATIE

1. Geslacht

☐ Man ☐ Vrouw

2. Leeftijd

☐ < 30 jaar
☐ 30 – 45 jaar
☐ 46 – 55 jaar
☐ 56 – 65 jaar
☐ 66 – 75 jaar
☐ > 75 jaar

3. Aantal inwoners gemeente praktijk

☐ > 10000
☐ <10,000

4. Jaar van afstuderen (JJJJ): _____

4a. Hoeveel jaar staat U reeds in de praktijk als apotheker ?

☐ < 5 jaar
☐ 5 – 10 jaar
☐ 11 – 15 jaar
☐ 16 – 20 jaar
☐ > 20 jaar

5. Kreeg U een tijdens uw studies aan de universiteit les over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, specificeer aub: _____

_____

B. KENNIS VAN NIEUWE TECHNOLOGIEËN

1. Gebruikt U het internet om informatie op te zoeken ?

☐ Ja ☐ Nee

2. Gebruikt U het internet om informatie op te zoeken over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

3. Indien U 'Ja' antwoordde op vraag 2, hoe vaak doet U dit ?

☐ Dagelijks ☐ Wekelijks ☐ Minder dan wekelijks ☐ Anders (specificeer: _____)

4. Heeft U ooit software gebruikt om informatie op te zoeken over het effect van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

5. Indien U 'Ja' antwoordde op vraag 4, om welke software ging dit ?

1. _____
2. _____
3. _____
4.
5. _____

6. Gebruikt U software om geneesmiddelen af te leveren in uw dagelijkse praktijk ?

☐ Ja ☐ Nee

7. Indien U 'Ja' antwoordde op vraag 6, om welke software gaat dit ?

1.
2. _____
3. _____
4.
5. _____

C. ATTITUDES EN BEWUSTZIJN

Evalueer aub de volgende stellingen:

1. Effecten op de rijvaardigheid zijn een belangrijke factor in mijn beslissing om een medicijn af te leveren.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Zou U dit (vraag 1) belangrijker vinden indien uw patiënt: (gelieve alle vragen te beantwoorden)

- een professionele bestuurder is? ☐ Ja ☐ Nee
- frequent rijdt? ☐ Ja ☐ Nee
- lange afstanden aflegt? ☐ Ja ☐ Nee
- een "onervaren" bestuurder is? ☐ Ja ☐ Nee
- een "ervaren" bestuurder is? ☐ Ja ☐ Nee
- een oudere bestuurder is? ☐ Ja ☐ Nee
- nog andere psychoactieve middelen neemt? ☐ Ja ☐ Nee

3. Ik ben bereid (in gevallen van *over the counter* medicatie) om een bepaalde mate van efficiënte van het geneesmiddel op te offeren indien het alternatieve geneesmiddel minder invloed heeft op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4. Ik voel me goed op de hoogte van de effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

5. Het is voor mij belangrijk dat ik goed geïnformeerd blijf over effecten van geneesmiddelen op de rijvaardigheid.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Ik denk dat het geven van informatie aan mijn patiënten hun beslissing om wel of niet te rijden beïnvloedt.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

D. GEDRAG

1. Ik vraag mijn patiënt naar zijn rijgedrag wanneer ik een geneesmiddel kies om af te leveren

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

2. Ik informeer een patiënt mondeling over risico's op de rijvaardigheid wanneer ik een geneesmiddel aflever.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

3. Ik geef een patiënt geschreven informatie mee als ik een geneesmiddel aflever met een invloed op de rijvaardigheid.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

4. Ik hou systematisch bij wanneer ik een rijgevaarlijk geneesmiddel aflever.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

5. Ik hou systematisch bij welk adviezen ik geef aan een patiënt als ik weet dat hij/zij mogelijks een auto zal besturen bij gebruik van een rijgevaarlijk geneesmiddel.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

6. Ik hou de verkeersdeelname van een patiënt bij (bvb. Hoe vaak hij/zij naar het werk gaat met de auto)

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

7. Ik praat over geneesmiddelengebruik en verantwoordelijkheid bij verkeersdeelname met de patiënt.

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

8. Hoe vaak verstrekt U gedetailleerde informatie aan de patiënt wanneer U een rijgevaarlijk geneesmiddel aflevert ?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

E. BRONNEN

1. Ik heb gemakkelijk toegang tot data en informatie over het effect van een geneesmiddel op de rijvaardigheid.

☐ Ja ☐ Nee

2. Vermeld aub uw bronnen:

☐ Professionele websites
☐ Nieuwsbrieven
☐ Verkeersveiligheidsorganisaties
☐ Beroepsverenigingen
☐ Wetenschappelijke tijdschriften
☐ Andere (specifieer: _____)

3. Heeft U een postgraduaatsopleiding gekregen over de invloed van geneesmiddelen op de rijvaardigheid ?

☐ Ja ☐ Nee

4. Indien U "Ja" antwoordde op vraag 3, specificeer aub :

F. KENNIS

1. Evalueer volgende stellingen op basis van uw dagelijkse praktijkervaringen. Duid telkens aan welk antwoord het best aansluit bij uw professionele inschatting.

Stelling	Totaal oneens	Oneens	Noch eens noch oneens	Totaal eens	Weet niet
Temazepam (tot 20 mg) heeft een sterk negatieve invloed op de rijvaardigheid 8 uur na inname.	☐	☐	☐	☐	☐
Diazepam (onafhankelijk van dosis) heeft een sterk negatieve invloed op de rijvaardigheid tot 2 maanden na het begin van de behandeling.	☐	☐	☐	☐	☐
Codeïne (tot 20 mg) is meestal veilig voor bestuurders.	☐	☐	☐	☐	☐
Fexofenadine (in normale dosis) heeft een sterk negatieve invloed op de rijvaardigheid.	☐	☐	☐	☐	☐
Amitriptyline bij het begin van een behandeling heeft evenveel negatieve invloed op de rijvaardigheid als 4 weken na de start van de behandeling.	☐	☐	☐	☐	☐
Paroxetine (tot 20 mg/dag) is veilig voor bestuurders	☐	☐	☐	☐	☐

2. Apothekers zijn verplicht om hun patiënten in te lichten over de mogelijke effecten van hun geneesmiddel op de rijvaardigheid.

☐ Waar ☐ Niet waar

3. Een patiënt kan aansprakelijk gesteld worden indien hij/zij een ongeval veroorzaakt en een potentieel rijgevaarlijk geneesmiddel neemt en nadat de dokter/apotheker hem geadviseerd heeft om niet te rijden.

☐ Waar ☐ Niet waar

G. AANVAARDING DOOR GEBRUIKER - INHOUD

1. Heeft U de richtlijnen gebruikt ter ondersteuning van uw communicatie naar de patiënt toe ?

☐ Ja ☐ Nee

2. Indien U "Ja" antwoordde op vraag 1, hoe vaak gebruikte U de richtlijnen ?

☐ altijd ☐ vaak ☐ soms ☐ zelden

3. Indien U 'zelden' of 'nooit' antwoordde op vraag 2, wat zijn Uw belangrijkste redenen om de richtlijnen niet te gebruiken?

---

4. De aangeboden richtlijnen voor het afleveren van potentieel rijgevaarlijke medicijnen zijn:

	Ja, heel erg	Tamelijk	Minder	Nee, helemaal niet
Nuttig				
Bruikbaar				
Toereikend				

5. Gebruikte U de patiëntenbrieven om uw patiënt te informeren over geneesmiddelen en rijvaardigheid?

☐ Ja ☐ Nee

6. Indien U "Ja" antwoordde op vraag 5, hoe vaak gebruikte U dit?

☐ altijd ☐ vaak ☐ soms ☐ zelden ☐ nooit

7. De aangeboden brieven zijn:

	Ja, heel erg	Tamelijk	Minder	Nee, helemaal niet
Nuttig				
Bruikbaar				
Toereikend				

8.Gebruikte U het pictogramsysteem om uw patiënt te informeren over geneesmiddelen en rijvaardigheid ?

☐ Ja ☐ Nee

9. Indien U "Ja" antwoordde op vraag 8, hoe vaak gebruikte U het labelling systeem ?

☐ altijd ☐ regelmatig ☐ soms ☐ zelden ☐ nooit

10. Het pictogramsysteem voor het afleveren van geneesmiddelen met mogelijk rijgevaarlijk effect is.

	Ja, heel erg	Tamelijk	Minder	Nee, helemaal niet
Nuttig				
Bruikbaar				
Toereikend				

11. Vindt U dat er extra informatie moet toegevoegd worden die nu nog ontbreekt ?

☐ Ja ☐ Nee

12. Indien U "Ja" antwoordde op vraag 16, specifieer aub:

_____
_____
_____

14. Denkt U dat de richtlijnen uw manier van afleveren van geneesmiddelen beïnvloed hebben?

Ja, heel erg ☐ ☐ ☐ ☐ ☐ Nee, totaal niet

15. Denkt U dat de richtlijnen uw manier van informatie geven aan patiënten beïnvloed hebben?

Ja, heel erg ☐ ☐ ☐ ☐ ☐ Nee, totaal niet

H. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID - SOFTWARE (indien u de USB-stick en het handboek gebruikte, ga naar vraag I en J)

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan.

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van de software omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. Deze software zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:

_____
_____
_____

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

_____
_____
_____

7. Vindt U dat de software nog extra opties moet hebben op het scherm of dat bepaalde functies momenteel ontbreken?

☐ Ja ☐ Nee

8. Indien U "Ja" antwoordde op vraag 7, specificeer a.u.b:

_____
_____
_____

I. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID – USB-STICK (indien u de software gebruikte, ga naar vraag K)

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan.

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van de USB-stick omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. Het gebruik van deze USB-stick zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:
---

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

---

7. Vindt U dat de USB-stick nog extra opties moet hebben of dat bepaalde functies momenteel ontbreken?

☐ Ja ☐ Nee

8. Indien U 'Ja' antwoordde op vraag 7, specificeer a.u.b:

J. AANVAARDING DOOR GEBRUIKER & GEBRUIKSVRIENDELIJKHEID – HANDBOEK

Geef a.u.b. aan in hoeverre de volgende stellingen uw persoonlijke opinie weergeven. Kruis telkens één van de vakjes aan.

1. Ik kon zonder problemen de informatie vinden die ik zocht.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

2. Ik vond het gebruik van het handboek omslachtig.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

3. Het gebruik van het handboek zou goed passen in mijn dagelijkse praktijk.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

4 Indien U 'helemaal niet akkoord' antwoordde op vraag 3, specificeer a.u.b:
---

5. Tekst en iconen zijn gemakkelijk te begrijpen.

☐ helemaal niet akkoord ☐ niet akkoord ☐ akkoord ☐ helemaal akkoord

6. Indien U 'helemaal niet akkoord' antwoordde op vraag 5, specificeer a.u.b:

---

7. Vindt U dat het handboek nog extra informatie moet bevatten?

☐ Ja ☐ Nee

8. Indien U 'Ja' antwoordde op vraag 7, specificeer a.u.b:

K. GEBRUIK VAN DE SOFTWARE IN DE TOEKOMST (indien u de usb-stick en het handboek gebruikte, ga naar vraag L en M)

1. Zou U deze software willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:

---

3. Waarvoor zou U de software het meest gebruiken? (specificeer a.u.b.)

L. GEBRUIK VAN DE USB-STICK IN DE TOEKOMST

1. Zou U deze USB-stick willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:

---

3. Waarvoor zou U de USB stick het meest gebruiken? (specificeer a.u.b.)

M. GEBRUIK VAN HET HANDBOEK IN DE TOEKOMST

1. Zou U dit handboek willen (blijven) gebruiken in de toekomst?

☐ Ja ☐ Nee ☐ Misschien

2. Indien U "Nee" of "Misschien" antwoordde op vraag 1, specificeer a.u.b:

---

3. Waarvoor zou U het handboek het meest gebruiken? (specificeer a.u.b.)

Bijkomende opmerkingen
(Gelieve hieronder alle eventuele bijkomende opmerkingen en aanbevelingen te vermelden)

Annex 6. Pre-post change: Wilcoxon tables

ViaNova Group

Table 89: ViaNova group pre-post change – attitudes and awareness

	Pre-post questionnaire change (within-group %)			
	Negative change	Positive change	No change	Total N
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	21.54	18.46	60	65
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	7.58	15.15	77.27	66
I feel being well aware of the effects of medicines on driving skills. *	11.94	**25.37**	62.69	67
It is important for me to be well-informed on medicinal effects on driving behaviour.	14.71	20.59	64.71	68
I feel that the information I provide to patients will influence their driving behaviour.	14.93	26.87	58.21	67
Composite Score Attitudes & Awareness (median)	13.43	11.94	76.12	68

* Wilcoxon Signed Ranks Test p≤0.05

Table 90: ViaNova group pre-post change – Detail attitudes and awareness

Would you consider this of more concern if your patient is:	Pre-post questionnaire change (within-group %)		
	Negative change	Positive change	No change
a professional driver	5.97	4.48	89.55
driving frequently	9.23	12.31	78.46
driving long distances	7.58	6.06	86.36
an 'inexperienced driver	17.74	19.35	62.90
an experienced driver	19.67	24.59	55.74
an elderly driver	7.69	12.31	80
using other CNS active drugs	7.58	3.03	89.39

Table 91: ViaNova group pre-post questionnaire comparison – Reported behaviour

	Pre-post questionnaire change (within-group %)			
	Negative change	Positive change	No change	Total N
I ask a patient about his/her driving exposure when dispensing a medicine.*	5.88	**60.29**	33.82	68
I inform a patient about driving related risks when dispensing a medicine.*	4.41	**60.29**	35.29	68
I provide a patient with written information materials when dispensing a driving impairing medicine.	29.41	35.29	35.29	68
I keep systematic records when I dispense a driving impairing medicine.*	7.69	**61.54**	30.77	65

I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.*	5.97	**61.19**	32.84	67
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).*	5.88	**32.35**	61.76	68
I discuss medicinal drug consumption and driving related responsibility issues with the patient.*	5.97	**62.69**	31.34	67
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?*	4.41	**69.12**	26.47	68
Composite Score Reported behaviour (median)*	7.35	**77.94**	14.71	68

* Wilcoxon Signed Ranks Test p≤.05

Table 92: ViaNova group pre-post change – Knowledge questions

ViaNova pre-post questionnaire change (within-group %)				
	Negative change	Positive change	No change	Total N
Diazepam (regardless of dose) is severely impairing within the first 2 months of treatment *	**10.61**	**27.27**	**62.12**	**66**
Codeine (up to 20 mg) is mostly safe for drivers *(trend)*	17.65	33.82	48.53	68
Fexofenadine (normal dose) is severely impairing driving	23.08	24.62	52.31	65
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment *	**13.64**	**37.88**	**48.48**	**66**
Paroxetine (up to 20 mg/day) is safe for drivers	19.40	10.45	70.15	67
Composite score – knowledge medicine risk (correct answers on 5)*	**25**	**52.94**	**22.06**	**68**
Physicians/pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	10.45	11.94	77.61	67
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.	6.56	14.75	78.69	61
Composite score – general knowledge (correct answers on 7)*	**26.47**	**50**	**23.52**	**68**

* Wilcoxon Signed Ranks Test p≤.05

USB group

Table 93: USB group pre-post change – attitudes and awareness (within-group %)

	Pre-post questionnaire change			
	Negative change	Positive change	No change	Total N
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	16.67	16.67	66.67	12
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	0	8.33	91.67	12
I feel being well aware of the effects of medicines on driving skills.	8.33	25	66.67	12
It is important for me to be well-informed on medicinal effects on driving behaviour.	0	8.33	91.67	12
I feel that the information I provide to patients will influence their driving behaviour.	8.33	16.67	75	12
Composite Score (median)	0	8.33	91.67	12

Table 94: USB pre-post change – Detail attitudes and awareness

	Pre-post questionnaire change (within-group %)		
Would you consider this of more concern if your patient is:	**Negative change**	**Positive change**	**No change**
a professional driver	0	0	100
driving frequently	16.67	0	83.33
driving long distances	9.09	0	90.90
an 'inexperienced driver'	25	16.67	58.33
an experienced'driver'	9.09	9.09	81.82
an elderly driver	8.33	0	91.67
using other CNS active drugs	16.67	0	83.33

Table 95: USB group pre-post change – Reported behaviour

	Pre-post questionnaire change			
	Negative change	Positive change	No change	Total N
I ask a patient about his/her driving exposure when dispensing a medicine.	16.67	41.67	41.67	12
I inform a patient about driving related risks when dispensing a medicine.	8.33	25	66.67	12
I provide a patient with written information materials when dispensing a driving impairing medicine.	16.67	25	58.33	12
I keep systematic records when I dispense a driving impairing medicine.	33.33	16.67	50	12
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	8.33	16.67	75	12

I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	16.67	8.33	75	12
I discuss medicinal drug consumption and driving related responsibility issues with the patient.*	**0**	**50**	**50**	**12**
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?	16.67	8.33	75	12
Composite Score Reported behaviour (median)	25	58.33	16.67	12

* Wilcoxon Signed Ranks Test p≤.05

Table 96: USB group pre-post change – Knowledge questions

	Pre-post questionnaire change (N -> within-group%)			
	Negative change	Positive change	No change	Total N
Diazepam (regardless dose) is severly impairing within the first 2 months of treatment	25	8.33	66.67	12
Codeine (up to 20 mg) is mostly safe for drivers	16.67	25	58.33	12
Fexofenadine (normal dose) is severely impairing driving	0	22.22	77.78	9
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment *	**0**	**33.33**	**66.67**	**12**
Paroxetine (up to 20 mg/day) is safe for drivers	41.67	16.67	41.67	12
Composite score Knowledge on selected medicines' risk (sum correct on 5)	50.0	50.0	0	12
Physicians/pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities. (trend) (Z= -1,732 ; p .083)	*25*	*0*	*75*	*12*
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.	8.33	25	66.67	12
Composite score Knowledge (total sum correct on 7)	50.0	41.7	8.3	12

* Wilcoxon Signed Ranks Test p≤.05

Control group

Table 97: Control group pre-post change – Attitudes and awareness

	Pre-post questionnaire change			
	Negative change	Positive change	No change	Total N
I am willing to take into account the effects of medicines on driving skills when dispensing medicines	20	15	65	20
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	15	15	70	20
I feel being well aware of the effects of medicines on driving skills.	10	0.0	90	20
It is important for me to be well-informed on medicinal effects on driving behaviour.	15.79	15.79	68.42	19
I feel that the information I provide to patients will influence their driving behaviour.	10	5	85	20
Composite Score (median)	20	5	75	20

Table 98: Control pre-post change – Detail attitudes and awareness

	Pre-post questionnaire change (within-group)		
Would you consider this of more concern if your patient is:	**Negative change**	**Positive change**	**No change**
a professional driver	0	0	100
driving frequently	0	0	100
driving long distances	0	5	95
an 'inexperienced driver'	21.05	10.53	68.42
an experienced'driver'	11.11	11.11	77.78
an elderly driver	5.56	0	94.44
using other CNS active drugs	5.26	5.26	89.47

Table 99: Control group pre-post change – Reported behaviour

	Pre-post questionnaire change			
	Negative change	Positive change	No change	Total N
I ask a patient about his/her driving exposure when dispensing a medicine.	20	30	50	20
I inform a patient about driving related risks when dispensing a medicine. (trend)	*10*	*40*	*50*	*20*
I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine.	15	25	60	20
I keep systematic records when I prescribe/dispense a driving impairing medicine.	10	10	80	20
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.	10	15	75	20
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	20	15	65	20

I discuss medicinal drug consumption and driving related responsibility issues with the patient.	15	35	50	20
How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?	25	35	40	20
Composite Score (median)	30	35	35	20

* Wilcoxon Signed Ranks Test p≤.05

Table 100: Control group pre-post change – Knowledge questions

	Pre-post questionnaire change (N -> within-group%)			
	Negative change	Positive change	No change	Total N
Diazepam (regardless dose) is severely impairing within the first 2 months of treatment (trend)	5.56	33.33	61.11	18
Codeine (up to 20 mg) is mostly safe for drivers	21.05	10.53	68.42	19
Fexofenadine (normal dose) is severely impairing driving	5.26	15.79	78.95	19
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment	10.53	26.32	63.16	19
Paroxetine (up to 20 mg/day) is safe for drivers	15.79	36.84	47.37	19
Composite score Knowledge on selected medicines' risk (sum correct on 5)	21.1	52.6	26.3	19
Physicians/pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.	10.53	10.53	78.95	19
A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.	0	5.26	94.74	19
Composite score Knowledge (total sum correct on 7)	26.3	52.6	21.1	19

* Wilcoxon Signed Ranks Test p≤0.05

Chapter 2: The Dutch study

Pharmacists' intervention study: implementation an evaluation of DRUID information materials regarding the influence of medicines on driving fitness.

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Table of Contents

List of Abbreviations

Abbreviation	Full Description
ATC	Anatomical Therapeutic Chemical (ATC) classification
CMPM	Commentaren Medicatiebewaking Pharmacom Medicom *(Commentary Medication Surveillance Pharmacom Medicom)*
CNS	Central Nervous System
D- …	Deliverable
DIM	Driving impairing medicines
DGV	Instituut voor Verantwoord Medicijngebruik *(The Dutch Institute for Rational Use of Medicines)*
DRUID	Driving Under the Influence of Drugs, Alcohol and Medicines
EU	European Union
EUB	Eerste Uitgifte Begeleiding *(First-time dispensing counselling)*
EUC	Eerste Uitgifte Controle *(First-time dispensing check)*
FTO	Farmacotherapeutisch Overleg *(Pharmacotherapeutic review group)*
GP	General Practitioner
GIT	Geneesmiddel Informatie Tekst *(personalised medicines information leaflet)*
HCP	Healthcare Providers
ICT	Information and Communication Technology
LESA	Landelijke Eerstelijns Samenwerkings Afspraak *(National primary care agreement)*
N05B	ATC code for anxiolytic medicines
N05C	ATC code for hypnotic medicines
N06A	ATC code for antidepressant medicines
RUGPha	University of Groningen, Pharmacy
OTC	Over-the-counter (self-medication without prescription)
TUB	Tweede Uitgifte Begeleiding (Second-time dispensing counselling)

WP	Work Package

1 Introduction

The intake of medicinal drugs, especially psychoactive medications such as sedatives, anxiolytics, hypnotics, antidepressants, either by themselves or in association with alcohol or other psychotropic substances, may lead to a decreased fitness to drive safely [1] [2] [3]. For that reason, psychoactive medicines are normally associated with an increase risk of traffic accident [3] [4]. Therefore, it is crucial to provide patients with clear information which should allow them to make their own judgments and decisions whether it is safe or not to drive their car.

In the Netherlands, awareness about the influence of medicines on driving fitness has increased over the past years and several information materials were developed and are currently available for health care providers (HCPs).

In October 2008, a Dutch public campaign entitled “Rij veilig met medicijnen” (drive safely with your medicines) was launched and aimed to advise drivers who take driving impairing medicines (DIM) to contact their general practitioner (GP), specialist or pharmacist for more information. Therefore, in May 2008, the Dutch Ministries of Transport and of Health, the Dutch traffic safety organizations, and the national associations of GPs and pharmacists developed and made available information materials to better prepare healthcare providers (HCPs) for the public campaigns. The information materials consisted of a brochure called “Geneesmiddelen in het verkeer” (medicines in traffic) that was developed by the Dutch Institute for Rational Use of Medicine (Instituut voor Verantwoord Medicijngebruik, DGV), a website (www.geneesmiddeleninhetverkeer.nl) and the new “Landelijke Eerstelijns Samenwerkings Afspraak (LESA) “Geneesmiddelen en Verkeersveiligheid” (medication and traffic safety), which is a national primary-care agreement between physicians and pharmacists concerning medicines and driving. These information materials were evaluated by means of a questionnaire that was sent to GPs and pharmacists, at the start of the public campaign in October 2008 [5] and two years after, in 2010 [6]. In 2008, 177 (out of 750) GPs and 163 (out of 500) pharmacists participated in the survey [5]. In 2010, the response rate was slightly lower, with 155 (out of 750) GPs and 144 (out of 500) pharmacists [6]. Despite having a good knowledge on the risks of driving while taking DIM, 83% of the GPs and 90.5% of the pharmacists felt better prepared to inform their patients after receiving the information materials, in 2008 [5]. Two years later, the percentage dropped and only 55% of GPs and 85% of pharmacists felt being better prepared than before [6]. From the comparison between the two questionnaire surveys, it was concluded that GPs and pharmacists were well informed about the possible risks of DIM but not always this knowledge is transferred to patients [6]. However, HPCs believe that patients are now better informed and more aware of the influence of medicines on driving fitness [6]. The Dutch campaign has increased awareness about DIM, in particular among pharmacists and the materials developed in 2008 are still being used [6]. The various computer systems existing in the Netherlands and that HCPs use in their daily practice include the information that was mention above. However, not all HCPs are active with their computer system when it comes to information about medicines and driving.

Besides the information materials that HCP have at their disposal to inform patients, it is common practice to label medicines that are known to impair driving fitness with a yellow warning sticker on the medicines’ box at dispensing. This warning sticker refers to the potential impairing effects of the medicine on one’s reaction time (which may include driving a car or operating machinery, for example) and that special attention should be paid to combined use with alcohol.

One of the goals of the European Union Project – DRUID (driving under the influence of drugs, alcohol and medicines)8 – is the implementation and evaluation of new technologies, such as computerized protocols and ICT (information and communication technology) tools referring to information about medicines and driving (Task 7.4). Such tools can be used in HCPs' daily practice, for selecting (while prescribing or dispensing) the least impairing medicine within a therapeutic class and to provide patient information that will meet patient's needs. In order to accomplish this specific aim, an ICT tool was developed. The DRUID ICT tool encompasses fact sheets of medicines that were categorized within the DRUID framework for the categorization and labeling of medicines. According to the level of impairment on the fitness to drive, a medicine can be classified as category 1 when there is a minor impairment, as category 2 when the impairment is moderate and, lastly, as category 3 when the impairment is severe. Medicines with no impairment have no category. A visual aid (pictogram) was developed as well and was also part of the tool (more information can be found in the DRUID deliverable 7.3.2 [7]). However, In the Netherlands, since October 2008 when the public campaign was launched, the Dutch government funded the development of information materials, websites and ICT–oriented support in dispensing practices (no specific ICT-oriented support for physicians), as mentioned above. Based on that assignment Health Base Foundation (supplier of the Pharmacom® system that is being used by 50% of all community pharmacies in the Netherlands) has developed additional information pertaining to the categorisation system as a support to counselling patients while dispensing a medicine. For that reason, in the Netherlands, the DRUID tool was not used. Instead, the Pharmacom® system was adapted based on DRUID materials.

The present study refers to the development, and consequent evaluation, of a training session that was carried out with the intention of informing Dutch pharmacists, who are not actively using their Pharmacom® computer system, about the influence of medicines on driving fitness. By attending the training, pharmacists should be able to understand the use of the categorization system for medicines that might impair driving performance; to know the recommendations on dispensing information of medicines that might influence driving skills, as these are described in the dispensing guidelines; and to have insight in their policy with regard to medicines that might impair driving performance. A change in dispensing patterns is also expected. By calculating the incidence of driving impairing medicines dispensed before and after pharmacists' training (intervention), it is our expectation to see a decrease in the delivery of medicines that have higher categories and, reversely, an increase in the dispensing of medicines with lower categories. Outcomes at the patient level are also expected and it is estimated that patients who take for the first time a DIM were provided with more detailed information about the influence of medicines on driving fitness.

[8] www.druid-project.eu

1.1 Objectives

The following objectives have been formulated:

1. To determine the effectiveness of pharmacists' training activities related with dispensing driving impairing medication as well as the use of ICT tools. The effectiveness will be measured in a questionnaire survey (compared to baseline measurement), after 6 months as a change in knowledge, attitudes/awareness and (reported) behaviour due to the implementation of the training..

2. To determine the effect of the pharmacists intervention at the patient level by investigating a change in knowledge, attitudes/awareness and (reported) behavior by comparing responses before and after the study period, by requesting patients to complete questionnaires sent by pharmacists belonging to the intervention and control groups..

3. To determine, at the patient level, the decrease in dispensing of moderately and severely impairing medicines to patients by a shift to more safer alternatives within the same therapeutic class of medicines, after interventions by the pharmacists.

1.1.1 Research Questions (RQs)

For practical reasons, and due to the fact that results at different levels are to be expected, from now on, and whenever needed, the information will be divided in 3 groups referring to the pharmacists outcomes, patients outcomes and dispensing data outcomes.

1. Pharmacist outcomes

   - Did pharmacists' awareness about medicines and driving changed after the training?
   - Did pharmacists' reported behaviour about medicines and driving change after the training?
   - Did pharmacists' actual knowledge about medicines and driving improve after the training?
   - What is the overall opinion of the training and information materials provided during intervention period?
   - Are pharmacists willing to accept and use ICT tools?

2. Patient outcomes

   - Are there differences in patients' knowledge before and after the training (measurement T0 and T1, 6 months after the training)?
   - Does the pharmacy group (intervention or control) influence patients' knowledge?
   - What is the role of healthcare providers (HCPs) in informing patients about the influence of medicines on driving fitness?
   - Does the information provided to patients differ within pharmacy group and between measurements?

- Will the information that patients receive from HCPs change their frequency of driving?

3. Dispensing data

- Is there any significant difference in the proportion of dispensed category I, II or III medicines (anxiolytics, ATC code: N05B; hypnotics, ATC code: N05C; and antidepressants, ATC code: N06A) to new users, before and an intervention (DRUID training course).

- Does the pharmacy group (intervention and control) influence the dispensing of different categories of medicines?

2 Methods

2.1 Study Design

The DRUID study was conducted in the Netherlands and consisted of the training of community pharmacists who do not actively use the Pharmacom® system for the first-time dispensing counselling (EUB) and the second-time dispensing counselling (TUB), with respect to anxiolytic (ATC code: N05B), hypnotic (ATC code: N05C), and antidepressant (ATC code: N06A) medicines, known to impair driving fitness.

The training was evaluated by means of a questionnaire that was presented to pharmacists before and 6 months after the training had been carried out (Annexes 1 and 2, respectively). The information that was provided to pharmacists regarding the information about the influence of medicines in driving fitness, which should be provided to patients while dispensing DIM, was evaluated as well at the patient level. This was done by means of a patient questionnaire (Annex 3), sent to patients visiting the participating pharmacies, before and 6 months after the training. The activities that were performed by pharmacists assigned to each group are described in Table 101.

It is important to stress that general practitioners, main prescribers, were contacted to participate in the study as well. However, no interest was shown and, therefore, this group was not included.

Table 101: Activities that were performed by each group of pharmacists during the study period.

	Group	
	Intervention	**Control**
T0 **Before the training**	Pharmacists' questionnaire Patients' questionnaire Dispensing data	– Patients' questionnaire Dispensing data
Oct/Nov 09	**TRAINING**	–
T1 **6-months after the training**	Pharmacists' questionnaire Patients' questionnaire Dispensing data	– Patients' questionnaire Dispensing data

2.2 Recruitment of Participants

2.2.1 Pharmacists

A total of 1031 invitation letters were sent out to all pharmacists using the pharmacy information system called Pharmacom® in their daily practice (Annex 4). The letter contained a small questionnaire about the frequency of the use of EUB/TUB tools of the Pharmacom® system, with respect to medicines that are known to impair driving fitness.

A total of 277 pharmacists (26.9% response rate) responded to the invitation and agreed to participate in this DRUID study. Pharmacists who did not use the EUB/TUB system for anxiolytic (ATC code: N05B), hypnotic (ATC code: N05C), and antidepressant (ATC code: N06A) medicines were selected to participate in the study and were randomly and equally distributed in 2 groups: the intervention (n=50) and the control (n=50) groups.

Drop-outs were verified and the final number of participants was as follows: 49 in the intervention group and 42 in the control group, which means a total of 91 pharmacists enrolled in the study. Figure 54 represents those numbers.

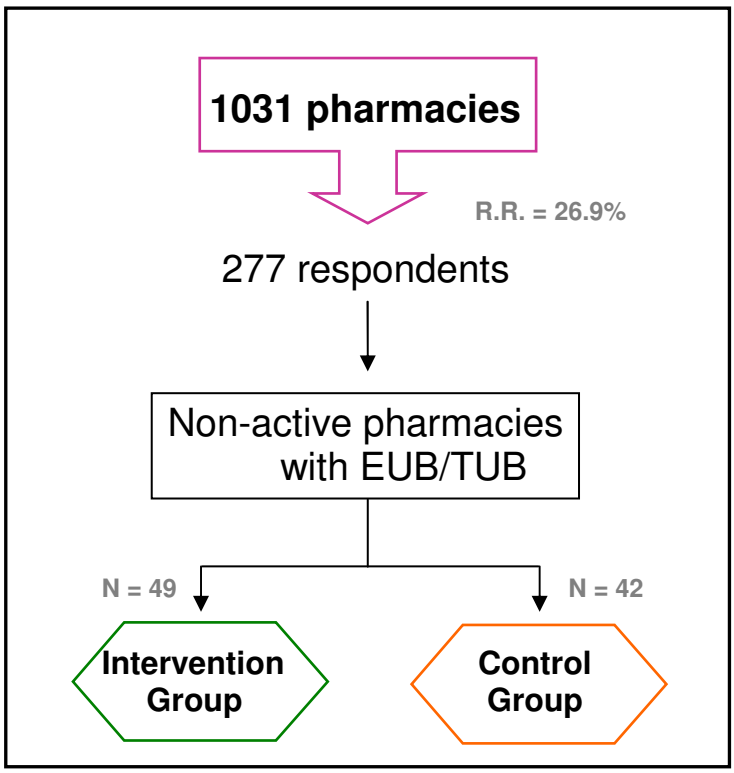


Figure 54: Number of participants per study group

2.2.2 Patients

Patients were selected by the pharmacist, if they were advised to take, any anxiolytic (ATC code: N05B), hypnotic (ATC code: N05C), or antidepressant (ATC code: N06A) medicine(s) for the first time, at both times (T0 and T1),

Every pharmacist was asked to include a maximum of 35 patients who met the inclusion criteria mention above. A patient information letter (Annex 5), a questionnaire, and stamped addressed return envelope were posted to the eligible patients.

Table 102 illustrates the number of patients included in each group, at both time measurements (T0 and T1). Regarding the baseline measurement (T0) it is not possible to calculate the actual response rate as there was no information on the actual number of patients that received the questionnaire. However, this situation was corrected for the follow-up measurement (T1), allowing to retrieve the actual response rate: in the second measurement, a total of 2968 questionnaires were sent to patients.

Table 102: Total number of patients included in each group, stratified by time of the measurement.

Measurement	**Group**			**Response Rate (%)**
	Intervention	**Control**	***Total***	
T0	244	177	421	13.2 (A)

T1	312	197	509	17.1 (B)
Total	556	374	**930**	

(A) – Assuming that the 91 pharmacies sent out the maximum number of questionnaires, 35 (total of 3185 questionnaires sent out to patients).
(B) – 509 out of 2968 questionnaires were received and analysed.

2.3 Honoraria and Ethical Considerations

Pharmacists who attended the course (only those from the intervention group) were given 4 points, as the course was considered part of the pharmacists' continuous training. Besides the points, all participants were offered 100€ (intervention group) or 50€ (control group) vouchers, depending on their contribution throughout the study period.

The study was approved by the Medical Ethical Committee of the Universitair Medisch Centrum Groningen (University Medical Centre Groningen), in the Netherlands. All data were extracted anonymously and the privacy of the participants was guaranteed throughout the whole study.

2.4 The Training (course)

The course was given 5 times to groups of 10 to 15 participating pharmacists, at the beginning of the study and was planned to last for 5 hours. All participants were asked to fill in a questionnaire at the start of the course (Annex 1) and a folder with several information materials was given to every course attendant (below there is a description of the content of this folder). A description of the objectives of the course as well as a description of the course folder and course content follows below. To follow-up on the training, three newsletters were monthly sent to pharmacists of the intervention group.(Annexes 6 to 8).

2.4.1 Main Objectives of the Course

The main objectives of the course were:

- To give insight in the DRUID project.
- To motivate the participation in the study, as well as to motivate the use of the ICT-tool.
- To explain participants' tasks and role during the study period.
- To provide information on the categorization system for medicinal drugs that might impair driving performance.
- To provide recommendations on dispensing information when delivering medicines that might influence driving skills.
- To give insight in pharmacists own policy with respect to medicines that might impair driving performance.
- To provide information materials to pharmacy technicians so that they can also use the ICT-tool (including informing patients).

2.4.2 Course Manual

At the beginning of each course participants received the course manual which consisted of:

- A 'to-do-list' with the activities in the study design that pharmacists were involved in.

- Background information upon drugs and driving (what is the impact driving under the influence of drugs, what are the juridical consequences)
- Detailed information on the categorization system (origin, how to use the system).
- Technical instructions on how to use the ICT-tool.
- Information materials to instruct and motivate pharmacy technicians and/or other pharmacists. The "in-pharmacy" training material provided the following information:
    - Outline of the course;
    - General background information about drugs and driving and the categorization system;
    - Example questions to trigger the discussion with the pharmacy team on this topic;
    - Cases to discuss with the pharmacy team;
    - Roll-plays to exercise with the pharmacy team the information that should be provided to patients when delivering a driving impairing medicine.
- Examples of information that should be provided to patients about the influence of medicines on driving fitness.

2.4.3 Course Content

The course was divided in 5 sections each one of them with specific aims. A brief description on the content of each section follows below:

- Introduction
    - DRUID questionnaire (T0 measurement for pharmacists of the intervention group).
    - Outline of the course.

- Medicines and driving
    - Information about estimated fatalities due to driving under the influence of psychotropic medicines was provided. It was stressed that medicines within the same therapeutical class may have different levels of impairment. An introduction to the categorization system (hereby referring to the DRUID efforts) was given.
    - The Dutch juridical consequences on the prescription and delivery of driving impairing medicines were mentioned. Example of the categorization of well known medicines was shown.
    - The knowledge questions that were in the questionnaire that the pharmacists filled in before the actual start of the course were discussed, and the correct answers were provided.

- Practical application
    - The consequences for patient information while dispensing DIM, as it is described in the Dutch Prescribing and Dispensing Guidelines. The available written materials, including warning signs, were shown and discussed.
    - The ICT- tool was introduced, including information on how to install and use it. A demonstration was displayed. Pharmacists already using parts of the tool (e.g. for medicines other than driving impairing ones) will exchange their experiences until now.
    - Discussion about the use of the tool, about how the tool displays patient information, and about some limitations of the tool.

- The DRUID intervention study
    - The research questions were presented. A detailed to-do-list was discussed so that pharmacists were completely informed of their role during the study

period.

- The "in-pharmacy" training (how to coach the pharmacy team)
  - The attending pharmacists usually manage ten to fifteen employees, mainly pharmacy technicians and they are the ones who mostly use the ICT-tool and inform patients. Therefore, it was discussed, in detail, how the pharmacy team should be coached and how to motivate all employees.
  - The material for the "in-pharmacy training" included cases and some roll-plays (as mentioned above). After making reference to these materials, the pharmacists had the opportunity to exercise, themselves on how to inform patients or on how to discuss this issue with the prescribers.

- GIT (Geneesmiddel Informatie Tekst) - Personalised medicines information leaflet
  - With the personalized medicines information leaflet, patients receive complete information about their medicines, which includes information on the influence of the medicine on driving fitness. In this leaflet, a pictogram was included, as well. The pictogram (DRUID warning label), displayed below (Figure 55), gives information on the severity of the impairment that is associated with the medicine (this implies a categorization system based on the level of impairment of a medicine on driving fitness). The warning label, combined with oral information and written warnings and instructions in the leaflet provides personalized information to the patient. The leaflet is printed and given to the patient during the first-time dispensing of a medicine. Additional information on the pictogram and risk communication can be found in DRUID deliverable 7.3.2 [7].

Figure 55: DRUID warning labels included in the GIT. Depending on the category of the medicine, it was added a category 1 (a), category 2 (b) or category 3 (c) pictogram.

2.5 Tool Description

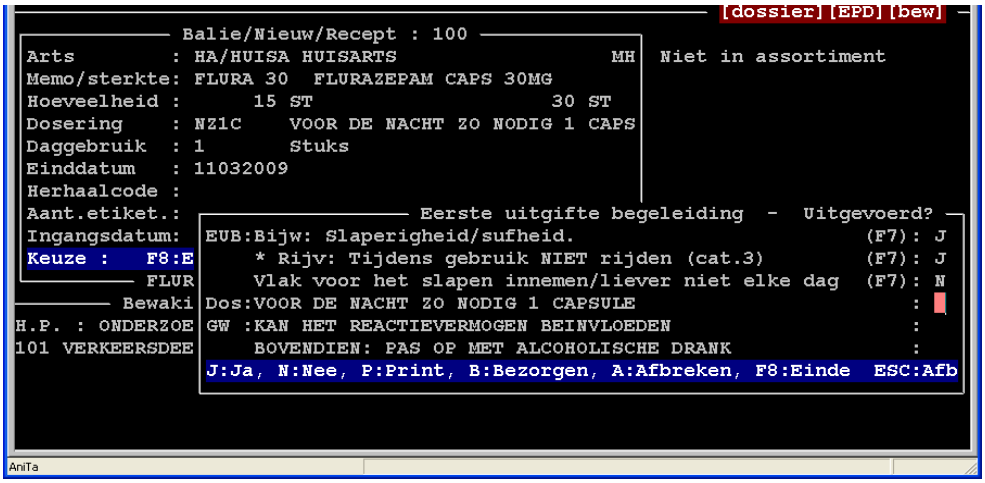
As previously mentioned in the introductory part, the DRUID tool was not implemented in the Netherlands. Instead, DRUID protocols and guidelines were implemented in the Pharmacom® system for medication surveillance in Dutch community pharmacy practice.

In case of a **first** prescription check (EUC) a signal informs the pharmacist that safer alternatives might be used, if available. If no safer alternatives can be used, the dispensing will follow based on the first dispensing counselling module.

In case of a **first** dispensing counselling (EUB) to an individual patient will follow (at the start of treatment) specific information is shown on the computer screen. See Figure 3 as an example of the information that is displayed on the computer screen when flurazepam 30mg (capsule) is dispensed, for the first time to a specific patient. By entering “Yes”(J) or “No” (N) after every line in this protocol responses will be logged to document the activity.
In case of a second dispensing, the information is again displayed on the screen, primarily with questions to inquire about possible side effects that might have occurred). However, those issues that have been logged with a “N” or blank response during the first dispensing will be shown again.

In general, the Pharmacom® system supports pharmacists in the following ways:

- First-time dispensing check advises the pharmacist to look for safer alternatives, if existing.
- First-time dispensing counselling after selecting the medicine that will be handed out to the patient.
- Warnings that are displayed on the dispensing label as well as printouts of the patient information leaflet can be printed.
- Second-time dispensing counselling to provide information to the patient when there is a second dispensing.
- Documentation of counselling activities.



Translations of the section *Eerste uitgifte begeleiding* PROTOCOL

First dispensing: Side effects: sleepiness, sedation	(F7)	: J
Driving: Do not drive while taking this medicine (cat.3) (F7)	: J	
Take before the night/preferably not every day	(F7)	: N
Dosage: Before the night 1 capsule if needed		:
Instruction for use: Might influence driving performance		:
Do not take with alcoholic beverages		:

Instructions to the pharmacy technicians:

Explain to the patient each of the lines in the PROTOCOL and indicated “J” (Yes) if you did and “N” (No) if you did not.

If you need background information please press “F7”.

In case of **“Driving: Do not drive while taking this medicine (cat.3)“** pressing (F7) will show the following background information:

GENERAL INFORMATION

The medicine has a severe influence on driving performance (cat 3).

If taken daily: do not drive.

If taken infrequently: do not drive during 3 days after intake.

Take care in circumstances that require unaffected attention (e.g. operating machinery).

Impairment by side effects, such as sedation, sleepiness, dizziness, blurred vision, impaired reaction time.

Even without these side effects impaired driving performance might occur.

Alcohol will potentiate impaired driving performance: do not drive!

Figure 56: Pharmacom® EUB information that is displayed on the computer screen, when flurazepam 30mg capsules is dispensed for the first time to an individual patient.

2.6 Training evaluation

The evaluation of the training was performed by means of questionnaires addressed to pharmacists, before (Annex 1) and 6-months after (Annex 2) the training. The effectiveness of the training was also evaluated at the patient level, by means of a questionnaire addressed to patients (Annex 3), as a way of verifying whether the information that was given to pharmacists during the training was, indeed, provided to patients at the time of the dispense of medicines. Dispensing data from the participating pharmacists was collected as well.

2.7 Dispensing data

Pharmacists who were enrolled in the study were asked to adjust their Pharmacom® system in a way that was possible to retrieve 1 year of dispensing data from patients' medication records concerning driver impairing medicines such as anxiolytics (ATC code: N05B), hypnotics (ATC code: N05C), and antidepressants (ATC code: N06A). Four databases were received and the data was analyzed.

2.8 Data Analysis

2.8.1 Pharmacists

As for the analysis and comparisons between the time of the measurement (intervention group T0 and T1), the t-test for independent samples to compare means was used, as most of the assumptions for parametric tests were covered: the dependent variables are continuous, the scores were obtained using a random sample of the population and the observations are independent. Regarding normality of the data, it is believed that the statistical tests are robust enough to overcome this problem, especially when the population has more than 30 cases, which was always the case. At all times, homogeneity of variance was confirmed (the Levene's test was always not significant).

In order to be able to compare means, at T0 and T1, several composite scores related to pharmacists' awareness, reported behaviour, and actual knowledge were created. Answers between strongly disagree (0) and strongly agree (3) were used to measure pharmacists' awareness. To measure pharmacists' reported behavior, a 5-point Likert scale was used, ranging from never (0) to always (4). Pharmacists' actual knowledge was evaluated by means of several statements related with the influence of a certain active substance on driving fitness. Pharmacists could totally agree or totally disagree with the statement. The range of answers was later on recoded into wrong (0) or right (1) answers ("do not know" (2) answers was also an option).

For all comparisons, a p-value < 0.05 was considered statistically significant (95% confidence interval).

For the evaluation of the tool and the materials that were provided during the course, descriptive analysis were conducted and presented.

2.8.2 Patients

Descriptive analysis was performed to give insight on participants' gender, education level, frequency of driving, experience of side effects, and information about medicines (who

provided information to patients, when was that information shared with the patient, and the content of that information).

To compare differences between the 2 groups of patients (at the baseline measurement, T0 and at the follow-up, T1), the t-test for independent samples to compare means was used, as most of the assumptions for parametric tests were covered. In order to be able to compare means, at T0 and T1, several composite scores related to patients' knowledge about causes of road accidents and related to patients' attitudes. To measure patients' knowledge, a 5-point Likert scale was used, ranging from never (0) to always (4). Knowledge about the risk of having a road accident while driving under the influence was evaluated by means of several statements. Patients could totally agree or totally disagree with each statement. The range of answers was later on recoded into wrong (0) or right (1) answers ("do not know" (2) answers was also an option) allowing to distinguish whether patients do acknowledge risk of having road accidents under a range of different situations which is also related to patients' awareness.

For all comparisons, a p-value < 0.05 was considered statistically significant (95% confidence interval).

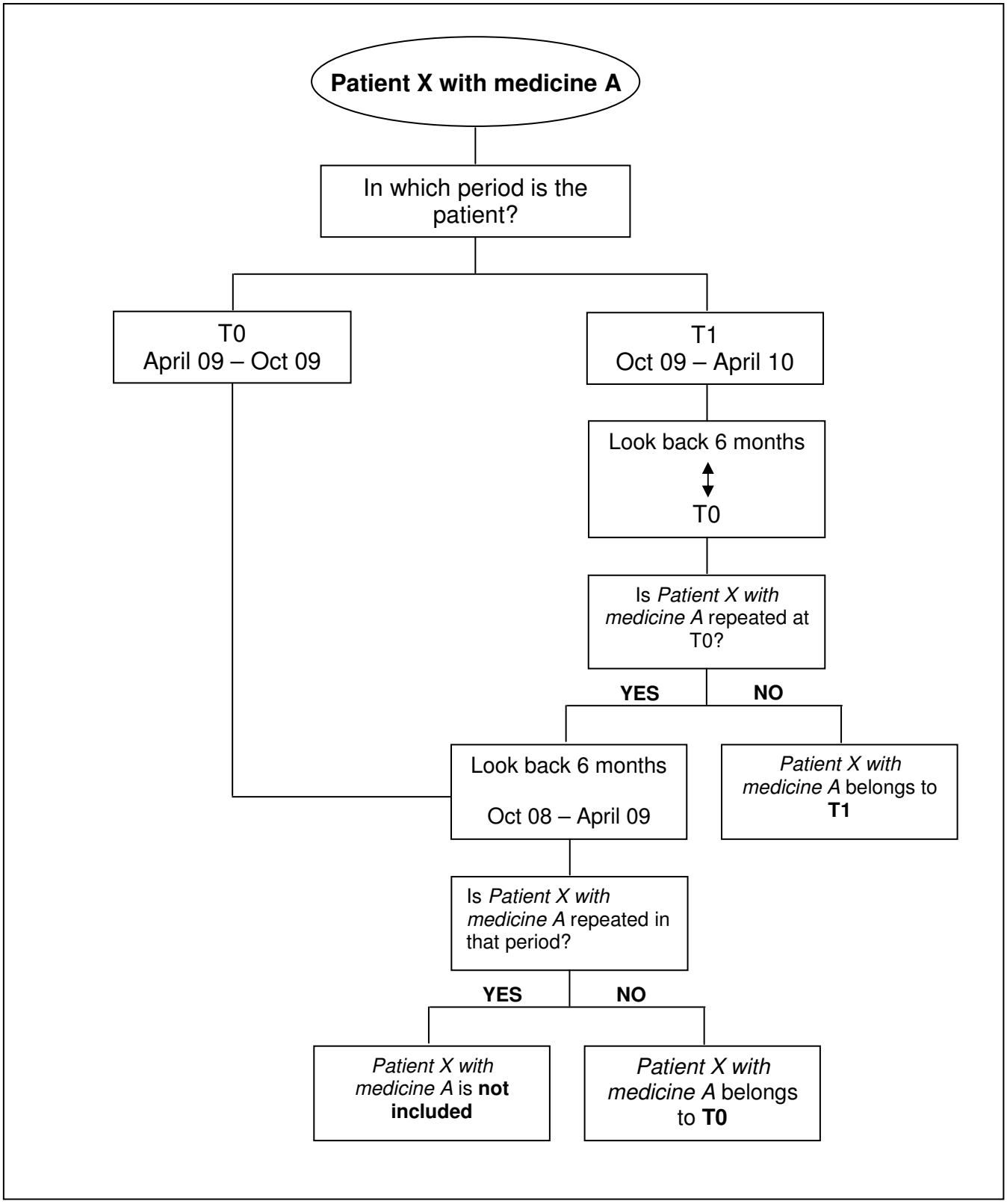
2.8.3 Dispensing Data

Incidence data of dispensed antidepressants (ATC N06A), anxiolytics (ATC N05B) and hypnotics (ATC N05C) was extracted by the participating pharmacists directly from the Pharmacom® system covering a period from July 2008 until April 2010. Data collection was captured using a unique number for each individual patient as identifier, which is randomly assigned and for which the key to the patient personal data is only known to the pharmacist of the patient. Incidence data on changed prescriptions that were switched to less impairing medicines in each therapeutic class during the 6 months of the study were collected as well.

Only new users of one of the selected classes of medicines (N65B, N05C and N06A) were considered. A new user is defined as a patient who had not used a specific medicine for a period of 6 months. As soon as the first prescription is detected, the upcoming records of the same patient having the same medicine are excluded. However, a patient can be repeated in the database as long as he/she is taking a different medicine for the first time (or for a period longer than 6 months). The extraction of the new users was conducted as it is described in the flowchart presented below (Figure 57).

The data that was collected was used to evaluate descriptive differences in the number of prescriptions of the medicines belonging to the N05B, N05C and N06, before (T0) and after (T1) the training, in the 2 groups of pharmacists (intervention and control groups). A time trend analysis was performed. *Note: in the dispensing data analysis, the control group was seen as a reference group and, therefore, it is called "reference group" in the sections referring to the dispensing data.* Data regarding the total number of patients that are registered in each pharmacy was collected as well.

As for the statistical analysis, the proportion per thousands of patients of new users of N05B, N05C and N06A medicines was calculated. Additionally, the distribution of new users during the study period was described (from April 2009 until April 2010). No time trend analysis was conducted as data from one year might not be enough to see significant differences. In order to verify whether or not there was a shift in the dispensing DIM into safer alternatives, the proportion per thousands of patients of category 1, 2 and 3 medicines in each pharmacy group was calculated.



.**Figure 57:** Flowchart representing the criteria for inclusion of patients/prescriptions in the database

3 Results

3.1 Pharmacists

3.1.1 Total number of participants

The results shown below are referred to the following number of participants:

- Pre-questionnaire (baseline measurement, T0)
  - *Intervention group* (pharmacists who attended the training).
  - N = 44 out of 49
  - Response Rate = 89.8%

- Post-questionnaire (follow-up, T1)
  - *Intervention group* (in some cases, the follow-up questionnaire was filled in by a different pharmacist from the one who attended the course).
  - N = 44 out of 49
  - Response Rate = 89.8%

3.1.2 Pharmacists' characteristics

At both measurements (T0, and T1), the percentage of females was higher than males, as illustrated in Figure 58, and the mean age of all participants (N=84) was 40.5 years old (s.d = 10.4). In average, pharmacists had 12.8 years of practice (s.d = 9.2).

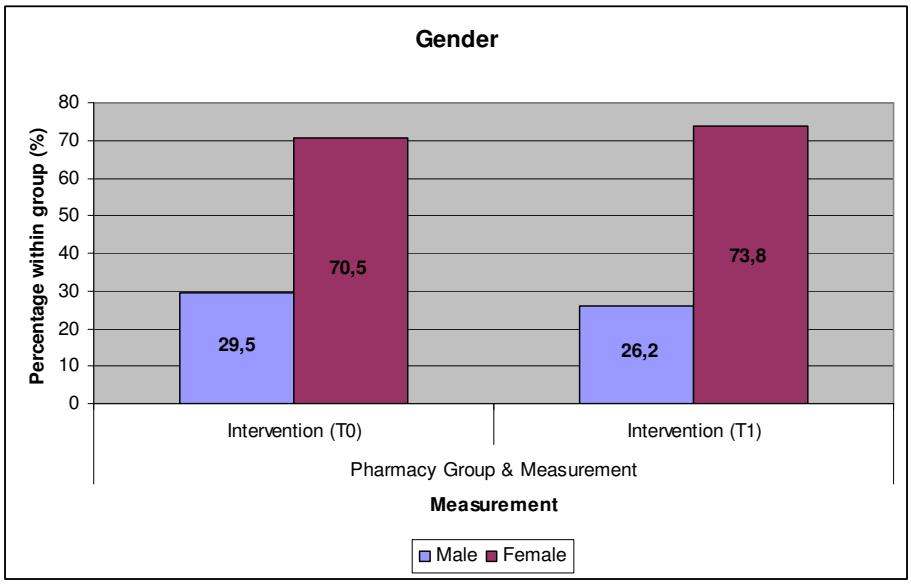


Figure 58: Pharmacists' gender, stratified per time of the measurement (T0 and T1).

Regarding new technologies literacy, 98% (n=84) of the pharmacists used internet to obtain general information about medicines. The percentage of pharmacists that used the internet to obtain information on medicines affecting driving behaviour increased after the

training (n=26, 59.1% baseline measurement T0 and n=27; 64.3% follow-up measurement, T1). Pharmacists used software packages less often than internet to obtain information on medicines affecting driving behaviour.

3.1.3 Pharmacists' Awareness

Awareness regarding the influence of medicines on driving fitness was measured by means of several statements. The answers to the statements could be: 0 – strongly disagree, 1 – disagree, 2 – agree, and 3 – strongly agree. Table 3 shows the comparison between pharmacists' awareness before and after the training (T0 and T1).

The mean composite scores for awareness statements were before and after the training 2.05 (s.d. 0.18) and 2.15 (s.d. 0.25), respectively, meaning that pharmacists agreed with the statements. Pharmacists' awareness, both before and after the training, increased every time the patient was taking other CNS medicines (95.5% and 100%), and every time the patient was a professional driving (90.9% and 97.6%), drives frequently (86.4% and 92.7%), and drives long distances (81.8% and 87.8%).

Table 103: Mean scores for awareness statements at both time measurements (intervention group).

	Time of the measurement						P-value
	T0			T1			
	N	Mean	S.D	N	Mean	S.D	
I am taking into account the effects of medicines on driving skills when dispensing medicines.	44	2,23	0.42	41	2,37	0.49	0,167
I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.	43	1,88	0.39	40	1,82	0.45	0,525
I am aware of the effects of medicines on driving skills.	44	1,82	0.45	42	2,26	0.44	<0,001*
It is important for me to be well-informed on medicinal effects on driving behaviour.	44	2,5	0.51	42	2,4	0.50	0,095
I feel that the information I provide to patients will influence their driving behaviour.	42	1,79	0.52	42	1,95	0.44	0,116

Answers to the statements: 0 – strongly disagree, 1 – disagree, 2 – agree, and 3 – strongly agree.

* A p-value < 0.05 considered to be statistically significant.

3.1.4 Pharmacists' Reported Behaviour

Reported behavior regarding the influence of medicines on driving fitness was measured by means of several statements. The answers to the statements could be: 0 – never, 1 –

seldom, 2 – sometimes, 3 – regularly, and 4 – always. Table 4 shows the comparison between pharmacists' reported behaviour before and after the training (T0 and T1).

The mean composite scores for reported behaviour statements were before and after the training 2.07 (s.d. 0.55) and 2.67 (s.d. 0.53), respectively, meaning that pharmacists behaviour towards medicines and driving was fair.

Table 104: Mean scores for reported behaviour at both time measurements (intervention group).

	Time of the measurement						**P-value**
	T0			**T1**			
	N	Mean	S.D	N	Mean	S.D	
I ask a patient about his/her driving exposure when dispensing a medicine.	44	1.64	0.94	41	2.66	0.82	<0,001*
I inform a patient about driving related risks when dispensing a medicine	44	2.86	0.79	41	3.34	0.62	0,003*
I provide a patient with written information materials when dispensing a driving impairing medicine.	44	3.20	0.76	41	3.59	0.55	0,01*
I keep systematic records when I dispense a driving impairing medicine (e.g. as in the EPD in Pharmacom).	44	2.52	1.61	41	2.76	1.20	0,448
I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine (e.g. as in the EPD in Pharmacom).	44	1.77	1.28	41	2.65	1.23	0,007*
I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).	44	0.25	0.72	42	0.57	0.83	0,059
I discuss medicinal drug consumption and driving related responsibility issues with the patient.	42	1.89	0.94	42	2.81	0.94	<0,001*
How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving	42	2.50	0.94	42	3.14	0.78	0,001*

performance?							

Answers to the statements: 0 – never, 1 – seldom, 2 – sometimes, 3 – regularly, and 4 – always.

* A p-value < 0.05 considered to be statistically significant.

3.1.5. Pharmacists' Sources of Information

Pharmacists, at both measurements (T0 and T1), considered they have easy access to data and information about the effects of a medicine on driving skills. The preferable sources of information are listed in Table 105.

Table 105: Preferable sources of information at both time measurements (intervention group).

Sources of information	Time of the measurement				P-value
	T0		T1		
	N	%	N	%	
Professional websites	36	81,8	37	30,2	0,26
Newsletters	6	13,6	2	4,9	0,17
Organizations	15	34,1	5	12,2	0,02*
Journals	6	13,6	4	9,8	0,58
Other	6	13,6	2	4,9	0,17
* A p-value < 0.05 considered to be statistically significant.					

3.1.5 Pharmacists' Actual Knowledge

Actual knowledge regarding the influence of medicines on driving fitness was measured by means of several statements. The answers to the statements could be: 0 – totally disagree, 1 – disagree, 2 – agree, 3 – totally agree, and 4 – don't know. Table 106 describes the statements that pharmacists were shown and which was the correct answer. For analysis purposes, pharmacists' answers were afterwards recoded into right or wrong. The differences between the answers at both time measurements are shown in Table 107.

Table 106: Statements asked to pharmacists and respective correct answers.

Statement	**Correct answer**	*Recoding* 0 – wrong; 1 – right; 2 – don't know
Temazepam (up to 20 mg) severely impairs driving 8 hours after intake.	Disagree	0 & 1 – right answer (1) 2 & 3 – wrong answer (0) 4 – don't know (2)
Diazepam (regardless the dose) severely impairs driving within the first 2 months of treatment.	Agree	0 & 1 – wrong answer (0) 2 & 3 – right answer (1) 4 – don't know (2)
Codeine (up to 20 mg) is mostly safe for drivers.	Totally agree	0 & 1 – wrong answer (0) 2 & 3 – right answer (1)

		4 – don't know (2)
Fexofenadine (normal dose) severely impairs driving.	Totally disagree	0 & 1 – right answer (1) 2 & 3 – wrong answer (0) 4 – don't know (2)
Amitriptyline has the same level of driving impairment at the start of treatment and 4 weeks after the start of the treatment.	Totally disagree	0 & 1 – right answer (1) 2 & 3 – wrong answer (0) 4 – don't know (2)
Paroxetine (up to 20 mg/day) is safe for drivers.	Totally agree	0 & 1 – wrong answer (0) 2 & 3 – right answer (1) 4 – don't know (2)

Table 107: Differences between the answers to the statements, at both time measurements (intervention group).

Statement	**Answer**	**T0**		**T1**		P-value
		N	**%**	**N**	**%**	
Temazepam (up to 20 mg) severely impairs driving 8 hours after intake.	Right	12	27,3	17	41,5	0,266
	Wrong	31	70,5	24	50,5	
	Don't know	1	2,3	0	0	
Diazepam (regardless the dose) severely impairs driving within the first 2 months of treatment.	Right	30	68,2	22	52,4	0,215
	Wrong	11	25	18	42,9	
	Don't know	3	6,8	2	4,8	
Codeine (up to 20 mg) is mostly safe for drivers.	Right	26	59,1	34	81	0,027*
	Wrong	18	40,9	8	19	
	Don't know	0	0	0	0	
Fexofenadine (normal dose) severely impairs driving.	Right	32	72,7	33	80,5	0,022*
	Wrong	5	11,4	8	19,5	
	Don't know	7	15,9	0	0	
Amitriptyline has the same level of driving impairment at the start of treatment and 4 weeks after the start of the treatment.	Right	26	59,1	34	82,9	0,045*
	Wrong	13	29,5	6	14,6	
	Don't know	5	11,4	1	2,4	
Paroxetine (up to 20 mg/day) is safe for drivers.	Right	18	40,9	36	87,8	<0,001*
	Wrong	22	50	4	9,8	
	Don't know	4	9,1	1	2,4	

* A p-value < 0.05 considered to be statistically significant.

For the majority of the pharmacists, a patient can be punished with criminal sanctions if he/she causes a traffic accident while using a medicine with impairing properties whenever the health care provider has advised him/her not to drive (95.4% (n=42) at baseline measurement and 97.6% (n=40) in the follow-up).
Almost 75% (n=33) of the pharmacists were willing to use a tool that allows to find information on medicinal drugs and driving, while dispensing.

3.1.6 Pharmacists' User Acceptance of the Materials

This result subsection only refers to the follow-up measurement, T1, as only pharmacists from the intervention group used the materials that were provided during the course (N=44). Bellow are shown the pharmacists' evaluation of the materials that were given to them during, and after, the course.

The use of the information materials that were provided during the course was limited: 48.9% (n=21) rarely used the materials whereas only 20.9% (n=9) used the information materials regularly (more than 10 times for a 6-months period). However, 90.7% (n=39) used the materials provided to inform the pharmacy technicians working in the pharmacy. The collaboration between GPs and pharmacists continues not to be very visible. Almost 90% of the pharmacists did not share the PowerPoint that was provided during the course with GPs. The four newsletters that were sent electronically to pharmacists were read by the majority of the participants (30 out of 43 pharmacists; 69.8%). Figure 59 illustrates how pharmacists evaluated the information materials that were developed and provided during the course.

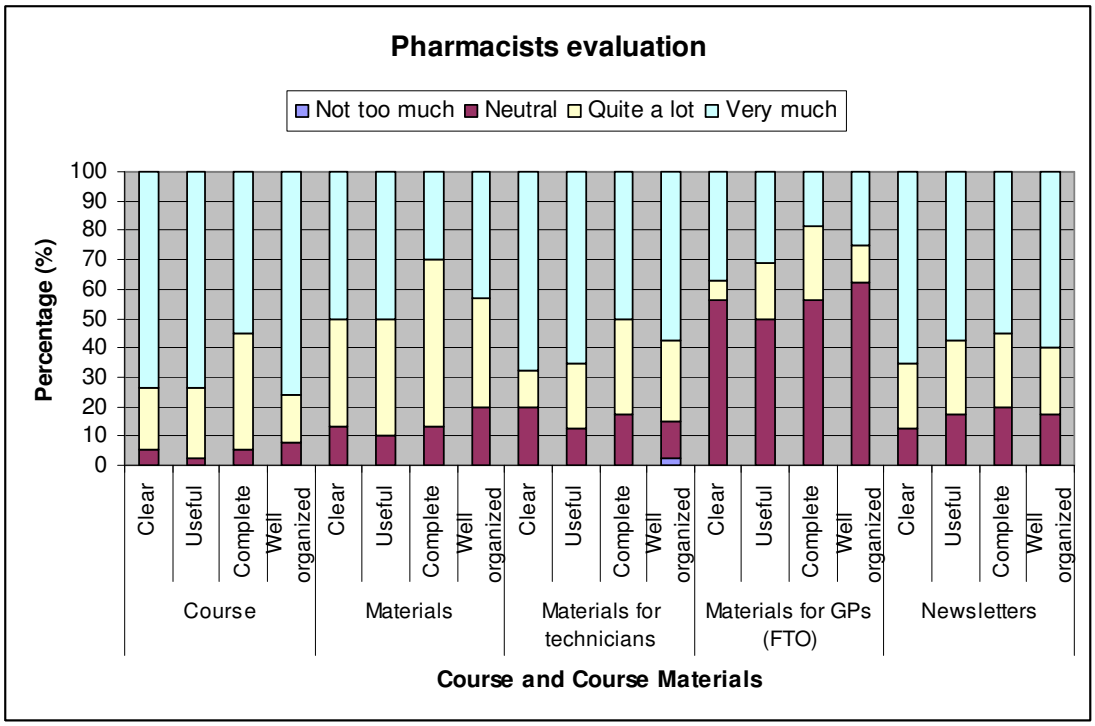


Figure 59: Evaluation of the course itself and of the materials that were developed.

3.1.7 Pharmacists' User Acceptance of the Materials and Usability of the Tool (EUB-TUB module)

This result subsection only refers to the follow-up measurement, T1 (N=44). Regarding the use of the Pharmacom® system, 97.6% of the pharmacists (41 out of 42) switched on the EUC module. In general, the EUB and TUB-module for N06 were more use than for N05 medicines (95.1% EUB N05; 90.2% TUB N05; 97.6% EUB N06 and 92.7% TUB N06).

The different functionalities that were incorporated in the Pharmacom® system were evaluated as clear, useful, complete and well organized, except for the EUC system that were classified as handy, clear and useful. The answers to the statements could be: 1 – not so much, 2 – neutral, 3 – quite a lot and 4 – very much. Table 108 shows the means of the evaluation of the materials by pharmacists.

Table 108: Evaluation of the materials that were incorporated in the Pharmacom® system (mean values).

		Intervention group		
		N	**Mean**	**Std. deviation**
EUC	Handy	41	3,49	0,87
	Clear	41	3,49	0,87
	Useful	41	3,54	0,711
EUB-TUB	Clear	40	3,68	0,526
	Useful	40	3,63	0,586
	Complete	40	3,7	0,516
Text F7	Clear	39	3,41	0,88
	Useful	39	3,33	0,898
	Complete	39	3,56	0,641
	Well organized	39	3,26	0,928
CMPM	Clear	40	3,1	0,841
	Useful	40	3,2	0,791
	Complete	40	3,03	0,8
	Well organized	40	3,08	0,797
Answers to the statements: 1 – not so much, 2 – neutral, 3 – quite a lot and 4 – very much.				

3.1.8 Pharmacists' way of Informing Patients, Technicians and Physicians about Medicines and Driving

This result subsection only refers to the follow-up measurement, T1. While dispensing medicines, pharmacists can make use of different sources of information to inform their patients, either orally or with written materials. In average, pharmacists from the intervention group regularly (mean score 3.69; s.d = 0.7) used the information presented in the EUB/TUB module to orally inform their patients about the influence of medicines on driving fitness. A reference to the yellow sticker (warning label affixed to medicines that influence driving fitness alerting to the combination with alcohol) was also regularly used while dispensing (mean score 3.48; s.d = 0.9), similarly to the use of the DRUID warning label (mean score 3.34; s.d = 0.9). Other available Dutch materials were not commonly used. Answers to the statements ranged from: 0 – Never, 1 – Seldom, 2 – Sometimes, 3 – Regularly to 4 – Always.

45.2% of the pharmacists (total n=44) found the DRUID warning label very useful to provide information to patients. Regarding the sufficiency of information on the DRUID warning label, 35.7% of the pharmacists mentioned that it was quite clear and 40.5% were neutral. The categorization of medicines according to their level of impairment on driving fitness was well received by pharmacists who found the categorization clear and useful.

Concerning the information that was provided during the course to inform technicians, the totality of the pharmacists trained their colleagues/technicians.

Pharmacists did not often change a prescription to a less impairing alternative due to the effects on driving fitness. When that happened, it was only 1-2 times (20 out of 40 pharmacists) and, more rarely, 3-4 times (8 out of 40 pharmacists).

3.2 Patients

3.2.1 Patients' characteristics and participation in traffic

A total of 930 respondents participated in the study. The mean age was 53.5 years-old (s.d. = 14.7), with a minimum of 19 years-old and a maximum of 90 years-old. Participants' gender (n=927), education level (n=924), frequency of driving (n=930) and experience of side effects (n=880), at both time measurements and per pharmacy group, are represented in Figure 60. No significant differences were found neither between the 2 times of measurement nor between groups, for all variables.

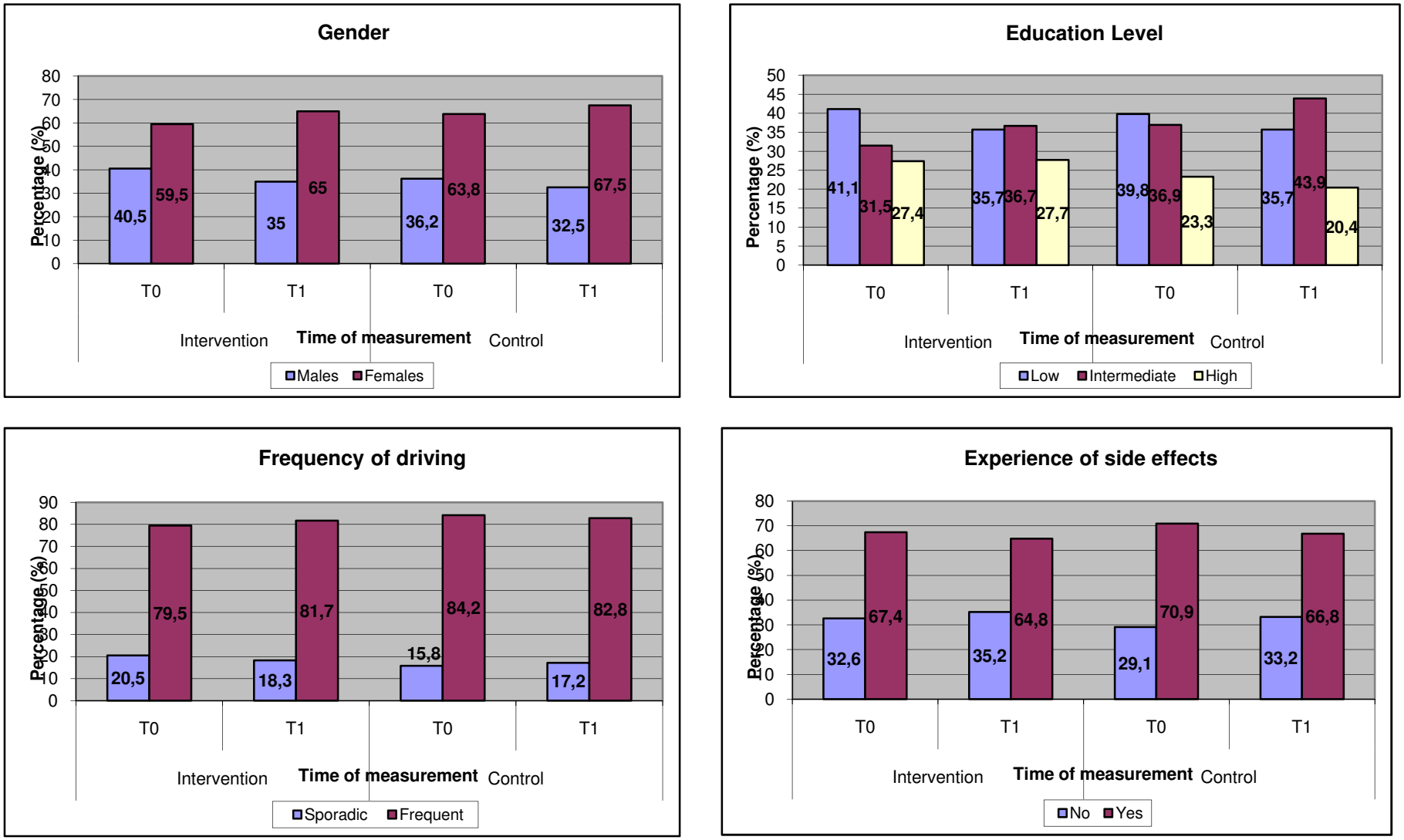


Figure 60: Participants' gender (A), education level (B), frequency of driving (C), and experience of side effects (D). The percentage is stratified by pharmacy group (intervention and control) and time of the measurement (T0 and T1).

3.2.2 Patients' knowledge about the influence of medicines on driving fitness

Mean scores for causes of road accidents materials (written materials included) were calculated. Answers to the statements ranged from: 1 – Never, 2 – Seldom, 3 – Sometimes to 4 – Often. The results are displayed on Table 109, where patients from both intervention and control groups were included.

Table 109: Mean comparison between causes of road accidents, stratified by time of measurement.

	T0			T1			P-value
Statement	**N**	**Mean**	**S.D**	**N**	**Mean**	**S.D**	
Driving when tired	370	3.55	0.72	463	3.61	0.64	0.169
Driving under the influence of alcohol	392	3.71	0.79	472	3.80	0.63	0.079
To short distance to the leading car	372	3.45	0.73	455	3.47	0.69	0.594
Speeding	370	3.42	0.75	458	3.59	0.63	0.134
Use of medicines that might impair driving	367	3.27	0.76	446	3.31	0.72	0.452
Use of illicit drugs	354	3.49	0.84	423	3.57	0.73	0.138
Use of a mobile phone while driving	372	3.37	0.80	457	3.39	0.73	0.759
Answers to the statements: 1 – never, 2 – seldom, 3 – sometimes and 4 – often.							

Despite no significant differences were found between time measurements, a general improvement was observed in the follow-up measurement, in patients' knowledge about causes of road accidents. Figure 61 shows the composite scores for knowledge, in each group stratified by time. No statistical significant differences were found.

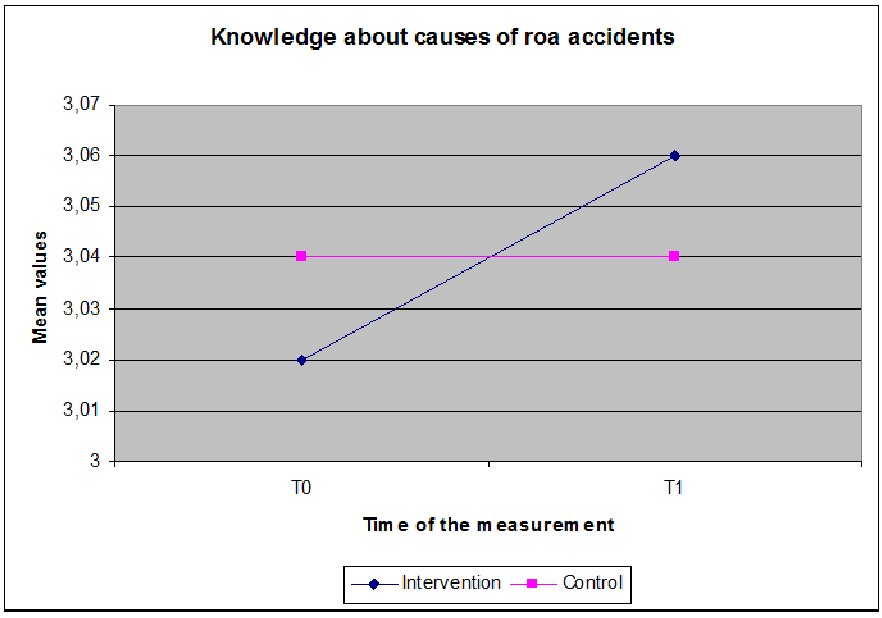


Figure 61: Composite scores for patients' knowledge, stratified by time and pharmacy group (n= 731).

Patients' knowledge can also be evaluated in terms of knowledge about the risk of having a road accident while driving under the influence of medicines. To do so, several statements about the risks of driving under the influence of medicines were developed. The answers to the statements could be: 1 – totally disagree, 2 – disagree, 3 – agree, 4 – totally agree, and 5 – no opinion. Table 110 describes the statements that patients were shown and percentage of right and wrong answers, as well as the percentage of answers that patients did know the correct answer. For analysis purposes, patients' answers were recoded into right, wrong and don't know. The differences between the answers at both time measurements are shown in Table 110.

Table 110: Risk of having a road accident while driving under the influence of medicines, stratified by time of measurement. .

Question about risk of driving under the influence of medicines	T0			T1			p-value
	Wrong	Right	Don't know	Wrong	Right	Don't know	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	
The risk of having a road accident is smaller when you have just started taking a driving impairing medicine compared to long term treatment	91 (22.1)	283 (68.7)	38 (9.2)	84 (16.8)	383 (76.4)	34 (6.8)	0.032 *
The risk of having a road accident may increase when you combine a driving impairing medicine and over the counter medicines (e.g. pain killers, cough remedy)	76 (18.5)	266 (64.9)	68 (16.6)	109 (21.8)	265 (53.0)	126 (25.2)	0.001 *
The risk of having a road accident increases when you use alcohol while taking a driving impairing medicine	18 (4.4)	388 (94.6)	4 (1.0)	22 (4.4)	475 (94.1)	8 (1.6)	0.723
The risk of having a road accident remains the same when you use several driving impairing medicines at the same time	143 (34.8)	239 (58.2)	29 (7.1)	167 (33.3)	291 (58.1)	43 (8.6)	0.667
The risk of having a road accident increases with a high dose of a driving impairing	34 (8.3)	345 (84.1)	31 (7.6)	43 (8.6)	421 (83.9)	38 (7.6)	0.989

medicine							
* A p-value < 0.05 considered to be statistically significant.							

3.2.3 Information about medicines

Either pharmacists or GPs (and sometimes both HCP) can inform patients about the use of medicines, being pharmacists the most likely source of information. Patients can either be spontaneously informed about the possible influence of medicines on fitness to drive or they might receive that information only after asking for it. The graph displayed in Figure 62 illustrates whether patients were spontaneously informed or not, at each time measurement (n=911). A statistical significant difference (p-value=0.007) was found between the control and the intervention group, at T1, referring to the information that is spontaneously provided to patients.

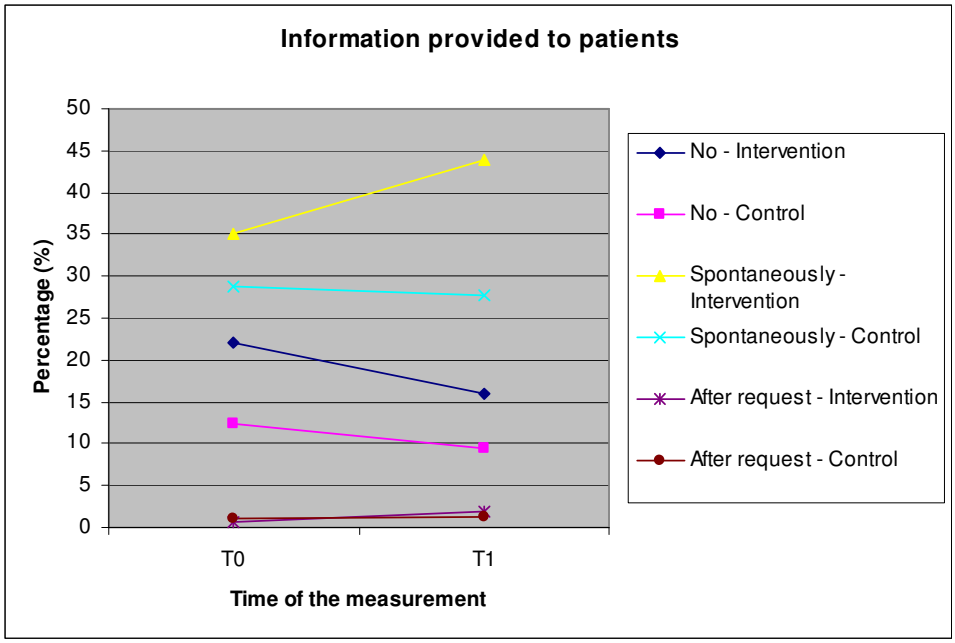


Figure 62: Percentage of patients who were not informed by their HCP or who were informed spontaneously or after request. The percentages are stratified by time and pharmacy group (n=911).

Patients (n=607) were mainly informed about the influence of their medicines on driving fitness and on operating machinery and about the severity of the impairing effects, when compared to the influence of alcohol on driving fitness. The percentages stratified by time and pharmacy group can be found in Table 111. Despite the increase, in the follow-up measurement (T1), in the percentage of patients stating being informed by their pharmacist about the influence of medicines on driving fitness or on operating machinery and about the severity of the impairment, no statistically significant differences were found between time of the measurement or between pharmacy group (intervention or control). Only 12 patients mentioned having discussed safer alternatives with their pharmacists. In those situations, 6 out of the 12 pharmacies belong to the intervention group. 46.9% of the total

number of patients (n=930) did not remember the duration of the impairing effect that was communicated by the HCP responsible for providing that information.

Table 111: Content of the information that was provided to patients, stratified by time of measurement and pharmacy group (n=607).

	Influence on driving ability (%)		Influence on operating machinery (%)		Severity of impairment (%)	
Pharmacy group	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**
Intervention	19.1	30.5	9.6	14.2	4.8	7.6
Control	16.6	20.9	7.6	8.2	4.6	4.5

3.2.4 Patients' behaviour towards the influence of medicines and driving

After receiving information about the possible impairing effects of the medicines, patients can decide whether they can stop driving their vehicles or not. Figure 63 illustrates whether patients (n=820) decided to change their frequency of driving or not (meaning whether patients changed their driving behaviour or not), stratified by time of the measurement and pharmacy group (intervention or control). No statistical significant differences were found.

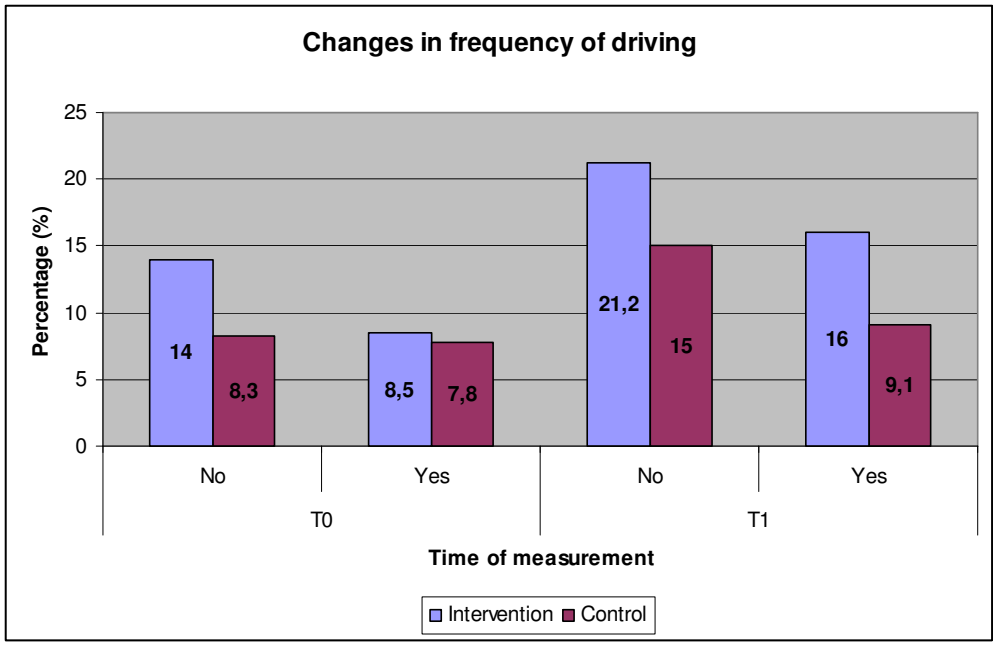


Figure 63: Changes in frequency of driving. The percentages presented are stratified by time and pharmacy group (n=820).

3.2.5 Patients' attitudes towards driving under the influence of medicines

Patients' attitudes towards the use of driving impairing medicines and the use of alcohol while driving was measured by means of several statements. The answers to the statements could be: 0 – totally disagree, 1 – disagree, 2 – agree, and 3 – totally agree.

Table 112 describes the statements that patients were asked at both time measurements. Similarly, patients' attitudes concerning the use of driving impairing medicines and its consequences on traffic participation was evaluated as well. Results are shown in Table 113.

Table 112:. Patients attitudes towards the use of DIM and the use of alcohol while driving, stratified by time of the measurement (T0 and T1).

	T0			T1			P-value
	N	Mean	S.D	N	Mean	S.D	
When using driving impairing medicines people should decide for themselves whether they drive/ride a motorised vehicle or not.	374	1.05	0.83	459	1.09	0.80	0.468
Driving while using driving impairing medicines should be punished more severely in the future.	357	2.00	0.68	437	1.91	0.74	0.073
Driving after the consumption of alcohol should be prohibited.	384	2.39	0.77	475	2.33	0.77	0.258
The risk of driving under the influence of driving impairing medicines is being exaggerated.	344	0.95	0.71	414	0.97	0.76	0.704
The risks of driving under the influence of alcohol are being exaggerated.	389	0.59	0.76	472	0.60	0.73	0.863
Answers to the statements: 0 – totally disagree, 1 – disagree, 2 – agree, and 3 – totally agree.							

Table 113: Patients' attitudes concerning the use of driving impairing medicines and its consequences in traffic participation, stratified by time of the measurement (T0 and T1).

	T0			T1			P-value
	N	Mean	S.D	N	Mean	S.D.	
Possible consequences of the use medication in traffic have never crossed my mind.	365	0.99	0.72	460	0.91	0.68	0.137
When I drive when using a driving impairing medicine I endanger my personal safety.	359	1.98	0.724	438	1.92	0.71	0.252
When I drive when using a driving impairing medicine I endanger the safety of other traffic participants.	363	2.05	0.72	442	2.01	0.74	0.458
If I know someone is using driving impairing medicines I will not let them drive me.	331	1.90	0.72	409	1.79	0.77	0.063
When I have been prescribed a driving impairing medicine I choose not to use my car and choose other types of transportation.	347	1.90	0.76	423	1.75	0.81	0.009*
I do not mind other traffic participants using driving impairing medicines.	347	0.84	0.71	432	0.95	0.75	0.043*

When I have been prescribed a driving impairing medicine I try to use my car/vehicle as little as possible.	352	2.08	0.75	451	1.97	0.79	0.060
When other drivers participate in traffic they take their use of driving impairing medicines into account.	226	1.10	0.71	263	1.20	0.78	0.124
Answers to the statements: 0 – totally disagree, 1 – disagree, 2 – agree, and 3 – totally agree. * A p-value < 0.05 considered to be statistically significant.							

3.3 Dispensing data

As mentioned in the methods section, data on the total number of patients registered in each pharmacy was collected as well. This information is needed to calculate the proportion of the new users of N05B, N05C and N06A medicines in each pharmacy group (intervention and reference), that can be calculated as the number of new users of one of the group of medicines divided by the total number of patients registered in the pharmacies belonging to the intervention or to the reference group.

From the 91 pharmacies enrolled in this study (49 from the intervention group and 42 from the reference group), 14 pharmacies did not provide information on the total number of patients registered in their pharmacies. Of the 14 pharmacies, 11 (4 from the intervention and 7 from the reference groups) failed to reply to our requests after 3 e-mails and 1 phone call, and 3 out of the 14 pharmacies (2 from the intervention and 1 from the reference group) refused to provide the requested information as it was considered to be confidential. Therefore, the dispensing data referring to 77 pharmacies (43 from the intervention and 34 from the reference groups) was used for the analysis.

The 77 pharmacies were equally distributed among the intervention and the reference group, both in terms of number of patients registered but also in terms of location. Table 114 illustrates this information.

Table 114: Pharmacies' location, number of inhabitants and number of registered patients

	Pharmacy group	
	Intervention (43 pharmacies)	**Reference (34 pharmacies)**
Area*		
Urban	15 pharmacies	11 pharmacies
Intermediate	23 pharmacies	18 pharmacies
Rural	5 pharmacies	5 pharmacies
Number of inhabitants		
Total	4.078.829	2.300.344
Mean	94.856	67.657
Number of registered patients		
Total	397.702	311.859
Mean	9.249	9.172

** Urban areas include locations with 70.000 up to 750.000 inhabitants; intermediate areas include locations with 10.000 up to 70.000 inhabitants and rural areas include locations with 5.000 up to 10.000 inhabitants.*

According to the definition of new users that was explained previously in the methods section, it was possible to extract a total of 23.344 new users of N05B, N05C and N06A medicines in the 77 pharmacies. Table 115 shows the distribution of new users stratified by ATC code, pharmacy group and time of measurement. The T0 (baseline measurement) covers the period from 01 April 2009 until 31 October 2009 and T1 (follow-up) refers to the 6 months after the training (from 01 November 2009 until 30 April 2010).

Table 115: Distribution of new users of N05B, N05C and N06A medicines in each pharmacy group stratified by time of measurement

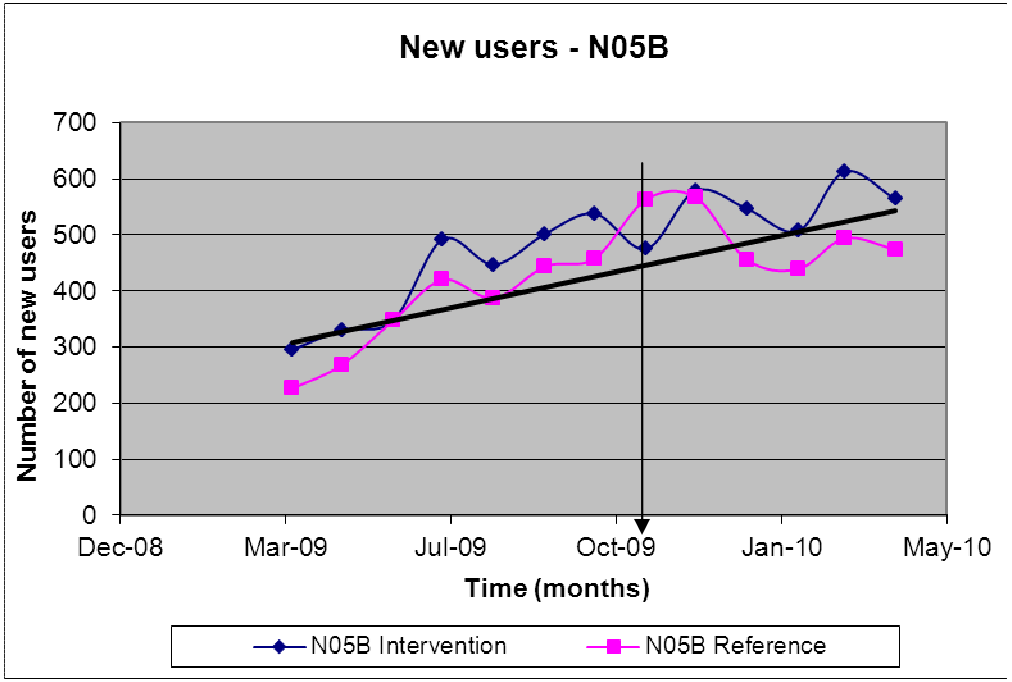
ATC code	Pharmacy group	Time of measurement	
		T0	T1
N05B	Intervention	2951	3285
	Reference	2550	2993
N05C	Intervention	2118	2343
	Reference	1725	2011
N06A	Intervention	1477	1555
	Reference	1205	1471

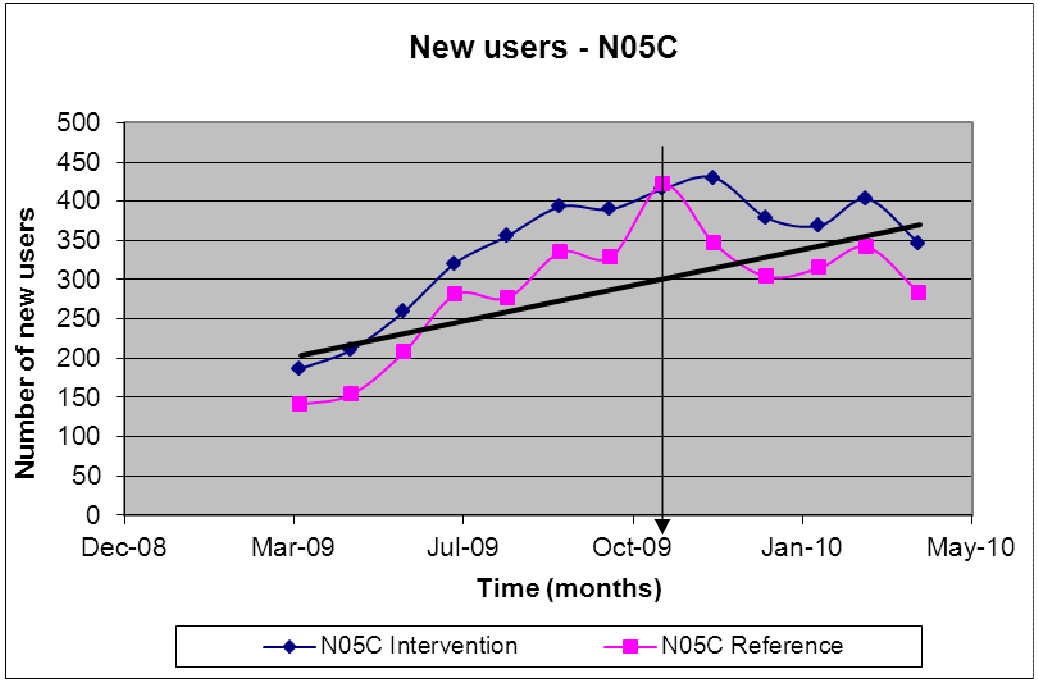
The proportion of new users of each of group of medicines is displayed in Table 116. In order to evaluate differences in the proportions that could be attributed to the training course, odds-ratio, and respective confidence intervals, were calculated between the intervention and the reference groups at T1. The results are presented in Table 116.

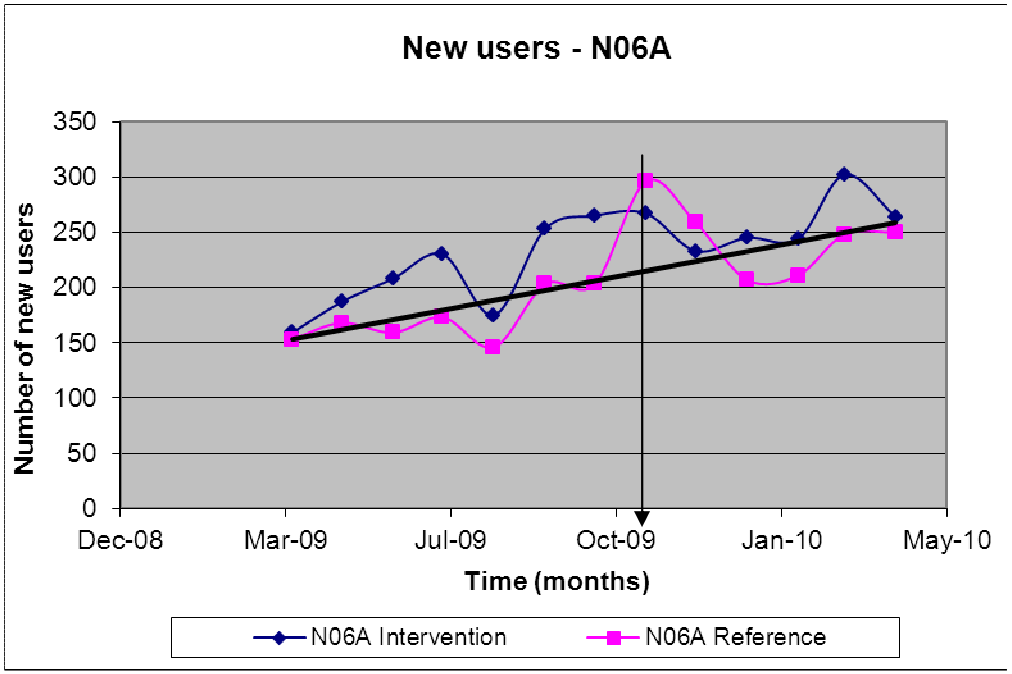
Table 116: Proportion per thousand patients of new users of N05B, N05C and N06A medicines in each pharmacy group, stratified by time of measurement

ATC code	Pharmacy group	Time of measurement		Odds-ratio	Confidence Interval (95%)	
		T0	T1		Lower	Upper
N05B	Intervention	6,81	7,52	0,868	0,8238	0,9145
	Reference	7,34	8,66			
N05C	Intervention	4,94	5,44	0,938	0,8812	0,9987
	Reference	4,90	5,80			
N06A	Intervention	3,41	3,53	0,825	0,7656	0,8897
	Reference	3,50	4,27			

The distribution over time of new users of the selected groups of medicines is presented as time trend analysis in Figure 64.







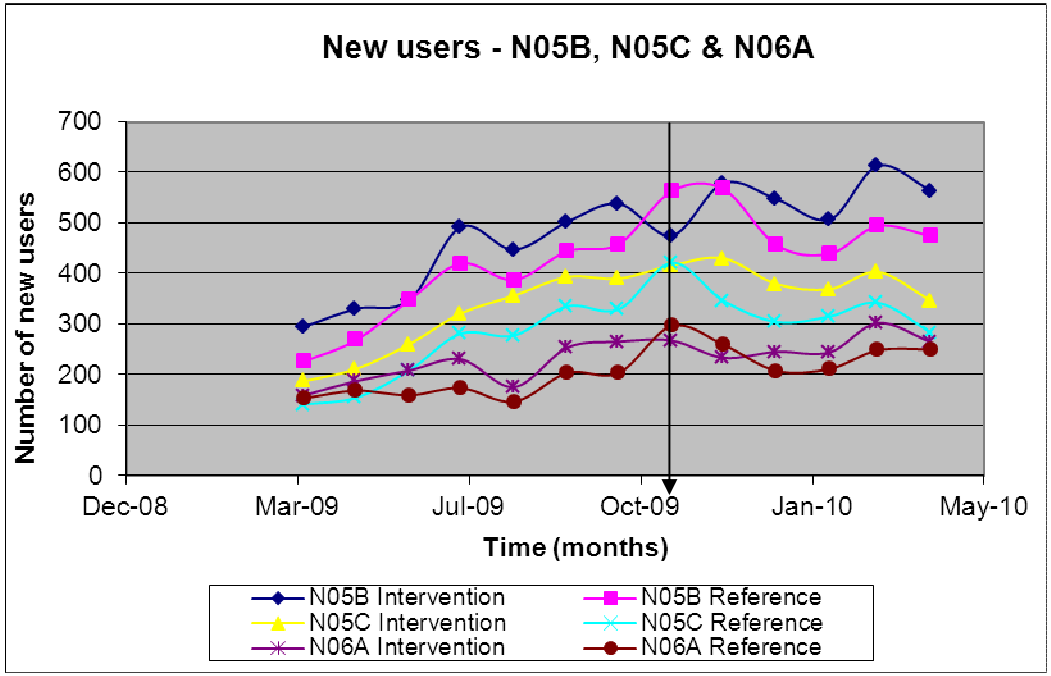


Figure 64: Time trend analysis. The vertical line in the graphs represents the beginning of the follow-up period (starts after the training, in November 2009 and lasts for 6 months, until end of April 2010).

Within DRUID, a categorization system was developed [8] [9] based on the level of impairment of a medicine on driving fitness. Table 117 shows the distribution of the medicines, and respective category, over a year, from 01 April 2009 until 30 April 2010, (both T0 and T1 included) stratified by each group.

Table 117: Proportion per thousand patients of category 1, 2 and 3 medicines in each pharmacy group, stratified by time of measurement

ATC code	**Category**	T0		T1	
		Intervention	Reference	Intervention	Reference
N05B	cat 1	0,03	0,01	0,03	0,00
	cat 2	0,18	0,14	0,21	0,20
	cat 3	6,72	7,25	7,36	8,57
N05C	cat 1	0,06	0,04	0,08	0,03
	cat 2	0,00	0,00	0,00	0,00
	cat 3	4,85	4,81	5,32	5,74
N06A	cat 1	1,13	1,18	1,05	1,49
	cat 2	1,18	1,15	1,18	1,35
	cat 3	1,21	1,24	1,39	1,56

4 Discussion

4.1 Pharmacists

Females were the majority of the participants. The mean age was approximately 40 years-old and, on average pharmacists had 12.8 years of practice. To obtain information on medicines affecting driving behaviour, pharmacists used preferably internet rather than software packages showing familiarity with these types of tools.

Pharmacists were, in general, aware of the influence of medicines on driving fitness. .After the course, pharmacists' awareness of the effects of medicines on driving fitness increased and became statistically (p-value<0.001) higher, especially for the awareness about the effects of medicines on driving fitness.

Pharmacists reported, on average, some regular routines, especially when it comes to provide patients with written information materials while dispensing driving impairing medicines. Pharmacists failed, however, to keep records of patients' participation in traffic, during their daily practice, both before and after the course. After the course, pharmacists' routine significantly improved, and become part of their regular practice. Pharmacists did report having easy access to data and information about the effects of a medicine on driving skills and the preferable source of information was professional websites. In the 1st measurement, pharmacists used significantly (p-value=0.02) more organizations as source of information than in the 2nd measurement, maybe still due to the effect that the public campaign had, as most of the information was provided by national organizations.

In general, pharmacists' knowledge about the influence of certain medicines on driving fitness can be considered good. In the follow-up measurement, pharmacists' knowledge significantly increased and, consequently, the percentage of correct answers about the influence of a certain active substance on driving fitness increased and the percentage of "don't know" decreased. The only exception seem to deal with Diazepam (statement: "diazepam, regardless the dose, severely impairs driving within the first 2 months of treatment") where the percentage of wrong answers was always higher. A possible explanation for this fact could be due to a lack of understanding of the question itself.

Regarding the use of information materials that were produced, data had shown that pharmacists did not use the information materials very often. However, 90% of the times the materials developed to train pharmacy technicians were used. The cooperation with GPs was not considered a common practice and, therefore, materials were not frequently used to discuss the influence of medicines on driving fitness with GPs. The majority of the pharmacists welcomed and read all the newsletters that were sent to them by e-mail. The course and the course materials were positively evaluated by the majority of the pharmacists, with the exception of the materials developed for GPs, as most of the pharmacists did not use it during the FTO (meeting with GPs and pharmacists). This could be due to the fact that the topics to be discussed during these meetings are selected in advance and pharmacists did not know, with so much time in advance, that they would be enrolled in a course on the influence of medicines on driving fitness. Therefore, the topic was probably not in the agenda for the FTO meetings that took place during the study period.

Pharmacists were willing to use a tool which allows finding information on medicinal drugs and driving, while dispensing. After the course, all pharmacists switched on the EUC module and were very active with the modules from the Pharmacom® system, in particular with the modules concerning N06 medicines. The materials that were integrated in the Pharmacom® system (EUC, EUB-TUB modules, and CMPM) were considered to be handy, clear, useful and complete.

Pharmacists regularly used written materials such as the information on the yellow sticker and the GIT to inform their patients about the possible influence of medicines on driving fitness. The DRUID warning label was also regularly used and pharmacists' opinion about the DRUID warning label was, in general, positive and considered clear and useful to provide information to patients. The categorization of driving impairing medicines in three categories of

impairment was considered clear and useful. However, according to some pharmacists, the DRUID warning label raised, from the patient side many questions, such as about the meaning of the categorization system, mainly about the real risk of taking the medicine while driving. According to the authors, the fact that patients have questions about the pictogram and about the influence of medicines on driving fitness is a good starting point for discussion and to have patients involved in their own decision-making process of whether they should stop driving or not.

Changing a medicine to a less impairing alternative was rarely done by pharmacists and when it happen, it was only done 1-2 times. This could be due to the fact that the prescription of medicines is something normally done by doctors and they are the ones deciding upon which medicine should be prescribed to the patient. Besides, when a pharmacist suggests a change in the prescription, the doctor has to agree with it. If the change is not immediately done at the pharmacy, the patient has to go back to their doctor for a change, causing delays in the treatment. If GPs would be addressed the same training as the one performed with pharmacists, the process could be faster and unnecessary burdens to the patients could be avoided.

4.2 Patients

At both time measurements there were more females than males and the mean age was 53 years-old with a relatively low education level. Participants experienced side-effects, such as sleepiness, decrease in alertness and reaction time, troubles concentrating while taking driving impairing medicines. Despite the presence of side effects, patients often participated in traffic by driving their cars very frequently.

Patients acknowledge the fact that driving when tired, driving under the influence of alcohol, keeping short distance to the leading car, speeding, driving under the influence of medicines or illicit drugs, and using a mobile phone while driving can be, sometimes or often, causes of road accidents. The mean scores slightly increased in the follow-up measurement without any statistically significant differences. When it comes to knowledge about the risk of having a road accident while driving under the influence of medicines, it was possible to identify some improvements which were statistically different (p-value = 0.032), particularly with respect to the risk of having road accident at the start of the treatment when compared to a long term treatment. However, patients' knowledge about the combination of medicines with OTC medicines did not seem to be clear, especially during the follow-up measurement, when the percentage of wrong answers significantly (p-value = 0.002) increased. One could hypothesize that patients do not know what over-the-counter medicines are (even if examples were given) or that they did not realize that a combination effect could occur. Therefore, pharmacists could provide some additional information on the effects of the combination of OTC medicines and DIM on driving fitness.

Regarding main sources of information about DIM, patients referred to pharmacists as the main source of information. After the training (follow-up measurement) a significantly (p-value = 0.007) higher percentage of patients were spontaneously informed about the influence of medicines on their driving fitness. The information that was provided relates with the influence of the medicine in driving fitness and operating machinery and about the severity of the impairment. No statistically significant differences were found between the two time measurements or between the two groups of pharmacists. Very few patients mentioned having discussed with their pharmacist the possibility of taking safer alternatives for the treatment of their disease. That could be, in a way, related with the fact that, as mentioned before, pharmacists rarely changed a prescription.
In any case, though patients receive information and mentioned having experience side-effects, they do not change their driving behaviour, by driving less frequently.

Patients' attitudes towards the use of DIM and the use of alcohol while driving did not significantly change between time of measurement or pharmacy group. Patients clearly referred that driving while using DIM should be punished more severely in the future and denied that the risk of driving under the influence of medicines is being exaggerated. Regarding attitudes towards the use of driving impairing medicines and its consequences in

traffic participation, patients showed more concern towards safety related to others rather than related to them

4.3 Dispensing data

Even if the number of pharmacies included in each group differed, the mean of registered patients in the pharmacies belonging to the intervention and the reference group was equally distributed in both groups (9.249 and 9.172 patients in the intervention group pharmacies and in the reference group, respectively). The number of new users of N05B, N05C and N06A medicines was always higher during the follow-up period, but the difference was never statistically significant. The same was valid for the proportion of new patients: the number was always higher in the follow-up measurement and in the reference group, however with no statistically significant differences.

Regarding the dispensing pattern of these groups of medicines, no changes in the follow-up period were verified. A decrease in the number of new prescriptions was seen after the training. However, it is not possible to attribute this change to the training because the drop in the prescriptions was also seen in the reference group and, besides, during the baseline measurement (T0) there were also periods where the number of new users decreased.

Considering the 3 categories on the different levels of impairment, it was not possible to see a decrease in the dispensing of higher categories medicines and a consequent increase in the safer alternatives. This could be easily explained by the fact that pharmacists do not prescribe medicines. To see and effective change, the training should have been carried out among prescribers (GPs or specialists).

4.4 Study strengths and limitations, problems encountered and solutions

The main strengths of the present study can be attributed to the outcomes at different levels (pharmacists, patients and dispensing data). The pre-post comparison at patient level as well as the dispensing data certainly added value to the study, and allow to investigate to what extent the pharmacists' training was effective. The large number of participants (mainly patients) ensured enough statistical power.

Some limitations should be considered in this study. Firstly, the main limitation deals with the fact that no pre-post test in the control group of pharmacists was conducted as no questionnaire was addressed to pharmacists belonging to the control group. This decision was made as the authors believed this could trigger pharmacists' attention to the topic and, therefore, could bias the results, mainly at the patient level. The results, however, showed no differences between the patients visiting the pharmacies belonging to the intervention or control groups. By not having any information from the pharmacists belonging to the control group makes it impossible to compare the differences between both groups in the main outcomes (awareness, knowledge and reported behaviour).

Secondly, general practitioners were not involved as participants, even if several attempts were made, however without any success. It would have been a challenge to investigate interventions at the patient level, when both GPs and pharmacists are highly involved in selecting the least driving impairing medicine and in providing the patient with very detailed information about the influence of medicines on driving fitness. Perhaps if GPs would have been involved, different dispensing results were to be expected as, in the Netherlands, GPs are the main prescribers and, therefore, responsible for the prescription of medicines, including those that affect driving fitness.

Thirdly, the outcomes of the public campaign on the influence of medicines on driving fitness, launched in the Netherlands in 2008, could have positively contributed to pharmacists' relatively high level of knowledge, as well as to their positive awareness towards the use of potentially impairing medicines while driving, at the baseline. If the campaign was not experienced in 2008 a more significant result of the training, expressed as observed behaviour, could be expected, after 6 months. Moreover, pharmacists' voluntary participation

in the study and willingness to be well informed and aware of the possible risks of medicines on driving may have positively biased the results obtained in the study.

Lastly, it is important to mention that the participants in this study were all users of one specific computer system. Even if the Pharmacom® system is used by half of the pharmacies in the Netherlands, the sample size of the population was restricted to the users of this software. The participation of pharmacists who use other software systems could have resulted in a more heterogeneous population, as the information provided and displayed in other computer systems can differ and, therefore, it could, in a way, influence pharmacists' knowledge. However, the authors believe that having participants using the same computer system is strength, as that resulted in uniformed procedures and instructions for presenting information to the pharmacists.

Besides the study limitations discussed above, several hurdles had to be overcome throughout the study period. The table below lists the problems encountered and the solutions that were decided upon to solve these.

Table 118: Problems encountered and solutions.

Problem encountered	Solution
Schedule of training sessions – it was difficult to find dates that would suit the majority of the participants. The location for the training as, sometimes, an issue for the pharmacists.	Several sessions, in different locations, were scheduled. The training was, at all times, given by the same person (Ms Hilka Wolschrijn).
Problems with English – because this study is part of the European project DRUID, the questionnaire that pharmacists had to fill in right before the training was in English. Some pharmacists felt it was difficult to understand some of the questions.	The person in charge of giving the course translated the questions that generate more problems. This was done in all training sessions to ensure the same level of understanding.
Pharmacy assistants – in the Netherlands, pharmacists' assistants play an important role in the information that is provided to patients while dispensing medicines. However, the training was aimed only at pharmacists.	Information materials were created for pharmacists' assistants and pharmacists were given instructions on how to train their pharmacy team. By doing so, it was ensured that all teams at all pharmacies received the same information.
Collaboration with general practitioners – in the Netherlands, there is a national primary care agreement (LESA) that refers to the collaboration between pharmacists and GPs.	Despite the fact that GPs were not included in the study, information materials were provided to pharmacists so that they could inform the GPs with whom they collaborate whenever they met. In this way, GPs were also up-to-date about the study and were aware of the influence of medicines on driving fitness.
Therapy compliance – some pharmacists warned that therapy compliance could be threatened when patients are informed about the negative influence of medicines on driving fitness.	During the training, practical solutions were provided to pharmacists on how they could instruct their patients to be more aware and to overcome the impairing effects of medicines on driving fitness at the start of the treatment. Suggestions like "start the treatment during the weekend, while not using their car", or "taking most of the daily dose at night while patient is

	sleeping" were mentioned.
Data extraction – the extraction of dispensing data required that pharmacists needed to work on their computer system in order to send us the selected data sets.	Instructions how to extract the data were developed with the help of the software developer (Pharmacom® system). Help-desk opportunities by the research team. were provided as well
Motivation – throughout the study period, pharmacists needed to carry out several activities, some of them time consuming, such as sending out questionnaires to their patients. Due to this fact, some pharmacists did not put in practice some of the activities.	To overcome this problem, frequent reminders were sent to the pharmacists, via email. References to the activities that needed to be conducted were mentioned in the monthly newsletters. Several motivational phone calls were made in order to give positive feedback to the pharmacists.

5 Overall conclusions and recommendations

It can be concluded that Dutch pharmacists were well aware of the influence of medicines on driving fitness and therefore not many significant changes in awareness were found to be caused by the training. However, the training did have a very positive influence in pharmacists' reported behavior which became much better after the training. Pharmacists' knowledge was already satisfactory at the baseline but, with no doubts, the knowledge significantly increased after the training. Thus, we can conclude that the training positively changed pharmacists' reported behavior and knowledge.

The DRUID information materials integrated in the Pharmacom® system and those provided during the course were very well accepted by the pharmacists. The training and the information materials developed helped pharmacists to improve some daily routines and contributed greatly to improve the information provided to patients, which became more adequate. Pharmacists are willing to use ICT tools which include information on medicines and driving, just as the one used in this study, in the future. The DRUID warning label, introduced as part of the information materials provided to the patient in the personalized medicine information leaflet, raised some questions and, as a consequence, started the discussion between patient and pharmacist about the influence of a medicine in driving fitness. Ultimately, this could be a good starting point for the patient decision-making process.

Patients who participated in the study had good knowledge about the influence of medicines on driving fitness and no changes on patients' knowledge were found, meaning that the training did not have an impact on patients' knowledge. According to patients, pharmacists are considered to be the main source of information about medicines and the message about driving under the influence of medicines was spontaneous and successfully transmitted to patients mainly going to pharmacies in the intervention group. Therefore, it is legitimate to conclude that the training had a positive impact on the spontaneity on the information given. Despite the knowledge acquired and the possible experience of side effects that can impair driving fitness, patients did not change their driving behaviour.

The training did not have any impact on the delivery of safer alternatives to first time users of driving impairing medicines.

As for recommendations, the authors believe that the collaboration between GPs and pharmacists is needed for appropriate prescribing and dispensing of medicines that might impair driving fitness. In the Netherlands, a national primary care agreement was achieved. However, improvements need to be implemented at the local level in order to observe more effectiveness of prescribing and dispensing guidelines. For example, the use of the categorization of medicines is not provided in all systems, although pharmacy software systems are more synchronized to present similar information than GP software systems, due to the activities performed during the campaign in 2008.
Keeping systematic and standardized records of patients' driving habits (for example if the patient is a professional driver or if the patients drives very frequently to work) could be of help to immediately identify the patients that are at a greater risk of being involved in a traffic accident and, therefore, think about less impairing alternatives, every time it is possible. Adding warning labels on the medicines' box is known to enhance the recall. Therefore, this could help patients to remember, just by looking at the medicines' box, that they are taking medicines that can potentially impair their driving fitness. The level of understanding of the developed pictogram was evaluated in another DRUID study (deliverable 7.3.2 [7]), presenting very positive and promising results.
The development of harmonized patient information leaflets is also of great importance and the European focus could be even stronger by involving the European drug regulatory agency. Furthermore, for maintaining the sources from which the information for health care providers and patients will be derived, new initiatives at the European level and the level of the Member States will be needed involving the different stakeholders.

6 Summary of results, conclusions and recommendations

Results - Pharmacists

- Dutch pharmacists frequently use the internet to look for information about medicines in general and about medicines that affect driving fitness. The use of ICT tools is also frequent but, less than internet.
- Pharmacists' awareness regarding the influence of medicines on driving fitness was positive at the baseline measurement and did not statistically increase six months after the training except for awareness on driving skills.
- Pharmacists' reported behaviour in their daily routines on informing patients about the influence of medicines on driving fitness significantly improved after the course.

- Pharmacists' actual knowledge concerning the influence of certain medicines (codeine, fexofenadine, amitriptyline and paroxetine) on driving fitness significantly increased after the course. For all medicines (temazepam, diazepam, codeine, fexofenadine, amitriptyline and paroxetine) where a higher percentage of questions answered correctly was verified and, as a consequence, a decrease in the percentage of wrong answers.
- The course and the information materials provided (course folder, information for technicians, information for GPs and newsletters) were positively evaluated by all pharmacists.
- Pharmacists' used the information materials provided to train their technicians but failed to use the information provided to informed the GPs during joint meetings (FTO).
- The functionalities incorporated in the Pharmacom® system were evaluated as clear, useful, complete and well organized and pharmacists are willing to use ICT tools during the dispensing of medicines.
- To help informing patients who take driving impairing medicines, pharmacists regularly used the yellow sticker and the DRUID warning label. Regarding the DRUID warning label, pharmacists found it very clear and useful to provide information to patients

Results - Patients

- Patients' knowledge about causes of road accidents did not significantly change after the training. Patients' knowledge remained stable 6 months after the training, in the control group, whereas the knowledge of patients in the intervention group increased, although not significantly.
- In patients' opinion, pharmacists are the preferable source of information about medicines and its use. This information is often spontaneously provided to patients, especially after the training.
- During a pharmacy consultation, patients were mainly informed about the influence of medicines on driving fitness and on operating machinery and about the severity of the impairment.
- The majority of the patients decided not to change their driving frequency, despite the information that was provided to them by their healthcare provider. This did not change depending on neither the pharmacy group nor time of measurement.
- Patients' attitudes towards the use of driving impairing medicines while driving and concerning the consequences on the use of driving impairing medicines while driving were not influenced by the pharmacy group or the time of measurement.

Results - Dispensing data

- The number of new users of N05B, N05C and N06A medicines was higher during the follow-up period than in the baseline. The differences were not statistically significant.
- The dispensing pattern of N05B, N05C and N06A medicines did not show any change that could possibly be attributed to the intervention (training).
- No shifts to less impairing medicines were verified, especially not in the pharmacies belonging to the intervention group after the training.

Main conclusions

- The training was effective at the pharmacists' level as pharmacists' knowledge and reported behaviour increased after the training.
- The use of information materials and ICT tools was used by pharmacists during the dispensing of driving impairing medicines. However, during daily practice, the training had no impact on the dispensing of safer alternatives of driving impairing medicines.
- The training did not have any impact at the patient level as no statistically significant changes were verified in patients' knowledge and behaviour.

Recommendations

- Collaborations between GPs and pharmacists regarding the prescription and dispensing of driving impairing medicines should be improved.
- Establishment of a uniform categorization system of driving impairing medicines (for example, by implementing the DRUID categorization system).
- Systematic use of ICT tools containing the relevant information that should be provided to patients at the time of dispense of driving impairing medicines.
- Use of ICT tools to keep records of patients' driving habits.
- More effective communications with patients are needed, by making use of pictograms or warning labels on the medicines' box, which is known to enhance recall of information.
- Development of harmonized patient information leaflets containing appropriate information for patients.

Acknowledgements

The research team would like to thank all pharmacists (and their teams) for their participation and high commitment throughout the DRUID study. We would also like to thank Ms Hilka Wolschrijn who gave the course to the participants and who was responsible for all contacts with pharmacists, keeping them updated and continuously motivated.

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Annexes

Annex 1 – Pharmacists' questionnaire – baseline measurement (T0)

EVALUATION QUESTIONNAIRE

Pharmacists

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract No. TREN - 05-FP6TR-SO7.61320-518404-DRUID

Co-funded by the European Commission

Dear participant,

This study is conducted as part of the DRUID European project (Driving under the influence of drugs, alcohol, and medicines). Specifically, it focuses on the actual impact drugs may have on driving safety. We are interested on your opinions on the way medicines may affect driving.

The questionnaire consists of 6 pages and it comprises 38 questions.

It will take you approximately 15 minutes to complete.

Please read each question carefully and tick a box ☑ to indicate your answer. In most cases you will only have to tick one box but please read the questions carefully as sometimes you will need to tick more than one box. Answer the next question unless asked otherwise. Once you have finished please take a minute to check whether you have answered all the questions that you should have answered.

We assure you that all your answers and statements will be handled anonymously and that they will be used for scientific research purposes only.

☐ **My participation in this questionnaire survey is voluntary (informed consent).**

Thank you for your valuable participation!

Research supervisor Prof. dr. J. J de Gier

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A. BACKGROUND INFORMATION

1. Gender

☐ Male ☐ Female

2. Date of birth (DD/MM/YYYY):_____

3. Country: _____

3a. Area: ☐ Urban ☐ Rural ☐ Other

4. Year of graduation medical school (YYYY): _____

4a. How many years are you practising as a Pharmacist?

(Please state in full years) _____

5. Did you get any education on medicinal effects on driving skills during your studies at University?

☐ Yes ☐ No

6. If you answered "Yes" in Q5, please specify:

_____
_____
_____

B. NEW TECHNOLOGIES LITERACY

1. Do you use the internet to obtain information?

☐ Yes ☐ No

2. Do you use the internet to obtain information on medicines affecting driving behaviour?

☐ Yes ☐ No

3. Have you ever used any software package / programme to obtain information on medicinal drugs effect on driving behaviour?

☐ Yes ☐ No

4. If you answered "Yes" in Q3, please specify which software packages you use:

_____
_____
_____

5. Do you use any medical/clinical software package / programme?

☐ Yes ☐ No

6. If you answered "Yes" in Q5, please specify which software packages you use:

1. _____
_____
2.

C. ATTITUDES / AWARENESS

Please evaluate the following statements:

1. I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

2. Would you consider this (Q1) of more concern if your patient is:

- a professional driver? ☐ Yes ☐ No
- driving frequently? ☐ Yes ☐ No
- driving long distances? ☐ Yes ☐ No
- an “inexperienced” driver? ☐ Yes ☐ No
- an “experienced” driver? ☐ Yes ☐ No
- an elderly driver? ☐ Yes ☐ No
- using other CNS active drugs? ☐ Yes ☐ No

3. I am willing to sacrifice some degree of efficacy by prescribing/dispensing a medicine that is less impairing to the driving skills.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

4. I feel being well aware of the effects of medicines on driving skills.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

5. It is important for me to be well-informed on medicinal effects on driving behaviour.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

6. I feel that the information I provide to patients will influence their driving behaviour.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

D. REPORTED BEHAVIOUR

Please reflect on the following statements according to your daily practice routines.

1. I ask a patient about his/her driving exposure when choosing/dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

2. I inform a patient about driving related risks when prescribing/dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

3. I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

4. I keep systematic records when I prescribe/dispense a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

5. I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

6. I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

7. I discuss medicinal drug consumption and driving related responsibility issues with the patient.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

8. How frequently do you usually provide detailed information when prescribing a medicine with impairing effects on driving performance?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

E. SOURCES

1. I have easy access to data and information about a medicine's effect on driving skills.

☐ Yes ☐ No

2. Please report your sources:

Professional websites ☐

Newsletters ☐

Organisations ☐

Journals ☐

Other ☐

Please specify:

_____
_____

---

3. Did you get any postgraduate education on medicinal effects on driving skills?

☐ Yes ☐ No

4. If you answered "Yes" in Q3, please specify:

_____
_____
_____

F. ACTUAL KNOWLEDGE

Please reflect on the following statements according to your daily practice routines.

For each statement tick the one which best fits your professional what ??

1. How much do you agree or disagree with the following statements?

Statements	Totally Disagree	Disagree	Agree	Totally Agree	Don't know
Temazepam (up to 20 mg) is severely impairi driving 8 hours after intake	☐	☐	☐	☐	☐
Diazepam (regardless dose) is severely Impairing within the first 2 months of treatmer	☐	☐	☐	☐	☐
Codeine (up to 20 mg) is mostly safe for drive	☐	☐	☐	☐	☐
Fexofenadine (normal dose) is severely impa driving	☐	☐	☐	☐	☐
Amitriptyline at the start of treatment is as imp driving as after 4 weeks of treatment	☐	☐	☐	☐	☐
Paroxetine (up to 20 mg/day) is safe for drive	☐	☐	☐	☐	☐

2. General Practitioners/Pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.

☐ True ☐ False

3. If a General Practitioner informs the Driving Licensing Authority (DLA) that his/her patient is using a driving impairment medication, in order to give the DLA the possibility to perform a check-up, you believe this is:

☐ Mandatory practice ☐ Good practice ☐ No obligation ☐ Do not know

4. A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.

☐ True ☐ False

G. USER ACCEPTANCE

1. If we propose to you a tool (e.g. website, cd-rom) that allows you to find information on medicinal drugs and driving, will you be willing to use it for prescribing/dispensing medicines?

☐ Yes ☐ No ☐ Maybe

2. If you answered "No" or "Maybe" to Q1, what are the main reasons for your reluctance to use them?

General comments

(Please provide any further comments you may have)

Thank you for your participation!

Please, provide your email address, in case you want to be informed about the general findings of this study.

Annex 2 – Pharmacists' questionnaire – follow-up (T1)

EVALUATION QUESTIONNAIRE

Pharmacists

EU Project DRUID

Driving under the influence of alcohol, drugs and medicines

Contract No. TREN - 05-FP6TR-SO7.61320-518404-DRUID

Co-funded by the European Commission

Dear participant,

This study is conducted as part of the DRUID European project (Driving under the influence of drugs, alcohol, and medicines). Specifically, it focuses on the actual impact drugs may have on driving safety. We are interested in your opinion about the way **medicines** may affect driving and about the way your pharmacy makes use of ICT possibilities that can improve safe dispensing of driving impairing drugs.

The questionnaire consists of **23 pages** and it is divided in 10 sections. The first 6 sections are in English and they consist of general knowledge questions about the influence of medicines on the ability to drive. The last 4 sections of the questionnaire are in Dutch and they refer to specific questions about the training you followed in October/November last year (2009). The questionnaire should take you approximately **20 minutes** to be completed.

Please read each question carefully and tick a box ☑ to indicate your answer. In most cases you will only have to tick one box but please read the questions carefully as sometimes you will need to tick more than one box. Answer the next question unless asked otherwise. Once you have finished please take a minute to check whether you have answered all the questions that you should have answered.

We assure you that all your answers and statements will be handled anonymously and that they will be used for scientific research purposes only.

PLEASE TICK THE FOLLOWING BOX TO INDICATE THAT YOUR PARTICIPATION IN THE STUDY IS VOLUNTARY.

☐ **My participation in this questionnaire survey is voluntary (informed consent).**

Thank you for your valuable participation!

Research supervisor Prof. dr. J. J de Gier

Rijksuniversiteit Groningen
Farmacotherapie & Farmaceutische Patiëntenzorg

Antonius Deusinglaan 1
9713 AV Groningen

A. BACKGROUND INFORMATION

1. Gender ☐ Male ☐ Female

2. Date of birth (DD/MM/YYYY):_____

3. Year of graduation from pharmacy school (YYYY): _____

3.1. How many years are you practising as a pharmacist? _____

(Please state in full years)

4. Did you get any education on medicinal effects on driving skills during your studies at University?

☐ Yes ☐ No

4.1. If you answered "Yes" in Q5, please specify:

_____

_____

_____

5. City where you are currently working: _____

B. NEW TECHNOLOGIES LITERACY

1. Do you use the internet to obtain information?

☐ Yes ☐ No

2. Do you use the internet to obtain information on medicines affecting driving behaviour?

☐ Yes ☐ No

3. Do you use any medical/pharmaceutical software package / programme (excluding Pharmacom)?

☐ Yes ☐ No

3.1. If you answered "Yes" in Q3, please specify which software packages you use:

1. _____

4. Have you ever used any software package / programme (not being the Pharmacom-system) to obtain information on medicinal drugs effects on driving behaviour?

☐ Yes ☐ No

4.1. If you answered "Yes" in Q4., please specify which software packages you use:

_____

_____

C. ATTITUDES / AWARENESS

Please evaluate the following statements:

1. I am taking into account the effects of medicines on driving skills when dispensing medicines.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

1.1. If you answered agree or strongly agree, would you consider this of more concern if your patient is:

- a professional driver?	☐ Yes	☐ No
- driving frequently?	☐ Yes	☐ No
- driving long distances?	☐ Yes	☐ No
- an “inexperienced” driver?	☐ Yes	☐ No
- an “experienced” driver?	☐ Yes	☐ No
- an elderly driver?	☐ Yes	☐ No
- using other CNS active drugs?	☐ Yes	☐ No

2. I am willing to sacrifice some degree of efficacy by dispensing a medicine that is less impairing to the driving skills.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

3. I am aware of the effects of medicines on driving skills.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

4. It is important for me to be well-informed on medicinal effects on driving behaviour.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

5. I feel that the information I provide to patients will influence their driving behaviour.

☐ strongly disagree ☐disagree ☐ agree ☐ strongly agree

D. REPORTED BEHAVIOUR

Please reflect on the following statements according to your daily practice routines.

1. I ask a patient about his/her driving exposure when dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

2. I inform a patient about driving related risks when dispensing a medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

3. I provide a patient with written information materials when dispensing a driving impairing medicine.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

4. I keep systematic records when I dispense a driving impairing medicine (e.g. as in the EPD in Pharmacom).

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

5. I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine (e.g. as in the EPD in Pharmacom).

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

6. I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

7. I discuss medicinal drug consumption and driving related responsibility issues with the patient.

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

8. How frequently do you usually provide detailed information when dispensing a medicine with impairing effects on driving performance?

☐ always ☐ regularly ☐ sometimes ☐ seldom ☐ never

E. SOURCES

1. I have easy access to data and information about the effect of a medicine on driving skills.

☐ Yes ☐ No

1.1. If yes, please report your sources:

Professional websites ☐

Newsletters ☐

Organizations ☐

Journals ☐

Other ☐

Please specify:

_____

_____

__

F. ACTUAL KNOWLEDGE

Please reflect on the following statements according to your daily practice routines. For each statement tick the one which best fits your professional experience.

1. How much do you agree or disagree with the following statements?

Statements	Totally Disagree	Disagree	Nor agree nor disagree	Totally Agree	Don't know
Temazepam (up to 20 mg) severely impairs driving 8 hours after intake.	☐	☐	☐	☐	☐
Diazepam (regardless the dose) severely impairs driving within the first 2 months of treatment.	☐	☐	☐	☐	☐
Codeine (up to 20 mg) is mostly safe for drivers.	☐	☐	☐	☐	☐
Fexofenadine (normal dose) severely impairs driving.	☐	☐	☐	☐	☐
Amitriptyline has the same level of driving impairment at the start of treatment and 4 weeks after the start of the treatment.	☐	☐	☐	☐	☐
Paroxetine (up to 20 mg/day) is safe for drivers.	☐	☐	☐	☐	☐

2. Pharmacists are obliged to inform the patients about the possible side effects of his/her medications on driving abilities.

☐ True ☐ False

3. If a General Practitioner ('huisarts') informs the Driving Licensing Authority ('het CBR') that his/her patient is using a driving impairing medication, in order to give 'het CBR' the possibility to perform a check-up, you believe this is:

☐ Mandatory ('verplicht') practice

☐ Good practice

☐ No obligation

☐ Do not know

4. A patient can be punished with criminal sanctions if he causes a traffic accident while using a medicine with impairing properties whereas the health care provider has advised him not to drive.

☐ True ☐ False

G. USER ACCEPTANCE – COURSE (OCT/NOV '09) and COURSE MATERIALS

The following questions will reflect your opinion about the information, as well as information materials, provided to you during the course:

During the course and in the course material the following information was provided to you:

- the influence medicines can have on driving ability
- the meaning of the way the categorization system
- guidelines on how to inform physicians and patients
- Information about how to use the EUC (Eerste-Uitgifte-Controle) in Pharmacom
- Information about how to use the EUB-TUB (Eerste- en Tweede- Uitgiftebegeleiding) in Pharmacom
- Material to inform pharmacy technicians ('materiaal voor werkoverleg')
- Powerpoint to inform physicians (sent to you by e-mail)

1. Did you attend the course Rijgevaarlijke geneesmiddelen in October/November last year?

☐ yes ☐ no → **go to question 2**

1.1 If you attended the course, what is your oppinion about it?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor 'Nauwelijks mee eens' of 'Absoluut niet mee eens'?

_____

_____

_____

2. How often did you used the information that was provided to you during the course?

☐ > 10 times. ☐ 9-5 times. ☐ 4-3 times. ☐ 2-1 time(s). ☐ never

2.1 Indien u informatie in de richtlijnen heeft opgezocht, wat is uw mening over deze richtlijnen?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

2.2 Bij beantwoording met ‘2-1 keer’ of ‘nooit’ in Vraag 2, kunt u hieronder toelichten waarom niet vaker?

_____

_____

_____

3. Did you use the materials provided to inform the pharmacy technicians working in your pharmacy (‘materiaal voor werkoverleg’)?

☐ yes ☐ no

3.1. Indien u ‘Nee’ heeft geantwoord bij vraag 3: Kunt u hieronder toelichten waarom u het materiaal niet heeft gebruikt?

_____

_____

_____

4. What is your opinion about the materias to inform your team (‘materiaal voor werkoverleg’)?

	Yes, very much	**Quite a lot**	**Neutral**	**Not too much**	**No, not at all**
Clear	☐	☐	☐	☐	☐

Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor 'Nauwelijks mee eens' of 'Absoluut niet mee eens'?

_____

_____

_____

5. Did you send the powerpoint concerning the FTO to the GPs you work with ('Powerpoint voor FTO')?

☐ yes ☐ no

5.1. Indien u 'Nee' heeft geantwoord bij vraag 5: Kunt u hieronder toelichten waarom u geen gebruik heeft gemaakt van de Powerpoint?

_____

_____

_____

6. What is your opinion about the powerpoint for the FTO (Powerpoint voor FTO)?

	Yes, very much	**Quite a lot**	**Neutral**	**Not too much**	**No, not at all**
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

7. Did you read the newsletters that were sent to you, by email, in December, January, February and March?

☐ Yes, I’ve read them all

☐ Yes, I’ve read a few

☐ No, I did not read any of the newsletters

7.1 What is your opinion about the newsletters that you receive?

	Yes, very much	**Quite a lot**	**Neutral**	**Not too much**	**No, not at all**
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

7.2 Bij beantwoording met “nee” in vraag 7: Kunt u hieronder aangeven waarom u de nieuwsbrieven niet heeft gelezen?

_____

_____

_____

8. Do you think that the course should have any additional topics/matters?

☐ Yes ☐ No

8.1 Bij ‘Ja’ bij vraag 8, graag hieronder toelichten:

_____

_____

_____

H. USER ACCEPTANCE & USABILITY – TOOL (EUC and EUB-TUB-module)

In this section, your opinion regarding the information provided by the Pharmacom-system is required

1. Was the 'Eerste Uitgifte Controle' in the Pharmacom system switched on during (part of) the last half year?

☐ Ja ☐ Nee

1.1 If yes, what is your opinion about the EUC-module application during the first delivery of a driving impairing medicine?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Handy (convenient)	☐	☐	☐	☐	☐
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor 'Nauwelijks mee eens' of 'Absoluut niet mee eens'?

_____

_____

_____

2. Did you use the 'Eerste- en Tweede-Uitgifte Begeleidings-module' from the Pharmacom system during (part of) the last half a year?

	Yes	No

N05 (slaap- en kalmeringsmiddelen)	EUB	☐	☐
	TUB	☐	☐
N06 (antidepressiva)	EUB	☐	☐
	TUB	☐	☐

3. What is your opinion about the EUB/TUB application?

	Yes, very much	**Quite a lot**	**Neutral**	**Not too much**	**No, not at all**
Handy (convenient)	☐	☐	☐	☐	☐
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

4. Do you know that the background information displayed with F7 supporst the EUB/TUB-texts?

☐ Yes ☐ No

4.1 If yes, what is your opinion about the information regarding driving impairment in and behind F7 of the first delivery module (‘EUB-teksten’)?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor 'Nauwelijks mee eens' of 'Absoluut niet mee eens'?

_____

_____

_____

5. In your opinion, is there anything missing in the EUB/TUB module?

☐ Yes ☐ No

5.1. If you said yes, please specify.

_____

_____

_____

6. What is your opinion about the information provided in the Chapter 'Verkeersdeelname' (traffic participation) in the Commentaren Medicatiebewaking from Pharmacom/Medicom (CMPM) (online and/or as a book)?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all

Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐
Complete	☐	☐	☐	☐	☐
Well organized	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor 'Nauwelijks mee eens' of 'Absoluut niet mee eens'?

_____

_____

_____

7. We are also interested in your opinion on the book Verkeersdeelname (Traffic Participation) issued by the KNMP. How often did you, after completing the course in October / November, used the book Traffic participation KNMP?

☐ > 10 times. ☐ 9-5 times. ☐ 4-3 times. ☐ 2-1 time(s). ☐ never

I. FUTURE USE OF THE TOOL (EUC and EUB-TUB-module)

1. Would you be willing to continue using the EUC-module, the EUB-module and the TUB-module in the future? (please select one option per module).

EUC - module	EUB - module	TUB - module
☐ yes	☐ yes	☐ yes
☐ maybe	☐ maybe	☐ maybe
☐ no	☐ no	☐ no

Q1.1. If you answered "maybe"or "no"in Q1., please explain why.

_____

_____

_____

_____

_____

J. IFORMATION PROVIDED TO PATIENTS, PHARMACY TEAM AND GPs

1. After the course in Nov 09, to which extent did the team in your pharmacy provide the following material to inform patients at a first delivery of a driving impairing medicine (antidepressants, sedatives and tranquilizers)?

	Always	Regularly	Sometimes	Seldom	Never
Reference to the participation in traffic section from the GIT	☐	☐	☐	☐	☐
Oral information about drugs and driving based on the information coming from the EBU / TUB	☐	☐	☐	☐	☐
Patients who did not appear at the desk were informed about drugs and driving by phone	☐	☐	☐	☐	☐
Others	☐	☐	☐	☐	☐

1.1. Bij Anders, kunt u hieronder toelichten op welke wijze dan?

_____

_____

2. To what extent has your pharmacy used the following written materials to inform patients who take driving impairing medicines for the first time?

	Always	Regularly	Sometimes	Seldom	Never
Yellow sticker (gele sticker)	☐	☐	☐	☐	☐
GIT (Pharmacombijsluiter)	☐	☐	☐	☐	☐
DRUID warning label	☐	☐	☐	☐	☐
VI-folder (stg UI)	☐	☐	☐	☐	☐
Folder from KNMP	☐	☐	☐	☐	☐
Folder 'Is jouw medicijn veilig in het verkeer?' from DGV	☐	☐	☐	☐	☐
Other _____	☐	☐	☐	☐	☐

Bij de keuze ‘anders’, kunt u hieronder aangeven welk materiaal dat betrof?

_____

_____

_____

3. What is your opinion about the DRUID warning label

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Useful to provide information	☐	☐	☐	☐	☐
Clear for the patient	☐	☐	☐	☐	☐
Gives suficient information	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

4. What is your opinion about the categorization of driving impairing drugs in three categories of impairment?

	Yes, very much	Quite a lot	Neutral	Not too much	No, not at all
Clear	☐	☐	☐	☐	☐
Useful	☐	☐	☐	☐	☐

Kunt u hieronder uw keuze toelichten als u heeft gekozen voor ‘Nauwelijks mee eens’ of ‘Absoluut niet mee eens’?

_____

_____

_____

5. After the course (Oct/Nov 09), were the technicians of your pharmacy trained about medicines affecting driving performance?

	Yes	No
By myself or by a colleague	☐	☐
External training (e-learning, SBA-training)	☐	☐
Other: _____	☐	☐

Bij de keuze 'anders', kunt u hieronder aangeven op welke manier het team dan is geïnformeerd?

_____

_____

6. After the course (Nov 09), were the physicians, with whom you collaborate locally, informed by you or any other collaborating pharmacist about medicines affecting driving performance?

☐ Yes ☐ No

6.1. If yes, which materials were used?

	Yes	No
Powerpoint from DRUID	☐	☐
Materials from the course that was given	☐	☐
DGV FTO-module Geneesmiddelen en verkeersveiligheid (IVM)	☐	☐
LESA Verkeersdeelname (Landelijke Eerstelijns Samenwerkingsafspraak)	☐	☐
Others: _____	☐	☐

Bij de keuze 'anders', kunt u hieronder aangeven welk materiaal u dan heeft gebruikt?

_____

_____

7. How many times, after the course, did you change a prescription to a less impairing alternative due to the effects on driving ability?

☐ > 10 times. ☐ 9-5 times. ☐ 4-3 times. ☐ 2-1 time(s). ☐ never

Algemene opmerkingen

Hieronder vindt u ruimte voor eventuele opmerkingen of aanvullingen:

_____

_____

_____

_____

_____

AUB de enquête in de antwoordenvelop terugsturen
aan de Rijksuniversiteit Groningen

HARTELIJK DANK VOOR UW MEDEWERKING!!!

Annex 3 – Patients' questionnaire – baseline and follow-up measurements

Questionnaire for patients

THE USE OF MEDICINES IN TRAFFIC

DRUID task 7.4

Introduction to the questionnaire

With the aid of this questionnaire we would like to evaluate people's opinion and knowledge about the use of potentially dangerous medicines in relation to participation in traffic. In this questionnaire you will find some questions about your participation in traffic, your use of medication and your knowledge about the influence medicines may have on your driving performance.

Some of the questions may seem to not be applicable to your situation. For example if you are not a regular participant in traffic. Nevertheless, all the information you provide to us will be of great importance to our research. Therefore we kindly ask you to answer all questions.

The majority of the questions can be answered by simply ticking the box next to the option of your choice. In some other questions you will be asked to write down the answer yourself or to specify your choice. This questionnaire is all about your opinion and experience. So there are no correct or wrong answers.

We greatly appreciate your willingness to complete this questionnaire. After completing please return the questionnaire to <<NAME OF RESEARCH INSTITUTE>> using the stamped response envelope.

If you have any questions or remarks please feel free to call <<NAME OF CONTACT PERSON>> at <<PHONE NUMBER (and email address (optional)) OF CONTACT PERSON (optional: days and hours available for this)>>.

Pharmacy

Firstly we would like to ask you which pharmacy supplied you with this questionnaire (we will refer to this pharmacy as "your pharmacy" or "your pharmacist" in some of our questions). The only purpose of this question is for us to determine the number of returned questionnaires per pharmacy. Privacy is guaranteed, it will not be possible to retrieve any of your personal information through this.

<<Name>>of your pharmacy: .....

Date of today: … … - … … - … … … … (day - month - year)

General information

1. What is you gender? ❑ male

❑ female

2. What is your age? ..... years

3. What is your level of education?

❑ Not completed primary education

❑ Completed primary education

❑ Lower vocational training or general education

❑ Intermediate vocational training or intermediate and higher general education

❑ Higher vocational training, college or university

Your participation in traffic

4. Please indicate how often you use the following modes of transportation as a driver. *If you travelled by bicycle, moped, motor cycle, car, lorry, truck or van only if you were the driver.*

	5 - 7 days per week	2 - 4 times per week	2 - 4 times per month	1 time per month or less	never
a. Bicycle	❑	❑	❑	❑	❑
b. Moped	❑	❑	❑	❑	❑
c. Motor cycle	❑	❑	❑	❑	❑
d. Car	❑	❑	❑	❑	❑
e. Bus or mini bus	❑	❑	❑	❑	❑
f. Lorry, truck or (mini)van	❑	❑	❑	❑	❑
h. Other, please specify …….	❑	❑	❑	❑	❑

Medicines in traffic

Questions 5 - 8 are about the use of medicines and driving performance. When you do not know the answer to any of these questions, please indicate so. This is also of great importance to this research.

5. *Do you know that certain medicines may have a negative effect on the ability to drive?*

- ❑ *No → PLEASE GO TO QUESTION 7*
- ❑ *Yes*

6. *And which kind of negative effects do you think these medicines could have?*

Please take your time to think this over

……

……

……

7. How often do you think that the factors mentioned below are (part of) the cause of road accidents? *(please select one option only for every factor)*

•	never	seldom	sometimes	often	don't know
- Driving when tired	❑	❑	❑	❑	❑
- Driving under the influence of alcohol	❑	❑	❑	❑	❑
- Too short a distance to leading car	❑	❑	❑	❑	❑
- Speeding	❑	❑	❑	❑	❑
- Use of medicines that might impair driving	❑	❑	❑	❑	❑
- Use of illicit drugs	❑	❑	❑	❑	❑
- Use of a mobile phone while driving	❑	❑	❑	❑	❑

8. To which extent do you agree or disagree on the following statements?

(please select one option per statement)

	totally agree	agree	disagree	totally disagree	no opinion
a. The risk of having a road accident is smaller when you have just started taking a driving impairing medicine compared to long term treatment	❑	❑	❑	❑	❑
b. The risk of having a road accident may increase when you combine a driving impairing medicine and over the counter medicines (e.g. pain killers, cough remedy)	❑	❑	❑	❑	❑
c. The risk of having a road accident increases when you use alcohol while taking a driving impairing medicine	❑	❑	❑	❑	❑
d. The risk of having a road accident remains the same when you use several driving impairing medicines at the same time	❑	❑	❑	❑	❑
e. The risk of having a road accident increases with a high dose of a driving impairing medicine	❑	❑	❑	❑	❑

Use of medicines

9. *Please fill in the table below* **only for your sedatives or tranquillizers or medicines for depression and/or for allergies?** *Please take into account only the medicines that you actually take. We kindly ask you to state the dosage you use, how many times a day and at which times for each medicine. Please record since when you have been using these medicines as well. In case you use more than three of these medicines please record those you have been using for the longest period of time.*

Please try to fill in the table as completely as you can.

Name of medicine Please copy this directly from the label or package	***dosage per tablet / capsule?***	***how many tablets/capsules do you take at these moments of the day?***				***since when?*** *(month/ year)*
		morning	***afternoon***	***evening***	***night***	
1.	…… *mg*	……	……	……	……	… / ……
2.	…… *mg*	……	……	……	…….	… / ……
3.	…… *mg*	……	……	……	……	… / ……

Please specify information that will clarify your statement on daily doses.

_____
_____
_____

10. Please indicate which of the following side effects you experience or have experienced while using these medicines? *(please select all options that apply)*

- ❑ Sleepiness or drowsiness
- ❑ Decreased alertness
- ❑ Problems concentrating
- ❑ Clumsiness, problems with coordination
- ❑ Blurred view
- ❑ Dizziness
- ❑ I did not experience any side effects
- ❑ Other, please specify .....

Information about medicines

Questions 11 - 15 cover the information you **received** about your medicines obtained last month in your pharmacy.

11. Did you at any time receive information regarding the possible influence of one of your medicines on your ability to drive? *(please select all options that apply)*

- ❑ No → PLEASE GO TO QUESTION 16
- ❑ Yes, I spontaneously received information from my GP/specialist.
- ❑ Yes, I spontaneously received information from pharmacist.
- ❑ Yes, after I asked my GP/specialist or pharmacist for the information myself.

12. Which medicine(s) did this concern?

.....

.....

.....

Please think of the one you obtained last month from your pharmacist while answering

questions 13-18.

13. Who informed you about the possible influence of this medicine on your ability to drive? And how did you receive this information? *(please select all that apply)*

	GP, specialist or other doctor	**Pharmacist**	**I was not informed**
a. Oral information	❑	❑	❑
b. Written information (e.g. brochure)	❑	❑	❑
c. With reference to the information in the leaflet of the pharmacy	❑	❑	❑
d. With reference to the leaflet that is included in the medicines' box	❑	❑	❑
e. With reference to the sticker on the box	❑	❑	❑
f. With reference to the text that was reported in the label of the pharmacy	❑	❑	❑
g. Other, please specify	❑	❑	❑

14. What information did you receive? *(please select all the options that apply)*

- ❑ this medicine might influence your driving performance.
- ❑ the severity of the impairment (for example compared with the effect of alcohol on driving).
- ❑ the option of using alternative medicines with minor influence on driving performance.
- ❑ the legal consequences of driving under the influence of my medicine.
- ❑ how to decrease my risk of becoming involved in traffic accidents while taking my medicine and drive my car or moped.
- ❑ the influence on operating machinery.
- ❑ The influence on activities at home.
- ❑ The influence on other activities that require attention.
- ❑ The duration of the effect on driving performance?

❑ 2 hours	❑ 3 days
❑ 8 hours	❑ One week
❑ 12 hours	❑ Two weeks
❑ 16 hours	❑ For ever

❑ 24 hours ❑ Other, please specify _____

❑ 2 days ❑ I forgot

❑ Other, please specify

_____

15. When was the duration of the impairing effect of your medicine discussed???

❑ at the first dispensing

❑ at the second dispensing

❑ I did not receive any information from my pharmacists

❑ other, please specify

_____

Question 16 and 17 refer to information you did look for yourself.

16. Did you look for any information regarding the possible influence on your driving performance caused by any of your medicines?

❑ No → PLEASE GO TO QUESTION 18

❑ Yes

17. Where did you look for this information? *(please select all options that apply)*

❑ <<I have contacted the national medicines information phone number>>

❑ I have looked in a medical reference book

❑ I have searched in magazines

❑ I have searched the following internet pages: *(please select the ones you have visited)*

- ❑ the medicines manufacturer's internet page
- ❑ an internet page about my disease or illness
- ❑ an internet page about medicines, for example <<www.apotheek.nl>>
- ❑ the internet page www.rijveiligmetmedicijnen.nl
- ❑ a general internet page about one's health
- ❑ a health care insurance company's internet page
- ❑ (an)other internet address(es), please specify .....

- ❑ I have asked the pharmacists for extra information
- ❑ I have asked he docter or doctre's assistantes for extra information
- ❑ Other, please specify .....

- *How did you apply the information you have found yourself?*

- *18. Did the information you found change your frequency of driving?*

❑ No, because:

- ❑ I did not think the information was relevant to me
- ❑ It was not feasible for me to change my frequency of driving
- ❑ I did not notice any negative effects that influence my driving ability and thus frequency of driving
- ❑ I found information stating the medicine does not have any driving impairing effects
- ❑ Other, please specify……..

❑ Yes, and:

- ❑ I decided *not* to drive a motorised vehicle anymore
- ❑ I decided to drive/ride a motorised vehicle *less often*
- ❑ I decided to drive/ride a motorised vehicle on *less parts of the day*
- ❑ I decided not to drive/ride a motorised vehicle because I also drunk alcohol
- ❑ Other, please specify……..

19. Did the information you found change your use of this driving impairing medicine?

❑ No, because:

- ❑ I did not think the information was relevant to me
- ❑ there was no alternative medicine available
- ❑ other, please specify .....

❑ Yes, and:

- ❑ I decided *not* to use the medicine
- ❑ I decided to use my medicine less often

❑ I decided to use my medicine for a shorter time than the time that was planned.

❑ I decided to use (most of) the medicine at night instead of during the day

❑ I decided to only use the medicine when I did not need to be driving

❑ I asked for or I was prescribed a medicine causing less impairment of the ability to drive

❑ other, please specify .....

• Attitude towards behaviour in traffic

Questions 20 and 21 ask for **your opinion** regarding some statements about behaviour in traffic.

20. To which extent do you agree or disagree on the following statements?

(please select one option per statement only)

	totally agree	agree	disagree	totally disagree	no opinion
a. When using driving impairing medicines people should decide for themselves whether they drive/ride a motorised vehicle or not	❑	❑	❑	❑	❑
b. Driving while using driving impairing medicines should be punished more severely in the future	❑	❑	❑	❑	❑
c. Driving after the consumption of alcohol should be prohibited	❑	❑	❑	❑	❑
d. The risk of driving under the influence of driving impairing medicines is being exaggerated	❑	❑	❑	❑	❑
e. The risks of driving under the influence of alcohol are being exaggerated	❑	❑	❑	❑	❑

21. To which extent do you agree or disagree on the following statements?

(please select one option per statement only)

	totally agree	agree	disagree	totally disagree	no opinion
a. Possible consequences of the use medication in traffic have never crossed my mind	❑	❑	❑	❑	❑
b. When I drive when using a driving impairing medicine I endanger my personal safety	❑	❑	❑	❑	❑
c. When I drive when using a driving impairing medicine I endanger the safety of other traffic participants	❑	❑	❑	❑	❑
d. If I know someone is using driving impairing medicines I will not let them drive me	❑	❑	❑	❑	❑
e. When I have been prescribed a driving impairing medicine I choose not to use my car and choose other types of transportation	❑	❑	❑	❑	❑
f. I do not mind other traffic participants using driving impairing medicines	❑	❑	❑	❑	❑
g. When I have been prescribed a driving impairing medicine I try to use my car/vehicle as little as possible	❑	❑	❑	❑	❑
h. When other drivers participate in traffic they take their use of driving impairing medicines into account	❑	❑	❑	❑	❑

• Remarks

Do you have any remarks as a result of this questionnaire? Please express them here.

.....

.....

.....

.....

.....

.....

.....

.....

.....

- Thank you very much for completing this questionnaire!

Please send the questionnaire to <<NAME OF RESEARCH INSTITUTE>> using the enclosed stamped addressed envelope.

Annex 4 – Invitation letter for recruitment of pharmacists

Betreft: Onderzoek naar interventies bij het afleveren van rijgevaarlijke geneesmiddelen

Geachte Pharmacom-gebruiker,

Sinds oktober 2008 is de aandacht in ons land voor het gebruik van rijgevaarlijke geneesmiddelen toegenomen door de start van een landelijke campagne "Geneesmiddelen in het verkeer". Maar ook in Europees verband is de aandacht groot en wil men graag weten hoe o.a. apothekers kunnen bijdragen tot het terugdringen van het gebruik van rijgevaarlijke geneesmiddelen (zie www.druid-project.eu).
De Rijksuniversiteit Groningen is betrokken bij dit Europese project en wil graag i.s.m. Health Base bestuderen hoe effectief de interventies in apotheken kunnen zijn, waar men gebruik maakt van EU-controle en EU- en TU-begeleiding. Met deze brief willen wij uw medewerking vragen bij het uitvoeren van dit onderzoek.

Wat bieden de onderzoekers van de Rijksuniversiteit Groningen u?

- Een **unieke kans** om in Europees verband te laten zien hoe de Nederlandse apotheker FPZ bij het gebruik van rijgevaarlijke geneesmiddelen aanbiedt.
- Een **cursus** (waaraan geen kosten zijn verbonden) in oktober a.s. over geneesmiddelen en verkeersdeelname (precieze betekenis van de geneesmiddelcategorieën, juridische gevolgen en wijze van implementatie van EUC, EUB en TUB met behulp van Pharmacom). **Accreditatie** zal worden aangevraagd.
- **Begeleiding** bij het implementatie traject van EUC, EUB en TUB en de daarbij behorende extracties van registraties.
- Een **kleine attentie** voor u en het apotheekteam.

Wat vragen de onderzoekers van u?

- Gebruik van EUC, EUB en TUB bij anxiolytica, hypnotica en antidepressiva (de EUC tabel redenen vervallen recipe zal hiervoor worden uitgebreid met een reden ”rijveiliger alternatief gekozen”) vanaf 1 november 2009 tot 1 mei 2010.
- Overzicht van de eerste verstrekkingen van genoemde geneesmiddelen in de periode 1 juli 2008-1 november 2009 (hiervoor wordt een speciaal extractie programma ontwikkeld door PharmaPartners).
- Overzicht van de eerste verstrekkingen van genoemde geneesmiddelen in de periode van 1 november 2009 – 1 mei 2010 (ook hiervoor kan genoemd extractieprogramma worden gebruikt)
- Overzicht van EUB- en TUB-gebruik in de periode 1 november 2009 - 1 mei 2010 (extractieprogramma is reeds beschikbaar).
- Verspreiding van een patiëntenenquête bij ieder EU van een geselecteerd aantal geneesmiddelen (anxiolytica, hypnotica en antidepressiva) gedurende de onderzoeksperiode van 6 maanden.

Wij willen de helft van de aanmeldende collega’s via loting vragen als controle-apotheek deel te nemen (dus zonder interventie maar met het verzoek extracties uit te voeren en enquêtes te verstrekken, de **cursus** en **attentie** worden natuurlijk wel aangeboden na afloop van de onderzoeksperiode)

Wij rekenen op uw medewerking en zien uw antwoordformulier met belangstelling tegemoet. Laat het formulier s.v.p. niet liggen tot na uw vakantie. Een snelle reactie wordt op prijs gesteld.

Met dank en vriendelijke groeten,

Jan-Kees Huyts
Health Base

Han de Gier
Rijksuniversiteit Groningen

.Bijlage: Antwoordformulier

.

JA, ik wil deelnemen aan het onderzoek naar de interventies bij aflevering van rijgevaarlijke geneesmiddelen

Wij maken op dit moment gebruik van de eerste-uitgifte-begeleiding

O ja
O nee

Indien ja, voor welke van de volgende groepen is dat het geval?

O antidepressiva
O benzodiazepines
O morfinomimetica
O anti-epileptica
O voor alle groepen

Indien nee, bent u bereid dat in oktober 2009 onder begeleiding te gaan doen?

O ja
O nee

DGV heeft in samenwerking met SBA afgelopen jaar in het land diverse cursussen Geneesmiddelen en Verkeersdeelname verzorgd. Zijn er apothekersassistenten in uw apotheek die daaraan hebben deelgenomen?

O nee
O ja namelijk ……. assistenten (s.v.p. aantal invullen)

Heeft u sinds begin 2008 in het FTO aandacht besteed aan het onderwerp geneesmiddelen en verkeersdeelname?

O ja, een volledig FTO is hieraan besteed
O ja, het is uitgebreid ter sprake gekomen tijdens een FTO
O nee, dit onderwerp is nog niet behandeld

Werkt u samen met Medicom-artsen die veelvuldig voorschrijven via het Formularium?

O ja
O nee

Wordt in uw apotheek op dit moment structureel extra schriftelijke informatie meegegeven bij rijgevaarlijke geneesmiddelen?

O nee, nooit

O nee, alleen als het in het gesprek met de patiënt ter sprake komt
O ja, bij alle medicijnen met een gele sticker
O ja, alleen bij een of meer specifieke groepen, namelijk……..……
……..……
……

Uw naam: …….

Naam apotheek: ……..
Omvang patiëntenbestand (geschat in duizendtallen) ……
Adres: ……..
Plaats ……..

Formulier terugsturen aan de Rijksuniversiteit Groningen met behulp van bijgevoegde antwoordenvelop

Annex 5 – Patient information letter

Geachte Mevrouw/Meneer,

Uw apotheek doet mee aan een groot Europees onderzoek naar de **invloed van medicijnen op verkeersongevallen**. In een deelonderzoek hiervan, uitgevoerd door de Rijksuniversiteit Groningen, wordt bestudeerd welke informatie mensen ontvangen als zij 'rijgevaarlijke' geneesmiddelen gebruiken. Meer (Engelstalige) informatie over het Europese onderzoek kunt u vinden op de website www.druid-project.eu.

Wij hebben u deze brief toegestuurd, omdat u een of meer medicijnen gebruikt die de rijvaardigheid beïnvloeden. De onderzoekers zijn geïnteresseerd in uw mening en uw ervaringen met deze medicijnen en met de informatie die u van uw arts en van ons ontvangt.

Het is voor ons zeer waardevol als u aan dit onderzoek deelneemt. Dat kan door bijgaande vragenlijst in te vullen.

Omdat de onderzoekers vooral uw mening en uw ervaringen willen weten, zijn er geen goede of foute antwoorden. De meeste vragen kunt u eenvoudig beantwoorden door een vakje aan te kruisen. Er zijn ook enkele vragen waarbij u zelf een antwoord op moet schrijven. Het zal ongeveer vijftien minuten kosten om de vragenlijst in te vullen.

De vragenlijst is anoniem, u hoeft uw naam dus niet in te vullen. De onderzoekers zullen de individuele antwoorden ook niet aan ons doorgeven.

Wij danken u bij voorbaat voor uw bereidheid om deel te nemen.

U kunt de vragenlijst terugsturen in de bijgaande antwoord-envelop aan de Rijksuniversiteit Groningen. Een postzegel is niet nodig.

Met vriendelijke groet,

(handtekening van de apotheker)

Annex 6 – Newsletter January 2010

Nieuwsbrief DRUID-onderzoek

Januari 2010

Allereerst wensen wij u allen een heel mooi 2010, dat, politiek gezien, beter uit mag pakken dan 2009!

Verder in deze nieuwsbrief:

- Laatste update patiëntenenquêtes
- Nulmeting nu uitvoeren
- FTO-powerpoint
- Eerste reacties patiënten
- Handige lijst met categorieën
- Stickers
- Vragen?

Reminder Nulmeting

Inmiddels heeft Pharmapartners de update 2009-4 in alle apotheken geïnstalleerd en hebben wij het extractieprogramma getest.
Aan u de vraag dit programma nu te draaien, zodat wij van uw apotheek de gegevens hebben over de afgeleverde rijgevaarlijke geneesmiddelen gedurende de afgelopen 1,5 jaar.

Bijgaand vindt u hier een verkorte instructie voor.

Patiëntenenquêtes

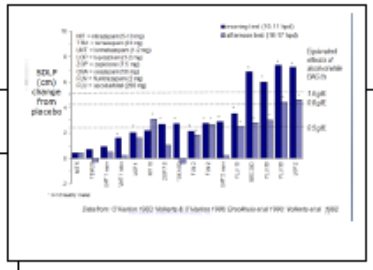
Uw inspanningen hebben ons meer dan het vereiste aantal geretourneerde patiëntenenquêtes opgeleverd. Voor dat onderdeel van het onderzoek daarom onze hartelijke dank!

Wij danken u ook omdat deze activiteit bij sommige apotheken meer tijd heeft gekost dan door ons was voorzien, vanwege bij hen een onverwacht groot aantal patiënten, met daarbij ook in sommige gevallen veel onterecht geselecteerde patiënten (zoals bij omzetting van capsules naar tabletten).

Het DRUID-team dankt u voor uw inspanning!

FTO-powerpoint

Heeft u over het onderwerp rijgevaarlijke geneesmiddelen al een FTO gehad?
Een aantal apothekers heeft gevraagd om een digitale versie van de powerpoint die op de cursus is gepresenteerd.
Bij deze mail ontvangt u hem. De ppt is enigszins aangepast aan artsen als doelgroep en voorzien van bronvermeldingen.



Positieve reacties patiënten

De deelnemers zijn al volop aan de gang met de eerste- en tweede uitgiftebegeleiding en het plakken van de stickers. Wij krijgen meldingen dat de meeste patiënten heel positief reageren op deze voorlichting over verkeersdeelname.

Handige lijst met categorieën

Hieronder vindt u (nogmaals) een lijst met categorieën. Deze is te gebruiken bij aanschrijven om de juiste sticker op de GIT te kunnen plakken.

Let op: er zijn een paar verschillen met het boekje Verkeersdeelname van de KNMP: citalopram, fluvoxamine en sertraline zijn in Pharmacom categorie 2 en bij het WINAp categorie 1. Ook de adviezen verschillen! Belangrijk om alert op te zijn als de artsen het boekje van het WINAp gebruiken.

Stickers

Zijn uw stickers al (bijna) op? Bestel nieuwe via druid@rug.nl onder vermelding van de naam en het adres van uw apotheek. Vermeld er ook bij welke stickers (categorie) u tekort komt.

Vragen?

druid@rug.nl
Susana de Monteiro (in English) 050 363 3261
Hilka Wolschrijn 020 644 0696

Categorieën tranquillizers, hypnotica en antidepressiva

Behalve de tranquillizers, hypnotica en antidepressiva staan er op onderstaande lijst ook enkele andere veel gebruikte rijgevaarlijke middelen en enkele medicijnen met dezelfde ATC, maar met andere dan bovengenoemde toepassingen.

Met onderstaande lijst kunt u bepalen welke sticker op de GIT moet worden geplakt.

deze:

deze:

of deze:

De categorie geeft het **acute effect** weer in de **gebruikelijke dosering**. Dus het effect in de paar uur na inname van een eenmalige dosis of het effect aan het begin van een chronisch gebruik.
De categorie zegt **niet** alles over het te geven **advies** om wel of niet te rijden en/of na hoeveel tijd men weer mag rijden. Dat advies staat onder andere in de Geneesmiddel Informatie Tekst en achter F7 bij de Eerste- en Tweede Uitgifte Begeleiding.

Agomelatine	2 [b]
Alprazolam	3
Amitriptyline	3
Bromazepam	3
Brotizolam	3
Bupropion	2
Buspiron	1 [c]
Chloordiazepoxide	3
Citalopram	2 [a]
Clobazam	2
Clomipramine	2
Clonazepam	2
Clorazepinezuur	2
Codeïne	2
Diazepam	3
Dosulepine	3
Doxepine	3
Duloxetine	2 [b]
Escitalopram	1 [c]
Flunitrazepam	3
Fluoxetine	1 [c]
Flurazepam	3
Fluvoxamine	2 [a]
Hydroxyzine	3
Hypericum	0
Imipramine	2
Loprazolam	3
Lorazepam	3
Lormetazepam	3
Maprotiline	2
Meprobamaat	3
Mianserine	3
Midazolam	3
Mirtazapine	3
Moclobemide	1 [c]
Nitrazepam	3
Nortriptyline	2
Oxazepam	3
Paroxetine	1 [c]
Prazepam	2
Pregabaline	2 [b]
Sertraline	2 [a]
Temazepam	3
Tramadol	3
Trazodon	3
Venlafaxine	1 [c]
Zolpidem	3
Zopiclon	3

Verklaring a, b en c

a Andere categorie dan die in de WINAP-uitgave 'Verkeersdeelname'.

b Niet genoemd in de WINAP-uitgave, maar is wel beoordeeld door SHB.

c Was eerst categorie 2, is nu 1, net als bij het WINAp. De categorie-vermelding in de EUB-teksten is aangepast per januari 2010.

Annex 7 – Newsletter February 2010

Nieuwsbrief DRUID-onderzoek

Februari 2010

Thema: Omzetten naar een rijveiliger alternatief

Uit het gesprek met de patiënt blijkt soms dat de restrictie om auto te rijden een te groot probleem is. In dat geval kunt u de arts vaak een rijveiliger alternatief voorstellen.
Uit onze gesprekken met de deelnemende apotheken merken wij dat dat nog maar weinig gebeurt. Vandaar in deze nieuwsbrief aandacht voor rijveiliger alternatieven:

- *op deze pagina een instructie om deze extra actie te registreren in Pharmacom,*
- *op volgende pagina een overzicht van de adviezen (N05 en N06) met de rijveilige alternatieven.*

Code opnieuw invoeren in Pharmacom

In november heeft u een wijziging in het systeem aangebracht om de keuze ´rijveiliger alternatief gekozen´ te kunnen kiezen bij veranderen van een recept. De instructie gaf daarbij niet de juiste tabel aan. Kunt u daarom de volgende instructie alsnog uitvoeren?

Vanuit het hoofdmenu van Pharmacom:
- Kies A. Onderhoud bestanden
- Kies 1. Onderhoud tabellen
- Kies 6. Tabellen recept verwerking/historie
- Kies 4. Redenen medicatie wijziging. Geef "enter"
- Ga na of record nr L 8 met tekst "Rijveiliger alternatief gekozen" reeds bestaat.
  → Zo ja: de betreffende tekst is op uw cluster reeds aangemaakt. U hoeft geen tekst meer aan te maken.
  → Zo nee: - Kies N (nieuw)
  - Vul in:
  2 Volgnummer: 8 *
  3 Centraal: Tekst: Rijveiliger alternatief gekozen
  4 Lokaal: Tekst: Rijveiliger alternatief gekozen
  - Bevestig met F8

* Voor het onderzoek is het nodig dat iedereen hier dezelfde code(L 8) gebruikt. Is in uw geval code L8 al in gebruik, laat ons dan per mail (druid@rug.nl) weten welke code u voor rijveiliger alternatief invoert.

Gebruik van de optie ´rijveiliger alternatief gekozen´

Met de optie 'Rijveiliger alternatief gekozen' code L8 in de tabel 'Redenen medicatiewijziging' kunnen wij meten hoe vaak door ingrijpen van de apotheek medicatie om die reden is veranderd.

Daartoe moet u vóór u het recept laat vervallen uit de medicatiehistorie eerst naar de medicatiestatus van de patiënt.*
In de medicatiestatus kiest u voor 'wijzigen' en daarna voor 'stoppen'. Vervolgens vraagt de computer om een einddatum en kunt u de reden van wijziging kiezen (met F7 krijgt u de codes hiervoor te zien, als het goed is staat code L8 'rijveiliger alternatief gekozen' nu tussen die redenen).
De medicatie verdwijnt vervolgens naar 'niet actieve medicatie'.

*Als u de medicatie eerst laat vervallen in de medicatiehistorie, dan ziet u deze niet meer in de medicatiestatus en kunt u daar dus de reden niet meer aangeven.

Stickers

Zijn uw stickers al (bijna) op? Bestel nieuwe via druid@rug.nl onder vermelding van de naam en het adres van uw apotheek. Vermeld er ook bij welke stickers (categorie) u tekort komt.

Angst en gespannenheid / gegeneraliseerde angststoornis
Hieronder staan die middelen waarvan het IM en/of de NHG de toepassing angststoornissen vermeldt.

Niet rijveilig zijn: de benzodiazepines alprazolam, bromazepam, chloordiazepoxide, diazepam, lorazepam, oxazepam. Bij eenmalig/kortdurend gebruik kan weer gereden worden vanaf 72 uur na de laatste inname (bij oxazepam na 16/24 uur) en hydroxyzine.

Iets rijveiliger, want **na een week** weer rijden, mits geen bijwerkingen: benzodiazepines clonazepam, clorazepaat en prazepam, buspiron>20mg/dag,
tricyclische AD's clomipramine, imipramine,
SSRI's escitalopram >20mg/dag, fluvoxamine en paroxetine>20mg/dag, overige AD's duloxetine, sertraline en venlafaxine>150mg/dag, en pregabaline.

Het rijveiligst (bij afwezigheid bijwerkingen meteen rijden): SSRI's escitalopram, fluoxetine en paroxetine in doseringen onder de 20 mg/dag
venlafaxine (mits maximaal 2dd 75mg).
bètablokkers atenolol en propranolol (voor incidenteel gebruik bij examenvrees of plankenkoorts).

Noten:
Het NHG adviseert bij angststoornissen meestal een SSRI of TCA en geen benzodiazepine.
Bij buspiron, de antidepressiva en pregabaline zal de arts in het begin vaak ook een benzodiazepine voorschrijven, aangezien het effect pas na een of meer weken optreedt. Deze combinatie met een benzodiazepine is gedurende die tijd **niet rijveilig**.
Veel van de rijveiliger middelen zijn ook te gebruiken bij **paniekstoornissen, sociale fobieën, dwangstoornissen** en **posttraumatische stressstoornis** (ook veel van de hier genoemde SSRI's,TCA's en sertraline).

Depressiviteit

Niet rijveilig zijn: *tri- en tetracyclische AD's:* amitriptyline (>75 mg of >50MGA), doxepine (>75mg), mianserine (>30mg en bij meermaal daags), mirtazepine (>30 mg en bij meermaal daags) en trazodon. Met dosulepine in een eenmalige dosering van ≤75 mg kunt u adviseren om na een week weer te kijken of men kan rijden, maar wel pas vanaf 16 u na de inname (voor de nacht). Bij hogere doseringen of meermaal daags nooit rijveilig.

Iets rijveiliger, want **na een week** weer rijden, mits geen bijwerkingen: tri- en tetracyclische AD's: amitriptyline (alleen ≤75mg of ≤50mg MGA per dag), clomipramine, doxepine (≤75mg/dag), imipramine, mianserine (≤30mg/dag), mirtazapine (≤30mg/dag), nortriptyline,
SSRI's citalopram, escitalopram (>20mg/dag), fluvoxamine, fluoxetine (>20mg/dag) en paroxetine (>20mg/dag),
overige AD's bupropion, duloxetine, sertraline en venlafaxine (>150mg/dag).

Het rijveiligst (bij afwezigheid bijwerkingen meteen rijden):
SSRI's: escitalopram , fluoxetine en paroxetine in doseringen onder de 20 mg/dag en
venlafaxine (alleen indien maximaal 2dd 75mg).

Slaapstoornissen

Ultrakortwerkend
Bij de meeste mensen rijveilig na **8 uur**:
- brotizolam ≤0,25 mg,
- midazolam ≤ 15 mg,
- zolpidem ≤ 10 mg

Kortwerkend
Voor zopidon, loprazolam en oxazepam is temazepam vaak een goed rijveilig alternatief:
Bij de meeste mensen rijveilig na **8 uur**
- temazepam ≤ 20 mg

Bij de meeste mensen rijveilig na **12 uur**
- lormetazepam ≤ 1 mg,

Bij de meeste mensen rijveilig na **16 uur**
- oxazepam ≤50 mg,

Bij de meeste mensen rijveilig na **24 uur**
- loprazolam ≤1 mg
- zopiclon ≤7,5 mg

Middellangwerkend
Bij de meeste mensen rijveilig na **12 uur** (voor incidenteel gebruik). Bij dagelijks gebruik: **niet rijden**)
- Nitrazepam ≤ 5 mg

Bij de meeste mensen pas rijveilig na **72 uur**
- flunitrazepam
- lorazepam

Langwerkend
Bij de meeste mensen pas rijveilig na **72 uur**.
Geen rijveiliger alternatieven.
- Flurazepam
- Diazepam

De bovenstaande adviezen gelden voor volwassenen onder de 65 jaar. Bij ouderen is het middel vaak alleen bij een lagere dosering na het genoemde aantal uur rijveilig.

Nazoeken van rijveiliger alternatieven

Rijveiliger alternatieven (van andere therapeutische indicaties) kunt u ook vinden in het CMPM CI101 Verkeersdeelname (pg 1011 e.v.).

Annex 8 – Newsletter March/April 2010

Nieuwsbrief DRUID-onderzoek

Maart/April 2010

Nu uw apotheekteam een aantal maanden heeft gewerkt met de EUB, de TUB en de voorlichting over verkeersdeelname, is het in april extra belangrijk dat ze daarmee doorgaan. De patiënten die in die maand een eerste uitgifte ontvangen zullen immers van u begin mei een enquête ontvangen en daaruit moet blijken hoe succesvol de voorlichting over verkeersdeelname is geweest.
Daarom in deze nieuwsbrief hier extra aandacht voor.

Einde DRUID-onderzoek
Het DRUID-onderzoek loopt in mei ten einde, maar wij hopen natuurlijk dat de apotheek ook na mei doorgaat met de voorlichting over rijgevaarlijke geneesmiddelen en de eerste- en tweede-uitgifte-module blijft gebruiken!

Patiëntenenquête
Begin mei ontvangt u van ons opnieuw een stapel enquêteformulieren om toe te sturen aan de patiënten die in april een eerste-uitgifte hebben ontvangen van een van de betrokken geneesmiddelgroepen.

Stickers
Vooral deze laatste maand is het van belang aandacht te blijven besteden aan de voorlichting over rijvaardigheidsbeïnvloeding, ook via schriftelijke hulpmiddelen, zoals de GIT.
Zorg er daarom voor dat u ook deze laatste maand nog voldoende stickers heeft om op de GIT te plakken.
Bestel eventueel nieuwe via druid@rug.nl onder vermelding van de naam en het adres van uw apotheek.
Schrijf er ook bij welke stickers (categorie) u tekort komt.

EU en TU bij Antidepressiva
Het Pharmaceutisch Weekblad van 5 februari 2010 (no 5) is een special over depressiviteit, met onder andere op de pagina's 32-33 aandacht aan EUB- en TUB-gesprekken bij antidepressiva.
Twee belangrijke punten: patiënten waarderen de extra aandacht en niet alleen de eerste uitgifte is bij antidepressiva een goed contactmoment, maar zeker ook de tweede uitgifte.

Tips bij Eerste-Uitgiftegesprekken

- Maak van het gesprek tweerichtingsverkeer door de patiënt open vragen te stellen:
  - Vraag wat de (huis)arts al verteld heeft (zoals effect, bijwerkingen, verkeersdeelname).
  - Vraag hoe de patiënt zelf tegen het geneesmiddel aankijkt.

  Uit de antwoorden kunt u opmaken wat de misverstanden en hiaten in kennis zijn. Daar kunt u nader op ingaan.
- Maak gebruik van F7 in de EU-module. Hier staat de belangrijkste informatie van elk middel genoemd, zoals effect, belangrijkste bijwerkingen en verkeersdeelname.
  - Beperk de eerste keer de informatie, te veel kunnen patiënten niet allemaal bevatten.
  - Bij antidepressiva is het bij een eerste uitgifte vooral relevant te vertellen dat het niet meteen werkt, maar dat er wel bijwerkingen kunnen optreden, zoals misselijkheid, angstgevoelens en sufheid. Dat is dan meteen een mooie brug naar de informatie over verkeersdeelname.
  - Druk de patiënt op het hart het vooral te melden als hij of zij erge last heeft van de bijwerkingen. Aan sommige bijwerkingen is immers wat doen, bijvoorbeeld als er een minder sederend alternatief bestaat.
- Voer een eerste-uitgifte-gesprek bij voorkeur in een spreekkamer, aan de balie is het altijd lastiger om met patiënten een gesprek op gang te brengen, zeker bij de tranquillizers en antidepressiva.

Mogelijk heeft u nog teksten nodig voor eventuele jaarplannen en jaarverslagen over het DRUID-project Rijgevaarlijke geneesmiddelen. Bijgaand enkele voorbeeldteksten.

Voor het jaarverslag 2009

Aanleiding

De aanleiding tot dit project is de deelname aan een onderzoek van de afdeling Farmacie van de Rijksuniversiteit Groningen. Het betreft een Europees onderzoek met de naam DRUID, een acroniem voor DRiving Under the Influence of Drugs, alcohol and medicines.
Een Nederlands onderdeel van het DRUID-onderzoek heeft als doel te bepalen hoe effectief de interventies kunnen zijn in apotheken waar men gebruik maakt van informatie over rijgevaarlijke geneesmiddelen in ICT-toepassingen. Men heeft daarbij gekozen voor de Eerste Uitgifte-controle (EUC) en Eerste Uitgifte (EUB)- en Tweede Uitgifte-begeleiding (TUB) van Pharmacom.
Het onderzoek was voor ons een goede gelegenheid actief voorlichting te geven en actief proberen in te grijpen bij voorschriften van rijgevaarlijke geneesmiddelen. De schattingen zijn namelijk dat rijgevaarlijke geneesmiddelen verantwoordelijk zijn voor tien procent van de verkeersongevallen.

Onze activiteiten

Het project loopt van november 2009 tot en met mei 2010. Naast de extra inspanningen ten behoeve van de data-verzameling voor de onderzoekers, kwamen onze activiteiten neer op deskundigheidsbevordering van het apotheekteam en het actief toepassen van de eerste- en tweede uitgiftebegeleiding bij de rijgevaarlijke geneesmiddelen uit de ATC-klasses N05 en N06.

- **Deskundigheidsbevordering**: Nadat een van de apothekers in november 2009 een training heeft gevolgd over dit onderwerp is ook het apotheekteam door middel van een werkoverleg en met schriftelijk materiaal op de hoogte gebracht.
- **Uitgiftebegeleiding**: Vanaf november 2009 zijn wij actief gebruik gaan maken van de EU- en TU-begeleiding in het Pharmacom-systeem voor de betrokken geneesmiddelgroepen. Andere veranderingen waren dat wij de patiënten specifiekere informatie over de beïnvloeding geven en concrete adviezen ten aanzien van verkeersdeelname. Deze voorlichting wordt zowel mondeling als schriftelijk gegeven, waarbij wij extra aandacht aan het onderwerp geven doordat wij een speciaal hiervoor ontworpen sticker op het schriftelijk materiaal plakken.
- **Dataverzameling**: Ten behoeve van het onderzoek hebben wij de onderzoekers voorzien van extractiedata van aflevergegevens en hebben wij een schriftelijke enquête verstuurd aan in totaal 35 patiënten die een eerste uitgifte van een van de betrokken geneesmiddelen hadden ontvangen. Deze schriftelijke enquête evalueert de kennis en houding van de patiënten en zodoende ook de effectiviteit van onze voorlichting en zal na afloop van de onderzoeksperiode worden herhaald bij 35 andere patiënten.

De verwachtingen

Wij verwachten dat wij ons deze nieuwe activiteiten tijdens het project dusdanig eigen hebben gemaakt dat zij ook na de projectperiode voortgezet aan worden.

Voor het jaarplan 2010

Doelstelling

Bij eerste- en tweede uitgifte patiënten informeren over de rijvaardigheidsbeïnvloeding van de geneesmiddelgroepen N05 en N06 en concrete adviezen geven over verkeersdeelname. Bij Eerste-uitgifte controle indien nodig een rijveiliger alternatief voorstellen.

Activiteiten

- Verzenden 35 enquête (voor- en nameting)
- Verstrekken afleverdata aan onderzoekers (voor- en nameting)
- Scholing apotheker Rijgevaarlijke geneesmiddelen
- Scholing apotheekteam
- Activeren EUB en TUB voor de ATC's N05 en N06
- Bij elke uitgifte waarbij de patiënt problemen heeft met het advies nagaan of er een rijveiliger alternatief mogelijk is.
- Bij elke EUB verstrekken van een GIT, inclusief DRUID-sticker met de categorie.
- Bij elke EUB mondeling toelichting van de mate van beïnvloeding en verstrekken concrete adviezen.

Tijdslijn: November 2009 – mei 2010

Chapter 3: The Spanish study

THE SPANISH TRIAL

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1 INTRODUCTION

1.1. Medicines and driving in Spain

It is estimated that between 5 and 10% of traffic accidents in the European Union may be due to driving under the influence of some medicines (1). Some medications can produce certain adverse reactions, such as decreased reaction time, dizziness, drowsiness, double and blurred vision, decreased alertness, etc., that could impair ability to drive (2).

In Spain, 16.7% of drivers are chronic users of medicines and 3.4% have two or more drugs daily. Most worrying is that 75% of these people who use drugs and lead, say they have not received an information on the effects of these medications on driving.It is also important to note that almost 30% of people self-medicate (unknown if medication has adverse effects on driving) (3)

At present many European countries that are strengthening information related to the effects of medicines on driving in order to reduce the road accidents rate, as it is considered one of the areas of intervention that can contribute prevent up to 50% of traffic injury collisions (2)

In Spain, regarding the consumption of medicines and driving the IV General Regulations Driver (BOE de 8 de junio de 2009) (4) say: “Not supported the habitual use of substances that compromise the ability to drive safely, or the habitual use of medicines that, individually or together, serious adverse effects on driving ability”. Recently in Spain (from 2011) medicines that can may influence the ability to drive, must carry a symbol, pictogram in the package, to indicate to drivers carefully read the package insert for extra precautions if they drive a vehicle (Royal Decree 1345/2007 of 11 October) (5). The section "Driving and using machines" of the leaflet for patients to contain warning about the adverse effects that may occur with respect to driving, so the pictogram indicates see leaflet and if necessary request information to doctor or pharmacist.

In this sense, doctors and pharmacists often prescribe or dispense medications to patients who drive, In order to be able to explain all risks to the patient, physicians and pharmacists need to be well prepared. The present study refers to the development, and consequent evaluation, of a training course that was carried out with the intention of informing at Health professionals of the Spanish National System of health (Physician and nurses) and pharmacist, about the influence of medicines on driving fitness, the DRUID categorization system (categorization for the relevant therapeutic groups of medicines) and implementation of the pictogram on the packaging of certain medicines in Spain. On the other hand, it would also be advisable to health professionals, develop an effective strategy to communicate the risk related to the use of medicines and driving.

It has carried out a study in patients to determine whether the users of medicines know that some medicines can negatively affect their fitness to drive, and to evaluate the influence that the pictogram on medicines and driving that is printed on the packaging of the medicine could have on the patient’s attitude to driving.

In order to understand how the Spanish trial was designed and carried out, some key issues should be highlighted:

1.2. The Spanish Health System

Spain has a universal, free, public health service that covers health care for all nationals and residents (6). Spain’s National Health Service can be divided into two basic areas of cover:

- Primary care: This is the initial and basic level of care that guarantees the global nature and continuity of care throughout the patient’s life. Primary care is administered in Primary Health Care Centres, which are the centre of reference for the “Basic Health Area”, which is the territory within a 30 minute radius of the

Primary Health Care Centre and may stretch over a single suburb or several suburbs; it may also cover a town or several villages (7).

- Hospital and specialist care: This is the second organisational level of public health care services in Spain. Access to this level is gained by first visiting the primary health care level, i.e., the general practitioner, who will forward the patient to the appropriate specialist. This type of care is administered in hospitals and in Specialised Centres, either as outpatients or under hospital admissions (8).

Included within the National Health Service is the pharmaceutical medication (Normal cost for the patient: 40% of the Recommended Retail Price (RRP). Reduced cost for the patient: 10% of the RRP in medicaments to treat some chronic illness. No cost for the patient: pensioners and treatments originating in professional illnesses and accidents at work). The pharmacist's mission is to dispense the medicaments to the patients and carry out an individualised control of the use of the said medicaments (9).

1.3. The Spanish pictogram on medicines and driving

Recently (Figure 65), Spain has introduced a mandatory pictogram on medicines and driving (5). When developing the current trial, this issue has been addressed during the training courses carried out in the study, and in fact has relevant importance in the design of the study. For further details, please see Annex 1.
In orden a

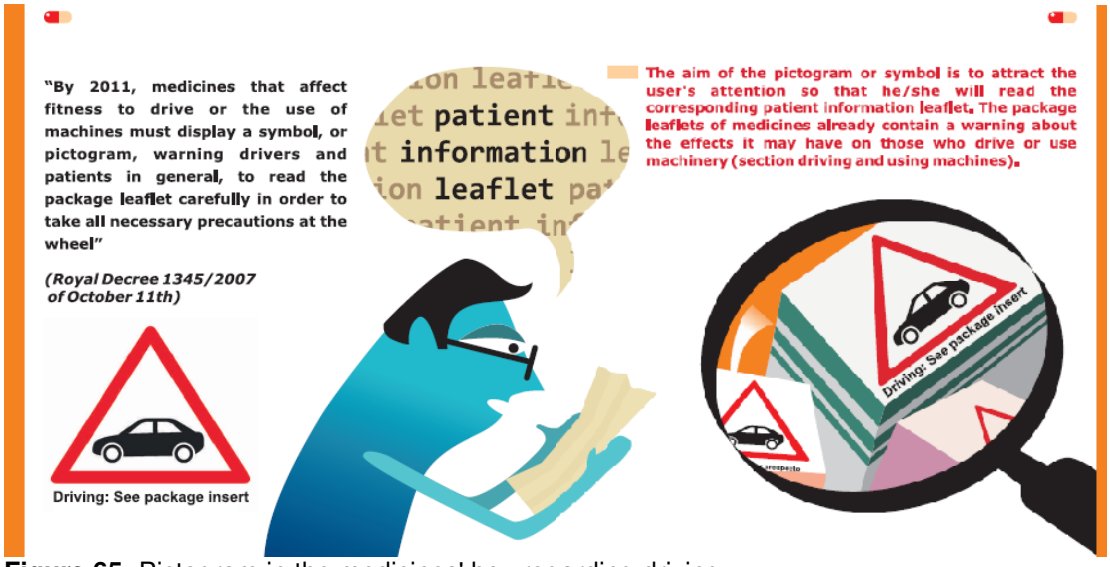

Figure 65: Pictogram in the medicines' box regarding driving.

1.4. The target population among health professional: physicians, pharmacist and nurses.

Among the health professionals, the Spanish trial included physicians (who prescribe the medication), pharmacists (who dispense the medication), as well as nurses. With the recent implementation of electronic prescriptions, nurses have a role in following up prescribed medicines. Therefore, following a suggestion by the national and regional health authorities, this target population, nurses, was included in the study.

1.5. The setting for training: Regular training activities at primary care centres

The current training activities in the present trial were done at primary health care centres following regular training activities for physicians and nurses. That is, participants were enrolled as currently they are involved in other training activities. However, the pharmacists involved in the current trial were attending also these regular training activities, while this is not a normal rule.

1.6. Granted continuous training activities

Participation at the trial was not rewarded in any specific form (money, tickets, etc).

As a normal rule, the training activities were submitted for approval as a continuous training activity twice; first for physicians and pharmacists, and later for nurses (please see methodology, section 2). These were granted the status of Continuous Training by the Health Authorities.

1.7. Training activity in cooperation with National and Regional Health Authorities

These training activities were done in co-operation with the National (Agencia Española de Medicamentos y Productos Sanitarios) and Regional Health authorities (Junta de Castilla y León, Consejería de Sanidad, Sacyl). Furthermore, the National (Consejo General de Colegios Oficiales de Farmacéuticos) and Local (Colegio Oficial de Farmacéuticos de Valladolid) Associations of Pharmacists, as well as scientific societies (SET, SEMT), were all consulted. Therefore, many aspects of the design were done in accordance with their recommendations and following their suggestions.

1.8. Intranet and software programmes for prescribing and dispensing

Health professionals currently use software programmes in their daily activity for prescribing or dispensing medicines and patient follow up. However, for the present study, as agreed with the partners involved, no DRUID information was integrated in the existing intranet software of the public health system for prescribing, or of pharmacies for dispensing. However, as mentioned in deliverable 7.4.1., some information on the Spanish pictogram on medicines and driving does exist in some resources. For the training course a web page was developed, this included clear, well-structured contents to facilitate access to the largest number of people possible, as this could also be consulted in the future, at least part of the contents, by the general public. This web page has been developed in Spanish (http://www.uva.es/medicamentosyconduccion), but will be translated to English in the near future.

2 METHODOLOGY

2.1 STUDY 1: HEALTH PROFESSIONALS: PHYSICIANS, PHARMACISTS AND NURSING STAFF

2.1.1 Objectives

Please see pages 379 and 383 of this report.

i) Common objectives to the DRUID-trial (please see page 390 of this deliverable)

- To assess health professional attitudes/awareness, reported behaviour, sources, actual knowledge and user's acceptance on the topic of medicines and driving (pre-training).
- To assess possible changes in these dimensions six months later, after the training activities (post-training).

ii) Specific objectives for the Spanish trial

- To assess the importance that the professionals give to the fact of offering information to their patients concerning medicines and driving while carrying out their daily work (at pre-training and post-training). With this aim two questions were developed:

  *In their daily practice, during the previous 6 months, what importance has been given to the question of medicines and driving (from 1 to 10, 10 being the maximum)?

  *In their daily practice over the previous year, with what frequency have they come across cases in which the effect of medication on driving has been an important aspect at the time of selecting medicines?

2.1.2 Target populations

As earlier indicated, it was included physicians and nurses working at primary health care centers, as well as community pharmacists.

2.1.3 Sample size

Please see page 379 and 384. The sample size was initially established at 93 physicians, 93 pharmacists and 93 nursing staff.

2.1.4 Groups: Control, information and intervention group

Three work groups were to be formed within these health professionals based on the means of administering the information (please see page 387 of this deliverable):

- **Control Group**: Group that did not receive any information on medicines and driving.
- **Information Group**: group that received information and training on medicines and driving through printed documents specifically designed for the trial. On occasions during the DRUID trial we denominated this group as a non-integrated tool.
- **Intervention Group**: Group that received specific information on medicines and driving throught printed documents and thought a web page. On occasions during the DRUID trial this group was denominated as integrated tool (ICT-tool). As pointed out in the introduction section, we had no access to current software used for prescription and dispensing. Therefore we did no use a "real" ICT-tool in this trial.

2.1.5 Setting

The study was carried out in 10 primary care health centres in the Province of Valladolid and among the pharmacists working within the area of influence of these 10 primary care health centres. Figure 66 shows the geographic distribution of the participating primary care health centres: Parquesol, Tordesillas, Huerta del Rey, Rondilla I and II, Circular, Pilarica, Canterac, Circunvalación, la Tórtola and Delicias.

The distribution was done in accordance with Regional Health Authorities for both Valladolid-west and Valladolid-east. Urban and rural centres were included. Prior to carrying out of the courses had a meeting with each of the coordinators of the participating health centers, they agreed to inform members of their medical health center on the theme of the course and agreed to the day the time of fulfillment.The pharmacists were invited by a mail informing him of the objectives, theme, date and venue of the course.Courses are carried out in each of the participating health centers, together pharmaceutical physicians and nurses.

All physicians, nurses and pharmacist belonging to these 10 primary health care centres were included in the study and the training courses were carried out as part of the regular training activities.

Figure 66: Geographic distribution of the participating Primary Health Care Centres

Finally, the sample was established as shown in Table 119 regarding health professional group and training group. It involved 141 physicians, 127 community pharmacist, and 139 nurses.

Table 119: Distribution of health professional by training group.

Groups	Background	Included
Control	**Physician**	41
	Pharmacist	33
	Nurses	41
Information	**Physician**	56
	Pharmacist	46
	Nurses	52
Intervention	**Physician**	44
	Pharmacist	48
	Nurses	46

2.1.6 Description of training activities and material produced for the three groups: control, intervention and experimental

- **Control group**

This group was made up of health professionals (41 physicians and 41 nursing staff) from the primary health care centres of Circunvalación, la Tórtola and Delicias (Figure 66) and 33 pharmacists in the same areas of influence.

They did not receive any specific information on medicines and driving.

- **Information group**

This group was made up of health professionals (56 physicians and 52 nursing staff) from the primary health care centres of Parquesol, Tordesillas and Huerta del Rey (Figure 66) and 46 pharmacists in the same areas of influence.

The information group received printed material concerning the effects of medicines on driving and concerning the Spanish pictogram on medicines and driving printed on the packaging (RD: 1345/2007).

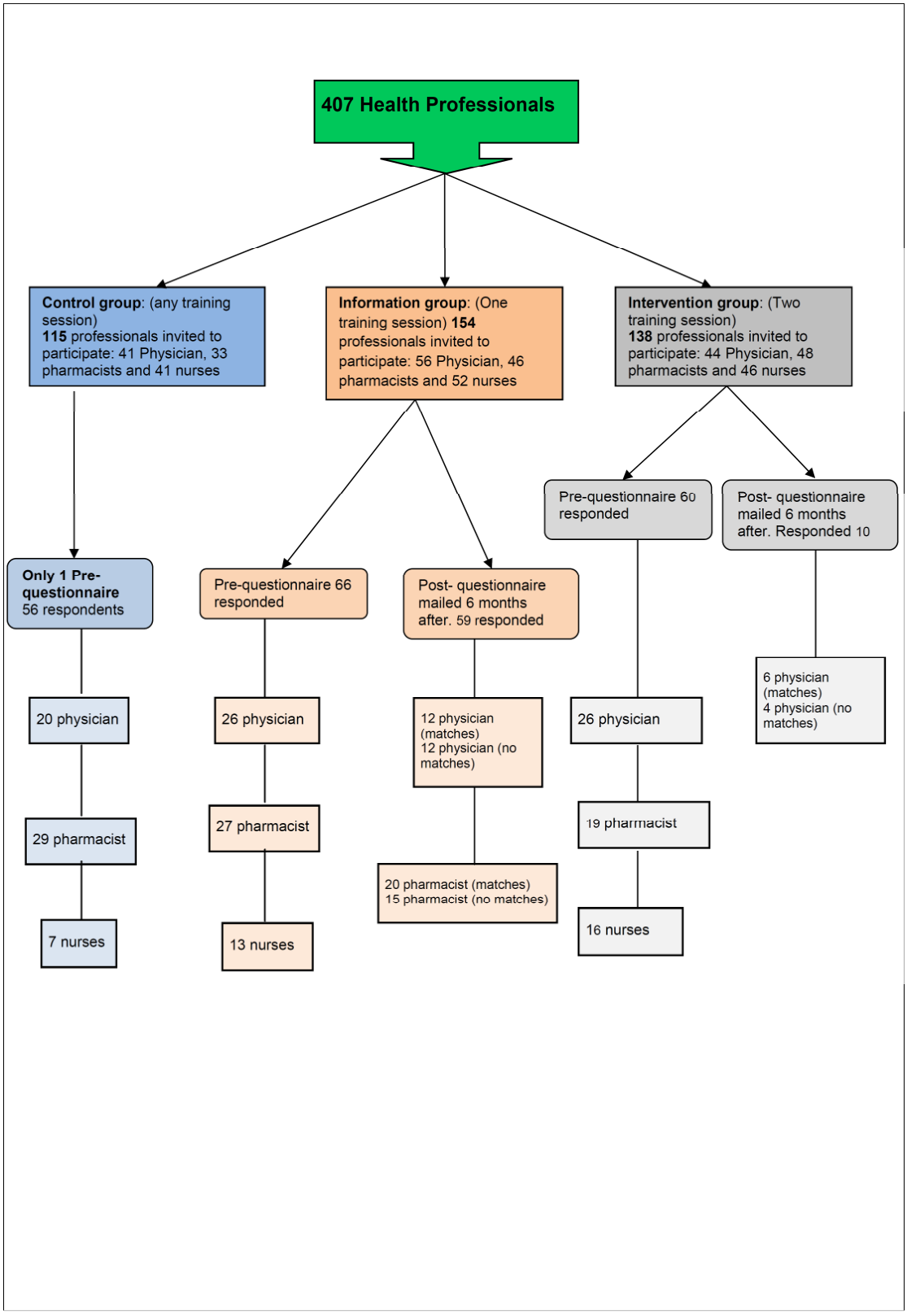

Figure 67: Flowchart representing the organization of training course

The following specific material has been produced for the trial:

- ***Posters about the Spanish pictogram on medicines and driving*** (Figure 68). They were distributed among participating primary health care centres and pharmacies.

Figure 68: Posters: English version

- ***Leaflets aimed at patients and the general public on medicines and driving***

Leaflets aimed at the general public, but mainly patients taking certain groups of medicines were developed (
Figure **69**).

- Leaflet 1: Medicines and driving
- Leaflet 2: Sleeping pills and driving
- Leaflet 3: Antidepressants and driving
- Leaflet 4: Elderly people, medicines and driving

Sixty thousand leaflets were printed and distributes in primary care health centres and pharmacies. The leaflet "Elderly people, medicines and driving" was distributed specifically by nursing staff (in Castile and León, the nursing staff are somewhat responsible for monitoring the treatment of chronic illnesses). The other three leaflets were distributed by physicians and pharmacists.

Figure 69: Leaflets for patients

- ***Brochure specifically aimed at health professionals***

This brochure, basically, provides information concerning the Spanish pictogram on medicines and driving and the methodology followed by the Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Health Products) to assign, or not, the pictogram on driving to a medicine. The brochure gives useful advice to the professional who must prescribe medicines to patients who are also drivers (Figure 70).

- ***Brochure "Medicines and driving: The prescription of medicines to patient who drive"***

The book concerns the implantation of the pictogram in Spain. It sets out the guidelines and protocols concerning the prescription of medicines to patients who drive and the effects of

medicines on psychomotor performance and traffic accidents. It introduces DRUID's categorization criteria for medicines with respect to driving (Figure 70). As this was the key document for describing DRUID categorization system as well as describing the guidelines and protocols for prescribing to the driver patient, the full brochure is presented in Annex I.

Figure 70: Cover page of the brochure "Medicines, driving and healthcare professionals".

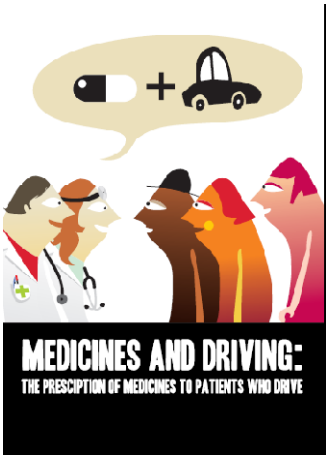

Figure 71: Cover page of the brochure "Medicines and driving: The prescription of medicines to patients who drive"
Please see Annex 2.

- ***Book on the "Workshop on medicines and their effect on driving: new warning pictogram for medicines"***

The book sets out a summary of the information from the workshop held in Madrid on June 8th 2009 in the Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Health Products), including the methodology and the criteria for the introduction of the Spanish pictogram on the packaging on medicines and driving. Three hundred copies of this short book have been printed and distributed among health professionals (Figure **72**).

- ***Book "Medicines and Driving. DRUID Categorization (N Group: Nervous System)"***

This book included the DRUID categorization system for N medicines (N01 to N07). It was translated from English to Spanish. Furthermore to the categorization for N medicines, it included the specific information to be provided by health professional to the driver patient. Also it was included wether or not the medicine has the Spanish Pictogram (Figure 73).

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. **Figure 72**:
. Cover page of the book about the workshop on medicines

Figure 73: Cover page of the book "Medicines and driving:DRUID Categorization (N Group: Nervous "Medicines and System)".

- **Intervention group**

This group was made up of primary health care centres professionals (44 physicians and 46 nursing staff) from the Centres of Rondilla I y II, Pilarica y Circular (Figure 66) and 48 pharmacists in the same areas of influence (Table 119).

Besides the material aimed at the information group, a web page was developed for the formation of this group I, which included clear, well-structured contents to facilitate access to the largest number of people possible, as this could also be consulted in the future, at least part of the contents, by the general public. This web page has been developed in Spanish (http://www.uva.es/medicamentosyconduccion), but will be translated to English in the near future. The general structure of the web page is as follows:

From the home page of "Medicines and Driving" (Figure 74), the desired language (Spanish or English) can be chosen and all the contents and the information accessible to the public in general can be accessed:

- **What you need to know**: General introduction to medicines and driving
- **Legislation**: Reference to the RD 1345/2007 of 11th October
- **Videos**
- **Materials**: All the materials in PDF format.
- **Links** to the pages of the collaborating organisms and institutions ("click" on the logo). Link to documents concerning medicines and driving
- Button to access the area reserved for **health professionals** (physicians, pharmacists and nursing staff).

Figure 74: Home page of "Medicamentos y Conducción"
http://www.uva.es/medicamentosyconduccion

Within the area reserved for health professionals, there are also unrestricted contents, which can be seen by anyone, and restricted contents that need a password. The open contents can be seen by clicking on the buttons **"Materials"**, **"Legislation"** and **"Links",** which are shown in Figure 75. Clicking on the "Search" button initiates access to the restricted area and user ID and password are asked for (Figure 76).

Figure 75: Area reserved for health professionals

Figure 76: Access to the restricted area

The page has a search button which, on introducing either the active ingredient or the ATC code, the user can discover whether a medicine carries the pictogram concerning medicines and driving in Spain or not, as well as the DRUID categorization of the medicine.

- **The training (course)**

A training manual including the relevant DRUID WP4 and WP7 information for health professionals was developed in DRUID Task 7.4.1 (D 7.4.1). Please consult the full report for

further details (http://www.druid-project.eu/nn_107548/Druid/EN/deliverales-list/downloads/Deliverable_7_4_1,templateId=raw,property=publicationFile.pdf/Deliverable_7_4_1.pdf).

This manual was slightly adjusted to the specific Spanish scope. It was used as guidance when training the health professionals.

The objectives of the training course were as follows (please see page 14, D 7.4.1):

- To understand the use of the categorization system for medicines that might impair driving performance;
- To know the recommendations on dispensing information when prescribing and delivering medicines that might influence driving skills, as these are described in the prescribing and dispensing guidelines;
- To have an insight into their own policy with regard to medicines that might impair driving performance;
- To be able to make joint agreements on patient information policies and allocation of tasks between the GP's practice and the community pharmacy with respect to those medicines that might impair driving skills (this objective is only applicable if a joint statement exists within the respective countries; an example of joint agreements is found in Appendix A4).

With this aim the training courses were given to the information and intervention groups in several sessions lasting each one about one hour.

- **Questionnaire PRE and POST**

An adapted version was used of the EVALUATION QUESTIONNAIRE Health care workers (pre-post) that appears as an annex in the Deliverable 7.4.1 (http://www.druid-project.eu/nn_107548/Druid/EN/deliverales-list/downloads/Deliverable_7_4_1,templateId=raw,property=publicationFile.pdf/Deliverable_7_4_1.pdf). Please see also page 389 of this deliverable.

Notice that in the questionnaire for nurses there was a slight change in two questions in order to accommodate them to the fact that they follow medication treatment, but do not prescribe or dispense medicines.

The PRE-questionnaire was completed before the training. The POST-questionnaire was completed 6 months after training started. The post-questionnaire was mailed together with a stamped envelope to facilitate its return by health professionals.

Notice that several persons participated in the training courses assist the training, but they did not want to fill in the questionnaire. Overall, there were very frequent criticisms about the usefulness of the questionnaire.

As agreed upon by the partners of task 7.4, annexes II and III present the pre and post questionnaires in their Spanish versions.

2.2 STUDY 2: PATIENT QUESTIONNAIRE

2.2.1 Objective

To find out whether the users of medicines know that some medicines can negatively affect their fitness to drive, and to evaluate the influence that the pictogram on medicines and driving that is printed on the packaging of the medicine could have on the patient's attitude to driving.

2.2.2 Target population

The target population is made up of "health service users". Throughout the current text, they shall be referred to as "patients". However, it should be taken into account that what we really mean by this term is people who come into contact with the National Health Service through Primary Care, Hospital-Specialized Attention or as consumers in pharmacies.

The "health service users" included in the study correspond to three different health service levels: i) Pharmacies; ii) Primary Care; iii) Hospital-Specialized Attention. The study was aimed at both patients with a driving license and those without.

2.2.3 Sample size

The sample size was established at 300 people in each of the three spheres of study (a total of 900 people). Finally, 1,385 valid interviews were carried out.

2.2.4 Setting

The study was carried out in different health care environments within the Province of Valladolid.

- The patients were interviewed in:
- Primary Care facilities by nursing staff,
- In pharmacies by trained survey personnel,
- In Specialist Attention (pre-anesthesia visits in the "Hospital Clínico" in Valladolid) by trained survey personnel.

2.2.5 Questionnaire used

For this study, the socio-demographic variables (sex, age, educational level, possession of a driving license or not and kilometers driven per year) and 3 of the questions from the questionnaire created for this purpose, and which can be seen in Annex IV, have been analyzed as was agreed by the partners of task 7.4. The analyzed questions were:

- Did you know that some medicines can influence fitness to drive? The options for answering are: Yes / No.
- Supposing that you are prescribed this medicine which has the pictogram about driving on the packaging. With what frequency would you drive during the period in which you were taking the medicine? Possible answers are: "The same frequency as usual", "Less frequently", "A lot less frequently", "I would only drive rarely", "I would not drive at all",
- What would you do if you were prescribed this medicine with the pictogram about driving on the packaging? Possible answers are: "I would drive without taking any other precautions", "I would not drive without first reading the package insert", "I would not drive without the advice of a doctor or pharmacist", "I would not drive until my doctor told me it was safe to do so".

2.3 Ethical principles

The study was approved by the Clinical Research Ethics Committee of the Faculty of Medicine at the University of Valladolid and by the Research Commission of the "Hospital Clínico Universitario" of Valladolid.

All the health professionals and patients were adequately informed of the nature of the study, participated voluntarily and their anonymity was preserved.

2.4 Statistical analysis

The data gathered from both studies have been recorded in a database of the statistical package PASW Statistics 18. The results are shown as mean ± standard deviation and/or median for the quantitative variables and percentages for the categorical variables. Also, respectively, the T-test and the Squared Chi test have been used to analyze the results. Within-group pre-post questionnaire change, for ordinal variables (attitudes and awareness, reported behaviour, knowledge) Wilcoxon matched pairs - signed-rank test was used. In each of the different tests, values of $P \leq 0.05$ were considered statistically significant.

2.5 Conflict of interests

The authors of the study declare there is no conflict of interests.

2.6 Acknowledgments

The authors of the study would like to thank the patients and health professionals (physicians, pharmacists and nursing staff) involved in the study for their participation.

We would also like to thank the health authorities ("Junta de Castilla y León", "Consejería de Sanidad", "Sacyl", "Ministerio de Sanidad y Consumo – Agencia Española de Medicamentos y Productos Sanitarios (AGEMED)"), the Primary Health Care Centers, the "Hospital Clínico Universitario" of Valladolid, the "Colegio Oficial de Farmacéuticos de Valladolid", SEMT and SET for their collaboration at all times.

2.7 Sources of finance for the study

This study has had additional finance from funds from the DRUID project through a grant following the ORDEN SAN/1778/2009 (BOCyL 170, 4th September 2009), Junta de Castilla y León, Consejería de Sanidad, and a grant from the 'Agencia Española del Medicamento y Productos Sanitarios' (Resolution 22nd March 2010) (BOE 30th March 2010, pp 29920-29930).

2.8 Accredited continuous formation

The participation of the health professionals in the activities of formation has been recognized by the National Health Service's Continuous Formation Commission with the following credits (1 credit = 10 hours of training).

Physicians	2.8
Pharmacists	2.8
Nursing staff	3.8

3 RESULTS

3.1 STUDY 1: HEALTH PROFESSIONALS: PHYSICIANS, PHARMACISTS AND NURSING STAFF

The sample was established as shown in Table 120 regarding health professional group and training group. It involved 141 physicians, 127 community pharmacists, and 139 nurses, of whom, 72 physicians, 75 pharmacists and 36 nursing staff answered the initial questionnaire.

Table 120: Distribution of health professionals by training group and responses (PRE).

Groups	Profession	Included	Responses Questionnaire PRE
Control	**Physician**	41	21
	Pharmacist	33	29
	Nursing	41	7
Information	**Physician**	56	26
	Pharmacist	46	27
	Nursing	52	13
Intervention	**Physician**	44	25
	Pharmacist	48	19
	Nursing	46	16

3.1.1 BACKGROUND INFORMATION

A total of 183 health professionals, 65 men (35.5%) and 118 women (64.5%) answered the initial questionnaire. There are significant differences in the distribution of the health professionals who answered the questionnaire with respect to sex (X^2_2=11.437; p<0.005); while, among physicians the proportion is 1:1, among the pharmacists and the nursing staff, the men: women ratio is 1:3 (Table 121). Within each collective, there are no significant differences with respect to sex among the control/information/intervention groups. No significant differences were observed in the distribution of the health professionals (physicians/pharmacists/nursing staff) who answered the questionnaire between urban and rural areas (X^2_2=1.217; p>0.05,Table 122).

Table 121: Gender distribution

	Male N (%)	**Female** N (%)	**Total** N (%)	$\mathbf{X^2_2}$; **p** (Control/Information/ Intervention)
Physicians	36 (50.0)	36 (50.0)	72 (100.0)	0.241; p>0.05
Pharmacist	21 (28.0)	54 (72.0)	75 (100.0)	0.065; p>0.05
Nursing	8 (22.2)	28 (77.8)	36 (100.0)	4.095; p>0.05
Total	65 (35.5)	118 (64.5)	183 (100.0)	
	X^2_2=11.437; p<0.005			

Table 122: Region distribution

		Physicians N (%)	**Pharmacist** N (%)	**Nursing** N (%)	**Total** N (%)	$\mathbf{X^2_2}$; **p**
Region	**Urban**	62 (86.1)	63 (84.0)	33 (91.7)	158 (86.3)	1.217; p>0.05
	Rural	10 (13.9)	12 (16.0)	3 (8.3)	25 (13.7)	
	Total	72 (100.0)	75 (100.0)	36 (100.0)	183 (100.0)	

The average age of the health professionals (Mean±SD) is 48.24±10.42 years. There are significant differences between the three collectives (F=19.272; p<0.0001), the pharmacists being the youngest collective (43.10±10.73 years). Similarly, there are significant differences in the average age of the professionals' work experience (F=28.555; p<0.0001), the pharmacists being the collective with the lowest work experience (14.81±9.60 years). Within each collective (physicians, pharmacists and nursing staff), no significant differences were observed between the control/information/intervention groups, neither in the average age nor the work experience (Table 123).

Table 123: Sampled population: Age and years practicing

	Age (years)			**Practising (years)**		
	N	Mean±SD	**F; p** (Control/Information/ Intervention)	**N**	Mean±SD	**F; p** (Control/Information/ Intervention)
Physicians	63	52.14±8.39	0.353; p>0.05	70	23.26±9.55	0.041; p>0.05
Pharmacist	72	43.10±10.73	1.424; p>0.05	70	14.81±9.60	2.460; p>0.05
Nursing	28	52.68±7.80	1.241; p>0.05	36	28.31±8.23	0.686; p>0.05
Total	163	48.24±10.42		176	20.93±10.68	
	F=19.272; p<0.0001			F=28.555; p<0.0001		

63.4% of the health professionals referred to not having received any type of formation concerning the effects of medicines on driving during their university studies. There are significant differences (X^2_2=11.736; p<0.005), the pharmacists being the group that most frequently referred to having received formation in this respect (51.4%). Within each collective, no significant differences were observed between the control/information/intervention groups (Table 124).

Table 124: Did you get any education on medicinal effects on driving skills during your studies at University?

	Yes N (%)	**No** N (%)	X^2_2; **p**	X^2_2; **p** (Control/Information/ Intervention)
Physicians	19 (27.5)	50 (72.5)		2.254; p>0.05
Pharmacist	37 (51.4)	35 (48.6)	11.736; p<0.005	0.180; p>0.05
Nursing	8 (23.5)	26 (76.5)		5.652; p>0.05
Total	64 (36.6)	111 (63.4)		

3.1.2 NEW TECHNOLOGIES LITERACY

The questions "Do you use the internet to obtain information on medicines affecting driving behaviour?" and "Have you ever used any software package/program to obtain information on the effects of medicines on driving behaviour?" are grouped into a single item which includes internet (Table 125).
Two out of every three health professionals (63.4%) referred to not using internet or any type of software and/or computer programme to obtain information about the effects of medicines on driving. The pharmacists most frequently referred to using one or more of these means (59.2%), and there were significant differences (X^2_2=17.405; p<0.0001). Within each collective, no significant differences were observed between the control/information/intervention groups (Table 125).

Table 125: Have you ever used any software package/program to obtain information on medicines effect on driving behaviour? (Internet is included in the Spanish version)

	Yes N (%)	**No** N (%)	X^2_2; **p**	X^2_2; **p** (Control/Information/ Intervention)
Physicians	19 (26.4)	53 (73.6)		0.402; p>0.05
Pharmacist	42 (59.2)	29 (40.8)	17.405; p<0.0001	0.494; p>0.05
Nursing	11 (31.4)	24 (68.6)		0.751; p>0.05
Total	64 (36.6)	111 (63.4)		

Almost all the pharmacists (98.7%) referred to using some kind of medical/clinical software package /program; this use id referred to less frequently by physicians (65.2%) and by nursing staff (58.3%). There were significant differences between the three collectives (X22=33.107; p<0.0001). No significant differences were observed among physicians or pharmacists in their replies to this question according to group (control, information or intervention), but there were significant differences among the nursing staff (X22=7.912; p<0.05,Table 126).

Table 126: Do you use any medical/clinical software package /program?

	Yes N (%)	**No** N (%)	X^2_2; **p**	X^2_2; **p** (Control/Information/ Intervention)
Physicians	45 (65.2)	24 (34.8)		0.917; p>0.05
Pharmacist	74 (98.7)	1 (1.3)	33.107; p<0.0001	2.987; p>0.05
Nursing	21 (58.3)	15 (41.7)		7.912; p<0.05
Total	140(77.8)	40 (22.2)		

3.1.3 ATTITUDES/AWARENESS

In order to evaluate the attitude of health professionals concerning the effects of medicaments on fitness to drive, a series of questionnaires were made that asked for their agreement or disagreement on certain questions (Tables 127-132).

The great majority of health professionals stated they "agreed" or "strongly agreed" with the statement "I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines", although there were significant differences (X^2_6=16.493; p<0.05). The nursing staff showed the greatest percentage of disagreement (Table 127).

Table 127: I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines.

	Strongly disagree N (%)	**Disagree** N (%)	**Agree** N (%)	**Strongly agree** N (%)	**X^2_6; p** (Control/Information/ Intervention)
Physicians	1 (1.4)	3 (4.2)	64 (88.9)	4 (5.6)	6.927; p>0.05
Pharmacist	2 (2.7)	7 (9.5)	52 (70.3)	13 (17.6)	5.805; p>0.05
Nursing	0 (0.0)	7 (20.0)	27 (77.1)	1 (2.9)	4.221; p>0.05*
Total	3 (1.7)	17 (9.4)	143 (79.0)	18 (9.9)	
		X^2_6=16.493; p<0.05			

(*) 4 degrees of freedom for this chi square

In addition, the health professionals were asked if they would take the above question even more into account if the patients were in any of the groups of drivers indicated in Table 128. In general, a high percentage of health professionals, including physicians, pharmacists and nursing staff, answered that they would. The affirmative answers were over 90% in almost all the groups. The highest percentage was for professional drivers, while the percentage was lower for the group of inexperienced drivers (81.0%) and even lower than that for experienced drivers (68.3%). Significant differences were only observed among health professionals on considering drivers who were taking other drugs that affected the CNS, (X^2_2=10.505; p<0.01). This fact would be taken into consideration more frequently by physicians (96.9%) and pharmacists (98.5%) than by nursing staff (83.9%).

Table 128: Would you consider this (Q1) of more concern if your patient is:

Q1		Yes N (%)	No N (%)	X^2_2; p
A professional driver?	**Physicians**	68 (98.6)	1 (1.4)	2.898; p>0.05
	Pharmacist	73 (98.6)	1 (1.4)	
	Nursing	29 (93.5)	2 (6.5)	
	Total	170 (97.7)	4 (9.4)	
Driving frequently?	**Physicians**	66 (95.7)	3 (4.3)	4.353; p>0.05
	Pharmacist	67 (94.4)	4 (5.6)	
	Nursing	28 (84.8)	5 (15.2)	
	Total	161 (93.1)	12 (6.9)	
Driving long distances?	**Physicians**	62 (91.2)	6 (8.8)	3.874; p>0.05
	Pharmacist	63 (92.6)	5 (7.4)	
	Nursing	24 (80.0)	6 (20.0)	
	Total	149 (89.8)	17 (10.2)	
An "inexperienced" driver?	**Physicians**	51 (76.1)	16 (23.9)	3.006; p>0.05
	Pharmacist	61 (87.1)	9 (12.9)	
	Nursing	24 (77.4)	7 (22.6)	
	Total	136 (81.0)	32 (19.0)	
An "experienced" driver?	**Physicians**	43 (66.2)	22 (33.8)	0.331; p>0.05
	Pharmacist	46 (68.7)	21 (31.3)	
	Nursing	23 (71.9)	9 (28.1)	
	Total	112 (68.3)	52 (31.7)	
An elderly driver?	**Physicians**	63 (91.3)	6 (8.7)	2.170; p>0.05
	Pharmacist	65 (95.6)	3 (4.4)	
	Nursing	28 (87.5)	4 (12.5)	
	Total	156 (92.3)	13 (7.7)	
Using other CNS active drugs?	**Physicians**	63 (96.9)	2 (3.1)	10.505; p<0.01
	Pharmacist	66 (98.5)	1 (1.5)	
	Nursing	26 (83.9)	5 (16.1)	
	Total	155 (95.1)	8 (4.9)	

Three out of every four health professionals would "agree" (70.6%) or "strongly agree" (6.2%), with changing the prescription/dispensation for another medicament that had less of an effect on fitness to drive vehicles (Table 129). Of the health professionals, 93.9% stated they "agreed" (74.7%) or "strongly agreed" (19.2%) with the statement "I feel I am well aware of the effects of medicines on driving skills" (Table 130). Almost all of them (96.2%) also agreed that "It is important for me to be well-informed on medicinal effects on driving behaviour" (Table 131).

Nevertheless, most health professionals (91.1%) are sceptical about the usefulness of information given to the patient: 80.1% "disagreed" and 11.0% "strongly disagreed" with the statement "I feel that the information I provide to patients will influence their driving behaviour" (Table 135). No significant differences were noted in any of these questions (Tables 132-135) among the different groups of health professionals (physicians, pharmacists and nursing staff). Within each of these groups, no significant differences were found between control, information or intervention groups either (p>0.05).

Table 129: I am willing to sacrifice some degree of efficacy by prescribing/dispensing a medicine that is less impairing to the driving skills

	Strongly disagree N (%)	Disagree N (%)	Agree N (%)	Strongly agree N (%)	X^2_6; p (Control/Information/ Intervention)
Physicians	0 (0.0)	14 (19.7)	51 (71.8)	6 (8.5)	5.903; p>0.05*
Pharmacist	5 (7.0)	15 (21.1)	48 (67.6)	3 (4.2)	9.136; p>0.05
Nursing	1 (2.9)	8 (17.1)	26 (74.3)	2 (5.7)	5.016; p>0.05
Total	6 (3.4)	35 (19.8)	125 (70.6)	11 (6.2)	
		X^2_6=6.629; p>0.05			

(*) 4 degrees of freedom for this chi square

Table 130: I feel being well aware of the effects of medicines on driving skills**.**

	Strongly disagree N (%)	Disagree N (%)	Agree N (%)	Strongly agree N (%)	X^2_6; p (Control/Information/ Intervention)
Physicians	1 (1.4)	3 (4.2)	57 (79.2)	11 (15.3)	12.517; p>0.05
Pharmacist	0 (0.0)	3 (4.0)	51 (68.0)	21 (28.0)	3.264; p>0.05*
Nursing	2 (5.7)	2 (5.7)	28 (80.0)	3 (8.6)	9.454; p>0.05
Total	3 (1.6)	8 (4.8)	136 (74.7)	35 (19.2)	
		X^2_6=11.376; p>0.05			

(*) 4 degrees of freedom for this chi square

Table 131: It is important for me to be well-informed on medicinal effects on driving behaviour.

	Strongly disagree N (%)	Disagree N (%)	Agree N (%)	Strongly agree N (%)	X^2_6; p (Control/Information/ Intervention)
Physicians	1 (1.4)	3 (4.2)	54 (75.0)	14 (19.4)	7.882; p>0.05
Pharmacist	0 (0.0)	1 (1.3)	42 (56.0)	32 (42.7)	2.840; p>0.05*
Nursing	1 (2.9)	1 (2.9)	25 (71.4)	8 (22.9)	8.616; p>0.05
Total	2 (1.1)	5 (2.7)	121 (66.5)	54 (29.7)	
		X^2_6=12.448; p>0.05			

(*) 4 degrees of freedom for this chi square

Table 132: I feel that the information I provide to patients will influence their driving behaviour.

	Strongly disagree N (%)	Disagree N (%)	Agree N (%)	Strongly agree N (%)	X^2_4; p (Control/Information/ Intervention)
Physicians	9 (12.7)	56 (78.9)	6 (8.5)	0 (0.0)	3.751; p>0.05
Pharmacist	6 (8.0)	63 (84.0)	6 (8.0)	0 (0.0)	6.281; p>0.05
Nursing	5 (14.3)	26 (74.3)	4 (11.4)	0 (0.0)	2.017; p>0.05
Total	20 (11.0)	145 (80.1)	16 (8.8)	0 (0.0)	
		X^2_4=1.774; p>0.05			

3.1.4 REPORTED BEHAVIOUR

In order to evaluate this aspect, the health professionals were given 6 statements, in which they had to evaluate the frequency (always, regularly, sometimes, seldom, never) with which, in the course of their daily activity, they asked the patients about the frequency of their driving and whether they informed patients about the possible effects of the medicaments they prescribed/dispensed/supervised on fitness to drive. On the other hand, they were also asked whether they made a record in the patients' files of the frequency with which the patients drove and the fact that of having informed them in the case where the medicament concerned negatively affected fitness to drive. In addition, they were asked whether, when prescribing/dispensing/supervising a medicament that could affect fitness to drive, they gave the patients printed information and whether they analysed, with the patient, the latter's responsibility when consuming medicaments while driving.

More than half the physicians (52.8%) "always" (13.9%) or "almost always" (38.9%) asked their patients about frequency of driving when prescribing a medicine. Only 1 out of every 3 did so in the case of pharmacists, while scarcely 1 out of every 6 did so in the case of nursing staff. Significant differences were observed between physicians, pharmacists and nursing staff (X^2_8=15.748; p<0.05). It should be pointed out that 1 in 3 health professionals "never" (7.7%) or "almost never" (23.2%) asked their patients about driving frequency (Table 133).

Table 133: I ask a patient about his/her driving exposure when choosing/dispensing a medicine.

	Always N (%)	**Regularly** N (%)	**Sometimes** N (%)	**Seldom** N (%)	**Never** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	10 (13.9)	28 (38.9)	15 (20.8)	15 (28.8)	4 (5.6)	9.734; p>0.05
Pharmacist	7 (9.5)	17 (23.0)	28 (37.8)	16 (21.6)	6 (8.1)	4.855; p>0.05
Nursing	1 (2.9)	5 (14.3)	14 (40.0)	11 (31.4)	4 (11.4)	4.649; p>0.05
Total	18 (9.9)	50 (27.6)	57 (31.5)	42 (23.2)	14 (7.7)	
	X^2_8=15.748; p<0.05					

Of the health professionals, 66.9% "regularly" (40.9%) or "always" (26.0%) inform patients about the possible adverse effects on fitness to drive when prescribing a medicament. Among physicians, 8 out of every 10 "almost always" (54.2%) or "always" (27.8%) inform patients. in the case of pharmacists and nursing staff, just over half "almost always" (28.4% and 40.0% respectively) or "always" (29.7% and 14.3% respectively) inform the patient about the negative effects on fitness to drive when dispensing medicaments to patients or advising patients on the medicaments they have to take (Table 134).

Table 134: I inform a patient about driving related risks when prescribing/dispensing a medicine.

	Always N (%)	**Regularly** N (%)	**Sometimes** N (%)	**Seldom** N (%)	**Never** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	20 (27.8)	39 (54.2)	11 (15.3)	0 (0.0)	2 (2.8)	6.966; p>0.05*
Pharmacist	22 (29.7)	21 (28.4)	24 (32.4)	5 (6.8)	2 (2.7)	10.915; p>0.05
Nursing	5 (14.3)	14 (40.0)	6 (17.1)	4 (11.4)	6 (17.1)	6.660; p>0.05
Total	47 (26.0)	74 (40.9)	41 (22.7)	9 (5.0)	10 (5.5)	
	X^2_8=31.189; p<0.0001					

(*) 6 degrees of freedom for this chi square

Most health professionals (8 out of every 10) "never" (59.1%) or "seldom" (21.0%) provide printed information concerning a medicament's possible negative effects on fitness to drive (Table 135). Neither is it frequent for health professionals to make a note in the patients' files of the advice they might give verbally concerning the negative effects of a medicament on driving. Of physicians and nursing staff, 8 out of every 10, and 9 out of every 10 pharmacists answered "seldom" or "never" to the statement: "I keep systematic records when I advise a patient about when and how he/she can consider driving a car when using a medicine that

impairs driving". Significant differences were, however, observed between the replies of the different health professionals (X^2_8=37.060; p<0.0001;Table 136).

Table 135: I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine.

	Always N (%)	Regularly N (%)	Sometimes N (%)	Seldom N (%)	Never N (%)	X^2_8; p (Control/Information/ Intervention)
Physicians	1 (1.4)	4 (5.6)	11 (15.3)	17 (23.6)	39 (54.2)	15.531; p<0.05
Pharmacist	2 (2.7)	4 (5.4)	8 (10.8)	11 (14.9)	49 (66.2)	4.590; p>0.05
Nursing	0 (0.0)	3 (8.6)	3 (8.6)	10 (28.6)	19 (54.3)	3.024; p>0.05*
Total	3 (1.7)	11 (6.1)	22 (12.2)	38 (21.0)	107 (59.1)	
	X^2_8=6.186; p>0.05					

(*) 6 degrees of freedom for this chi square

Table 136: I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.

	Always N (%)	Regularly N (%)	Sometimes N (%)	Seldom N (%)	Never N (%)	X^2_8; p (Control/Information/ Intervention)
Physicians	0 (0.0)	4 (5.6)	12 (16.7)	26 (36.1)	30 (41.7)	3.189; p>0.05
Pharmacist	1 (1.4)	3 (4.3)	2 (2.9)	7 (10.1)	56 (81.2)	12.369; p>0.05
Nursing	0 (0.0)	6 (17.1)	7 (20.0)	6 (17.1)	16 (45.7)	10.149; p>0.05*
Total	1 (0.6)	13 (7.4)	21 (11.9)	39 (22.2)	102 (58.0)	
	X^2_8=37.060; p<0.0001					

(*) 6 degrees of freedom for this chi square

In general, health professionals "never" (59.3%) or "seldom" (24.3%) make a note of patients' driving habits. Only 8.4% of physicians and 2.4% of pharmacists "always" or "regularly" do so (Table 140). Significant differences can be observed between the health professionals (X^2_8=23.458; p<0.01). Neither is it usual for health professionals to analyse, with their patients, the latter's responsibility when consuming medicaments that have a possibly negative effect on fitness to drive: Over half the health professionals "never" (22.3%) or "seldom" (27.4%) did so, while there were no significant differences between the three collectives.

Table 137: I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).

	Always N (%)	Regularly N (%)	Sometimes N (%)	Seldom N (%)	Never N (%)	X^2_8; p (Control/Information/ Intervention)
Physicians	2 (2.8)	4 (5.6)	11 (15.3)	25 (34.7)	30 (41.7)	12.119; p>0.05
Pharmacist	1 (1.4)	1 (1.4)	4 (5.7)	9 (12.9)	55 (78.6)	6.327; p>0.05
Nursing	0 (0.0)	0 (0.0)	6 (17.1)	9 (25.7)	20 (57.1)	2.205; p>0.05*
Total	3 (1.7)	5 (2.8)	21 (11.9)	43 (24.3)	105 (59.3)	
	X^2_8=23.458; p<0.01					

(*) 4 degrees of freedom for this chi square

Table 138: I discuss medicinal drug consumption and driving related responsibility issues with the patient.

	Always N (%)	**Regularly** N (%)	**Sometimes** N (%)	**Seldom** N (%)	**Never** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	2 (2.8)	15 (21.1)	24 (33.8)	17 (23.9)	13 (18.3)	12.661; p>0.05
Pharmacist	9 (12.3)	4 (5.5)	22 (30.1)	20 (27.4)	18 (24.7)	8.689; p>0.05
Nursing	1 (2.9)	4 (11.4)	9 (25.7)	12 (34.3)	9 (25.7)	8.964; p>0.05
Total	12 (6.7)	23 (12.8)	55 (30.7)	47 (27.4)	40 (22.3)	
			X^2_8=15.044; p>0.05			

3.1.5 SOURCES

Of the health professionals, 63.9% referred to having easy access to information concerning the effects of medicines on driving. Significant differences were observed (X^2_2=29.464; p<0.0001): the pharmacists (86.7%) being those who most frequently referred to having easy access to the said information. Within each collective, no differences were observed between the control/information/intervention groups (Table 139).

Table 139: I have easy access to data and information about a medicine's effect on driving skills

	Yes N (%)	**No** N (%)	**X^2_2; p**	**X^2_2; p** (Control/Information/ Intervention)
Physicians	37 (51.4)	35 (48.6)		0.888; p>0.05
Pharmacist	65 (86.7)	10 (13.3)	29.464; p<0.0001	1.767; p>0.05
Nursing	15 (41.7)	21 (58.3)		1.512; p<0.05
Total	117 (63.9)	66 (36.1)		

Table 140 shows the percentage of health professionals who use each of the sources of information concerning the effects of medication on driving. The most frequently referred to sources were: "Professional websites" (40.4%), "Journals" (39.9%) and "Newsletters" (36.6%).

Table 140: Reported sources

	Professional websites N (%)	**Newsletters** N (%)	**Organisations** N (%)	**Journals** N (%)	**Other** N (%)
Physicians (n=72)	21 (29.2)	19 (26.4)	4 (5.6)	25 (34.7)	3 (4.2)
Pharmacist (n=75)	45 (60.0)	39 (52.0)	29 (38.7)	42 (56.0)	10 (13.3)
Nursing (n=36)	8 (22.2)	9 (25.0)	3 (8.3)	6 (16.7)	3 (8.3)
Total	74 (40.4)	67 (36.6)	36 (19.7)	73 (39.9)	16 (8.7)

73.8% of the health professionals referred to having received no formation on the effects of medication on driving after finishing their university degrees. There were significant differences (X^2_2=14.022; p<0.005), physicians being the collective that least frequently received this kind of formation (11.1%). No significant differences were observed within each collective between the control/information/intervention groups (Table 141).

Table 141: Did you get any postgraduate education on medicinal effects on driving skills?

	Yes N (%)	**No** N (%)	**X^2_2; p**	**X^2_2; p** (Control/Information/ Intervention)
Physicians	8 (11.1)	64 (88.9)		5.075; p>0.05
Pharmacist	27 (36.0)	48 (64.0)	14.022; p<0.005	0.420; p>0.05
Nursing	13 (36.1)	23 (63.9)		1.563; p>0.05
Total	48 (26.2)	135 (73.8)		

If you answered "Yes", please specify:
The types of post-graduate formation that health professionals indicated they had received were: "Courses" (9.3%), "Journals and/or reading material" (3.8%), "Seminars/conferences" (2.7%), and "On-line formation" (0.5%).

3.1.6 ACTUAL KNOWLEDGE

The knowledge that health professionals have concerning the effects of some medicines on driving was analyzed. Tables 142-147 show the results for the medicines in which significant differences were found in answers to the question "How much do you agree or disagree with the following statements?" The possible answers were "Totally Disagree", "Disagree", "Disagree nor Agree", "Totally Agree" and "Don't Know".

Table 142: Lormetazepam (1 mg) is severely impairing driving 8 hours after intake.

	Totally Disagree N (%)	**Disagree** N (%)	**Disagree nor Agree** N (%)	**Totally Agree** N (%)	**Don't Know** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	1 (1.4)	1 (1.4)	36 (52.2)	30 (43.5)	1 (1.4)	9.257; p>0.05
Pharmacist	1 (1.3)	2 (2.7)	35 (47.9)	35 (47.9)	0 (0.0)	3.837; p>0.05*
Nursing	0 (0.0)	0 (0.0)	21 (60.0)	10 (28.6)	4 (11.4)	3.228; p>0.05**
Total	2 (1.1)	3 (1.7)	92 (52.0)	75 (42.4)	5 (2.8)	
	X^2_8=16.069; p<0.05					

(*) 6 degrees of freedom for this chi square (**) 4 degrees of freedom for this chi square

Table 143: Diazepam (regardless dose) is severely impairing within the first 2 months of treatment.

	Totally Disagree N (%)	**Disagree** N (%)	**Disagree nor Agree** N (%)	**Totally Agree** N (%)	**Don't Know** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	3 (4.3)	11 (15.9)	36 (52.2)	15 (21.7)	4 (5.8)	2.570; p>0.05
Pharmacist	2 (2.8)	24 (33.8)	25 (35.2)	18 (25.4)	2 (2.8)	8.931; p>0.05
Nursing	1 (2.9)	2 (5.7)	18 (51.4)	7 (20.0)	7 (20.0)	9.310; p>0.05
Total	6 (3.4)	37 (21.1)	79 (45.1)	40 (22.9)	13 (7.4)	
	X^2_8=23.182; p<0.005					

Table 144: Codeine (up to 20 mg) is mostly safe for drivers.

	Totally Disagree N (%)	**Disagree** N (%)	**Disagree nor Agree** N (%)	**Totally Agree** N (%)	**Don't Know** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	10 (14.3)	32 (45.7)	22 (31.4)	0 (0.0)	6 (8.6)	2.419; p>0.05*
Pharmacist	12 (16.7)	31 (43.1)	22 (30.6)	5 (6.9)	2 (2.8)	6.569; p>0.05
Nursing	6 (17.1)	13 (37.1)	9 (25.7)	2 (5.7)	5 (14.3)	10.727; p>0.05
Total	28 (15.8)	76 (42.9)	53 (29.9)	7 (4.0)	13 (7.4)	
	X^2_8=9.998; p>0.05					

(*) 6 degrees of freedom for this chi square

Table 145: Fexofenadine (normal dose) is severely impairing driving.

	Totally Disagree N (%)	**Disagree** N (%)	**Disagree nor Agree** N (%)	**Totally Agree** N (%)	**Don't Know** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	2 (3.0)	19 (28.4)	31 (46.3)	3 (4.5)	12 (17.9)	5.596; p>0.05
Pharmacist	9 (12.7)	30 (42.3)	25 (35.2)	2 (2.8)	5 (7.0)	4.924; p>0.05
Nursing	0 (0.0)	9 (26.5)	11 (32.4)	2 (5.9)	12 (35.3)	8.146; p>0.05*
Total	11 (6.4)	58 (33.7)	67 (39.0)	7 (4.1)	29 (16.9)	
	X^2_8=23.494; p<0.005					

(*) 6 degrees of freedom for this chi square

Table 146: Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment.

	Totally Disagree N (%)	Disagree N (%)	Disagree nor Agree N (%)	Totally Agree N (%)	Don't Know N (%)	X^2_8; p (Control/Information/ Intervention)
Physicians	0 (0.0)	5 (7.4)	41 (60.3)	14 (20.6)	8 (11.8)	5.202; p>0.05*
Pharmacist	1 (1.4)	10 (13.9)	46 (63.9)	11 (15.3)	4 (5.6)	4.541; p>0.05
Nursing	1 (2.9)	3 (8.6)	16 (45.7)	6 (17.1)	9 (25.7)	4.740; p>0.05
Total	2 (1.1)	18 (10.3)	103 (58.9)	31 (17.7)	21 (12.0)	
	X^2_8=13.199; p>0.05					

(*) 6 degrees of freedom for this chi square

Table 147: Paroxetine (up to 20 mg/day) is safe for drivers.

	Totally Disagree N (%)	Disagree N (%)	Disagree nor Agree N (%)	Totally Agree N (%)	Don't Know N (%)	X^2_8; p (Control/Information/ Intervention)
Physicians	4 (5.7)	33 (47.1)	23 (32.9)	4 (5.7)	6 (8.6)	2.483; p>0.05
Pharmacist	5 (6.8)	35 (47.9)	29 (39.7)	2 (2.7)	2 (2.7)	5.894; p>0.05
Nursing	2 (5.7)	15 (42.9)	8 (22.9)	1 (2.9)	9 (25.7)	10.028; p>0.05
Total	11 (6.2)	83 (46.6)	60 (33.7)	7 (3.9)	17 (9.6)	
	X^2_8=16.372; p<0.05					

The answers corresponding to the questions in ACTUAL KNOWLEDGE (Tables 142-147) were recoded as dichotomies, correct/not correct, except for the first of them (lormetazepam,Table 142) as it was different in the Spanish questionnaire. The answers of "Disagree nor Agree" and "Totally agree" were considered to be "correct" in the questions referring to diazepam, codeine, and paroxetine; while the replies "Disagree" and "Totally disagree" were considered "correct" in the questions referring to fexofenadine and amitriptyline. The answer "don't know" and no answer at all were also considered "not correct" in the recoding. As can be seen in Table 145, for the recoded answers, significant differences between physicians/pharmacists/nursing staff are only noted in the case of fexofenadine (X22=11.234; p<0.01). No significant differences were observed between the control/information/intervention groups for any of the questions, neither in the sample as a whole, nor in each collective of professionals separately.

Table 148: How much do you agree or disagree with the following statements?

		Correct N (%)	Not correct N (%)	X^2_2; p
Diazepam (regardless dose) is severely impairing within the first 2 months of treatment.	**Physicians**	51 (70.8)	21 (29.2)	3.328; p>0.05
	Pharmacist	43 (57.3)	32 (42.7)	
	Nursing	25 (69.4)	11 (30.6)	
	Total	119 (65.0)	64 (35.0)	
Codeine (up to 20 mg) is mostly safe for drivers.	**Physicians**	22 (30.6)	50 (69.4)	0.595; p>0.05
	Pharmacist	27 (36.0)	48 (64.0)	
	Nursing	11 (30.6)	25 (69.4)	
	Total	60 (32.8)	123 (67.2)	
Fexofenadine (normal dose) is severely impairing driving.	**Physicians**	21 (29.2)	51 (70.8)	11.234; p<0.01
	Pharmacist	39 (52.0)	36 (48.0)	
	Nursing	9 (25.0)	27 (75.0)	
	Total	69 (37.7)	114 (62.3)	
Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment.	**Physicians**	5 (6.9)	67 (93.1)	2.252; p>0.05
	Pharmacist	11 (14.7)	64 (85.3)	
	Nursing	4 (11.1)	32 (88.9)	
	Total	20 (10.9)	163 (89.1)	
Paroxetine (up to 20 mg/day) is safe for drivers.	**Physicians**	27 (37.5)	45 (62.5)	2.836; p>0.05
	Pharmacist	31 (41.3)	44 (58.7)	
	Nursing	9 (25.0)	27 (75.0)	
	Total	67 (36.6)	116 (63.4)	

3.1.7 G. USER ACEPTANCE

Most health professionals would be willing to use a tool that would provide information concerning the effects of medication on driving (Table 149). 3.3% would not use such a tool, while 13.7% said “maybe”. There were no significant differences in the answers of physicians, pharmacists and nursing staff. The main reasons referred to were: A lack of time, no computer or internet connection problems in the surgery (
Table **150**).

Table 149: If we propose you a tool (e.g. website,cd-rom) that allows you to find information on medical drugs and driving, will you be willing to use it for prescribing/dispensing medicines?

	Yes N (%)	**No** N (%)	**Maybe** N (%)	X^2_4; **p** (Control/Information/ Intervention)
Physicians	56 (78.9)	1 (1.4)	14 (19.7)	4.906; p>0.05
Pharmacists	63 (84.0)	3 (4.0)	9 (12.0)	7.324; p>0.05
Nursing	32 (88.9)	2 (5.6)	2 (5.6)	4.490; p>0.05
Total	151 (83.0)	6 (3.3)	25 (13.7)	
	X^2_4=5.511; p>0.05			

Table 150: If you answered "No" or "Maybe" to Q1, what are the main reasons for your reluctance to use them?

	Lack of time N (%)	**I already have a program** N (%)	**No computer/connection problems** N (%)	**Only useful for few cases** N (%)	**Other reason** N (%)	**X^2_8; p** (Control/Information/ Intervention)
Physicians	4 (33.3)	0 (0.0)	5 (41.7)	1 (8.3)	2 (8.6)	5.340; p>0.05
Pharmacists	2 (16.7)	6 (50.0)	0 (0.0)	3 (25.0)	1 (2.7)	7.500; p>0.05
Nursing	1 (33.3)	0 (0.0)	1 (33.3)	0 (0.0)	1 (33.3)	3.000; p>0.05
Total	7 (25.9)	6 (22.2)	6 (22.2)	4 (14.8)	4 (14.8)	
			X^2_8=15.777; p<0.05			

3.1.8 SPECIFIC QUESTIONS: SPANISH QUESTIONNAIRE

The health professionals were asked to score (from 1 to 10 where 10 is the maximum) the importance they give in their daily practice to the subject of medicines and driving. The average score given (Mean±SD) was 7.38±2.06 points, and no significant differences were observed between the three collectives (F=1.481; p>0.05). Within each collective (physicians, pharmacists and nursing staff), there were no significant differences either between the control/information/intervention groups, in their average scores (Table 151).

Table 151: In your daily practice, what importance do you give to the subject of medication and driving (from 1 to 10, where 10 is the maximum)?

	N	Mean±SD	**F; p** (Control/Information/intervention)
Physicians	67	7.58±1.66	0.197; p>0.05
Pharmacists	70	7.06±2.11	0.497; p>0.05
Nursing	32	7.66±2.61	2.681; p>0.05
Total	169	7.38±2.06	
		F=1.481; p>0.05	

44.2% of the health professionals have "frequently" or "very frequently" had cases in which the effect of medicines on driving was an important aspect at the time of selecting medication. No significant differences were observed in the answers from physicians, pharmacists and nursing staff. There were no significant differences either, within each collective, between the control, information and intervention groups (Table 152).

Table 152: Over the last year, in your daily practice, how often have you had a case in which the effect of medicines on driving has been an important aspect at the time of selecting medication?

	Very frequently N (%)	**Frequently** N (%)	**Seldom** N (%)	**Hardly ever** N (%)	**X^2_6; p** (Control/Information/ Intervention)
Physicians	9 (13.2)	29 (42.6)	14 (20.6)	16 (23.5)	6.497; p>0.05
Pharmacists	11 (15.5)	19 (26.8)	17 (23.9)	24 (33.8)	12.854; p>0.05
Nursing	3 (9.1)	5 (15.2)	10 (30.3)	15 (45.5)	4.727; p>0.05
Total	23 (13.4)	53 (30.8)	41 (23.8)	55 (32.0)	
		X^2_6=11.134; p>0.05			

3.1.9 POST TRAINING

For legal reasons, and to preserve the privacy of the interviewees, both questionnaires ("Pre" and "Post") were done anonymously. The correspondence between one questionnaire and the other was made via the coincidence of the socio-demographic variables: "Profession", "Gender", and "Date of birth", "Date of graduation medical/pharmacist school" and "Years practicing". A total of 69 health professionals answered the "Post" questionnaire, of which the correspondence in the "Pre" questionnaire was only established in 38 cases. The other 31 cases did not correspond to any cases from the initial questionnaire (Table 153).

Table 153: Participants included in the study and replies obtained in the 2nd questionnaire

Groups	Profession	Included	Responses / post (matches)	Responses / post (not matches)
Information	**Physician**	56	12	12
	Pharmacist	46	20	15
	Nursing	52		
Intervention	**Physician**	44	6	4
	Pharmacist	48		
	Nursing	46		
Total		292	38	31

3.1.10 ANALYSIS PRE / POST

For the comparative analysis between the answers obtained in both questionnaires, we therefore had 38 questionnaires: 22 corresponding to the information group and only 6 to the intervention group (Table 153). Given the low number of replies obtained and the impossibility of supposing any kind of normality from the sample, a non-parametric test has been used, the Wilcoxon sign test, as an alternative to the "t" of Student for related samples. In what follows, only the results where significant Pre/Post differences were found on applying the Wilcoxon test are shown.

3.1.11 ATTITUDES/AWARENESS (PRE / POST)

Significant changes were observed between the first and second questionnaires in the degree of agreement with the first statement of this section: "I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines". For both the whole sample and among the collective of the physicians, an increase in the degree of agreement with this statement was observed (Tables 154-155 and Figures 77-78). In the following question: "Would you consider this (previous sentence) of more concern if your patient is", differences were only observed in cases where the patient was a professional driver (for the whole sample and among the collective of pharmacists, Tables 156-157) or where the patient was taking other substances which affected the CNS (Tables 158-159).

Table 154: I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines.

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	18	2.94±0.24	3.00	18	3.22±0.43	3.00	-2.236; p<0.05
Pharmacists	20	3.00±0.73	3.00	20	3.20±0.52	3.00	-1.069; p>0.05
Total	38	2.97±0.55	3.00	38	3.21±0.47	3.00	-2.065; p<0.05

Table 155: I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	Negative Ranks	0	0.00	0.00	-2.236	<0.05
	Positive Ranks	5	3.00	15.00		
	Ties	13				
	Total	18				
Total sample	Negative Ranks	4	8.00	32.00	-2.065	<0.05
	Positive Ranks	12	8.67	104.00		
	Ties	22				
	Total	38				

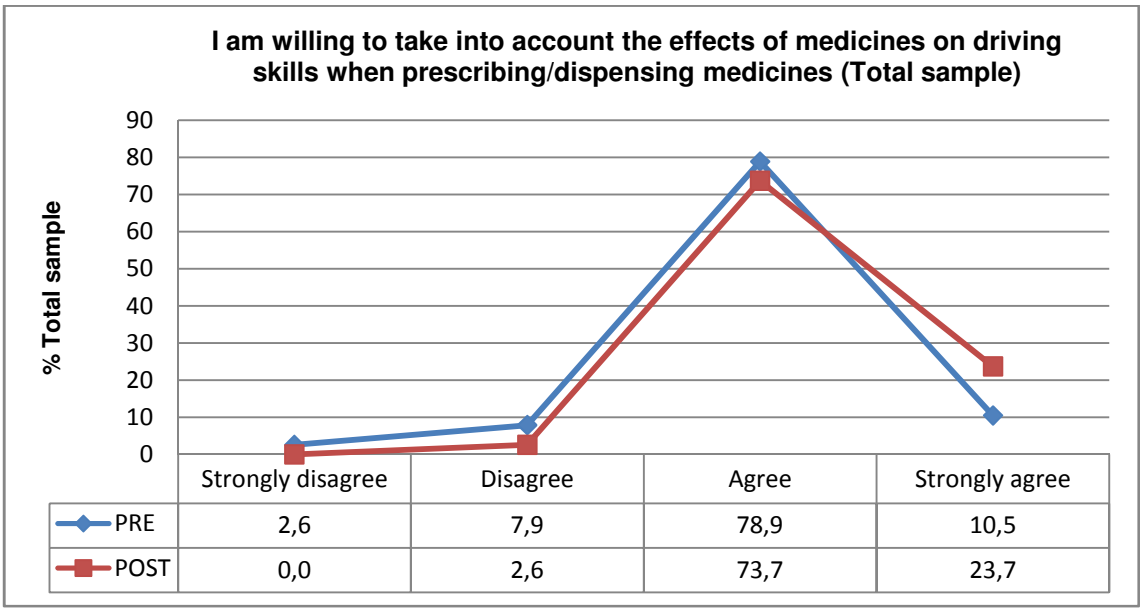

Figure 77: Significant pre-post change - I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines- % in the total sample.

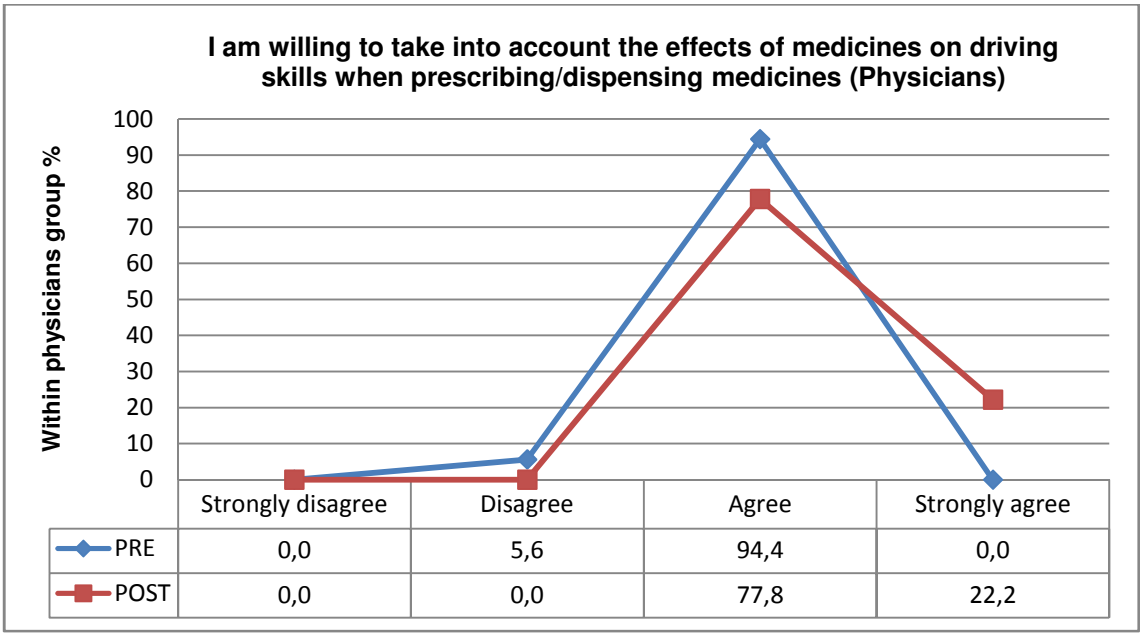

Figure 78: Significant pre-post change - I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines- within physicians group %

Table 156: "Would you consider this of more concern if your patient is": a professional driver

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	17	1.00±0.00	1.00	17	0.94±0.24	1.00	-1.000; p>0.05
Pharmacists	19	1.00±0.00	1.00	20	0.80±0.41	1.00	-2.000; p<0.05
Total	36	1.00±0.00	1.00	37	0.86±0.35	1.00	-2.236; p<0.05

Table 157: "Would you consider this of more concern if your patient is": a professional driver. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Pharmacist	**Negative Ranks**	4	2.5	10.00	-2.000	<0.05
	Positive Ranks	0	0.00	0.00		
	Ties	15				
	Total	19				
Total sample	**Negative Ranks**	5	3.00	15.00	-2.236	<0.05
	Positive Ranks	0	0.00	0.00		
	Ties	30				
	Total	35				

Table 158: "Would you consider this of more concern if your patient is": using other CNS active drugs

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	17	1.00±0.00	1.00	15	0.80±0.41	1.00	-1.732; p>0.05
Pharmacists	18	1.00±0.00	1.00	20	0.85±0.37	1.00	-1.732p>0.05
Total	35	1.00±0.00	1.00	35	0.83±0.38	1.00	-2.449; p<0.05

Table 159: "Would you consider this (Q1) of more concern if your patient is": using other CNS active drugs. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Total sample	Negative Ranks	6	3.50	21.00	-2.449	<0.05
	Positive Ranks	0	0.00	0.00		
	Ties	26				
	Total	32				

Composite score. The answers obtained in each of the 5 statements in this section, which had 4 possible answers, had the following scores: Strongly disagree (1 point); Disagree (2 points); Agree (3 points); Strongly agree (4 points). The points obtained were added for each of the 5 statements and the results for the PRE and POST questionnaires were compared using the Wilcoxon test. No significant differences were found for either the whole sample or for each collective separately (Table 160).

Table 160: Composite score "Attitudes/awareness" (points sum)

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	14.78±1.63	15.00	18	15.56±1.50	15.00	-1.589; p>0.05
Pharmacists	20	15.25±1.86	15.00	20	15.45±1.76	15.00	-0.648; p>0.05
Total	38	15.03±1.75	15.00	38	15.50±1.62	15.00	-1.372; p>0.05

3.1.12 REPORTED BEHAVIOUR (PRE / POST)

As for the first questionnaire, in both the whole sample and among the physicians, a significant change was observed in favor of the statement: "I ask a patient about his/her driving exposure when choosing/dispensing a medicine" (Tables 161-162). In general, the percentages decreased for those who replied "never" or "seldom" and the percentages increased for those who replied "sometimes" and "always" (Figure 79).

Table 161: I ask a patient about his/her driving exposure when choosing/dispensing a medicine.

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	1.94±1.11	2.00	18	2.50±0.99	3.00	-1.997; p<0.05
Pharmacists	20	1.70±0.87	2.00	20	1.90±0.97	2.00	-0.884; p>0.05
Total	38	1.82±0.98	2.00	38	2.18±1.01	2.00	-2.048; p<0.05

Table 162: I ask a patient about his/her driving exposure when choosing/dispensing a medicine. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	Negative Ranks	3	5.00	15.00	-1.977	<0.05
	Positive Ranks	9	7.00	63.00		
	Ties	6				
	Total	18				
Total sample	Negative Ranks	7	10.57	74.00	-2.048	<0.05
	Positive Ranks	16	12.63	202.00		
	Ties	15				
	Total	38				

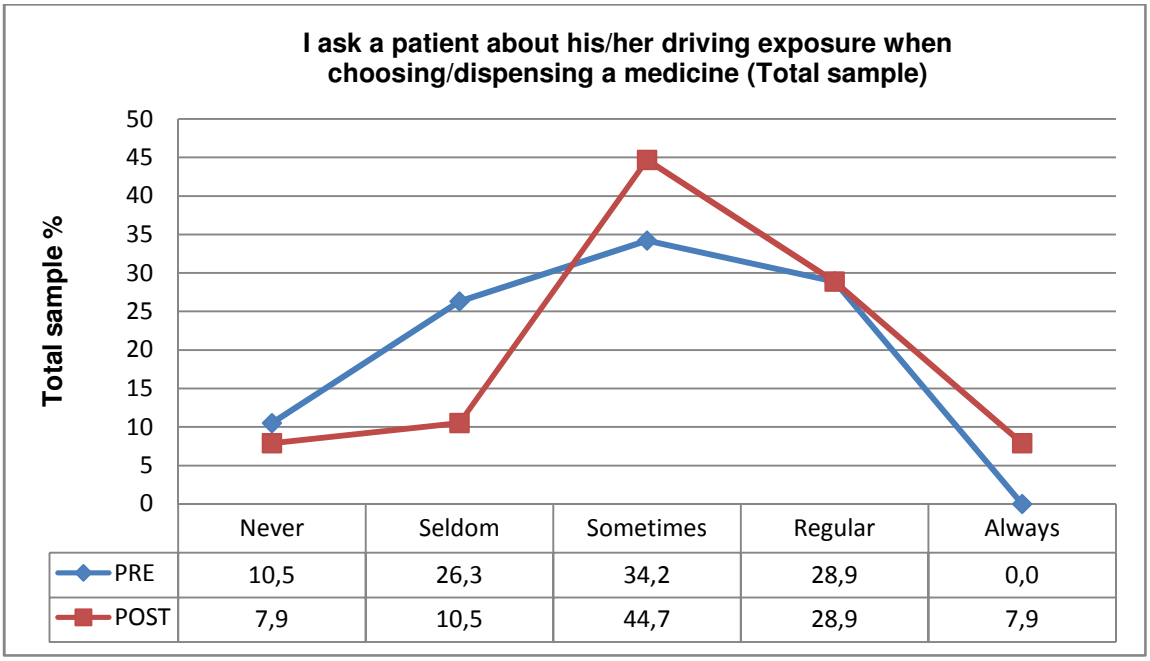

Figure 79: Significant pre-post change - I ask a patient about his/her driving exposure when choosing/dispensing a medicine- % in the total sample.

There were also significant differences between both questionnaires among the whole sample and among the collective of physicians in "I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine" (Tables 163-164), "I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine" (Tables 165-166) and "I keep a record of the patient's traffic participation" (Tables 167-168). The percentages of the replies (for the whole sample) in the PRE and POST questionnaires are shown in Figures 80-82.

Table 163: I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine.

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	0.28±0.46	0.00	18	0.83±0.99	0.50	-2.308; p<0.05
Pharmacists	20	0.85±1.82	0.00	20	1.15±1.10	1.00	-1.097; p>0.05
Total	38	0.58±0.95	0.00	38	1.00±1.04	1.00	-2.309; p<0.05

Table 164: I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	1	4.00	4.00	-2.308	<0.05
	Positive Ranks	8	5.13	41.00		
	Ties	9				
	Total	18				
Total sample	**Negative Ranks**	7	9.50	66.50	-2.309	<0.05
	Positive Ranks	16	13.09	209.50		
	Ties	15				
	Total	38				

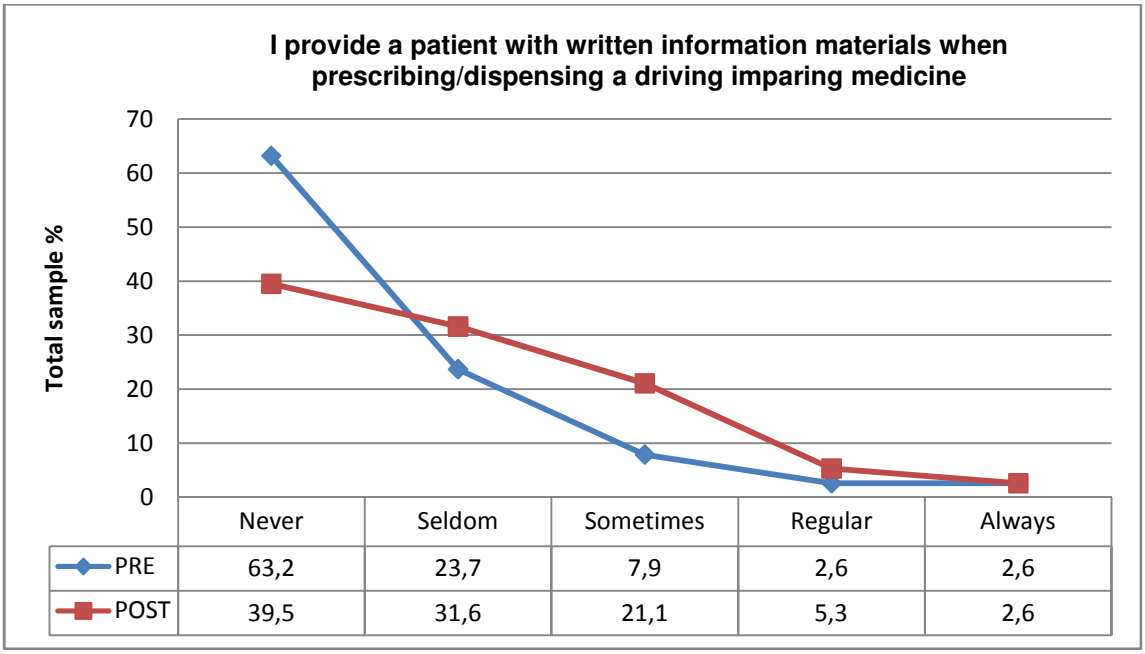

Figure 80: Significant pre-post change -I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine - % in the total sample.

Table 165: I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine.

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	0.44±0.62	0.00	18	1.50±1.20	1.00	-2.844; p<0.05
Pharmacists	19	0.47±0.84	0.00	19	0.53±0.91	0.00	-0.356; p>0.05
Total	37	0.46±0.73	0.00	37	1.00±1.16	1.00	-2.365; p<0.05

Table 166:I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	0	.00	.00	-2.844	<0.005
	Positive Ranks	10	5.50	55.00		
	Ties	8				
	Total	18				
Total sample	**Negative Ranks**	3	10.67	32.00	-2.365	<0.05
	Positive Ranks	15	9.27	139.00		
	Ties	18				
	Total	36				

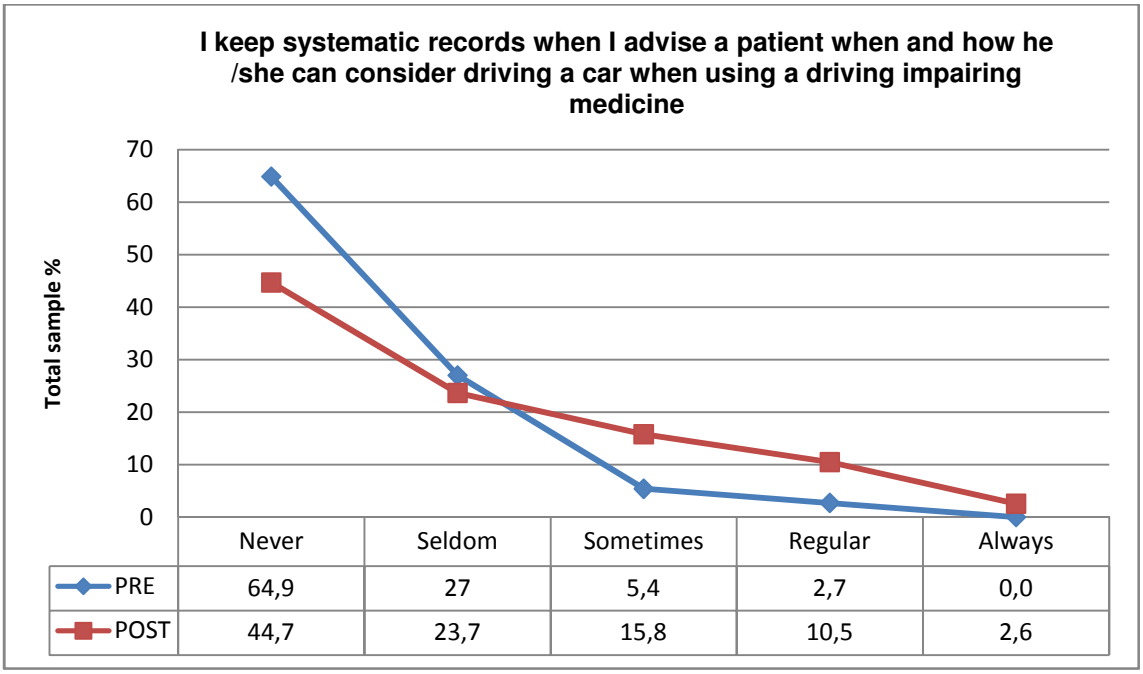

Figure 81: Significant pre-post change -I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine - % in the total sample.

Table 167: I keep a record of the patient's traffic participation (e.g. how often he/she drives to work).

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	0.44±0.62	0.00	18	1.22±0.94	1.00	-2.697; p<0.01
Pharmacists	19	0.37±0.68	0.00	19	0.74±0.87	1.00	-1.897; p>0.05
Total	37	0.41±0.64	0.00	37	0.97±0.93	1.00	-3.279; p<0.005

Table 168: I keep a record of the patient's traffic participation (e.g. how often he/she drives to work). Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	1	3.50	3.50	-2.697	<0.01
	Positive Ranks	10	6.25	62.50		
	Ties	7				
	Total	18				
Total sample	**Negative Ranks**	2	6.50	13.00	-3.279	<0.005
	Positive Ranks	16	9.88	158.00		
	Ties	18				
	Total	36				

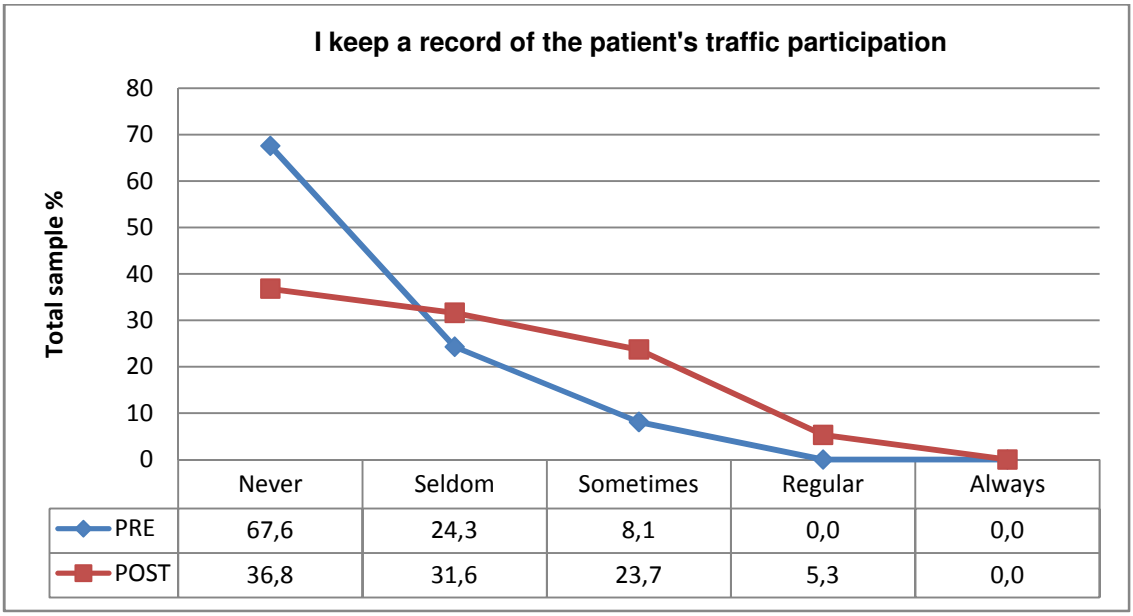

Figure 82: Significant pre-post change -I keep a record of the patient's traffic participation (e.g. how often he/she drives to work) - % in the total sample.

The significant changes in this section point to an increase in the effort health professionals make both to inform the patient about medicines and driving and to inform him/herself about the patient's involvement in driving and to leave a record of these aspects in the patient's medical history.

Composite scores. The replies obtained in each of the 6 statements in this section were scored as follows: Never (0 points); Seldom (1 points); Sometimes (2 points); Regularly (3 points); Always (4 points). The points obtained in each of the 6 questions were aadded and the results from the PRE and POST questionnaires were compared using the Wilcoxon test (Tables 169-170). A significant positive change on the "reported behaviour" composite score was observed for the whole sample and for the collective of physicians (Tables 172-173). The percentages according to the range of scoring (between 0 and 24 points) in the PRE and POST questionnaires are shown in Figure 83.

Table 169: Composite score "Reported Behaviour" (points sum)

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	7.28±3.23	7.5	18	10.72±4.39	12.00	-2.848; p<0.005
Pharmacists	20	7.40±3.90	6.00	20	8.70±3.23	8.50	-1.686; p>0.05
Total	38	7.34±3.55	7.00	38	9.66±3.91	9.00	-3.272; p<0.005

Table 170: Composite score "Reported Behaviour" (points sum). Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	3	5.50	16.5	-2.848	<0.005
	Positive Ranks	14	9.75	136.5		
	Ties	1				
	Total	18				
Total sample	**Negative Ranks**	9	12.89	116.00	-3.272	<0.005
	Positive Ranks	26	19.77	515.00		
	Ties	3				
	Total	38				

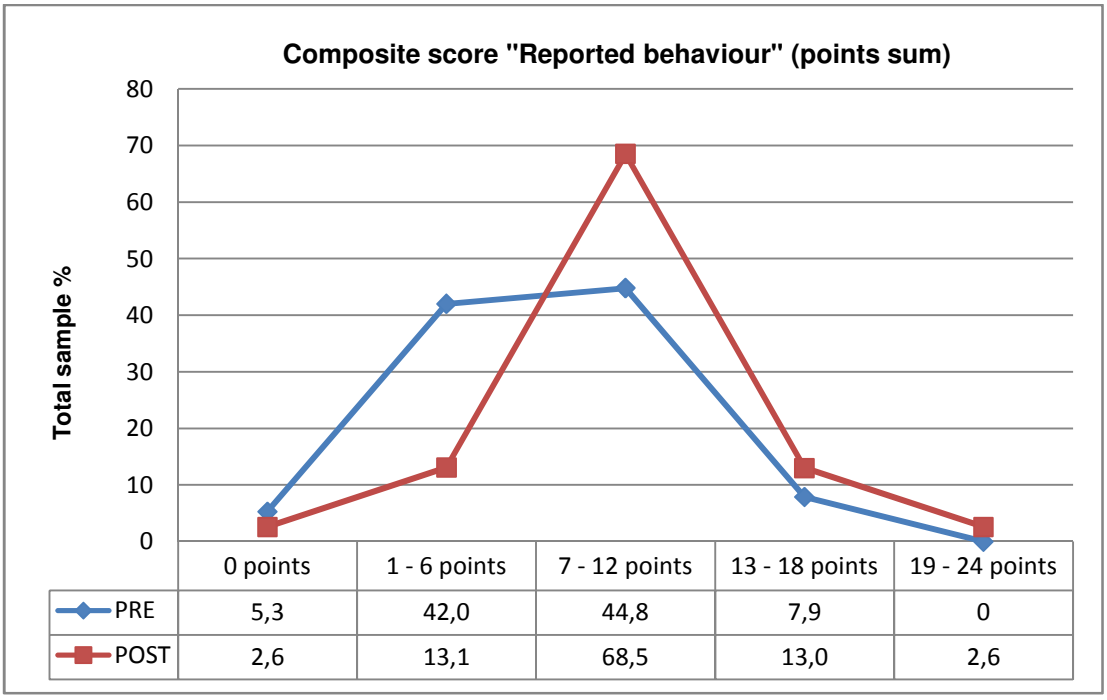

Figure 83: Significant pre-post change questionnaire: Reported behaviour score - % in the total sample**.**

3.1.13 ACTUAL KNOWLEDGE (PRE / POST)

The evolution in knowledge concerning the effects of some medicines on driving has been analyzed, using the replies obtained from the pre / post questionnaires. Tables 171--176 show the results in which significant differences have been found (Wilcoxon test) using the original categories of the variables ("Totally Disagree", "Disagree", "Disagree nor Agree", "Totally Agree" and "Don't Know").

How much do you agree or disagree with the following statements?

Table 171: Codeine (up to 20 mg) is mostly safe for drivers**.**

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	17	1.88±0.93	2.00	18	2.39±0.502	2.00	-2.066; p<0.05
Pharmacists	18	2.11±0.76	2.00	20	2.30±0.98	2.00	-0.647; p>0.05
Total	35	2.00±0.84	2.00	38	2.34±0.78	1.00	-1.927; p>0.05

Table 172: Codeine (up to 20 mg) is mostly safe for drivers. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	3	6.00	18.00	-2.066	<0.05
	Positive Ranks	10	7.30	73.00		
	Ties	4				
	Total	17				

Table 173: Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment.

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	16	2.94±1.24	3.00	18	2.22±1.22	2.00	-2.280; p<0.05
Pharmacists	18	2.72±0.96	3.00	20	2.10±1.17	2.00	-2.648; p<0.01
Total	34	2.82±1.09	3.00	38	2.16±1.18	2.00	-3.426; p<0.005

Table 174: Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	7	4.86	34.00	-2.280	<0.05
	Positive Ranks	1	2.00	2.00		
	Ties	8				
	Total	16				
Pharmacists	**Negative Ranks**	10	6.15	61.50	-2.648	<0.01
	Positive Ranks	1	4.50	4.50		
	Ties	7				
	Total	18				
Total sample	**Negative Ranks**	17	10.47	178.00	-3.426	<0.005
	Positive Ranks	2	6.00	12.00		
	Ties	15				
	Total	34				

Table 175: Paroxetine (up to 20 mg/day) is safe for drivers.

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	17	1.59±1.06	2.00	18	2.50±0.62	2.00	-2.801; p<0.01
Pharmacists	19	2.37±0.60	2.00	20	2.15±0.93	2.00	-0.971; p>0.05
Total	36	2.00±0.93	2.00	38	2.32±0.81	2.00	-1.642; p>0.05

Table 176: Paroxetine (up to 20 mg/day) is safe for drivers. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	1	4.50	4.50	-2.801	<0.01
	Positive Ranks	11	6.68	73.50		
	Ties	5				
	Total	17				

Recoding the replies as right/wrong, as was done in the “pre” questionnaire, the Wilcoxon Signed Rank Test showed a significant positive change after the training in the replies given for amitriptyline, for both the whole sample and both collectives separately (physicians and pharmacists, Tables 177-178).

Table 177: Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment - Right / Wrong**-**

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	18	0.00±0.00	0.00	18	0.39±0.50	0.00	-2.646; p<0.01
Pharmacists	20	0.15±0.37	0.00	20	0.50±0.51	0.50	-2.648; p<0.01
Total	38	0.08±0.27	0.00	38	0.48±0.50	0.00	-3.742; p<0.005

Table 178: Amitriptyline at the start of treatment is as impairing driving as after 4 weeks of treatment - Right / Wrong. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	0	0.00	0.00	-2.646	<0.01
	Positive Ranks	7	4.00	28.00		
	Ties	11				
	Total	18				
Pharmacists	**Negative Ranks**	0	0.00	0.00	-2.646	<0.01
	Positive Ranks	7	4.00	28.00		
	Ties	13				
	Total	20				
Total sample	**Negative Ranks**	0	0.00	0.00	-3.742	<0.0001
	Positive Ranks	14	7.50	105.00		
	Ties	24				
	Total	34				

Composite score: Giving a score of “1” to each correct answer and adding up the points obtained in this section by each participant in the study, scores of between 0 and 5 are obtained for the PRE and POST questionnaires. These scores will be used as variables to evaluate knowledge evolution. For both the whole sample as well as for physicians and pharmacists separately, a significant positive change can be observed in the second

questionnaire with respect to the first (Tables 179-180). Figure 100 shows the percentages of those who obtained each of the possible scores (from 0 to 5 points) in the PRE and POST questionnaires.

Table 179: PRE-POST questionnaire knowledge composite score

	PRE			POST			Z; p
	N	Mean±SD	Median	N	Mean±SD	Median	
Physicians	18	1.22±1.11	1.00	18	2.39±1.09	2.00	-3.250; p<0.005
Pharmacists	20	1.80±1.06	2.00	20	2.40±1.05	2.00	-2.012; p<0.05
Total	38	1.53±1.11	1.00	38	2.40±1.05	2.00	-3.742; p<0.0001

Table 180: PRE-POST questionnaire knowledge composite score. Significant differences pre-post (Wilcoxon test)

		N	Mean Rank	Sum of Ranks	Z	p
Physicians	**Negative Ranks**	0	0.00	0.00	-3.250	<0.005
	Positive Ranks	13	7.00	91.00		
	Ties	5				
	Total	18				
Pharmacists	**Negative Ranks**	3	7.17	21.50	-2.012	<0.05
	Positive Ranks	11	7.59	83.50		
	Ties	6				
	Total	20				
Total sample	**Negative Ranks**	3	12.17	36.50	-3.764	<0.0001
	Positive Ranks	24	14.23	341.50		
	Ties	11				
	Total	38				

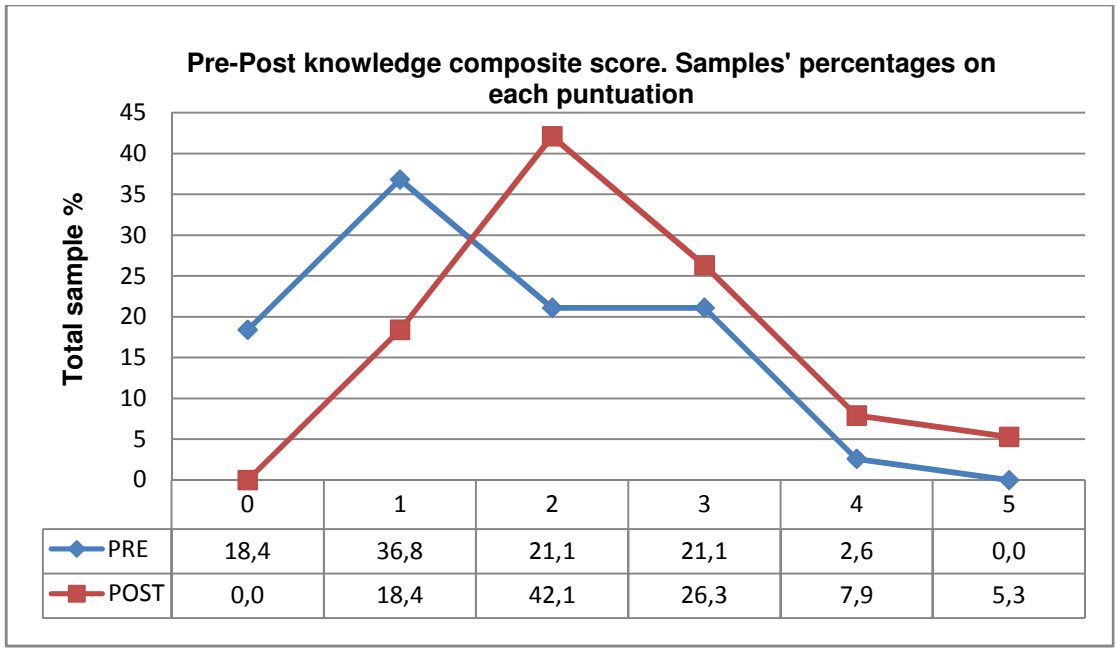

Figure 84: Significant pre-post change questionnaire: knowledge composite score - % in the total sample.

3.1.14 SPECIFIC QUESTIONS: SPANISH QUESTIONNAIRE (PRE / POST)

As for the importance given in their daily practice to medicines and driving by health professionals, a significant positive change can be seen after the training among the coolective of pharmacists (Wilcoxon test, Tables 181-182).

Table 181: In your daily practice, what importance would you give to the subject of medicines and driving (on a scale of 1 to 10, where 10 is the maximum)?

	PRE			POST			Z; p
	N	Mean±SD	**Median**	**N**	Mean±SD	**Median**	
Physicians	17	7.41±1.84	8.00	17	6.24±1.99	7.00	-1.805; p>0.05
Pharmacists	19	6.74±2.16	7.00	18	7.17±2.16	8.00	-2.489; p<0.05
Total	36	7.06±2.01	7.50	35	6.71±1.89	7.00	-0.738; p>0.05

Table 182: In your daily practice, what importance would you give to the subject of medicines and driving (on a scale of 1 to 10, where 10 is the maximum)?

		N	Mean Rank	Sum of Ranks	Z	p
Pharmacists	**Negative Ranks**	1	4.00	4.00	-2.489	<0.05
	Positive Ranks	9	5.67	51.00		
	Ties	7				
	Total	17				

No significant differences were found for the question “In your daily practice over the last year, how often have you had cases in which the effect of medicines on driving has been an important aspect at the time of selecting medication”.

3.2 STUDY 2: PATIENT QUESTIONNAIRE (PICTOGRAM)

3.2.1 BACKGROUND INFORMATION

A total of 1,385 questionnaires were done, 47.7% to men (n= 660) and 52.3% to women (n= 725). 79.3% had a driving license (n= 1098) and 20.7% did not (n= 287). There were significant differences between men and women (X^2=123.63; p<0.0001). The drivers had a better level of education (Table 186) and there were significant differences between drivers and non-drivers (X^2_4=100.75; p=0.0001). The average age was 50.50±15.55 years, differences being observed between drivers (47.27±14.72 years) and non-drivers (50.50 ±15.55 years, t=5.277; p<0.0001). The average number of kilometers driven annually (in thousands of kilometers/year) by the 1,041 patients who provided this data (some patients had a license but did not drive) was of 14.83±26.23 thousand kilometers /year (Table 183).

93.9% of those interviewed (95.4% of the drivers and 88.5% of the non-drivers (X^2=18.76; p<0.05), knew that some medicines can influence fitness to drive (Table 184).

Table 183: Socio-demographic characteristics of the interviewed patients

		No Conductor	Conductor	Total	
Gender N (%)	**Male**	53 (18.5)	607 (55.3)	660 (47.7)	X^2=123.63; p<0.0001
	Female	234 (81.5)	491 (44.7)	725 (52.3)	
	Total	287 (100.0)	1098 (100.0)	1385 (100.0)	
Educational level N (%)	**Did not finish primary school**	38 (13.4)	49 (4.5)	87 (6.3)	X^2_4=100.75; p<0.0001
	Finished primary school	144 (50.9)	334 (30.4)	478 (34.6)	
	Finished secondary school	38 (13.4)	142 (12.9)	180 (13.0)	
	Completed "A" level (age 18)	35 (12.4)	260 (23.7)	295 (21.4)	
	University degree/diploma	28 (9.9)	312 (28.4)	340 (24.6)	
	Total				
Edad (Mean ± SD)		55.23 ± 17.61	47.27 ± 14.72	50.50 ± 15.55	t(1383)=5.277; p<0.0001
Thousand Km/año (Mean ± SD)			14.83 ± 26.23		

Table 184: Did you know that some medicines can influence fitness to drive?

	No conductor N (%)	**Conductor** N (%)	**Total** N (%)	**X^2; p**
Yes	254 (88.5)	1047 (95.4)	1301 (93.9)	18.76; p<0.0001
No	33 (11.5)	51 (4.6)	84 (6.1)	
Total	287 (100.0)	1098 (100.0)	1385	

3.2.2 ATTITUDES / AWARENESS

The interviewed patients were asked the following question: "Supposing you were prescribed this medicine which has the pictogram concerning driving on the packaging. How frequently would you drive during the period in which you were taking the medicine?" The question had 5 possible answers: the first answer would imply no change in attitude –"With the same frequency"- while the other four present a growing degree of change –"Less frequently"; "A lot less frequently"; "I would hardly drive at all" and "I would not drive at all". As can be seen in Table 185, only 14.6% of those interviewed would not reduce the frequency with which they drove (16.1% of drivers and 8.6% of non-drivers) but differences were observed between both, drivers being those who were the least likely to change their attitude (X^2_4=41.78; p<0.0001).

Table 185: Supposing you were prescribed this medicine which has the pictogram concerning driving on the packaging. How frequently would you drive during the period in which you were taking the medicine?

	Non-driver N (%)	**Driver** N (%)	**Total** N (%)	**X^2_4; p**
With the same frequency	24 (8.6)	172 (16.1)	196 (14.6)	
Less frequently	46 (16.4)	213 (20.0)	259 (19.2)	
A lot less frequently	23 (8.2)	157 (14.7)	180 (13.4)	41.78; p<0.0001
I would hardly drive at all	58 (20.7)	232 (21.7)	290 (21.5)	
I would not drive at all	129 (46.1)	293 (27.5)	422 (31.3)	
Total				

Those interviewed were asked: "What would you do if you were prescribed this medicine with a pictogram about driving on the packaging?" There were 5 possible answers i) I would drive without taking extra care; ii) I would not drive without first reading the package insert; iii) I would not drive without the advice of a doctor or a pharmacist and iv) I would not drive until my doctor indicated that it was safe to do so.

Most patients would take some kind of measure when faced with this situation (Table 186): 40.0% (43.2% of drivers and 28.0% of non-drivers) would not drive without having first read the package insert; 34.5% (29.8% of drivers and 52.5% of non-drivers) would not drive until their doctor told them it was safe to do so and 21.8% (23.1% of drivers and 17.0% of non-drivers) would not drive without the advice of a doctor or a pharmacist. That is, only 3.7% (4.0% of drivers and 2.5% of non-drivers) would ignore the pictogram and drive without taking extra care.

Table 186: What would you do if you were prescribed this medicine with a pictogram about driving on the packaging?

	Non-driver N (%)	**Driver** N (%)	**Total** N (%)	**X^2_3; p**
I would drive without taking extra care	7 (2.5)	43 (4.0)	50 (3.7)	
I would not drive without first reading the package insert	79 (28.0)	464 (43.2)	543 (40.0)	
I would not drive without the advice of a doctor or a pharmacist	48 (17.0)	248 (23.1)	296 (21.8)	51.38; p=0.0001
I would not drive until my doctor indicated that it was safe to do so	148 (52.5)	320 (29.8)	468 (34.5)	
Total				

It is the doctor whom most people would consult if they had to take a medicine with a pictogram about driving on the packaging (Table 187), followed by the pharmacist and finally the nursing staff. 89.5% would "probably" or "very probably" consult the doctor (75.5% of drivers and 82.0% of non-drivers), 76.2% would consult the pharmacist (88.0% of drivers and

95.4% of non-drivers) and 47.8% would consult nursing staff (48.4% of drivers and 45.3% of non-drivers).

Table 187: If you had to take a medicine with a pictogram about driving on the packaging, would you ask for advice about driving?

		No conductor N (%)	Conductor N (%)	Total N (%)	X^2_4; p
Pharmacist	**Very improbable**	6 (2.2)	95 (9.1)	101 (7.6)	24.88; p<0.0001
	Improbable	7 (2.5)	67 (6.4)	74 (5.6)	
	Neither probable nor improbable	37 (13.3)	95 (9.1)	132 (10.0)	
	Probably	127 (45.7)	438 (41.8)	565 (42.6)	
	Very probably	101 (36.3)	353 (33.7)	454 (34.2)	
	Total	278 (100.0)	1048 (100.0)	1326 (100.0)	
Nursing	**Very improbable**	13 (4.7)	102 (9.9)	115 (8.8)	17.04; p<0.005
	Improbable	28 (10.1)	119 (11.5)	147 (11.2)	
	Neither probable nor improbable	111 (39.9)	313 (30.2)	424 (32.3)	
	Probably	101 (36.3)	362 (35.0)	463 (35.3)	
	Very probably	25 (9.0)	139 (13.4)	164 (12.5)	
	Total	278 (100.0)	1035 (100.0)	1313 (100.0)	
Physician	**Very improbable**	2 (0.7)	43 (4.0)	45 (3.3)	29.40; p<0.0001
	Improbable	1 (0.4)	33 (3.1)	34 (2.5)	
	Neither probable nor improbable	10 (3.6)	53 (5.0)	63 (4.7)	
	Probably	44 (15.8)	256 (24.0)	300 (22.3)	
	Very probably	222 (79.6)	683 (64.0)	905 (67.2)	
	Total	279 (100.0)	1068 (100.0)	1347 (100.0)	

4 DISCUSSION

4.1 Study 1: implementation, evaluation and new technologies of practice guidelines and information materials for health professionals: physicians, pharmacists and nursing staff

4.1.1 Main study results

- **PRE-QUESTIONNAIRE**

The sociodemographic characteristics and the replies obtained in the first questionnaire (PRE) for the control, information and intervention groups showed a great homogeneity within each collective (physicians, pharmacists and nursing staff).

- **Training at university studies on medicines and driving, and sources of information on medicines and driving**

• Overall, the health professionals participating in the study referred to lack of training on medicines and driving, both in their university studies and after finishing their university degrees:

- Two out of every three health professionals participating in the study referred to not having received any type of formation concerning the effects of medicines on driving during their university studies. The pharmacists (51.4%) referred to having received formation in this topic twice as much as the physicians (27.5%).
- Seven out of every 10 of the health professionals referred to not having received formation on the effects of medicines on driving after finishing their university degrees.

• On the contrary, 2 out of every 3 health professional referred to having easy access to information concerning the effects of medicines on driving.

- **New technologies literacy, and user acceptance**

• On average, 3 out of every 4 participants in the study referred to using some kind of medical/clinical software package /program (in their daily activity). Of note, almost all the pharmacists (98.7%) use them, and less frequently physicians (65.2%) and nursing staff (58.3%).

• However, two out of every three health professionals (63.4%) referred to not using internet or any type of software and/or computer programme to obtain information about the effects of medicines on driving. Again, the pharmacists (59.2%) doubled the physicians (26.4%) in the percentage referring to using one or more of these means.

• Most health professionals (83%) would be willing to use a tool that would provide information concerning the effects of medication on driving

- **Attitudes/awareness**

In the current study the attitude/awareness of health professionals on medicines on driving was assessed through the agreement or disagreement on certain statements. A composite score was calculated based on the responses to 5 of the 6 statements.

- Overall, health professionals participating in the study showed a high positive attitude/awareness regarding medicines and driving:

    - Most health professionals (88.9%, 94.5% for physicians) are "willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines".
    - This is even more evident for those patients who are professional drivers (97.7%), are using CNS medicines (95.1%), those who drove frequently (93.1%), and are elderly drivers (92.3%).
    - Three out of every four health professionals would "agree" (70.6%) or "strongly agree" (6.2%), with changing the prescription/dispensation for another medicine that had less of an effect on fitness to drive vehicles (Table 11).
    - Furthermore, most health professionals (93.9%) referred to being well aware of the effects of medicines on driving skills.
    - Almost all of them (96.2%) also agreed that "It is important for me to be well-informed on medicinal effects on driving behaviour"

- However, we should underline that most health professionals (91.1%) have a negative attitude about the usefulness of information given to the patient regarding medicines and driving: they do not support the statement that the information they provide to patients will influence their driving behaviour.

- **Reported behaviour**

The reported behaviour of health professionals concerning medicines on driving was assessed through six questions-statements, and a composite score was calculated based on the responses to these questions.

- Overall, and contrary to attitude/awareness, health professionals participating in the study showed a low reported behaviour regarding medicines and driving as measured by the 6 questions used in the study. For example:

    - It is quite infrequent that health professionals ask their patients about driving exposure (km driven). More than half the physicians "always" (13.9%) or "almost always" (38.9%) asked their patients about frequency of driving when prescribing a medicine. Only 1 out of every 3 did so in the case of pharmacists, while scarcely 1 out of every 6 did so in the case of nursing staff.
    - It is even less frequent that health professionals make a note in the patient's clinical record regarding driving exposure (km driven)
    - or discuss legal issues on medicines and driving with the patient.

- However, 2 out of every three health professionals say that they inform (always + regularly) patients about the driving related risk of medicine prescribed.

- But, in only in 8 out of every 100 cases, do they keep a record of when they advise a patient about when and how he/she can consider driving a car when using a medicine that impairs driving.

- **Actual knowledge**

As in previous dimensions, the reported actual knowledge of health professionals concerning medicines on driving was assessed through six questions-statements, and a composite score was calculated based on the responses to questions 2-6, because the first question was different from those formulated in the other participating countries.

- The responses show a very low knowledge regarding medicines and driving as measured by the 6 questions used in the study. Another issue is whether or not the low knowledge could be attributed to the ambiguity of the questions (please see limitations, text below). As an example, to highlight that only 10.9% give the correct answer to the statement “Amitriptyline at the start of treatment is as impairing for driving as after 4 weeks of treatment”.

- **Relevance on medicines and driving in the daily practice**

- Health professionals give a high score to this issue (mean ± sd, 7.38 ± 2.06 points, on a maximum of 10).

- 55.8% of physicians and 42.3% of pharmacists have “frequently” or “very frequently” had cases in which the effect of medicines on driving was an important aspect at the time of selecting medication.

- **PRE/POST [SIX MONTHS LATER] DIFFERENCES**

Below are highlighted the changes (positive or negative) observed after the training course. The post questionnaire was fulfilled 6 month later than the pre-questionnaire.

- **Attitudes/awareness**

- There were hardly any changes in the section attitudes/awareness among health professionals after the 6 months of training on medicines and driving:

  - There were no statistically significant changes in the composite score (pre= 1515.03±1.75; post = 15.50±1.62, $p > 0.05$).

  - There was only one positive significant change for the entire sample and for the collective of pharmacists in the question "I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines" and significantly negative changes (for the entire sample and among the pharmacists) with respect to taking into account the fact of whether the patient is a professional driver and "using other CNS active drugs" (for the entire sample).

- **Reported behaviour**

- The study shows a "positive" change in the reported behaviour of health professionals after the training course on medicines and driving.

  - There was an increase in the composite score from 7.34±3.55 (pre) to 9.66±3.91 (post), $p < 0.005$.

  - There were several significant changes in the entire sample and among the collective of the physicians. All such changes were positive and point to an increase in the effort health professionals make, both to inform the patient about medicines and driving and to find out about the patient's driving habits and to note them down in the patient's file. The changes were observed in the questions: "I ask a patient about his/her driving exposure when choosing/dispensing a medicine"; "I provide a patient with written information materials when prescribing/dispensing a driving impairing medicine"; "I keep systematic records when I advise a patient when and how he/she can consider driving a car when using a driving impairing medicine" and "I keep a record of the patient's traffic participation".

- **Actual knowledge**

- The study shows a "positive" change in the actual knowledge of health professionals after the training course on medicines and driving.

  - There was an increase in the composite score from 1.53±1.11 (pre) to 2.40±1.05 (post), $p < 0.0001$. Worthy of mention is the fact that this "positive" change was observed among both physicians and pharmacists.

- In 4 out of the 5 statements an improvement in actual knowledge was observed (except in the question regarding diazepam, from which the higher frequency of correct responses was observed in the pre-questionnaire).

- **Relevance on medicines and driving in the daily practice**

- After the training course pharmacists, but not physicians, give higher scores to the importance given in their daily practice to medicines and driving.

- **Drop outs**

Of the 407 professionals included in the study, initially 183 answered the first questionnaire. Given the anonymous character of the questionnaires, it is not possible to establish whether there are differences between those who answered the questionnaire and those who finally did not participate.

The answers obtained for the second questionnaire (post) were few: of the 126 PRE questionnaires obtained from the information and intervention groups, correspondence was only found with the POST questionnaires in 38 cases (30.2%). However, using the replies from the PRE questionnaire, we were able to determine that there were no significant differences with respect to sociodemographic data (gender, age), mean number of years of professional experience or education received during or after the degree among those who answered the second questionnaire and the rest who did not answer.

- **Limitations of the study**

The following limitations must be borne in mind before taking into account the results of the Spanish trial.

Related to the questionnaire:

- The questionnaire used in the study was developed by the DRUID task 7.4. However, it is a non-validated questionnaire, and we are not sure what dimensions it is measuring in reality. However, as it is the first one developed in the field, there is no better option. Further studies are needed with this questionnaire to confirm the findings observed.

- There is the risk that some questions-statements are inadequately given. For example, those that measure actual knowledge. The low figures obtained in the pre-questionnaire brought up the issue of whether these are well formulated or whether they are too ambiguous.

- At least, during the Spanish trial a considerable number of health professionals started answering the questionnaire, but did not finish. Many stated that they did not like it (see methodology, study 1, section 1.8).

Related to drop-out:

- We have had a very high level of drop-outs. There are various possible reasons. Among them, we could highlight the fact that the questionnaires were anonymous. In many cases, we were not able to link pre and post-questionnaires. Questionnaires were anonymous due a question of ethic approval.

Not really an intervention group with an integrated tool:

- As explained in the methodology, in the introduction to the Spanish trial, section 7, we had no access to current software used for prescription and dispensing. Therefore, we did not use a “real” integrated-tool in this trial. A web page was therefore developed.

Some advantages of the study were that:

- The study included nursing staff
- Participation in the trial was not rewarded in any specific form (money, tickets, etc).
- The current training activities were done at primary health care centres following regular training activities for physicians and nurses, and these were granted the status of Continuous Training by the Health Authorities.

5 OVERAL CONCLUSIONS AND RECOMMENDATIONS

The number of professionals who responded to the Post-Questionnaire was small, higher in the group information on the intervention. In what follows, only the results where significant Pre/Post differences were found on applying the Wilcoxon test are shown. The questionnaire was sent by mail a postcard with a letter with a letter encouraging your answer. We do not know the reason why so few professionals responded to the post-questionnaire, it might be a very long time (6 months) that did reduce their interest by topic or lack of stimuli to respond.

There were hardly any changes in the section attitudes/awareness among health professionals after the 6 months of training on medicines and driving:

There was only one positive significant change for the entire sample in the question “I am willing to take into account the effects of medicines on driving skills when prescribing/dispensing medicines”. However, health professionals would only be willing to change the prescription for another drug with less effect on driving, when the patient was a professional driver or take other drugs that act on the CNS.

Across the sample and particularly among physicians, there has being a significant shift in favour of asking patients about their driving exposure when choosing/dispensing a medicine, and for a systematic record of the patient’s traffic participation and the advice offered a patient when and how he/she can consider driving a car when using a driving impairing medicine. Also increasingly the willingness for provide a patient with written information materials when prescribing/dispensing a driving impairing medicine. This significant changes point to an increase in the effort health professionals make both to inform the patient about medicines and driving and to inform him/herself about the patient’s involvement in driving and to leave a record of these aspects in the patient’s medical history.

For both the whole sample as well as for physicians and pharmacists separately, a significant positive change can be observed in the evolution in knowledge concerning the effects of some medicines on driving. As for as, the importance given in their daily practice to medicines and driving by health professionals.

A large majority of patients are aware that some drugs affect driving, also a significant proportion of them who have been prescribed a drug with a pictogram on the package would, decrease the frequency of driving, would not lead without having read the prospectus before. The physician is the health professional to consult when they first had to take a medication on driving with a pictogram on the package, followed by the pharmacist and nurse.

As for recommendations the authors believe that it is recommended that special attention will be paid in educating those subjects who might play an active role in traffic safety. With this respect, medical and pharmacy schools could develop targeted educational programs covering the issue of medication use and driving whereas police officers and driving instructors could be adequately trained on this topic in order to be able to transfer the message to potential patients who also participate in traffic.

It would be important for the whole group of health professionals of Spain, conducting training courses (similar to the DRUID Trining course) on prescribing /dispensing and advice on medicines and driving.

The categorization system could be seen as a tool to improve prescribing and dispensing procedures both at a national and European level, and, therefore, as a instrument to better inform and involve HCPs (Health Care Professionals). With this respect, it is important that

HCPs know the fundamentals of the categorization system, and, consequently, use it properly in order to fully inform their patients about the risks of driving under the influence of impairing medicines. Furthermore, HCPs should be able to distinguish between the four levels of impairment, and, therefore, if possible, choose the least impairing medication within the same therapeutic group. Moreover, this system should encourage HCPs to update their knowledge on medicines and driving in order to be prepared to answer questions that patients might have on this topic.

The training in DRUID categorization system should also be used as a tool to motivate health care professionals to provide patients with clear information, communicate to patients the risk associated with driving under the influence of medicines, and start HCP-patient discussion leading to both safer prescriptions and the patient's conscious decision whether to drive or not [1, 21].

From the patient point of view, this classification could play an active role in helping them to be involved along the decision-making process, to understand the hazards of some medications to traffic safety, and to remind them to use caution while driving until their individual responses to the therapy have been well established.

Finally, a guideline should be developed to explain the use of the categorization system to HCPs and to serve as a support in the decision making process. On the other hand, since the patient package leaflet is the most accessible source of information for patients, it would also be advisable to develop an effective strategy to communicate the risk related to the use of medicines and driving. For instances, a straightforward grading system could be included in the patient package leaflet and the use of pictograms (warning labels) could be printed on the medication box to provide clear directions for patients.

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ANNEX I: Brochure "Medicines and driving: The prescription of medicines to patient who drive"

MEDICINES AND DRIVING:

THE PRESCIPTION OF MEDICINES TO PATIENTS WHO DRIVE

"Medicines may have side-effects or adverse reactions that influence safe driving and handling dangerous machinery, so the full society should work in collaboration with the aim that healthcare professionals and patients will take this fact into account when medicines are being prescribed, dispensed to or consumed by drivers"

This is one of the main conclusions of the informative workshop "Medicines and their Effect on Driving: New warning pictogram on medicines" organised by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) [Spanish Agency of Medicines and Healthcare Products (AEMPS)] in the Ministerio de Sanidad y Política Social [Ministry of Health and Social Policy] on June 8th 2009. http://www.aemps.es/actividad/actCongresos/2009/jor_conduMedica_junio09.htm

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CONTENTS

INTRODUCTION

The prescription of medicines is a common fact in clinical practice. On the other hand, the implications of the medication, both in the occurrence of road traffic accidents and their prevention, are aspects that have attracted growing interest. An important percentage of the driving population has a chronic consumption of medicines and although this medicines consumption is not the main factor in the occurrence of road traffic accidents, it is becoming ever more important.

Even though there are safer and more effective medicines coming onto the market, some of them do have adverse effects on the psychomotor performance which can affect fitness to drive safely.

Thus, one aspect to be taken into consideration when prescribing and dispensing a medicine is its possible influence on fitness to drive.

A categorization of medicines on driving in four levels has recently been accepted that depends on their possible effects on fitness to drive safely. This classification has been proposed following the research carried out as part of the European project DRUID (DRiving Under the Influence of Drugs, Alcohol and Medicines).

DRUID (http://www.druid-project.eu) is an ambitious project financed by the European Union within the Sixth Framework Programme, whose aim is to reach a deeper understanding of the effects that driving under the influence of alcohol, drugs and medicines may have on road safety. These data will be extremely valuable when considering the different possibilities for preventive interventions and coordinating any activities within the framework of the different countries.

THE PICTOGRAM ON MEDICINES AND DRIVING IN SPAIN

The Royal Decree 1345/2007 regulating the procedure for authorizing, registering and dispensing industrially manufactured medicines for human use was published in November 2007. This Decree establishes that newly authorized medicines which may negatively affect fitness to drive, or the ability to handle dangerous machinery, must include a warning symbol (or Pictogram) on the packaging. It also establishes a maximum period of five years for adapting the labelling and the package insert of medicines that had already been authorized before the Decree became law (Law 29/2006, of July 26th). Therefore, in 2011, all medicines that may negatively affect fitness to drive safely being sold commercially in Spain must include the Pictogram on the packaging.

The said symbol must have the following characteristics:

- A red equilateral triangle with the vertex in the upper part on a white background and a black car inside the red triangle, in the manner of a road traffic sign, and the legend below it which reads: *"Driving: See package insert".*
- The size of the Pictogram should be adapted to the size of the package, but in no case should each side of the triangle be inferior to ten millimetres.

The aim of the pictogram or symbol is to attract the user's attention so that he/she will read the corresponding patient information leaflet or package insert. The package inserts of medicines already contain a warning about the effects it may have on those who drive or use machinery (section driving and using machines).

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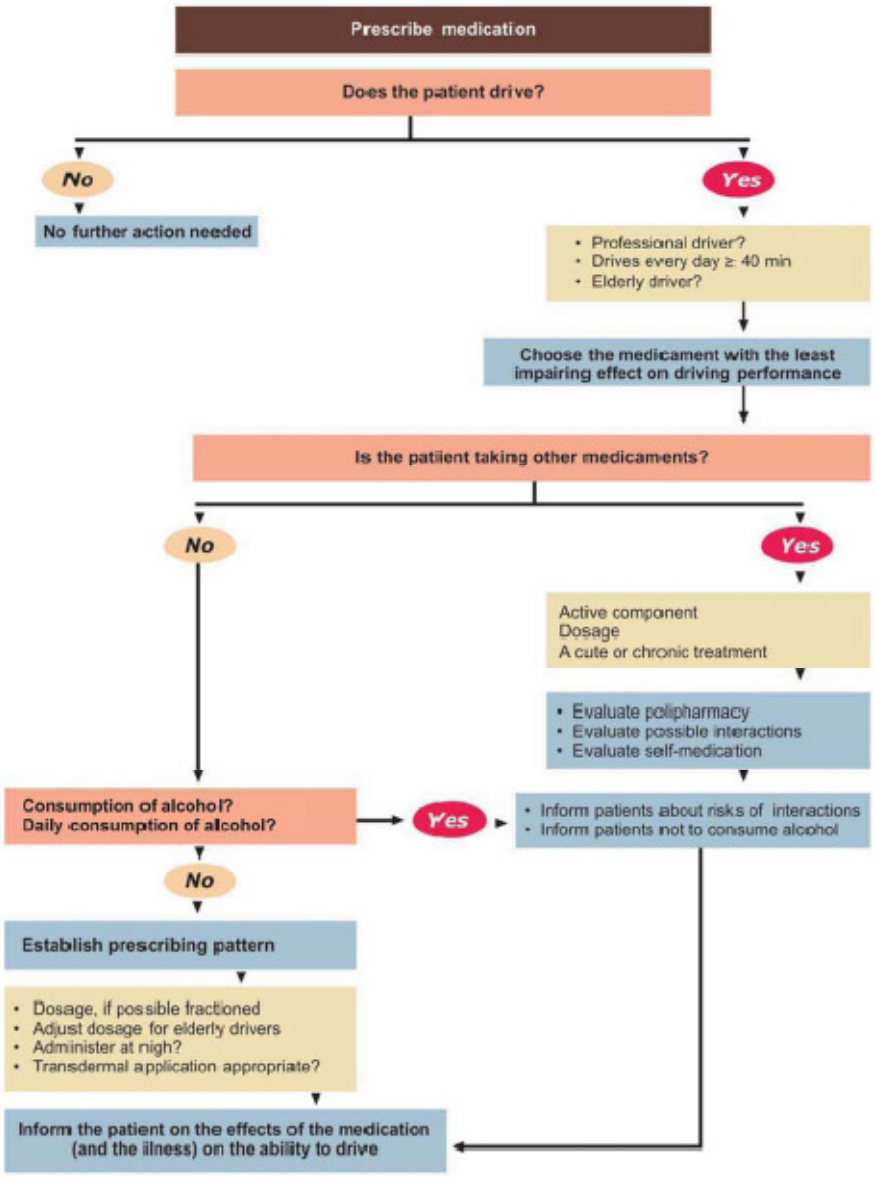
PRINCIPLES OF PRESCRIBING MEDICINES TO PATIENTS WHO DRIVE

Six steps are proposed for facilitating the adequate prescribing and dispensing of medicines to patients who drive: Figure 1 shows a decision tree for prescribing medicines to patients who drive.

Figure 1. Steeps in the prescription of medicines to the driver patient



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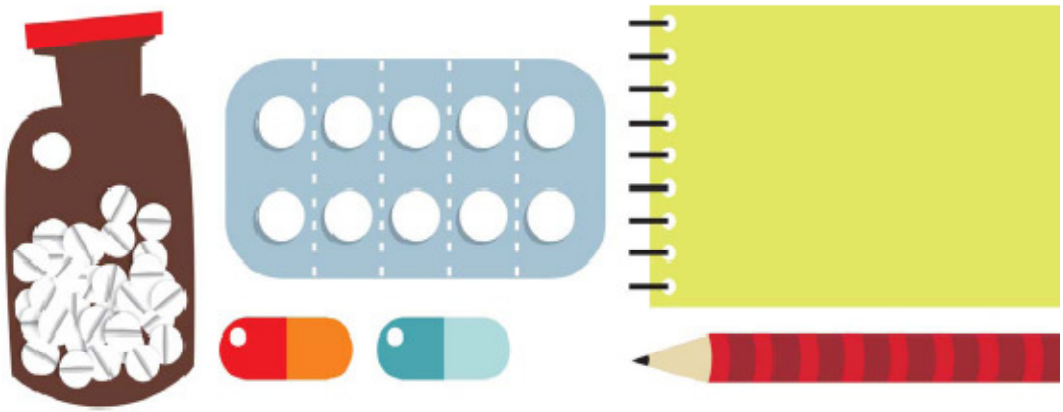
STEP 1. AN ADEQUATE CLINICAL HISTORY. IS THE PATIENT A DRIVER?

Health professionals should ask the patients about the types of activities they carry out during their daily lives. Special attention should be paid to those activities that require an adequate state of alertness and of the psychomotor performance, such as driving a motor vehicle. Different factors, such as the presence of certain pathologies, the consumption of medicines or alcohol, etc., can negatively affect a driver's psychomotor performance and consequently increase the probability of being involved in a road traffic accident.

Since the majority of the adult population has a driving licence and, in general, there is very little time in which to make the patient's clinical history, special attention should at least be paid to the following segments of society:

- Those who are professional drivers.
- Those who drive practically every day for at least 40-45 minutes.
- Senior citizens who habitually drive.



STEP 2. INFORMATION GATHERING ON MEDICINES CONSUMPTION PATTERNS AND THEIR EVALUATION.

One primordial aspect is to gather detailed information concerning drivers' medicines consumption patterns.

Every patient should be asked about their driving habits and whether they are taking any medicines on either a temporary basis or a long term basis at the time of visiting the doctor's surgery. Information should be obtained concerning each of the medicines being taken, the number and timing of doses and how long the treatment is to last. Special attention should be paid to the question of self-medication.

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This will provide us with the following information concerning the patient in general or the driver in particular:

- Whether he/she consumes only one or more medicines (polypharmacy).
- Whether the treatment, or treatments, is/are acute or chronic.
- Whether there is self-medication and who is controlling the prescription of the medication (doctor or pharmacist).

If the clinical history has gathered information concerning the pattern of alcohol consumption, then the following can also be evaluated:

- The possibility of interaction between the medicine(s) being taken by the patient and the alcohol. Should this be the case, adequately inform the patient/driver.

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STEP 3. SELECT THE MEDICINE THAT LEAST AFFECTS FITNESS TO DRIVE:

Once the diagnosis has been made, and assuming that a pharmacological treatment is necessary, the medicine that least affects fitness to drive should always be chosen if at all possible. Alternative therapeutic treatments should always be considered.

Information for physicians and pharmacists – Categories	Category 0	Category 1
	Presumed to be safe or unlikely to produce an effect on fitness to drive.	Likely to produce **minor** adverse effects on fitness to drive.
Information on how to advise their patients	- Confirm that the medicine will be safe for driving, provided that combinations with alcohol and other psychotropic medicines are excluded.	- Inform the patient that impairing side effects may occur especially during the first days and that they have a negative influence on his/her driving ability. - Give the patient the advice not to drive if these side effects occur.
Warning for patients	[no warning needed]	**Warning level 1** Do not drive without having read the relevant section on driving impairment in the package insert.

DRUID CATEGORIZATION OF MEDICINES ACCORDING TO THEIR EFFECT ON FITNESS TO DRIVE.

In this sense, the DRUID categorization of medicines on driving into four levels is useful for the health professional as it helps in the choice of an adequate medication, as well as to decide on the type of information the patient should be given.

Category 2	Category 3
Likely to produce **moderate** adverse effect on fitness to drive.	Likely to produce **severe** effects on fitness to drive or presumed to be potentially dangerous.
- Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. - Advise the patient not to drive during the first few days of the treatment. - If possible prescribe a safer medicine, if effective and acceptable by the patient.	- Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. - Urgently advise the patient not to drive. - Consider prescribing a safer medicine, if acceptable by the patient.
Warning level 2 Do not drive without advice of a health care professional. Read the relevant sections on driving impairment in the package insert before consulting the physician or pharmacist	**Warning level 3** Do not drive. Seek medical advice after a period of treatment about the conditions to restart driving again.
0 1 2 3	0 1 2 3
Pictograms	

** The assigned categories relate to the acute or first time use of the medicine (at the start of treatment)*

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STEP 4. EVALUATE THE FACTORS THAT INFLUENCE THE EFFECT A MEDICINE CAN HAVE ON FITNESS TO DRIVE.

When a medicine is prescribed for a driver, in addition to choosing the treatment that will have the least possible effect on the psychomotor performance, there are other factors that must be taken into account. The possibility that the patient is already taking other medicines, or that some of his/her habits, such as the consumption of tobacco and/or alcohol, should be taken into account as these factors may influence the final effect of the medicine(s) on fitness to drive. Therefore, the following points (see STEP 2) should be considered:

- The appearance of adverse effects and each patient's sensitivity to the medication (for example, drowsiness). Table 1 shows the possible adverse effects of the medicines which can interfere with the fitness to drive safely.
- The possible interaction between the prescribed medication and the medicines the patient was already taking.
- If the patient self-medicates, any possible interaction between the medicines being taken and the new prescribed medication.
- The taking of the medication at the same time as alcohol is consumed and the possible increase in the sedative effect of the medication.

Table 1. Undesirable effects or adverse effects to be considered in relation to driving (and using machines)

System organ class	Selection of undesirable effects that can impair the ability to drive safely
Nervous system disorders	▪ Somnolence, dizziness, drowsiness ▪ Confusion - cognitive disorder- disorientation ▪ Involuntary movement disorders: ataxia, tremor, Parkinsonism, acute dystonic (dyskinesia) and dyskinetic reactions (dystonia) ▪ Convulsions -seizures
Psychiatric disorders	▪ Perception disturbances (hallucination, visual hallucination, auditory hallucination, illusion) ▪ Psychotic reactions and psychotic disorder (including paranoia psychosis) ▪ Other: Emotional lability, mood swings, aggression, nervousness, irritability, personality disorders, thinking abnormal, abnormal behaviour, euphoric mood, restlessness (emotional state of excitement), depersonalisation
Eye disorders	▪ Diplopia or double vision, ▪ Blurred vision ▪ Accommodation disorders ▪ Visual acuity reduced ▪ Photophobia ▪ Other: visual field defect, peripheral vision loss, altered visual depth perception, oculogyric crisis.
Ear and Labyrinth disorders	▪ Vertigo ▪ Hearing loss ▪ Other: buzzing, tinnitus
Metabolism and nutrition disorders	▪ Hypoglycaemia

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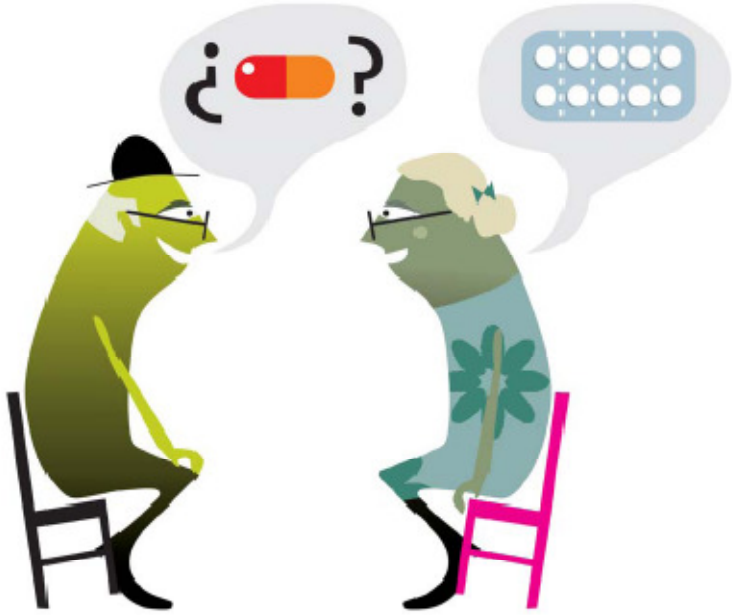
STEP 5. CHOOSE THE MOST ADEQUATE PRESCRIPTION PATTERN.

The possibility of using a prescription pattern that minimises the adverse effects of medication on fitness to drive should always be considered. For instance:

- The use of nocturnal doses so that the most intense sedative effects will occur during sleep.
- The use of a fractioned dosage spread out over the day: The administration of smaller doses each time may result in a lower frequency and intensity of any adverse effects.
- The use of preparations taken topically (through the nose or the eye or transdermal application, for instance), instead of orally, may diminish the appearance of some adverse effects on fitness to drive (for example, the sedative effect).
- Particular attention should also be paid to the dosage in certain groups within the population, for instance, elderly people.



STEP 6. INFORMATION FOR THE PATIENTS AND THEIR FAMILIES.

Healthcare personnel should inform the patients of the effects that both the illness itself and the prescribed treatment may have on their fitness to drive a vehicle safely.

The patients and their families should also be informed of the warning signs of a possible deterioration in fitness to drive (the appearance of blurred vision, difficulties to remain alert, and problems with maintaining a straight line, among others).

Patients should be given some recommendations so that, once they have left the doctor's surgery, they will be aware of their responsibility and the risk that they may incur by driving under the effects of some medicines.

Key points for the patient:

- Consult the doctor or pharmacist about whether the medication you are taking might affect your fitness to drive.
- Before starting the treatment, read the paragraph concerning driving and use machines in the package insert.
- Avoid driving during the first few days when taking a new medication or when the dosage has been modified.
- Follow the doctor's or the pharmacist's instructions as far as dosage and timetable are concerned.
- Take note of any effect the medication may have when you take it: Do you feel sleepy or weak, or do you have blurred vision?
- If the medication you are taking affects your fitness to drive, stop driving and consult your doctor or pharmacist. Do not stop taking the medication without first consulting your doctor or pharmacist.
- Do not drink alcohol when taking medication. The best option is not to drink alcohol at all.

15

TEN QUESTIONS AND ANSWERS CONCERNING MEDICINES, THEIR EFFECTS ON PSYCHOMOTOR PERFORMANCE AND TRAFFIC ACCIDENTS

1. DO SPANISH DRIVERS CONSUME MANY MEDICINES?

According to the National Health Survey of 2003, over half the population (54.6%) had taken some medication in the two weeks prior to the survey. It is, therefore, reasonable to assume that a great percentage of drivers are also taking medicines. According to a study begun in 2002 (IMMORTAL Project; http://www.immortal.or.at), 34.1% of drivers in Spain take some kind of medication; of which 22.8% are chronic (for more than a month). There were 5,234 participants in this study, all of whom attended Driver Medical Test Centres to obtain or renew a driving licence.

2. IS DRIVING UNDER THE EFFECTS OF MEDICINES FREQUENT?: THE PRESENCE OF MEDICINES IN THOSE INJURED AND KILLED IN TRAFFIC ACCIDENTS IN SPAIN.

In 2008, psychotropic medicines were found in 12.6% of drivers killed in road traffic accidents in Spain. This does not necessarily mean that the medicine was to blame for the accident; in fact, it must be pointed out that in more than half the cases (55%) in which medicines were detected, the driver was also under the effects of alcohol and/or illicit drugs, which notably increases the risk of being involved in a road traffic accident.

3. IS THERE A GREATER RISK OF TRAFFIC ACCIDENTS AMONG DRIVERS TAKING MEDICINES?

One aspect in which interest is growing is to discover whether driving under the influence of medicines can be associated with a greater risk of being involved in a road traffic accident.

The majority of studies published focus on benzodiazepines, and there is much less information available concerning other groups of medicines. Table 2 (below) shows the relative risk of being involved in a road traffic accident due to the consumption of some benzodiazepines or hypnotics, as well as the levels of alcohol in blood associated with a similar risk. The risk is greater during the first two weeks of treatment.

Table 2. Relative risks of injurious road traffic accidents associated with the use of particular hypnotic and anxiolytic drugs and comparable blood alcohol concentrations.

Medicine	Relative Risk	Comparable to Blood Alcoohol Concentration (%)
Diazepam	3.1	0.075
Flurazepam	5.1	0.095
Lorazepam	2.4	0.070
Oxazepam	1.0	0.050
Triazolam	3.2	0.075
Zopiclona	4.0	0.080

Taken from: Álvarez FJ, De Gier JJ, Chistophersen AS, Del Río MC, Donelson AC, Karlovsek MZ, Maes VA, Morland J, Mercier-Guyon Ch, Ogden EJD, O'Hanlon JF, Verstraete AG, Walsh JM. Prescribing and dispensing guidelines for medicinal drugs affecting driving performance. Utrecht: International Council on Alcohol, Drugs and Traffic Safety, 2001.
http://raru.adelaide.edu.au/icadts/reports/ICADTSpresguiderpt.pdf

4. HOW ARE THE EFFECTS OF MEDICINES ON THE PSYCHOMOTOR PERFORMANCE EVALUATED?

The negative effects of medicines on the psychomotor performance can be analysed using several different laboratory tests (or batteries of tests), by means of electro-physiological techniques and carrying out studies in driving simulators as well as studies of real driving.

5. EUROPEAN UNION REGULATIONS ON THE EFFECTS OF MEDICATION ON DRIVING. WHERE CAN INFORMATION BE FOUND ON MEDICINES AND FITNESS TO DRIVE?

The Summary of Product Characteristics (SmPC) and the Package Inserts of all medicines include a paragraph concerning medication and driving (SmPC section 4.7 "Effects on ability to drive and use machines" and package leaflet: "driving and using machines".

6. PICTOGRAMS ON THE EFFECT OF MEDICINES ON DRIVING.

Current legislation permits the inclusion of some symbols or pictograms on the outside of the packaging -outer packaging carton box- (Directive 92/27/EEC, updated in the Directive 2001/83/EEC).

From the year 2007 onwards in Spain (Royal Decree 1345/2007), all newly authorised medicines that may adversely affect fitness to drive or handle dangerous machinery must display a warning symbol (pictogram) on the outside of the packaging. Those medicines which were already authorised have had to adapt to the ruling little by little. In 2011, all medicines that may adversely affect fitness to drive or handle dangerous machinery must include the pictogram on the packaging.

7. DO ALL MEDICINES AFFECT FITNESS TO DRIVE SAFELY?

In some countries, including Spain, there are more than 13,000 authorised medicines available, yet only some of them have a clearly negative effect on fitness to drive. Nevertheless, the possible appearance of interactions due to the joint consumption of various medicines, or the consumption of medicines together with alcohol, as well as each patient's individual susceptibility, all mean that close attention should be given to the possible effects of any medication on fitness to drive, whatever the case.

8. WHAT IS THE EFFECT OF MEDICINES? CATEGORIZATION OF MEDICINES WITH RESPECT TO DRIVING.

With the aim of improving the information available to both healthcare professionals and patients, in addition to including an epigraph in the Summary of Product Characteristics and the Package leaflet of authorised medicines in the European Union, there was, some years ago, a proposal to categorize medicines with respect to their effect on fitness to drive.

The categorization proposed in the European project DRUID (DRiving under the Influence of Drugs, Alcohol and Medicines) has recently been accepted. According to this categorization, medicines are classified according to their possible effects on fitness to drive (see pages 8-9, Druid Categorization).

9. WHAT HAS THE GREATEST INFLUENCE ON DRIVING, ILLNESS OR MEDICINES?

Most medicines are prescribed for drivers with one or several pathologies, some of which might, of themselves, have a negative effect on fitness to drive safely. The medical treatment prescribed to stabilise or improve the patient's clinical situation, in certain cases, might also improve fitness to drive. In this sense, when the patient is under treatment, his/her fitness to drive safely may also be improved. However, the fact that some medicines, due to their adverse effects, may negatively affect the psychomotor performance and fitness to drive must also be taken into account.

The relationship between illness, pharmacological treatment and driving is complex and it is the responsibility of the healthcare personnel to evaluate the risk/benefit at the time of prescribing medication for a driver. It is the healthcare personnel who has the best information, both about the patient and the medication, to know, as far as is possible, how the medicines can affect the fitness to drive of any particular patient. The risk/benefit should always be evaluated through a joint consideration of the illness/medication.

10. IS MEDICINES AN IMPORTANT FACTOR WHEN EVALUATING FITNESS TO DRIVE?

In Spain, the evaluation of fitness to drive is carried out in Driver Medical Test Centres. A doctor, an ophthalmologist and a psychologist all participate in this evaluation. It is currently quite rare for a Driver Medical Test Centre to give a negative evaluation ("fit with restrictions", "interrupted" or "unfit") due to the habitual or chronic consumption of medicines. The cases in which a licence is restricted or denied are conditioned by the binomial illness/medication.

"Medicines that affect fitness to drive or the use of machines must display a symbol, or pictogram, warning drivers and patients in general, to read the package leaflet carefully in order to take all necessary precautions at the wheel"

(Royal Decree 1345/2007 of October 11th)

9 788461 441518

Con la financiación de

ANNEX II: Health professional questionnaire (Study 1 PRE)

MEDICAMENTOS Y CONDUCCIÓN

EU Proyecto DRUID

DRiving Under the Influence of alcohol, Drugs and medicines

Este estudio forma parte del proyecto europeo DRUID. Este proyecto se centra específicamente en el impacto que puede tener el consumo de alcohol, drogas y medicamentos sobre la seguridad en la conducción.

Nos sería de gran utilidad conocer su opinión a cerca de los medicamentos y la conducción en relación a su práctica diaria.

Por favor, lea con atención cada una de las preguntas y marque la casilla ☑ para indicar su respuesta. En la mayoría de los casos sólo deberá marcar una casilla pero en algún caso podrá marcar más de una respuesta.

Todas sus respuestas serán tratadas de forma anónima y solamente serán utilizadas con fines de investigación. El presente estudio ha sido aprobado por el Comité Ético de Investigación Clínica de la Facultad de Medicina, Universidad de Valladolid.

Muchas gracias por su participación,

Con la financiación de:

Si tuviera cualquier duda sobre el cuestionario no dude en contactar con F. Javier Álvarez en el Área de Farmacología (Facultad de Medicina. C/ Ramón y Cajal, 7. 47005 Valladolid; Tel. 983 423077).

1

☐ **Médico** ☐ **Farmacéutico** Fecha: (DD/MM/AA):___/___/_____

Sexo ☐ Varón ☐ Mujer **Fecha de nacimiento** (DD/MM/AA):___/___/_____

Tamaño de la ciudad / población donde trabaja:

☐ >500.000 habitantes ☐ 100.000-500.000 habitantes ☐ 20.000-99999 habitantes
☐ 5000-19999 habitantes ☐ 2000-4999 habitantes ☐ < 2000 habitantes

Año de graduación en la Facultad (AAAA): _____

Cuántos años completos lleva practicando su profesión/especialidad actual _____

¿Ha recibido algún tipo de formación sobre cómo afectan los fármacos a la capacidad para conducir?

Durante la carrera
☐ Si ☐ No
↓↓
↓↓
Que tipo de formación:

Posteriormente a la graduación en la universidad
☐ Si ☐ No
↓↓
↓↓
Que tipo de formación:

¿Utiliza actualmente algún tipo de software o programa informático relacionado con el desarrollo de su profesión (medicina/farmacia)?

☐ Si ☐ No
↓↓
↓↓
por favor, **especifique** el tipo de **software** y/o **programas** que utiliza: ----------
---

¿Utiliza internet o algún tipo de software o programa informático para obtener información a cerca del efecto de los medicamentos sobre la capacidad de conducir?

☐ Si ☐ No
↓↓
↓↓
por favor, **especifique** el tipo de **software** y/o programa que **utiliza**: ----------
---

Tiene fácil acceso a la información y datos existentes acerca de los efectos de los medicamentos sobre la capacidad para conducir.

☐ Si ☐ No
↓↓
↓↓
Cual o cuales han sido dichas fuentes de información:

Páginas web para profesionales	☐	Revistas científicas	☐
Boletines informativos	☐	A través de Organizaciones profesionales	☐
Otras: precise su respuesta: _____			

Si le propusiéramos una herramienta (por ejemplo, una página web o un CD/DVD) que le permitiera encontrar información sobre medicamentos y conducción, ¿estaría usted dispuesto a utilizarla cuándo prescribiera/dispensara un medicamento?

☐ Si ☐ No ☐ Quizá

¿Cual es el motivo principal por el que no le interesaría la herramienta?

2

¿Qué grado de acuerdo o desacuerdo le merecen las siguientes afirmaciones?

	Totalmente en desacuerdo	En desacuerdo	De acuerdo	Totalmente en desacuerdo
Tengo en cuenta los efectos de los medicamentos sobre la capacidad de conducción cuando prescribo/dispenso medicamentos.	☐	☐	☐	☐
Estaría dispuesto a prescribir/dispensar un medicamento con menor interferencia sobre la capacidad de conducción aunque la efectividad sea algo menor.	☐	☐	☐	☐
Soy consciente de los efectos de los medicamentos sobre la capacidad de conducir.	☐	☐	☐	☐
Para mi es importante estar bien informado a cerca del efecto de los medicamentos sobre la capacidad de conducir.	☐	☐	☐	☐
Creo que la información que puedo proporcionar a mis pacientes influirá en su comportamiento a la hora de conducir.	☐	☐	☐	☐

En mi actividad profesional diaria.....

	Siempre	Casi siempre	A veces	Casi nunca	Nunca
Pregunto al paciente sobre su frecuencia de conducción cuando selecciono /dispenso un medicamento.	☐	☐	☐	☐	☐
Anoto sistemáticamente en la historia clínica – registro del paciente – su frecuencia de conducción.	☐	☐	☐	☐	☐
Informo al paciente sobre los efectos para la conducción cuando le receto/dispenso un medicamento con posibles efectos negativos sobre la capacidad de conducir.	☐	☐	☐	☐	☐
Proporciono información impresa al paciente cuando prescribo/dispenso un medicamento que pudiera afectar a la capacidad de conducir.	☐	☐	☐	☐	☐
Anoto sistemáticamente en la historia clínica – registro del paciente – que informo al paciente cuando prescribo/dispenso un medicamento que pudiera afectar a la capacidad de conducir.	☐	☐	☐	☐	☐
Analizo con el paciente la responsabilidad derivada del consumo de medicamentos y la conducción de vehículos.	☐	☐	☐	☐	☐

3

Tendría más en cuenta el efecto de los medicamentos sobre la capacidad de conducción cuando prescribe/dispensa medicamentos, si su paciente…..

	Si	No		Si	No
Es un conductor profesional	☐	☐	Es un conductor novel (menos de dos años)?	☐	☐
Conduce frecuentemente	☐	☐	Es un conductor experimentado	☐	☐
Conduce largas distancias	☐	☐	Es un conductor mayor	☐	☐
	☐	☐	Toma otras sustancias con efectos sobre el SNC?	☐	☐

¿Qué grado de acuerdo o desacuerdo le merecen las siguientes afirmaciones?

	Totalmente en desacuerdo	En desacuerdo	De acuerdo	Totalmente de acuerdo	NS/NC
Lormetazepam (1mg) (Noctamid®, Lorametm®) produce un deterioro importante de la capacidad de conducir durante las primeras 8 horas después de su ingesta.	☐	☐	☐	☐	☐
Diazepam (a cualquier dosis) (Valium®) produce un deterioro importante de la capacidad de conducir durante los primeros dos meses de tratamiento.	☐	☐	☐	☐	☐
Codeína (hasta 20 mg)(Codeisan®) es generalmente segura para los conductores.	☐	☐	☐	☐	☐
Fexofenadina (a dosis normales)(Telfast®) produce un deterioro importante de la capacidad de conducir.	☐	☐	☐	☐	☐
Amitriptilina (Tryptizol®) produce un deterioro de la capacidad de conducir durante las 4 primeras semanas de tratamiento.	☐	☐	☐	☐	☐
Paroxetina (hasta 20 mg/día)(Seroxat®) es segura para los conductores.	☐	☐	☐	☐	☐

¿En cual de las siguientes situaciones informaría al paciente de que la medicación podría afectar a la capacidad de conducción?

	Si	No		Si	No		Si	No		Si	No
difenhidramina	☐	☐	risperidona	☐	☐	buprenorfina	☐	☐	salmeterol	☐	☐
desloratadina	☐	☐	flunitrazepam	☐	☐	paracetamol	☐	☐	insulina	☐	☐
sumatriptan	☐	☐	zoplicona	☐	☐	atenolol	☐	☐	rosiglitazona	☐	☐
primidona	☐	☐	venlafaxina	☐	☐	enalapril	☐	☐	ondasetron	☐	☐

En su práctica diaria que importancia daría el tema de los medicamentos y conducción de vehículos (de 1 a 10, siendo 10 la máxima): _____

En su práctica diaria durante el último año con qué frecuencia se ha encontrado con casos en los que el efecto de la medicación sobre la conducción de vehículos ha sido un aspecto importante a la hora de la selección del medicamento

Muy frecuentemente (al menos algún caso cada día de consulta)	☐	Frecuentemente (al menos algún caso cada 2 o 3 días de consulta)	☐	Raramente (al menos algún caso en toda la semana de consulta)	☐	Muy raramente (menos de un caso en toda la semana de consulta)	☐

4

ANNEX III: Health professional questionnaire (Study 1 POST)

MEDICAMENTOS Y CONDUCCIÓN

EU Proyecto DRUID

DRiving Under the Influence of alcohol, Drugs and medicines

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Nos sería de gran utilidad conocer su opinión acerca de los medicamentos y la conducción en relación a su práctica diaria.

Por favor, lea con atención cada una de las preguntas y marque la casilla ☑ para indicar su respuesta. En la mayoría de los casos sólo deberá marcar una casilla pero en algún caso podrá marcar más de una respuesta.

Todas sus respuestas serán tratadas de forma anónima y solamente serán utilizadas con fines de investigación. El presente estudio ha sido aprobado por el Comité Ético de Investigación Clínica de la Facultad de Medicina, Universidad de Valladolid.

Muchas gracias por su participación,

Con la financiación de:

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1

☐ **Médico** ☐ **Farmacéutico** Fecha: (DD/MM/AA):___/___/_____

Sexo ☐ Varón ☐ Mujer **Fecha de nacimiento** (DD/MM/AA):___/___/_____

Año de graduación en la Facultad (AAAA): _____

Cuántos años completos lleva practicando su profesión/especialidad actual _____

Por favor tenga en cuenta su experiencia los últimos 6 meses para completar este cuestionario

Tendría más en cuenta el efecto de los medicamentos sobre la capacidad de conducción cuando prescribe/dispensa medicamentos, si su paciente…..

	Si	No		Si	No
Es un conductor profesional	☐	☐	Es un conductor novel (menos de dos años)?	☐	☐
Conduce frecuentemente	☐	☐	Es un conductor experimentado	☐	☐
Conduce largas distancias	☐	☐	Es un conductor mayor	☐	☐
	☐	☐	Toma otras sustancias con efectos sobre el SNC?	☐	☐

¿Qué grado de acuerdo o desacuerdo le merecen las siguientes afirmaciones?

	Totalmente en desacuerdo	En desacuerdo	De acuerdo	Totalmente en desacuerdo
Tengo en cuenta los efectos de los medicamentos sobre la capacidad de conducción cuando prescribo/dispenso medicamentos.	☐	☐	☐	☐
Estaría dispuesto a prescribir/dispensar un medicamento con menor interferencia sobre la capacidad de conducción aunque la efectividad sea algo menor.	☐	☐	☐	☐
Soy consciente de los efectos de los medicamentos sobre la capacidad de conducir.	☐	☐	☐	☐
Para mi es importante estar bien informado acerca del efecto de los medicamentos sobre la capacidad de conducir.	☐	☐	☐	☐
Creo que la información que puedo proporcionar a mis pacientes influirá en su comportamiento a la hora de conducir.	☐	☐	☐	☐

2

En mi actividad profesional diaria durante los últimos 6 meses.....

	Siempre	Casi siempre	A veces	Casi nunca	Nunca
Pregunto al paciente sobre su frecuencia de conducción cuando selecciono /dispenso un medicamento.	☐	☐	☐	☐	☐
Anoto sistemáticamente en la historia clínica – registro del paciente – su frecuencia de conducción.	☐	☐	☐	☐	☐
Informo al paciente sobre los efectos para la conducción cuando le receto/dispenso un medicamento con posibles efectos negativos sobre la capacidad de conducir.	☐	☐	☐	☐	☐
Proporciono información impresa al paciente cuando prescribo/dispenso un medicamento que pudiera afectar a la capacidad de conducir.	☐	☐	☐	☐	☐
Anoto sistemáticamente en la historia clínica – registro del paciente – que informo al paciente cuando prescribo/dispenso un medicamento que pudiera afectar a la capacidad de conducir.	☐	☐	☐	☐	☐
Analizo con el paciente la responsabilidad derivada del consumo de medicamentos y la conducción de vehículos.	☐	☐	☐	☐	☐

¿Qué grado de acuerdo o desacuerdo le merecen las siguientes afirmaciones?

	Totalmente en desacuerdo	En desacuerdo	De acuerdo	Totalmente de acuerdo	NS/NC
Lormetazepam (1mg) (Noctamid®, Loramet®) produce un deterioro importante de la capacidad de conducir durante las primeras 8 horas después de su ingesta.	☐	☐	☐	☐	☐
Diazepam (a cualquier dosis) (Valium®) produce un deterioro importante de la capacidad de conducir durante los primeros dos meses de tratamiento.	☐	☐	☐	☐	☐
Codeína (hasta 20 mg)(Codeisan®) es generalmente segura para los conductores.	☐	☐	☐	☐	☐
Fexofenadina (a dosis normales)(Telfast®) produce un deterioro importante de la capacidad de conducir.	☐	☐	☐	☐	☐
Amitriptilina (Tryptizol®) produce el mismo deterioro de la capacidad de conducir al inicio del tratamiento que después de 4 semanas de tratamiento.	☐	☐	☐	☐	☐
Paroxetina (hasta 20 mg/día) (Seroxat®) es segura para los conductores.	☐	☐	☐	☐	☐

3

En su práctica diaria, durante los últimos 6 meses, que importancia ha dado al tema de los medicamentos y la conducción de vehículos (de 1 a 10, siendo 10 la máxima): _____

En su práctica diaria durante el último año con qué frecuencia se ha encontrado con casos en los que el efecto de la medicación sobre la conducción de vehículos ha sido un aspecto importante a la hora de la selección del medicamento

Muy frecuentemente (al menos algún caso cada día de consulta)	☐	Frecuentemente (al menos algún caso cada 2 o 3 días de consulta)	☐	Raramente (al menos algún caso en toda la semana de consulta)	☐	Muy raramente (menos de un caso en toda la semana de consulta)	☐

(POST) **En los cursos de formación sobre medicamentos y conducción realizados en su Centro de Salud se le proporcionó una guía de prescripción al paciente conductor**

¿Utiliza en su práctica diaria esta guía de prescripción?

☐ SI ☐ NO

Si ha respondido que si a la pregunta anterior ¿con cuanta frecuencia la utiliza?

☐ Siempre ☐ Casi siempre ☐ A veces ☐ Casi nunca ☐ Nunca

Respecto a la guía de prescripción al paciente conductor esta ha sido

☐ Muy útil ☐ Útil ☐ Suficiente ☐ Poco útil ☐ Nada útil

4

ANEX IV: Patient questionnaire (Study 2)

MEDICAMENTOS Y CONDUCCIÓN

Este estudio forma parte del proyecto europeo DRUID, y se hace conjuntamente con la Agencia Española de Medicamentos y Productos Sanitarios del Ministerio de Sanidad y Política Social, así como con la Junta de Castilla y León, Consejería de Sanidad – Sacyl.

Nos sería de gran utilidad conocer su opinión a cerca de los medicamentos y la conducción. Por favor, lea con atención cada una de las preguntas y marque la casilla ☑ para indicar su respuesta.

En esta encuesta no tiene que poner su nombre, ni ningún dato que le identifique personalmente. El presente estudio ha sido aprobado por el Comité Ético de Investigación Clínica de la Facultad de Medicina, Universidad de Valladolid.

Muchas gracias por su participación.

Con la financiación de:

Sexo: ☐ Varón ☐ Mujer	¿Cuál es su edad? ..... años
¿Tiene permiso de conducir? ☐ Si → cuál.....	¿Cuántos kms conduce al año? .....

¿Cuál es su nivel de estudios?

- ☐ No completó la educación primaria (EGB)
- ☐ Completó la educación primaria (EGB)
- ☐ Bachillerato elemental o ESO
- ☐ Bachillerato superior o COU
- ☐ Diploma ó licenciatura Universitaria

¿Sabía que algunas medicinas pueden influir en la capacidad para conducir?	☐ Si	☐ No
¿Conocía la existencia de un pictograma sobre conducción (triángulo de borde rojo con fondo blanco y un coche en el centro) en los envases de algunos medicamentos?	☐ Si	☐ No

Presentación de un envase de un medicamento de **España** con el pictograma medicamento y conducción

En su opinión, ¿qué significado tiene para Vd. el pictograma sobre conducción?:

_____

¿Como evaluaría usted el grado de influencia de este medicamento en la conducción?, es decir, el riesgo que tiene usar ese medicamento y conducir vehículos.

☐ Alto riesgo	☐ Riesgo moderado	☐ Bajo riesgo	☐ Sin riesgo	☐ No lo sé

Supongamos que a usted le prescriben este medicamento en el que aparece el pictograma sobre conducción en el envase. ¿Con qué frecuencia conduciría en el periodo en el que estuviese tomando este medicamento?

☐ Con la misma frecuencia	☐ Menos frecuentemente	☐ Bastante menos frecuentemente	☐ Casi no conduciría	☐ No conduciría

¿Qué haría usted si le prescribiesen este medicamento con un pictograma sobre la conducción en su envase?

☐ Conduciría sin tomar otras medidas	☐ No conduciría sin haber leído antes el prospecto	☐ No conduciría sin el consejo de un médico o farmacéutico	☐ No conduciría hasta que me lo indicara el médico

Según su opinión, valore del 1 al 10 (1-negativo, 10-positivo), el pictograma es

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	
Innecesario	O	O	O	O	O	O	O	O	O	O	Útil
No informativo	O	O	O	O	O	O	O	O	O	O	Informativo
Incomprensible	O	O	O	O	O	O	O	O	O	O	Comprensible
Complejo	O	O	O	O	O	O	O	O	O	O	Sencillo

Si tuviera que tomar un medicamento con pictograma sobre la conducción en su envase, ¿Pediría consejo sobre la conducción de vehículos?

	Muy improbable	Improbable	Ni probable/ ni improbable	Probablemente	Muy probablemente
Farmacéutico/a	☐	☐	☐	☐	☐
Enfermero/a	☐	☐	☐	☐	☐
Médico/a	☐	☐	☐	☐	☐

En conjunto como valora este pictograma (1-mínimo a 10-máximo):.....