How to prescribe and dispense driving impairing medicines: application of the DRUID materials in software for physicians and pharmacists

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Abstract

Background: The assessment of whether a patient is medically fit to drive can be addressed by physicians under various conditions (e.g. neurological disorders). But also if they prescribe medications that can cause significant adverse effect across a range of skills required for safe driving. Patients in most situations will obtain their medications dispensed by pharmacists who, similar to physicians, have a responsibility to provide the patient with information as how to use the medication safely.

Aims: To illustrate the added value of the DRUID categorization system after implementation of the DRUID system (e.g. in computer systems for prescribing physicians and dispensing pharmacists).

Methods: Based on DRUID materials an intervention study was carried out in Belgium, the Netherlands and Spain, in which electronic provision of relevant information (as a stand-alone tool or integrated in the software packages used in daily practice) to select the least impairing medicine within a therapeutic class, if available, was provided during prescribing and dispensing of driving impairing medicines.

Results: The implementation of computerized guidelines and DRUID categorization was highly accepted by both physicians and pharmacists and participants. For physicians significant increase in reported behaviour was found. On the contrary, no significant differences in actual knowledge and attitudes were revealed. For pharmacists attitudes and awareness were significantly more positive after the implementation of DRUID information. Significant increase in reported behaviour and actual knowledge was found.

Discussion and conclusion: Health care professionals can improve their prescribing and dispensing practices if supported by DRUID materials (in particular by offering integrated software applications). Dispensing support tools with information on the potential impairing effects of medicines on the fitness to drive increases awareness, reported risk communication behavior as well as knowledge of pharmacists.

Introduction

The main goals of DRUID Work Package 7 were the development of guidelines for healthcare professionals and on risk communication aimed at different target groups based on DRUID outcomes (see www.druid-project.eu).
The following objectives focusing on improving prescribing and dispensing practices regarding driving impairing medicines were pursued in DRUID WP7:

- Reflections on improvements of procedures for assessing fitness to drive;
- Development of prescribing and dispensing guidelines for physicians and pharmacists to select the least impairing medicine within a therapeutic class and to inform a patient meeting his/her needs;
- Evaluation of practice guidelines and protocols in every day medical and pharmaceutical practice by focussing on different practice models, with and without the application of Information and Communication Technologies (ICT).

Professional Guidelines and Standards

A questionnaire survey among driving licensing authorities and experts was conducted in 29 European countries (all EU member states, Switzerland, Norway) in order to obtain better insights into the current situation in Europe concerning guidelines for physicians on prescribing medicines with impact on driving performance and on assessing fitness to drive (Deliverable 7.2.1; see www.druid-project.eu). In addition, existing guidelines for pharmacists on advising patients while dispensing those medicines were considered (Deliverable 7.2.2).

Based on the feedback on the questionnaire, an overview of the current European regulations and guidelines is presented. Concerning prescribing and dispensing of psychotropic medicines, which might have an impact on the driving performance, it was concluded that strict and binding regulations are the exception rather than the rule. The compiled guidelines are typically recommendations, not regulations. The role, responsibilities and tasks of physicians and pharmacists are not defined uniformly. Despite the great diversification of recommendations in the different countries one can deduct a common denominator. Physicians and pharmacists usually should give their patients the most comprehensive and adequate advice on medicines and their effect on driving performance. This includes a request of not leaving the patient alone with the decision whether to drive or not while using medicines.

In most cases physicians and pharmacists will not be made legally responsible in case an accident happens to one of their patients under a certain medication. But they are advised to keep a proper record of the consultation, as they might be sued in civil court cases (by insurance companies).

The regulations in the different countries dealing with the procedures of assessing fitness to drive are mainly in line with the European Council Directive (91-439-EEC) for issuing and renewing driving licenses. Practical implementations and the assignment of responsibilities differ from country to country. It is very difficult to derive a “best practice” from the present results.

Several opportunities to improve guidelines and procedures for assessing fitness to drive are presented based on the progress made within DRUID Work Packages 4 and 7. Several reflections on the existing guidelines and regulations, in particular on the text of Art 15 of Council Directive 91-439-EEC, resulted in 8 recommendations.
Some of the recommendations point at the vague terms that are used in Article 15 (such as “substance abuse”, “regular use”, both for medicines and illicit drugs, etc.), whereas more internationally accepted terms exist. It is also recommended to include the underlying cause or reason for taking medicines, as well as all co-morbidity factors, while assessing fitness to drive. Another recommendation points at the term “combinations of medicines with central nervous system activity”. It is emphasized that combinations of psychotropic medicines with other medication that can alter the metabolism of the psychotropic medicine (with a possible consequence of increased blood levels of the latter) will always call for an individual judgement by the prescribing physician. This is especially of interest for drivers with co-morbidities and in case of polypharmacy.

It is also recommended to apply the DRUID categorization system for medicines affecting driving performance in developing national requirements on fitness to drive.

Finally it is recommended that in situations where physicians will advise a patient to start driving again after a period in which the advice was given not to drive while using the medicine, specific procedures are needed to structure the consultation and to manage the risk of litigation in case an accident could occur.

It will take special efforts to derive a consensus at a European level for the use of terms and procedures that allow improvements for assessing fitness to drive. Therefore it is recommended that working groups and expert rounds should discuss the DRUID recommendations involving physicians, pharmacists, driving licensing authorities and policy makers (Deliverable 7.2.1 and Deliverable 7.2.2; see www.druid-project.eu).

Application of the DRUID categorisation system in communicating risk to patients who drive and use driving impairing medicines

The DRUID categorisation system should also be used as a tool to motivate health care professionals (HCPs) 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. 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 road safety, and to remind them to use caution while driving until their individual responses to the therapy have been well established.

It has been recommended to use the categorisation system for defining specific warnings for patients (Table 1). Especially at the start of treatment more tailor-made consultation to patients will be needed to decide on the adverse side effects on driving performance. It was suggested that the DRUID guidelines would change the HCPs knowledge, attitudes and reported behaviour and encourage them to be more reflective to the problems patients could encounter while using their medicines as drivers. It was also made clear that application of these guidelines would be more effective if made available in the daily process of prescribing and dispensing driving impairing medicines.
Methods

The effectiveness of the implementation of developed protocols and guidelines on the attitude, knowledge and reported behaviour of healthcare professionals’ (physicians, pharmacists, nurses) in clinical practice were evaluated via two different approaches: i) by using an integrated (ICT) tool (additional software integrated into the ICT software used by professionals in 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).

Table 1: DRUID Categorization system for medicines and driving.

<table>
<thead>
<tr>
<th>Information for physicians and pharmacists</th>
<th>Warning for patients (with warning symbols and standard descriptions per country)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description of categories with levels of impairment</strong></td>
<td><strong>Information on how to advise their patients</strong></td>
</tr>
<tr>
<td><strong>Category 0</strong></td>
<td><strong>Category I</strong></td>
</tr>
<tr>
<td>Presumed to be safe or unlikely to produce an effect on fitness to drive.</td>
<td>Confirm that the medicine will be safe for driving, provided that combinations with alcohol and other psychotropic medicines are excluded.</td>
</tr>
<tr>
<td></td>
<td>[no warning needed]</td>
</tr>
<tr>
<td><strong>Category II</strong></td>
<td><strong>Category III</strong></td>
</tr>
<tr>
<td>Likely to produce minor adverse effects on fitness to drive.</td>
<td>Inform the patient that impairing side effects may occur especially during the first days and that have a negative influence on his/her driving ability. Give the patient the advice not to drive if these side effects occur.</td>
</tr>
<tr>
<td></td>
<td>Warning level 1</td>
</tr>
<tr>
<td></td>
<td>Do not drive without having read the relevant section on driving impairment in the package insert.</td>
</tr>
<tr>
<td>Likely to produce moderate adverse effect on fitness to drive.</td>
<td>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 acceptable by the patient.</td>
</tr>
<tr>
<td></td>
<td>Warning level 2</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td>Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Warning level 3</td>
</tr>
<tr>
<td></td>
<td>Do not drive. Seek medical advice after a period of treatment about the conditions to restart driving again.</td>
</tr>
</tbody>
</table>

* The assigned categories relate to the acute or first time use of the medicine (at the start of treatment)
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) 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. After the testing period ended they filled in a post-questionnaire in order to evaluate the effectiveness of the tool and the applied guidelines (Deliverable7.4.1 and Deliverable 7.4.2).

**Results**

The country studies showed that almost 74% of participants received no education regarding medicines and driving during their academic studies and their professional participation in post-graduate education. The information 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%).

For pharmacists positive changes in attitude, self-reported behaviour and knowledge were measured mostly if the DRUID information was used integrated in their daily used software (Legrand et al, 2012). These pharmacists (Belgian study) asked significantly more about the patients’ driving experience, informed them more about driving related risk and impairing effects of the medicines. The knowledge on the topic ‘medicines and driving’ remained generally low.

After the implementation of DRUID guidelines, a 10% increase in the positive change of reported behaviour was observed in the overall physicians’ samples across the country studies. Patients visiting pharmacists in the intervention group (Dutch study) were significantly better informed about driving impairing effects of their medication, but did not change their driving behaviour. The majority of patients (83.4%) visiting a health service or pharmacy (Spanish study) would reduce frequency of driving, if a prescribed medicine has the warning pictogram on the package.

**Discussion and conclusions**

The application of DRUID guidelines was successful and shows the readiness of health care professionals to adopt them. The 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 training. However, this training should not be a short-term endeavour, but flexible, adaptable, and personalized to local settings.

Based on the comments made by the health professionals within the country reports, the implementation of computerized guidelines and DRUID categorization 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 categorization scheme and the adaptation of information 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 seniors information).

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

It is concluded that health care professionals can improve their clinical practices if supported by DRUID materials (in particular by offering integrated software applications). Dispensing support tools with information on the potential impairing effects of medicines on the fitness to drive increases awareness, reported risk communication behavior as well as knowledge of pharmacists.

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References

For DRUID Deliverables cited in this paper see [www.druid-project.eu](http://www.druid-project.eu).