A study of the effectiveness of driving medication warnings

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Funded by the NRMA-ACT Road Safety Trust

October 2011

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Acknowledgements

The authors would like to acknowledge the funding provided by the NRMA-ACT Road Safety Trust fund and the ongoing support of Mr Eddie Wheeler and Ms Linda Cooke. The authors would also like to thank the staff and clients of the participating hospitals and pharmacies, and CARRS-Q staff, Hanna Thunstrom, Dominique Lynch and Melissa Bailey, for their assistance with data collection.

The work has been prepared exclusively by the Grant Recipient, and has not been endorsed and is not guaranteed by the Trustees.

EXECUTIVE SUMMARY

Background

There is evidence that certain medications can impair driving performance. A key traffic safety countermeasure used in Australia to alert consumers to the risk is the display of warnings on medications that have the potential to impair driving. There is recent evidence, supported in some areas in this study, that Australian consumers have low levels of knowledge and awareness of possible impairing effects. This raises the question of the effectiveness of the warnings, and whether there are ways in which they can be improved to enhance their impact on consumer awareness and behaviour.

While there is a large body of research investigating warning effectiveness, very little research has specifically investigated medication warnings about driving impairment. The Australian warning approach requires consumers to self-assess any impairment, while an alternative approach in use in France advises consumers to seek advice from a health professional about driving. The French warnings also differ on visual characteristics and have a system of graded risk communication. Another difference is that the highest risk Australian warning also raises the need monitor associated alcohol use.

Research objectives and design

The project aims to examine the effectiveness of medication warnings about driving from the perspective of consumers and health professionals. The project compares differing content messages, different readability and visual presentations, and measures knowledge of, attitudes towards, and responses to the warnings currently used in Australia. It provides baseline Australian data in this increasingly important area and for clarification it compares Australian labeling with the new French medication labeling system. The study provides evidence to inform the development of future effective medication labeling in order to raise community awareness of the risks of impaired driving as a consequence of using medications, particularly in combination with alcohol.

Baseline (n = 358) and follow-up (n = 53) surveys of public hospital outpatients were conducted in Queensland, Australia. Information was obtained from a sample of hospital pharmacy outpatients who were selected for study because they were considered to be high-level medication users in an optimal pharmacy best practice situation. Questions were asked about their driving; medication use; perceptions and ratings of the characteristics of the Australian and French warnings; knowledge; attitudes, measured by risk perceptions and driving behaviour after taking a medication that displayed a warning label. A complementary study of 98 community based French health professionals is also reported.

In the initial design of this NRMA – ACT Trust study a parallel comparison of warning label expectations of an Australian Health Professional sample was also proposed and approved. Recruitment for this phase has proved more difficult than anticipated and at the time of writing is incomplete.

Results

Study results suggest that the Australian warning approach of using a combination of visual characteristics is important, but that the use of a pictogram could enhance effects. Significantly higher levels of risk perception were found among the Australian sample for the French highest severity label

compared with the analogous mandatory Australian warning, with a similar trend evident in the French study results. Knowledge of warning labels was relatively high with the exception of underestimating the risk incurred from exceeding the prescribed dose, and at the time of commencing treatment.

Participants reported generally accurate knowledge concerning the effects of medicines and other substances on driving. However, three of the assessment items were associated with incorrect responses. These concerned underestimating the risk incurred from discontinuing medication; exceeding the prescribed dose, and at the time of commencing treatment.

It is of concern that at the follow up survey of this well advised sample of people who were on high risk medications only just over half (51%) recalled seeing a warning label on their medications. Whilst three quarters (78%) of these respondents reported following the warning label advice this still leaves a large proportion of people who do not take the warning into account in making their decisions about driving.

Responses also showed variation concerning alcohol intake and there was evidence that patients would consider modifying the dose of medication or driving habits so that it was possible to continue driving.

The French Health Professionals noted the Australian warning and expressed some concerns about the absence of reference to the possible increase of impairment due to alcohol use in the French warning system.

Conclusions and recommendations

The results are potentially important for the Australian approach to medication warnings about driving impairment. The research contributes both practical and theoretical findings that can be used to enhance the effectiveness of warnings and developing countermeasures in this area. Suggestions for future research relate to continued investigation of the effects of medication and other substances on driving skills, warning label design, and validation of consumer self-assessment of impairment. This project has involved persons with the highest level of likelihood of knowledge and awareness of medication warning labelling. Even in this context it would appear that a review of the Australian messaging system would be useful particularly in the context of increasing evidence relating to associated driving risks. The inclusion of the warning regarding potential increased risk associated with alcohol use was well supported. Reviewing text size, readability and simplicity of messages including the addition of pictograms as well as clarifying the importance of potential risk in a general community context is recommended for consideration and further research.

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1 INTRODUCTION

1.1 BACKGROUND

There is growing research evidence that certain medications can negatively impair driving performance. Although methodological complications make comparisons and estimates difficult, epidemiological and experimental studies provide evidence of impairing effects. A review by Walsh et al. (2004) highlights six different drug types that are implicated: benzodiazepines, opioids, amphetamines/stimulants, cannabis, antihistamines, and antidepressants. Other researchers have identified up to nine classes of medicines that can impair driving (Alvarez and del Rio, 2002). The use of medications in combination with alcohol and other at risk medications or other classes of medications has also been found to exacerbate negative effects, and evidence of dose and treatment effects have also been demonstrated (Barbone et al., 1998; Drummer et al., 2004; Mura et al., 2003; Neutel, 1995, 1998; Ray, 1996; Ray, Fought & Decker, 1992).

Community knowledge

A recent internet survey of Australian drivers was conducted to obtain data on the prevalence of drug driving, including pharmaceutical drugs (Mallick et al., 2007). The sample responses indicated substantial pharmaceutical drug use and driving, with 15% reporting driving within three hours of taking analgesics, 4% after taking benzodiazepines, and 2.3% after taking prescription stimulants (Mallick et al., 2007). When asked how likely they would be to drive under the influence of prescription medication in the next 12 months, 13.6% responded that they would be "very likely" to drive following the use of analgesics. Approximately 14% responded that they would be "very likely" to drive after taking prescription stimulants, and 10.2% responded also being "very likely" to drive following use of benzodiazepines (Mallick et al., 2007, p. 78). The sample also indicated very low levels of knowledge on this issue. Between one third and a half of the driver sample reported not knowing how much time after taking analgesics, benzodiazepines or prescription stimulants it is safe to drive (Mallick et al., 2007).

Australian labeling regulations

A primary safety countermeasure used in Australia and internationally to alert consumers to the risk is the display of warnings on medications that have the potential to impair driving. Medication labelling is primarily the responsibility of the Therapeutic Goods Administration (TGA). Labelling (including labelling warning about driving impairment) is based upon the active ingredient of the medication. All drugs and poisons are scheduled according to active ingredients in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) (TGA, 2010). The SUSMP (TGA, 2010) is intended to provide consistent guidelines for scheduling, packaging and labelling of drugs and poisons throughout Australia, based on the recommendations of the Advisory Committee on Medicines Scheduling (ACMS) (recently known as the National Drugs and Poisons Schedule Committee [NDPSC]). Thus the scheduling controls the source of the substance (e.g., pharmacist only, prescription only, over-the-counter, etc.) and the information given to the consumer about the product. The *Required Advisory Statements for Medicine Labels* (RASML) (TGA, 2008b) stipulates the particular statements that should appear on the label of medication if it contains certain active ingredients and meets certain conditions. A further linked document, the Labelling Order, *Therapeutic Goods Order 69 – General Requirements for Labels for Medicines* (TGA, 2009), mandates medicine labels to include any advisory statements specified in the RASML.

In addition, pharmacists in Australia are required to comply with the Pharmaceutical Society Australia (PSA) Code of Professional Conduct (PSA, 1998) and Professional Practice Standards (PSA, 2010). The PSA Professional Practice Standards stipulate that pharmacists "use appropriate cautionary

advisory labels on dispensed medicines as recommended in the current edition of the Australian Pharmaceutical Formulary and Handbook" (Standard 5, Criterion 8, p. 30, 2010). It also specifies that counselling be offered to ensure consumers have adequate knowledge of their medications. The Australian Health Practitioner Regulation Agency (AHPRA), which became the registering body for pharmacists in Australia in 2010, also provides professional guidelines for the dispensing of medicines, which recommend that relevant legislation regarding labelling should be followed. According to national guidelines, the current medication warning system requires the display of ancillary Label 1 or 1a, on medications that may cause drowsiness, which are listed in Appendix K of the SUSMP (2010). An additional ancillary label, Label 12, is applied at pharmacists' discretion. A potentially related Australian warning, black-box warning labels, which alert prescribers to important safety information related to a medication and appear with a bold black surrounding box, are excluded from the scope of this research. While a black-box warning has recently been imposed upon the medication Stilnox due to reported adverse effects such as sleep-driving, the warnings have been recommended for a small number of medicines only (TGA, 2008a). The black-box warnings are therefore used in exceptional cases and are considered to lie outside the scope of this study.

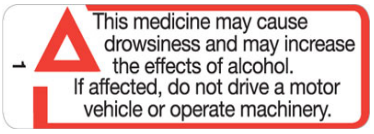
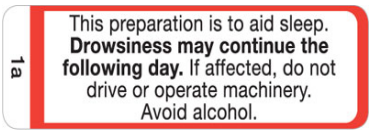
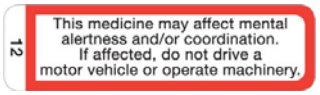
The Australian approach to minimising the risk, as delivered through the content of the warning, relies upon consumers to self-assess any impairment, and make their own decision about whether they are safe to drive. A review of the literature revealed a deficiency in research related to the approach to medicine warnings about driving currently in use in Australia. The little information available suggests that there are areas in which improvements can be made. It has been found in Australia (and elsewhere) that medication information, including labelling, is often too complicated to be understood, difficult to read, or simply not read or only partially read (Ley, 1995; Webb et al., 2008). To address such difficulties, researchers have recommended that medication labelling be developed to improve comprehension, and that patients be included in review and development processes to ensure materials are appropriately designed (Davis et al., 2006; Wolf & Cooper Bailey, 2007).

Most recently, in 2006, an extensive review of the ancillary labels was undertaken by the Cautionary Advisory Labels Working Group, and included consultation with policy makers, consumer groups and external stakeholders such as Vision Australia to ensure the needs of the elderly and vision-impaired are met (Australian Pharmacist, 2006). The review aimed to address consumer issues concerning label design and enhance their health outcomes by reducing variation and error in labelling and improving consistency of the use of the labels by Australian pharmacies and the safe use of medicines by patients (Australian Pharmacist, 2006). The review outcomes included the stipulation of specific label colours, black or dark blue sans serif font on a white background to increase contrast, coloured borders, increasing the size of Labels 1 and 1a to allow for larger font size, increasing label width by 1mm on all other labels, and simplification of label wording (Australian Pharmacist, 2006). Although it is reported that "various options" and "different label presentations" were reviewed and trialed (Australian Pharmacist, 2006, p. 598), further details on the background and design of the labels were not available (TGA, PSA, PGA (QLD), personal communication, May 2010). The current label specifications are the result of the review by experts in pharmacology, label design and readability. However, as demonstrated by Mallick et al.'s study, there is evidence that Australian drivers have low levels of knowledge and drive soon after taking potentially impairing medication. This calls into question the effectiveness of the warnings and their impact on behaviour of the intended audience.

The Australian warning labels are presented in Table 1 following.

Table 1

Australian ancillary warning labels relating to driving

Label name	Warning labels
Label 1	
Label 1a	
Label 12	

In contrast to the Australian system, an alternative approach in use in France advises consumers to seek advice from a health professional about driving. The French warnings also differ on visual characteristics and have a system of graded risk communication. This is based on the categorisation of medication classes into four categories of risk for driving impairment. In this categorisation system, Level 1 is a low level of risk, and associated with a yellow pictogram, Level 2 is a medium level of risk and associated with an orange pictogram, and Level 3 (the highest level of risk) is associated with a red pictogram. Table 2 displays the French (English translation) warning labels.

Table 2

French medication warnings about driving

Medication class	Warning labels
Class 0 Drugs which according to current knowledge do not pose any identified pharmacodynamic effect likely to impair control capacities.	No pictogram
Class 1 Drugs which do not call into question control but require that the patients are informed.	
Class 2 Drugs which can call into question the aptitude for driving and require a medical opinion.	
Class 3 Drugs which call into question the aptitude for driving during their use.	

Note. AFSSAPS, 2005.

1.2 PROJECT AIM AND OBJECTIVES

This NRMA-ACT Trust funded project examines the effectiveness of the Australian and French medication warnings about driving from the perspective of medication consumers and health professionals. It compares the differing content messages, different readability and visual presentations of the two approaches to warnings, and measures knowledge of, attitudes towards, and responses to the warnings currently used in Australia. The study aims to inform knowledge regarding the most effective medication labelling to raise community awareness of the risks of impaired driving as a consequence of using medications.

The objectives of the study are to:

1. Examine the effectiveness of medication information and warnings regarding potential for impaired driving performance in terms of user recall and comprehension
2. Compare the Australian and the new French warning messages in terms of user recall and comprehension including the impact of alcohol
3. Determine patient knowledge, attitudes and intentions regarding medication warnings and the barriers to following such warnings
4. Examine the effect of patient variables such as age, ethnicity, attitudes to road safety on these factors
5. Examine doctors and pharmacists attitudes and expectations about the effectiveness of medication warnings

1.3 STRUCTURE OF THE REPORT

The report outlines separately three components of the research. In Section 2, the study of hospital outpatients is reported (baseline survey). This includes an overview of the literature review findings concerning factors demonstrated to influence the effectiveness of warnings, the survey methodology, the results and discussion. In Section 3, the follow-up study of a sub-group of the baseline survey participants is reported. This section discusses the study methodology and findings. Section 4 reports the study of perceptions of French health professionals on the medication warnings.

1.4 PROGRESS OF PROPOSED RESEARCH TASKS

The present research program was undertaken as part of a PhD thesis. The thesis was submitted for external review on 25 August 2011. Selected results of the research have been presented at two international traffic safety conferences, including the International Traffic Medicine Association in The Hague (2009), and the International Council of Alcohol, Drugs and Traffic Safety in Oslo (2010). Peer-reviewed journal publications from the research are currently in progress.

2 STUDY 1: HOSPITAL OUTPATIENTS

2.1 METHODOLOGICAL ISSUES

There is a large body of research investigating warning effectiveness, but very little research has specifically investigated medication warnings about driving impairment. A review of the literature relating to warning design highlights several key factors that have been demonstrated in research to influence warning noticeability and user compliance with warning advice. Evaluations of warning effectiveness have used varied measures of effectiveness. There is consensus among researchers in the field that behavioural compliance is a key indicator of effectiveness, and theoretical models of warning evaluation have been developed utilising this as the primary outcome measure (for example, the Communication-Human Information Processing model) (Wogalter, DeJoy, & Laughery, 1999).

Factors such as resource costs and ethical considerations related to user safety have made studies using objective measures of behavioural compliance problematic (Smith-Jackson & Wogalter, 2006; Wogalter, Conzola, & Smith-Jackson, 2002). Research often uses behavioural intentions as a proxy measure of actual compliance (Wogalter et al., 2002). Some studies have utilised subjective ratings of other dimensions related to effectiveness, such as preferences, likelihood of reading or noticing the warnings, likelihood of compliance (Adams, Bochner, & Bilik, 1998; Kalsher, Wogalter, & Racicot, 1996). Research has also used objective measures such as observation and warning recall (Barlow & Wogalter, 1993) though these have been noted as being potentially limited by measurement error, and they are resource-intensive (Smith-Jackson & Wogalter, 2006; Wogalter et al., 2002). Numerous studies have incorporated experimental manipulation (for example manipulating the presence or absence of warning characteristics), however these have also relied upon subjective ratings of outcome measures, making actual compliance in a real-world setting difficult to determine (Adams et al., 1998; Laughery, Young, Vaubel, & Brelsford, 1993).

The present study uses self-report behaviour obtained from surveys. This method has been used extensively to determine the attention given to warnings and information obtained from them (for example, Davies, Haines, Norris, & Wilson, 1998; Kalsher et al., 1996). This method commonly assesses retrospective behaviour and is relatively inexpensive and easily conducted. In the warning efficacy context, it has been useful in determining the reasons for non-compliance, and beliefs and attitudes (Smith-Jackson & Wogalter, 2006).

2.1.1 Factors influencing noticing and perceptions of warnings

Laughery (2006) conducted a review of the relevant research and identified that the most important factors determining warning effectiveness were those that influence noticing, encoding, and compliance decisions. These factors relate to characteristics of the warning design and of the message recipients (Laughery, 2006). Warning design characteristics that have been demonstrated to be important for noticing and encoding include size, location, colour/contrast, signal words, and pictorials (Hellier, Edworthy, Derbyshire, & Costello, 2006; Laughery, 2006; Ley, 1995).

2.1.1.1 Size of warning and text

The size of the warning has been found to be important for noticing and recall, with bigger and bolder print demonstrating a positive effect on recall of the warning (Bernadini, Ambrogi, Fardella, Perioli, & Grandolini, 2001; Wogalter et al., 2002).

2.1.1.2 Signal words and colour

There is evidence that coloured labels are perceived as more hazardous than black and white labels (Braun, Kline & Silver, 1995). Signal words attract attention and indicate the level of danger present with the three most common being “caution”, “warning”, and “danger” (Laughery, 2006). These are each associated with a colour that indicates the level of risk: caution with yellow, warning with orange, and danger with red (Laughery, 2006, p. 471). Research has demonstrated that the word “danger” attracts attention more than the words “caution” or “warning”, and implies the greatest hazard (Adams et al. 1998; Braun, Kline & Silver, 1995; Kline, Braun, Peterson, & Silver, 1993; Laughery et al., 1993; Wolgalter et al., 2002).

2.1.1.3 Pictograms

Pictograms (also referred to as pictorials) attract attention and communicate information, and may be in the form of photographs, drawings, and abstract symbols (Laughery, 2006; Wogalter, Silver, Leonard, & Zaikina, 2006). To be effective, they need to be both noticeable and understandable (Davies et al., 1998). The evidence for the effectiveness of pictograms in warning labels is mixed. They can be useful for attracting attention (Davies et al., 1998) and communicating messages to people who have difficulty reading printed text (Kalsher et al., 1996), and studies demonstrate that warnings with a pictogram are more quickly detected than those without (Laughery et al., 1993) and enhance understanding and recall of verbal medical instructions (Houts et al., 1998; Katz, Kripalani, & Weiss, 2006).

Encouragingly, positive effects of pictograms on noticing, reading and comprehension have been demonstrated across different age groups and literacy levels. For example, Kalsher et al. (1996) studied the presence and absence of pictorials on participant ratings of prescription drug label preference in a sample with mean age of 21.8 years. The results of the study showed that the standard label without pictorials was rated as less readable and noticeable, and less likely to be read (Kalsher et al., 1996). Further, labels containing pictorials were always preferred to the same label without pictorials (Kalsher et al., 1996). Replication with an elderly sample with a mean age of 72.9 years also revealed a significant preference for pictorials on the label for the measures of likelihood of noticing and of reading the label (Kalsher et al., 1996). However other researchers have recommended that pictograms should be used as a way of reinforcing information and not as a primary education tool (Davies et al., 1998).

2.1.2 Factors influencing compliance with warnings

2.1.2.1 Warning characteristics

Much research has been conducted to understand the factors that influence compliance with warnings. Drawing on a review by Kalsher and Williams (2006), the following sections outline the influential factors that research has demonstrated to be the most significant.

Location and mode

The location of the warning can have significant influence on behavioural compliance (Frantz, 1994). Warnings that are placed at the front of the package or at the start of the product instructions for use have been shown to be more effective and quicker to find, and reducing clutter around the warning has also been found to be preferable (Laughery et al., 1993).

Colour

Research has further demonstrated that the colour red tends to increase compliance (Braun, Sansing & Silver, 1994; Shaver & Braun, 2000). Research by Rudin-Brown et al. (2004) found that colour-

coded warnings indicating the level of risk increased compliance behaviour, compared with monochromatic warnings.

Content and design

Rudin-Brown et al. (2004) investigated combinations of content and format characteristics and the optimal label which included colour-coded borders and pictograms was associated with greater behavioural compliance and usability ratings. Further, explicit procedural instructions were found to lead to greater compliance and risk perception than non-explicit instructions (Frantz, 1994; Laughery & Smith, 2006).

2.1.2.2 Context and recipient characteristics

Product familiarity

There is conflicting evidence for the influence of prior experience and awareness of the product on warning compliance. In the recent Australian study by Mallick et al. (2007), users of benzodiazepines perceived significantly less risk than non-users. In Laughery's (2006) review of literature concerning warning effectiveness, it was noted that research findings indicate that greater familiarity is associated with lower likelihood of reading and complying with warnings (Wogalter, Brelsford, Desaulniers, & Laughery, 1991).

Perceived risk

Researchers note the difficulty that lay people and experts alike have in accurately judging risk (Slovic, Fischhoff, & Lichtenstein, 1979). People are more likely to be cautious when perceived hazard levels (risk) increase (Wogalter, Young, Brelsford, & Barlow, 1999). Risk or hazard perception is generally considered to be a result of the interaction between two variables: likelihood of injury, and the severity of the potential injury (Wogalter et al., 1991). In other research, (Wogalter et al., 1999) it was demonstrated that severity was a more important determinant than likelihood of occurrence when lay people were asked to judge consumer product hazards. Research by Wogalter et al. (1991) has revealed that the greater the levels of perceived risk, the greater the likelihood that people will seek and attend to warnings. However, it has been found that people that are more familiar with a product or situation are less likely to read warnings, which is suggested to be a result of decreased hazard perception associated with the product or situation (Laughery, 2006).

Habituation

A phenomenon that can impede compliance with warning labels is a response known as habituation (Ajzen, 2002). Habituation results in the failure to attend to warnings due to overexposure (Kalsher & Williams, 2006). Overexposure to the warnings and the potential for habituation was a factor prompting France to reconsider their warning label system and instigate changes to the label design (AFSSAPS, 2005).

Cost of compliance

A review by Silver and Braun (1999) identified research demonstrating that the cost (such as time, resources, convenience or comfort) of compliance influences whether an individual will comply with a warning. Studies indicate that if an individual considers that following the warning advice will be too expensive, time consuming, inconvenient, or will cause too much discomfort, it will be less likely that they will comply (Dingus, Wreggit, & Hathaway, 1993).

Recipients

The characteristics of the predominant users of certain medication can influence the effectiveness of safety information and warnings relating to medicines. It is noted that chronically ill patients and the elderly are more likely to experience medication errors as they take more prescription drugs than

younger and healthier patients (Wolf & Cooper Bailey, 2007). It is important for labelling to incorporate characteristics that are likely to enhance reading and comprehension, and thus compliance, within the user group. Information about medications is most commonly given verbally; however, according to a study by Houts et al. (1998) only 14% of verbal instructions are remembered. To overcome the inherent shortfalls of verbally counselling patients, written information is used as a supplement, and warning labels play an important role in this strategy.

2.2 METHOD: BASELINE SURVEY

The study was designed to investigate consumer perceptions of the Australian and French warnings and identify any benefits of adopting characteristics of the French warning approach in Australia. Through baseline and follow-up surveys of public hospital outpatients in Queensland, Australia, information was obtained from a sample of a high-level medication user group about their driving, medication use, perceptions of the Australian and French warnings, knowledge, risk perceptions and driving behaviour after taking a medication that displayed a warning label. This section outlines the method and results related to the baseline survey of hospital outpatients, while Section 3 outlines the method and results related to the follow-up survey.

Purposive sampling was used to recruit outpatients who accessed the Pharmacy Services of a Brisbane public hospital to the study. The recruitment procedure utilised in the study was trialled and developed during a pilot study. Participants were screened by asking if they drove regularly (at least once a week). Drivers were needed to provide accurate information about decisions and intentions to drive while taking potentially impairing medications. People who did not drive regularly and those who were less than 18 years of age were excluded from participating in the study. No incentive for participation was offered. A total of 1070 people were identified as potential recruits to the study. Of these, 358 people participated in the study, giving a response rate of 33.5%.

The materials used in this study consisted of a written baseline questionnaire, developed by the researchers specifically for the study. The baseline questionnaire depicted both the Australian and French warning labels, with English translations of the French warnings provided for use in Australia.

2.2.1 Questionnaire constructs

2.2.1.1 Participant demographic, driving behaviour, and alcohol and illicit drug use

Demographic information included age group, gender, employment status and education level. Information about the individuals' driving habits was obtained by asking whether they drove regularly, whether they needed to drive to and from work and as part of their professional duties, what they drove for their professional duties, licence class held, and estimates of the number of annual kilometres driven and number of hours driven in an average week. Information was also collected on alcohol and illicit substance use.

2.2.1.2 Medication use

Medication use was included to enable evaluation of the intentions and behaviour of people who were taking medications that display a warning about driving. Participants were asked to list the name, dose and frequency of medications taken in the last seven days. They were also asked to indicate the class(es) and frequency of medications taken in the last 12 months. Participants were also asked "*Have you ever taken a medication that could affect your driving*?"

The reported medications were classified using the MIMS Online Database according to their medication class. The active ingredient of each medication was identified so that the relevant ancillary warning label that would appear on the medication (according to Australian guidelines) could be identified and used as the basis for further analysis (e.g., warning label recall).

2.2.1.3 Visual impact of warning characteristics

Participants were asked to signify the level of visual impact that each of the individual characteristics of the Australian and French warning labels had for them on a 3-point scale where 1 = low, 2 = medium, and 3 = important. Participants were also asked to indicate which label characteristic was the most important for them. The characteristics were identified as text size, colour, pictogram, readability, size of warning, triangle shape.

2.2.1.4 Recall of warnings

Participants' recall of warnings was assessed by asking two items, "*Have you already seen a warning about driving on certain medication boxes*?" and "*Which warning do you remember seeing most recently on the box of your medication*?" Participants indicated which of the warning labels pictured they recalled. These items were used as a measure of whether people noticed and remembered the warnings on their medications. In this case the relevant warning on the medication prescribed was used as the reference.

2.2.1.5 Risk perceptions associated with the warning labels

Personal perceptions of the risk of driving after taking a specific medication were used in comparison with a general risk assessment. To obtain a measure of comparisons of risk perceptions for different labels, risk perceptions specific to the French Level 3 warning label and the Australian mandatory label were assessed by items such as "*How impaired do you think your ability to drive would be after taking a medication that displayed Label C*?" and "*What do you think is the chance of having a crash after consuming a medication which displays Label C*?" To capture variations in the strength of the response, the items were recorded on 10-point Likert-format scales, where 1 reflected low levels of strength and 10 represented the highest level of strength.

2.2.1.6 Knowledge

Knowledge of the potential effects of medication and illicit drugs on driving was assessed by eight items including "*The risk of having an accident does not change when you take more than the prescribed dose of a medication*", "*Combining medications can exacerbate the effects of medications on driving*", "*Alcohol can exacerbate the effects of certain medications on driving*". Responses to the items were ranked on a 4-point continuous scale where 1 = agree and 4 = disagree. The items were developed and structured with the assistance of medical doctors and pharmacists.

2.2.1.7 Behavioural intentions to comply with warning advice

General intentions to drive while potentially affected by medication were assessed by nine items in response to the question "*If you were prescribed a medication displaying the strongest warning about risk for driving, what would you be likely to do*?" Participants indicated the likelihood of a given response on a 5-point continuous scale where 1 = very unlikely and 5 = very likely. Intentions were also assessed by seven response items for the question "*What do you intend to do if you take a medication with a warning that advises you not to drive*?" Participants indicated agreement with each intention statement on a 10-point Likert-type scale where 1 = strongly disagree and 10 = strongly agree. Intentions specific to the strongest French warning label and the strongest Australian warning label were assessed by seven associated items after being asked "*If you were prescribed a medication displaying Label [x], what would you be likely to do*?" in relation to each label. Responses included options to follow or not follow the advice, change their driving (e.g., driving when traffic was less heavy), modify their medication/dose/time, and consult a doctor or pharmacist. Participants

indicated the likelihood of the intention on a 10-point Likert-format scale where 1 = very unlikely and 10 = very likely.

2.3 RESULTS: BASELINE SURVEY

2.3.1 Participant demographic, driving behaviour, and alcohol and illicit drug use

Participants reported their gender and age (by age group). The sample consisted of slightly more males (*n* = 186) than females (*n* = 165) and just over a quarter were aged between 51 and 60 years (26.5%). The majority (64.8%) were aged between 41 and 70 years. The median age was 53.2 years. Two-fifths of the participants (40.6%) had attained a Senior High School Certificate, which is less than the current Queensland high school retention rate (79.4% Year 7/8 to Year 12) cited by the Australian Bureau of Statistics (2010). The proportion of the sample who had a bachelor degree or above was 17.5%, which is slightly lower than the Queensland state proportion for 2009 of 22% of those aged 25 – 64 years) (ABS, 2010). Just over half of the total number of participants (54.1%) was engaged in either full-time or part-time employment. This is lower than the Australian labour force participation rate of 65.4% for the same time period (ABS, 2010).

As the current Australian ancillary labels warn about possible increased impairment due to alcohol (Label 1) and instruct the user to avoid alcohol (Label 1a), data on the frequency (categorised as daily, occasionally, and rarely/never) of alcohol consumption among the sample was recorded. Most participants (56.1%, *n* = 188) reported drinking alcohol on an occasional basis. Approximately 35% (*n* = 117) reported never or rarely drinking alcohol. Nine per cent (*n* = 30) reported drinking alcohol on a daily basis, which is slightly higher than National Drug Strategy Household Survey (NDSHS) data (8.1% of persons aged 14 years and over) (Australian Institute of Health and Welfare [AIHW], 2008).

Participants were asked about the frequency of their illicit drug (cannabis, cocaine, ecstasy and heroin) consumption. Table 5.3 reports illicit drug use among the survey respondents. While illicit drug use in the sample was lower than national drug use statistics reported in the 2007 NDSHS, the pattern of use was consistent (AIHW, 2008). As with the NDSHS data, the most common was the occasional use of cannabis (*n* = 20, 6%), followed by occasional use of ecstasy (*n* = 8, 2.4%) and cocaine (*n* = 4, 1.2%). Cannabis was the only drug reported to be used daily, by 4 participants (1.2%).

Information was obtained from the sample on aspects of driving activities, including frequency of driving, license held, and vehicle type driven. The majority of the sample (97.5%) drove regularly (at least once a week). Of these, 28.1% reported that they drove to and from work, and a slightly smaller number reported that they drove to and from work and also for their work activities. The majority of the sample (87.6%) reported holding a car license, and a smaller number reported holding a heavy vehicle license, followed by a motorcycle license. These categories were not mutually exclusive. The majority of those who drove in association with work drove an automobile.

Cross tabulations were conducted to explore the demographic characteristics and alcohol and illicit drug use of individuals on the basis of their daily use of medication, either unlabelled or labelled with Label 1 or Label 12 (Label 1a was omitted from analysis as it appeared only a small number of times – refer Table 8).

Pearson's chi square tests of significance were used to determine the presence of any significant differences between the groups based on the selected demographic and substance consumption characteristics. The results of the analyses are provided in Tables 3 and 4. According to the analyses, individuals who took any medication on a daily basis that displayed Label 1, or Label 12, or no ancillary label warning about driving, did not significantly differ from each other according to

characteristics of gender, age, education attainment, work status, driving activity, alcohol consumption or illicit drug use.

Table 3

Demographic characteristics of Australian hospital outpatients who take medication on a daily basis

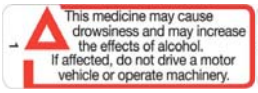
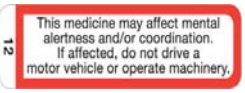
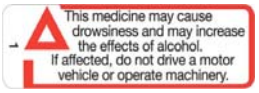
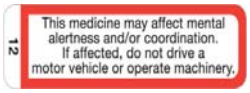
Variable	Label category: Label 1 daily 	Label category: Label 12 daily 	Label category: Neither label daily	χ^2
Gender				$\chi^2(2) = 0.32$, $p = .851$
Male	25 (50.0%)	64 (54.7%)	97 (52.7%)	
Female	25 (50.0%)	53 (45.3%)	87 (47.3%)	
Age				$\chi^2(6) = 8.23$, $p = .220$
18 – 30	7 (14.0%)	10 (8.3%)	29 (15.5%)	
31 – 50	12 (24.0%)	44 (36.7%)	56 (29.9%)	
51 – 60	11 (22.0%)	35 (29.2%)	49 (26.2%)	
61+	20 (40.0%)	31 (25.8%)	53 (28.3%)	
Education				$\chi^2(6) = 5.61$, $p = .468$
Primary	1 (2.0%)	7 (5.8%)	8 (4.3%)	
Secondary	23 (46.9%)	50 (41.7%)	93 (50.0%)	
Certificate/Dip	14 (28.6%)	45 (37.5%)	52 (28.0%)	
University (Bachelor, Postgrad)	11 (22.4%)	18 (15.0%)	33 (17.7%)	
Work				$\chi^2(4) = 2.59$, $p = .628$
Full-time	15 (30.6%)	38 (31.7%)	66 (35.9%)	
Part-time	9 (18.4%)	22 (18.3%)	41 (22.3%)	
Do not work	25 (51.0%)	60 (50.0%)	77 (41.8%)	
Driving				$\chi^2(4) = 8.89$, $p = .064$
Yes (to and from work and for work activities)	23 (46/9%)	55 (45.5%)	107 (57.5%)	
No	6 (12.2%)	21 (17.4%)	14 (7.5%)	
Do not work	20 (40.8%)	45 (37.2%)	65 (34.9%)	

Table 4

Alcohol and illicit drug use of Australian hospital outpatients who take medication on a daily basis

Variable	Label category			χ^2
	Label 1 daily 	Label 12 daily 	Neither label daily	
Alcohol use				$\chi^2(4) = 7.82$, $p = .098$
Never	19 (39.6%)	40 (34.8%)	42 (24.4%)	
Occasionally	23 (47.9%)	65 (56.5%)	116 (67.4%)	
Daily	6 (12.5%)	10 (8.7%)	14 (8.1%)	
Cannabis use[a]				-
Never	43 (91.5%)	108 (94.7%)	145 (84.8%)	
Occasionally	4 (8.5%)	6 (5.3%)	22 (12.9%)	
Daily	0	0	4 (2.3%)	
Cocaine use[a]				-
Never	45 (93.8%)	112 (98.2%)	164 (96.5%)	
Occasionally	6 (6.3%)	2 (1.8%)	6 (3.5%)	
Daily	0	0	0	
Ecstasy use[a]				-
Never	44 (91.7%)	112 (98.2%)	162 (94.7%)	
Occasionally	4 (8.3%)	2 (1.8%)	9 (5.3%)	
Daily	0	0	0	
Heroin use[a]				-
Never	45 (95.7%)	114 (100%)	170 (99.4%)	
Occasionally	2 (4.3%)	0	1 (0.6%)	
Daily	0	0	0	

[a] Cells have expected frequencies less than 5.

2.3.2 Medication use

The reported medications were grouped according to their medication class as listed in the MIMS medications database. A total of 1214 medications were reported and 9% of these were unable to be identified. On average people reported taking four different medications in the last seven days, and the number of medications ranged from one to 14 medications per person. A total of 78 medication classes made up the total 1107 classified medications used by the sample in the last seven days. Table 5 provides the complete list of medication classes reported being used by the sample within the last seven days prior to the survey. The frequency of medication classes used by the sample that potentially represent a risk for driving impairment and may display a warning label is highlighted in bold. The medications reported most frequently belonged to the Antihypertensive Agents and Immunomodifiers medication classes. Medications belonging to the Adrenal Steroid Hormones, Hyperacidity, Reflux and Ulcers and Simple Analgesics and Antipyretics classes were also frequently reported.

Table 5

Frequency of 78 MIMS medication classes taken in last 7 days

MIMS medication class	Frequency	Per cent
Adrenal steroid hormones	70	6.3
Agents affecting calcium and bone metabolism	26	2.3
Agents used in drug dependence	**3**	**0.3**
Agents used in gout and hyperuricaemia	13	1.2
Alkylating agents	1	0.1
Aminoglycosides	2	0.2
Anorectic and weight reducing agents	1	0.1
Antiangina agents	20	1.8
Antianxiety agents	**6**	**0.5**
Antiarrhythmic agents	2	0.2
Anticoagulants, antithrombotics	19	1.5
Anticonvulsants	**33**	**2.5**
Antidepressants	**47**	**3.6**
Antidiarrhoeals	5	0.4
Antiemetics, antinauseants	1	0.1
Antifungal agents	3	0.3
Antihistamines	**9**	**0.8**
Antihypertensive agents	107	9.7
Antihypertensive agents/antiangina agents	7	0.6
Antimetabolites	10	0.9
Antimigraine preparations	2	0.2
Antipsychotic agents	**6**	**0.5**
Antirheumatoid agents	4	0.3
Antituberculotics and antileprotics	6	0.5

Antiviral agents	18	1.6
Beta-adrenergic blocking agents	**34**	**3.1**
Bladder function disorders	3	0.3
Bronchodilator aerosols and inhalations	2	0.2
Bronchospasm relaxants	4	0.4
Cephalosporins	2	0.2
Combination simple analgesics	**7**	**0.6**
Detoxifying agents, antidotes	3	0.3
Digestive supplements and cholelitholytics	3	0.3
Diuretics	22	2.0
Emollients, antipruritics and protective preparations	1	0.1
Erectile dysfunction agents	1	0.1
Expectorants, antitussives, mucolytics, decongestants	1	0.1
Fat soluble vitamins	20	1.8
General well-being, multiple use preparations	3	0.3
Glaucoma preparations	1	0.1
Gonadal hormones	9	0.8
Haemopoietic agents	5	0.4
Herbal analgesics and anti-inflammatories	6	0.5
Hormonal antineoplastic agents	1	0.1
Hyperacidity, reflux and ulcers	72	6.5
Hypoglycaemic agents	30	2.7
Hypolipidaemic agents	67	6.1
Immunomodifiers	**104**	**9.4**
Infant formulas	1	0.1
Insulin preparations	11	1.0
Iron	7	0.6
Laxatives	4	0.4
Macrolides	3	0.3
Mens' supplements	1	0.1
Movement disorders	3	0.3
Multivitamins and minerals	62	5.6
Muscle relaxants	**3**	**0.3**
Narcotic analgesics	**47**	**4.2**
Neuromuscular agents	1	0.1
Noncytotoxic and supportive therapy	1	0.1
Nonsteroidal anti-inflammatory agents	**16**	**1.4**
Ocular decongestants, anaesthetics, anti-	1	0.1

inflammatories		
Other antibiotics, anti-infectives	16	1.4
Other antineoplastic agents or immunomodifiers	1	0.1
Other respiratory agents	1	0.1
Penicillins	4	0.4
Peripheral vasodilators	1	0.1
Pituitary hormones	3	0.3
Preventative aerosols and inhalations	5	0.4
Psoriasis, seborrhoea and ichthyosis	1	0.1
Quinolones	1	0.1
Sedatives, hypnotics	**5**	**0.4**
Simple analgesics, antipyretics	68	6.1
Tetracyclines	1	0.1
Thyroid hormones and antithyroid agents	13	1.2
Topical nasopharyngeal medication	1	0.1
Topical ocular anti-infective preparations	2	0.2
Topical ocular steroid preparations	1	0.1

2.3.2.1 Prescription medication class use in last 12 months

Participants were asked to report their consumption of selected classes of prescription drugs (i.e., sedatives, tranquillisers or anti-anxiety medication, antidepressants, antihistamines or anti-allergy medication, analgesics, anticonvulsives, or other drugs for mental health) in the 12 months prior to the survey. These classes were selected on the basis of the earlier literature review findings in which these medication classes are implicated for potential driving impairment. Nearly three quarters of the 358 respondents (73.2%, *n* = 262) reported that they had taken at least one of these classes of medication in the last 12 months. The majority (58.4%, *n* = 209) reported having taken at least one class on an occasional basis, while a third of the sample (33.5%, *n* = 120) reported taking at least one class of medication on a daily basis. Frequency of daily and occasional use in the last 12 months of each surveyed medication class is presented in Table 6. As indicated in the table in bold, antidepressants and analgesics were the most common drug types to be consumed on a daily basis, and analgesics and antihistamines/anti-allergy drugs were the most common drug types to be taken occasionally. Sedatives were almost as likely as antihistamines to be used occasionally.

Table 6

Selected medication class – daily and occasional use in the last 12 months

	Medication			
	Daily		Occasionally	
Medication class	**n**	**%**	**n**	**%**
Sedatives	9	2.5	**65**	**18.2**
Tranquillisers or anti-anxiety	20	5.6	16	4.5
Antidepressants	**58**	**16.2**	9	2.5
Antihistamines or anti-allergy	15	4.2	**77**	**21.5**
Analgesics	**57**	**15.9**	**158**	**44.1**
Anticonvulsives	10	2.8	1	0.3
Other (for mental health)	12	3.4	7	2.0
Total	120	33.5	209	58.4

Of the people who took medications in the last 12 months, 43.9% reported having ever taken one class of medication in the last 12 months, while 56.1% participants took more than one class of medication. Table 7 presents the number of classes of prescription medication taken daily in the 12 months prior to the survey. Most commonly, only one class of medication was taken on a daily basis.

Table 7

Number of selected classes of prescription medication taken daily in last 12 months

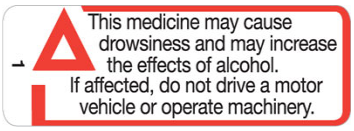
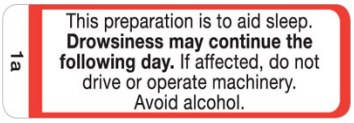
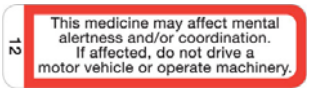
	Daily	
Number of medication classes	**n**	**%**
One class	80	66.7
Two classes	22	18.3
Three classes	15	12.5
Four classes	3	2.5
Total	120	100

2.3.2.2 Prevalence of warning labels on medications taken in last seven days

All reported medications were classified according to their associated ancillary warning label, as stipulated by the APF guidelines (PSA, 2006). According to the analysis, Label 12 was the most common label that would be expected to appear on medications used by the sample. Of those who reported using prescription medication in the last seven days prior to the survey, 25.4% (*n* = 78) had taken at least one medication on which Label 1 would appear, 2.9% (*n* = 9) had taken at least one Label 1a medication, and 55% (*n* = 169) had taken at least one Label 12 medication. Table 8 displays the labels and frequency of appearance that should occur on the medications used by the sample in the seven days prior to the survey.

Table 8

Frequency of Labels 1, 1a and 12 on medications used in the 7 days prior to survey

	Daily	
Warning label	**n**	**%**
Label 1		
	78	25.4
Label 1a		
	9	2.9
Label 12		
	169	55.0

Note. Ancillary Labels pictured are actual size.

2.3.3 Visual impact of warning characteristics

Participants were asked to signify the level of visual impact that individual characteristics of the warning labels held for them. Of the characteristics rated as having high importance, the size of the warning label was most frequently identified as having high importance (74.7%). Text size was the next most frequently identified (70.4%), followed by red colour (69.1%), picture of car (50.8%) and triangle shape (50.2%) were rated of equal importance and finally the yellow colour (34%). The orange colour was regarded as of least importance (19.4%). Table 5 presents the frequency of the perception of characteristics as having high importance. Participants were also asked to identify the most important characteristics. Most frequently, participants indicated that using a combination of elements held the most impact (37.2%), followed by the colour of the warning (20.4%). Table 9 displays the results.

Table 9

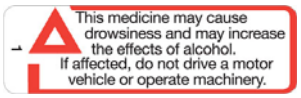
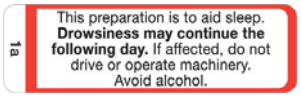
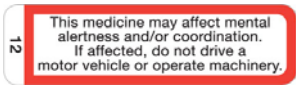
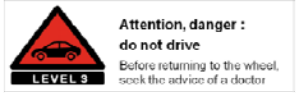
Australian hospital outpatients' ratings of impact of warning label visual characteristics

	Frequency	
Warning characteristic rated as having high importance/impact	**n**	**%**
Orange colour	61	19.4
Yellow colour	111	34.0
Triangle shape	165	50.2
Pictogram	169	50.8
Red colour	**228**	**69.1**
Text size	**231**	**70.4**
Size of label	**245**	**74.7**

In relation to individual ratings of the ease of reading the Australian and French warning labels, participants most frequently rated the Australian Label 1 as being the easiest warning to read (37%), followed by the French Level 1 (yellow) label. The most difficult to read were the Australian Label 12 and the French Level 2 labels. Table 10 presents the ratings for all warning labels.

Table 10

Australian hospital outpatients' ratings of easiest warning to read

	Frequency	
Warning label	**n**	**%**
Australian labels		
	121	37.3
	47	14.5
	22	6.8
French labels		
	80	24.7
	19	5.9
	35	10.8
Valid Total	324	90.5
Missing	34	9.5
Total	358	100

Note. Labels pictured in the table are not actual size.

2.3.4 Recall of warnings

2.3.4.1 Label recall according to number of medication classes consumed

The frequency of warning label recall among those who had taken at least one medication was analysed according to the number of medication classes consumed. Label recall in general was high but was found to differ according to the number of classes of medication taken. The lowest rate of recall (85.9%) occurred when people were taking only one class of medication. This increased to approximately 93% when taking two and three classes of medication, but then decreased to approximately 91% when taking four classes of medication. For those people who took five or more classes of medications, there was 100% recall of a warning about driving. Table 11 shows the

frequency of recall of warning labels among participants who had taken at least one medication in the seven days prior to the survey. Table 12 presents the recall of a warning label about driving by number of classes of medication.

Table 11

Australian hospital outpatients' frequency of recall of warning label among participants who had taken at least one medication in last seven days

	Taken at least one medication	
Recall of warning about driving	**n**	**%**
Yes	162	89.5
No	18	9.9
Valid Total	180	99.4
Missing	1	0.6
Total	181	100

Table 12

Australian hospital outpatients' recall of warning label according to number of classes of medications taken

	Recall of warning					
	Yes		**No**		**Total**	
Number of medication classes	**n**	**%**	**n**	**%**	**n**	**%**
One class	67	85.9	11	14.1	78	100
Two classes	49	92.5	4	7.5	53	100
Three classes	26	92.9	2	7.1	28	100
Four classes	10	90.9	1	9.1	11	100
Five classes	8	100	0	0	8	100
Six classes	2	100	0	0	2	100

2.3.4.2 Label recall according to label type on medication used in last seven days

The majority of participants (89.6%) who reported receiving medication with Label 1 in the last seven days recalled seeing the label on their medication, with eight people (10.4%) unable to recall the label. Similarly, the majority of participants (87.8%) who received only medication displaying Label 12 were able to recall the label, while 12.2% were unable to recall the label. Table 13 presents the frequency of label recall among those who received a medication that according to the APF (PSA, 2006) guidelines would be labelled with Label 1 (including those who received a combination of medications labelled with Label 1, 1a, and 12).

Table 13

Australian hospital outpatients' frequency of medication warning label recall according to warning label type, for medications used in last seven days

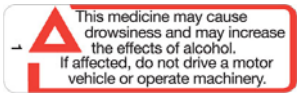
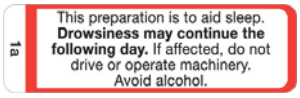
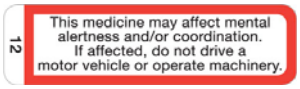
	Medication			
	Label 1		**Label 12**	
Already seen warning label about driving?	**n**	**%**	**n**	**%**
Yes	69	89.6	108	87.8
No	8	10.4	15	12.2
Total	77	100	123	100

2.3.5 Attitudes measured by risk perceptions associated with the warning labels

Attitudes as measured by risk perceptions were assessed by asking participants to indicate which warning label they perceived as carrying the strongest message of risk. The French Level 3 (red) label was most commonly (51.2%) perceived to have the strongest message of risk. The Australian Label 1 was the second most frequently rated at a much lower 22.2%. The results for perceptions of all warning labels are shown in Table 14.

Table 14

Australian hospital outpatients' perceptions of which warning conveys the strongest message of risk

	Frequency	
Warning label	**n**	**%**
Australian labels		
	74	22.2
	36	10.8
	15	4.5
French labels		
	21	6.3
	17	4.7
	171	51.2
Valid Total	334	93.3
Missing	24	6.7
Total	358	100

Note. Labels pictured in the table are not actual size.

Risk perceptions for the French (Level 3) and Australian (Label 1) warning labels were further assessed by asking participants about their perceptions of impairment and the chance of being involved in a crash. Perceptions of impairment were assessed by asking "*How impaired do you think your ability to drive would be after taking a medication that displayed Label [x]?*" Responses were recorded on a 10-point Likert-type scale with 1 = slightly impaired and 10 = very impaired. Participants most frequently indicated that they thought that they would be moderately impaired (27.7%) after taking a medication that displayed the Australian label (Label 1). With the same question repeated but referring to the French label (Level 3), participants most frequently perceived that they would be very impaired (69.2%). A Wilcoxon Signed Rank test revealed that the difference between perceptions of possible impairment were significantly stronger for the French label, $z = -13.26$, $p < .001$ ($n = 325$), with a large effect size ($r = .52$), according to Cohen's (1996) criteria.

The chance of being involved in a crash was measured by asking "*What do you think is the chance of having a crash after consuming a medication which displays Label [x]?*" with responses indicated on a 10-point Likert-type scale where 1 = very unlikely and 10 = very likely. For the Australian label (Label 1), participants most frequently perceived their chance of being in a crash as likely (37.5%). Repeating the same question for the French label (Level 3), participants most frequently perceived their chance of being in a crash as very likely (56.4%). A Wilcoxon Signed Rank test revealed that this difference was also significant, $z = -11.87$, $p < .001$ ($n = 322$), with a large effect size ($r = .46$) according to Cohen's (1996) criteria.

2.3.6 Knowledge about effects of certain medications and substance combinations on driving

Knowledge was assessed by asking participants to respond with the extent to which they agreed or disagreed with a list of general statements about effects and use of medications, other substances, and combinations of these. Responses were recorded on a 4-point scale, and recoded into two categories (responses 1 – 2 = agree, and responses 3 – 4 = disagree), and the frequencies are displayed in Table 15. Correct responses are indicated by an asterisk. The overwhelming majority (90% or more) of participants gave the correct answer to most items. Just over one fifth (21.8%) incorrectly believed that the risk of having an accident does not change when taking more than the prescribed dose of a medication. A similar proportion (23.2%) incorrectly believed that risk of having an accident is weaker at the beginning of treatment.

Table 15

Australian hospital outpatients' knowledge about the effects of medications, alcohol, illicit drugs and driving

Knowledge statement	Disagree (%)	Agree (%)
Discontinuing any medication without the advice of your doctor can be harmful to your health	8.7	91.3[a]
A sudden discontinuation of your medication can be harmful to your health	7.2	92.8[a]
The risk of having an accident does not change when you take more than the prescribed dose of a medication	78.2[a]	21.8
Combining medications can exacerbate the effects of medications on driving	8.9	91.1[a]
The risk of having an accident is weaker at the start of treatment than during long term treatment	76.7[a]	23.2
Alcohol can exacerbate the effects of certain medications on driving	4.5	95.5[a]
Driving under the influence of alcohol is dangerous	2.4	97.6[a]
Driving under the influence of cannabis is dangerous	4.5	95.5[a]

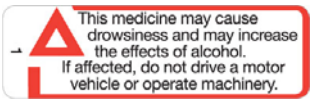
[a] Correct answer.

2.3.7 Behavioural intentions to comply with warning advice

Participants' intentions to comply with the advice of the strongest warning labels in both Australia (Label 1) and France (Level 3) were explored by asking participants to rate the likelihood of numerous behavioural options. Participants were asked "*If you were prescribed a medication displaying Label 1, what would you be likely to do?*" and responses for each behavioural option were recorded on a 10-point Likert-type scale where 1 = very unlikely and 10 = very likely. For simplicity the responses were recoded into categorical variables where 1 – 5 = unlikely and 6 – 10 = likely. The differences in intentions related to the Australian and French warning labels were tested for significance using McNemar chi square for paired samples. There were no differences in regard to *driving when the traffic was less heavy* or *not taking the medication so that they could drive*. All other differences were significant with the stronger effect being observed for the French label. Table 16 shows the responses for this item.

Table 16

Australian hospital outpatients' intentions

	Australian Label (Label 1)				French Label (Level 3)				
									
	Likely		Unlikely		Likely		Unlikely		
Response	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**χ^2**
Consult doctor or pharmacist	225	62.8	108	30.2	292	81.6	40	11.2	$\chi^2(1) = 55.14$, $p < .001$
Modify medicine so can continue to drive	135	37.7	190	53.1	93	26.0	225	62.8	$\chi^2(1) = 15.84$, $p < .001$
Wait some time before driving	177	49.4	150	41.9	124	34.6	197	55.0	$\chi^2(1) = 16.66$, $p < .001$
Drive when traffic less heavy	75	20.9	248	69.3	60	16.8	260	72.6	$\chi^2(1) = 2.42$, $p = .120$
Not drive	163	45.5	161	45.0	248	69.3	84	23.5	$\chi^2(1) = 51.13$, $p < .001$
Not take the medication	47	13.1	275	76.8	39	10.9	282	78.8	$\chi^2(1) = 0.65$, $p = .418$
Take medication and not drive	194	54.2	133	37.2	261	72.9	68	19.0	$\chi^2(1) = 41.37$, $p < .001$

3 STUDY 2: FOLLOW-UP SURVEY

3.1 INTRODUCTION

3.2 METHOD

A follow-up telephone survey was conducted with a subgroup of consenting participants who reported at the baseline survey to be taking at least one medication that required an ancillary warning label about driving impairment. From the total sample of 358 participants, 176 participants gave their permission and telephone contact details for participation in a follow-up telephone survey, and of these, 67 participants were not followed up as analysis revealed that they were not taking medication that would be expected to have a warning label about driving impairment. The remaining 109 participants were contacted by telephone to participate in the follow-up study. A maximum of four attempts to contact participants was made. If after the fourth attempt the person was unreachable, no further attempts were made to contact them. A total of 53 (48.62%) participants completed the follow-up survey.

3.2.1 Questionnaire constructs: Follow-up survey

A questionnaire was developed for the follow-up study of the outpatients which was designed to obtain self-report information on actual behaviour in response to the medication warnings about driving. The questionnaire was administered in a telephone survey with individual participants, and used a mix of open-ended questions with closed response questions. In the present research context, behaviour initiative refers to avoiding driving if an effect on driving ability was noticed, in accordance with the Australian warning label advice. The questionnaire assessed any changes to medication use since the baseline survey, behavioural responses to medication warning advice, information seeking, self-assessment of impairment, and understanding of the terms used in the ancillary warning labels.

3.2.1.1 Driving and medication

Participants were first asked if they had still been driving since the last survey, and if they were still taking the same medication. Any changes in medication use were recorded. Changes in driving due to medication use were assessed by asking "*If you are no longer driving, is that because of any of the medication you told us about or because your driving was affected*?", and "*Can you please describe what it was that happened that made you stop driving*?" with participant comments recorded as necessary. Participants were also asked "*Did you ever have to think about whether you could drive while you were taking this medication*?" with responses recorded as either Yes or No.

3.2.1.2 Warning labels

Warning label recall was assessed by two items, "*Do you recall seeing any warning label about driving on any of the medications that you told us about*?" and if applicable, "*What did the warning label say*?" Responses in the participants' own words were recorded. Aspects of the decision to drive were investigated with the items "*Did you think about the warning when you made your decision about driving*?" and "*Did you follow the advice on the warning label*?" Response options were Yes, No, Do not recall, and Not applicable, which were used to encapsulate all foreseeable circumstances of the participant.

3.2.1.3 Response to advice

Following the advice about driving impairment was assessed by four items, "*Did you read the information leaflet inside any of your medication boxes*?" (response options included Yes, No, Do not recall, No medication leaflet, and Not applicable), "*Did you follow the advice on the leaflet inside any of your medication boxes*?" (response options included Yes, No, Do not recall, Other, and Not applicable), "*Did you follow the advice of your doctor about driving*?" (response options included Yes,

No, Do not recall if advice given, Do not recall if advice followed, and Not applicable), and "*Did you follow the advice of your pharmacist about driving*?" (response options included Yes, No, Do not recall if advice given, Do not recall if advice followed, and Not applicable).

3.2.1.4 Behavioural responses

Behavioural responses were explored by using ten items that included possible behavioural options in response to taking medication that displayed a warning about driving. The response options for all the items included Yes, No, Do not recall, Other, and Not Applicable, to encapsulate all possible circumstances of the participant. If a participant answered "other", they had the option of giving their specific response otherwise unlisted, which the Research Officer recorded verbatim. The items were:

1. *Did you take the medication as directed and drive as usual*?
2. *Did you avoid driving because you noticed an effect on your driving ability*?
3. *Did you modify the way you took the medication (e.g., the dose, the time) so that you could continue to drive*?
4. *Did you change when or where you drove (e.g., when or where there was less traffic)*?
5. *Did you decide not to take the medication at all so that you could continue to drive*?
6. *Did you not take the medication because you had to drive*?
7. *Did you drive only when you thought the medication didn't affect you anymore*?
8. *Did you take the medication and not drive*?
9. *Did you ask your doctor or pharmacist only after you noticed an effect of the medication*?
10. *Did you reduce the amount of alcohol you drank while taking the medication*?

3.3 RESULTS

3.3.1 Behavioural responses to taking medication that can impair driving

The follow-up survey data was examined to explore participants' behavioural responses to taking a medication that displays a warning about driving (see Table 17). Of those who completed the follow-up survey and reported at follow-up taking at least one medication that required an ancillary warning label about driving impairment (*n* = 53), only just over half (51%, *n* = 27) reported that they recalled seeing a warning label about driving on at least one of their medications. Of these, 70% reported that they had thought about the warning when they made their decision about driving and three quarters (78%) reported that they followed the advice on the warning label.

Table 17

*Follow-up of hospital outpatients' behavioural responses to taking medication that displayed a warning label (*N = *53)*

	Frequency			
	Yes		No	
Response	**n**	**%**	**n**	**%**
Took medication and drove as usual	42	79.4	10	18.9
Modified the medication (e.g., dose, time) so could continue to drive	9	17.0	42	79.2
Changed when or where drove (e.g., when there was less traffic)	8	15.1	42	79.2
Did not take medication so could continue to drive	5	9.4	47	88.7
Reduced alcohol intake while taking medication	11	20.7	10	18.9

Note. Number excludes participants who answered 'other' or 'does not apply'.

Ability to detect impairment and confidence in the accuracy of self-assessment of impairment was assessed with two items. Participants were asked "*Do you think you would be able to tell if you were affected [by your medication]*?" and "*How confident are you that your judgment would be correct*?" Of the 53 participants that responded to these items, the majority (88.7%) thought that they would be able to tell if they were affected (through their own assessment), and were very confident (*M* = 8.09, *SD* = 1.58, where 10 = very confident) in the accuracy of their judgment.

4 STUDY 3: HEALTH PROFESSIONALS

4.1 INTRODUCTION

This study aimed to investigate health professionals' perceptions of the Australian and French warning labels. This report provides information from French Doctors and Pharmacists (as prescribers and dispensers of medicines) on the medication labels. As noted earlier the research team has experienced considerable difficulty completing the originally proposed study to conduct focus groups with Australian Health professionals. To date this component remains incomplete and this report only provides the findings of the complementary study of French Health professionals on the same issues.

4.2 METHOD

The study includes a survey of doctor and pharmacists' perceptions of the Australian and French warning labels. Results draw on two surveys of French doctors' and pharmacists' knowledge, preferences, and actions in relation to the warning labels, and include their recommendations for the improvement of the labels. It was designed to obtain information from the perspective of health professionals. Specifically, it investigated the following issues:

- Perceived visual impact of the Australian and French warning characteristics
- Perceived need for improvements to warnings
- Perceived advantages and disadvantages of the Australian and French warnings

Participants were required to be currently practicing doctors or pharmacists in either a hospital or community setting in France. No incentives for participation were offered. Based on the recruitment rate in recent relevant research (Dubois, 2007), it was aimed to have 100 completed questionnaires from medical doctors (50) and pharmacists (50) in France. A total of 48 doctors (n = 33 males, n = 15 females) aged between 30 and 70, and 50 pharmacists (n = 13 males, n = 35 females, 2 unspecified) currently practicing in the Region Isere, France, volunteered to participate in the study. All responses were anonymous and the only identifying information recorded was the age and sex of the participant.

A written questionnaire and project information sheet was developed in French by the researcher specifically for the study. The first page of the questionnaire provided the project information sheet, which informed participants of the research aims, research team contacts, the nature of participation, and information about ethics and privacy. For participants' reference, the questionnaire included a copy of all medication warning labels relating to driving currently in use in Australia and France. The labels were replicated to scale and colour accuracy, and the Australian warnings labels were translated into French.

The questionnaires consisted of 18 items to assess demographics, perceptions, awareness and impact of the medication warning labels, as described in the research aims. To obtain greater understanding of the health practitioners' experiences, both quantitative and qualitative data was collected. The quantitative data provided an opportunity to obtain frequencies and rankings of preferences, while the qualitative data consisted of open-ended questions which allowed health professionals to describe their experiences in detail. A sample of questions and the response format relating to each of the constructs is provided in Table 18.

Table 18

Sample Doctor and Pharmacist questionnaire items

Concept	Questionnaire item	Response type
Awareness	Are you aware of these pictograms and warnings?	Yes/No
Knowledge	Can you name a medication or therapeutic class associated with each of the warnings?	Written
Perceptions of warning characteristics	Which label characteristics have the strongest visual impact?	Ranking
Patient/practitioner interactions	Indicate in which way the warnings have had an impact on the advice accompanying the prescription or your prescribing practice?	Written
	If you patient saw one of these warnings on a box, what would your advice be?	Likert scale
Information needs	Have you, yourself, received sufficient information to inform your patients?	Yes/No
	If not, what information and types of information would you like to have?	Written
Recommendations	Do you think the warnings need to be improved? If yes, please specify.	Written

The study was conducted with the assistance of colleagues at the Centre de Pharmacovigilance (CRPV), at the Grenoble University Hospital, France. Prior to conducting the study, ethical clearance was obtained from the ethics committee of both the Grenoble University Hospital and the Queensland University of Technology. To recruit participants, the names and addresses of all doctors and pharmacists of the Isère region of France were obtained from the White Pages and compiled into a spreadsheet. Using a randomisation function, 400 pharmacists and 1000 doctors were approached to volunteer to participate in the study, until the desired sample size was reached. Questionnaires sent from the CRPV to the practitioners, which the practitioners then completed and returned to the CRPV. All completed questionnaires received at the CRPV were numbered and photocopied, and forwarded to the researcher in Australia for data analysis.

4.3 RESULTS

4.3.1 Perceptions of warning labels

4.3.1.1 Perceived visual impact of Australian and French warning label characteristics

Both individual and combinations of warning label characteristics including text, colour, pictogram and form were assessed by the doctors and pharmacists for visual importance. The analyses indicated that the characteristics selected as most important varied between the doctors and pharmacists. For the doctors, the colour of the warning was most frequently cited as the most important visual characteristic, closely followed by the pictogram. Following these, the size of the warning, the appearance of the triangle, and the text were perceived as being less important. By contrast, the most frequently cited warning characteristic of importance to the pharmacists was the pictogram, followed by a preference for a combination of characteristics. The colour of the warning was the next most visually important, followed by triangle and size (equally important).

Perceptions of visual impact of warning characteristics

The visual impact of warning labels were measured on a 3-point Likert scale where a value of 1 = 'low impact', 2 = 'medium impact' and 3 = 'strong impact'. Pharmacists reported the vehicle pictogram as having the highest visual impact (*M* = 2.8, *SD* = .49), followed by the appearance of a triangle (*M* = 2.58, *SD* = .61), and red colour (*M* = 2.50, *SD* = .71). Sufficient text or label size, text message, and colours of orange and yellow had less impact. By contrast, doctors perceived the red colour as having the most visual impact (*M* = 2.74, *SD* = 57), followed by the vehicle pictogram (*M* = 2.60, *SD* = .69), triangle shape (*M* = 2.47, *SD* = .66) and sufficient size of text or label (*M* = 2.40, *SD* = .72). Text message (*M* = 2.13, *SD* = .75), orange colour (*M* = 2.12, *SD* = .70) and yellow colour (*M* = 1.81, *SD* = .80) had the least visual impact.

4.3.1.2 Perceived need for improvements to warnings

Eleven doctors thought that no changes were needed, and ten of those eleven didn't comment any further. One doctor commented '*I find it well done. It allows the doctors and pharmacists to give the patient more explanation*'. Three doctors stated they had no opinion regarding the warnings, one said this was due to never having seen them. Five doctors thought that the warnings and pictograms should be improved, but did not specify how they thought this could be done. Of the remaining responses suggesting that the warnings and pictograms could be improved, four distinct categories emerged: enhanced visibility, increased size, clarity of information, and simplification.

Of those who suggested increased size, doctors commented '*increase the size of the vehicle*', and '*more visible*'. Another suggested '*the pictogram should be bigger*', and another suggested the warnings should be bigger, such as those displayed on cigarette packets. Several doctors suggested simplifying the warnings by having '*not too many things written on the box*'. Several others thought the warnings could be improved by clarifying the message, while conversely, others thought the warnings required '*improved explanations and publicity campaigns*'. One doctor suggested the warning should '*give an idea of the delay between driving and taking the medication: e.g., do not drive during the first week of treatment, during 6 hours following taking a dose*'. Another commented that '*the word 'Level' is unnecessary. You could replace it with 'caution' or 'danger, or, 'attention, danger''*.

Thirteen pharmacists indicated that they thought no changes needed to be made to the warnings and pictograms; however, the majority of the pharmacists had some suggestion for improvements. Three main themes emerged from those suggestions: Noticeability/visibility, simplification, and prevalence. These are discussed in more detail below.

Noticeability

The overwhelming majority of suggestions for improvements concerned the visibility of the warnings and pictograms. Within this category, three sub-categories appeared.

Size

The largest number of comments concerned increasing the size of the warnings to make them more likely to be noticed by patients: '*they must be improved to be more visible and comprehensible to the greatest number of people*', '*bigger and more visible*'. One pharmacist also commented on the size of the text: '*Good signalisation, but the text should be more visible/readable. The large text should be made a little bigger*'.

Position

Other pharmacists referred to the position of the label on medication packaging, and suggested placing the warning on the front of the box.

Colour

Pharmacists also thought that the colours of the warnings could be made to be 'more visible' to improve noticeability. Some suggested improving the colours in conjunction with placing the warnings more prominently on the medication packaging.

Simplification

The second most frequent theme was simplification of the warnings. Suggestions included making the warnings more precise. One pharmacist commented, '*There should not be too many similar pictograms – this becomes a source of error. Labels 1, 2 and 3 are too close – the text is not read to the end!*'

Prevalence

Several pharmacists called attention to the problem of prevalence of the warnings, suggesting that the frequency of the appearance of the warnings could lead to the '*banalisation*' of the message. '*The pictograms should be reserved for bans or severe side effects*'; '*less frequency. There are a lot of Level 1 that are rarely justified and lead to a diminution in the effectiveness of the pictogram. If Levels 2 and 3 were larger, it would have more impact on patients*.'

4.3.1.3 Perceived advantages and disadvantages of the Australian and French warnings

French doctors and pharmacists were asked, "What are the advantages and disadvantages of the warnings A, B and C (the French warnings), compared with the warnings D, E and F (the Australian warnings)". The responses were categorised according to the themes raised in each response.

A very strong theme emerging from the pharmacists' responses was the concern that consumers would not read the Australian warnings, due to their lengthy text and the small font size. The pictograms used in the French approach were perceived to have much more visual impact, allowing the warning to be rapidly identified and attract attention, resulting in a warning that is more visible than the Australian warnings. In addition, the pictogram was perceived to have the advantage of conveying the warning message in a glance, and of being understood by everyone (for example, those who are illiterate, those with vision difficulties such as older drivers who may not be able to read the text), which was in contrast to the Australian labels. This characteristic was also seen to be an advantage for both health professionals and consumers in communicating information.

The grading system of risk for driving was seen to be an advantage, while the Australian warnings were perceived by some to lack characteristics that enable viewers to distinguish between the warnings and their message. There were mixed perceptions of the clarity of the warnings, with some pharmacists perceiving the Australian warnings to be more specific than the French, while others held the opposite perception.

Similar sentiments were revealed in the responses from the sample of medical doctors. The most frequently occurring theme was that the use of the pictograms in the French approach was an advantage. The pictograms were perceived to draw attention and have immediate visual impact for the viewer, and again this was thought to especially benefit those with vision difficulties. The pictograms were also perceived to convey information easily, and to be understood without it being necessary to read the text. Overall, the French warnings were thought to be more memorable and easily understood than the Australian warnings, which were considered to contain too much text in too small a font to be easily read. The issue of familiarity with the French warning labels and its potential impact on their perceptions of visual impact could not be tested here. This remains a possible confound of these findings.

As with the pharmacists, there were somewhat mixed and opposing perceptions of the medical doctors concerning the explicitness of the Australian and French warning content. One medical doctor noted the caution against alcohol consumption, and considered this to be an advantage of the Australian warnings over the French warnings.

5 CONCLUSIONS AND RECOMMENDATIONS

This project has critically examined the currently established Australian approach to medication warnings regarding potential driving impairment.

A sample (*n* = 358) of hospital pharmacy outpatients recruited at a large public hospital were surveyed concerning their responses to the current Australian medication warning labels and to the recently developed French approach to labelling. Differing content messages and presentations in the three Australian and three French labels were considered. Readability, visual presentations, knowledge, attitudes towards and responses to these warnings were compared for the Australian sample. Associated information for some of these issues was obtained from a group of French Health professionals (*n* = 98). In addition a follow-up survey of a sub sample (*n* = 53) of the hospital outpatients was conducted at a later date to determine their responses to the Australian medication labelling that had been on the medications reported in use at the time of the recruitment hospital visit. It is to be noted that these three samples represent highly informed respondents. Persons recruited in a hospital pharmacy are in a situation in which conformity to best practice standards of using labels and actively counselling consumers is highly likely to occur.

5.1 MESSAGE CONTENT

Using recall of the content of the warning label as an indicator of user response to the message content the majority of users recalled messages on medications taken within the last seven days. At the same time in the context of this well-informed sample the fact that around 10% did not recall these messages is of some concern.

The French Health professionals expressed some concerns about the absence of reference to the possible increase of impairment due to alcohol use in the French labelling system.

5.2 READABILITY

None of the labels was rated as easiest to read by a majority of respondents. Just over a third (37.3%) considered the most serious Australian warning label as the easiest to read and a quarter (24%) considered the Level 1 French label (yellow pictogram) as the easiest to read. This finding probably indicates that no particular label stood out as easy to read.

5.3 VISUAL PRESENTATIONS

The Australian respondents indicated that the most important features of a medication warning label in terms of visual impact were its size and the related text size. Colour of the label was also very important with the colour “red” being rated as of most importance. Of less importance but still considered important by half the sample were the pictograms used in the French warning label system and the triangle used in the Australian highest severity warning label. The use of orange and yellow colours (French system) was not rated as of high importance in terms of visibility. The implications of these findings for driving warning labelling are important. They support the current system of using additional labelling over and above the advice provided directly on medication packaging.

Whilst there was some variation in the responses of the French doctors and pharmacists the key characteristics of colour, size and pictographic presentation emerged as the most important warning label features.

5.4 KNOWLEDGE OF WARNINGS

The recall of driving warnings was related to the number of labelled medications that the respondent was currently using. The more medications with a warning label used the higher the recall of the message content. In the context of the survey being conducted in a hospital pharmacy and the findings of the other major Australian general community survey of knowledge of warnings, this finding suggests that there is a need to raise community awareness of this aspect of driving safety. Participants reported generally accurate knowledge concerning the effects of medicines and other substances on driving. However, two of the assessment items were associated with incorrect responses. These concerned the risk incurred from exceeding the prescribed medication dose, and at the time of commencing treatment.

5.5 ATTITUDES ASSOCIATED WITH THE WARNING LABELS

Attitudes were primarily measured through estimates of risk. The most significant finding in relation to attitudes related to respondents' estimates of their potential risk of being involved in a car crash when driving if they were taking one of the labelled medications. The majority (51.2%) rated the French highest risk label (Level 3, red pictogram) as that carrying most risk and the highest risk Australian label was only considered as the highest risk warning by one fifth (22.2%) of the sample. This finding was replicated in respondent's assessments of the likelihood that they could be involved in a car crash when driving after taking a medication with these labels. This may partially reflect an habituation response to the Australian label but in the context of the previous assessments supports the French labelling system (with pictographs) as more effective if the medication is potentially impairing.

5.6 RESPONSE TO DRIVING WARNINGS

Participants' intentions to comply with the advice of the strongest warning labels in both Australia (Label 1) and France (Level 3) were explored by asking participants to rate the likelihood of numerous behavioural options. Participants were asked "*If you were prescribed a medication displaying Label 1, what would you be likely to do?*" and the differences in intentions related to the Australian and French warning labels were tested for significance using McNemar chi square for paired samples. There were no differences in regard to *driving when the traffic was less heavy* or *not taking the medication so that they could drive*. All other differences were significant with the stronger effect being observed for the French label. It is of concern that at the follow up survey of this well advised sample of people who were on high risk medications only just over half (51%) recalled seeing a warning label on their medications. Whilst three quarters (78%) of these respondents reported following the warning label advice this still leaves a large proportion of people who do not take the labelling into account in making their decisions about driving.

5.7 CONCLUSIONS AND RECOMMENDATIONS

The results are potentially important for the Australian approach to medication warnings about driving impairment. The research contributes both practical and theoretical findings that can be used to enhance the effectiveness of warnings and developing countermeasures in this area. Suggestions for future research relate to continued investigation of the effects of medication and other substances on driving skills, warning label design, and validation of consumer self-assessment of impairment. This project has involved persons with the highest level of likelihood of knowledge and awareness of medication warning labelling. Even in this context it would appear that a review of the Australian messaging system would be useful particularly in the context of increasing evidence relating to associated driving risks. The inclusion of the warning regarding potential increased risk associated with alcohol use was well supported. Reviewing text size, readability and simplicity of messages including the addition of pictograms as well as clarifying the importance of potential risk in a general community context is recommended for consideration and further research.

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