EVALUATION OF AN EDUCATIONAL RESOURCE FOR THE EFFECTIVE COMMUNICATION BETWEEN HEALTH CARE PROFESSIONALS AND PATIENTS ABOUT IMPAIRING RISKS OF PRESCRIPTION PAIN MEDICATION IN RELATION TO DRIVING

TIRF USA Inc. TIRF

The knowledge source for safe driving

THE TRAFFIC INJURY RESEARCH FOUNDATION

The mission of the Traffic Injury Research Foundation (TIRF) is to reduce traffic-related deaths and injuries. TIRF is a national, independent, charitable road safety research institute. Since its inception in 1964, TIRF has become internationally recognized for its accomplishments in a wide range of subject areas related to identifying the causes of road crashes and developing programs and policies to address them effectively.

Traffic Injury Research Foundation
171 Nepean Street, Suite 200
Ottawa, Ontario K2P 0B4

Ph: (613) 238-5235
Fax: (613) 238-5292
Email: tirf@tirf.ca
Website: www.tirf.ca

Copyright © March 2020

EVALUATION OF AN EDUCATIONAL RESOURCE FOR THE EFFECTIVE COMMUNICATION BETWEEN HEALTH CARE PROFESSIONALS AND PATIENTS ABOUT IMPAIRING RISKS OF PRESCRIPTION PAIN MEDICATION IN RELATION TO DRIVING

By: Robyn D. Robertson[1,2], Heather Woods-Fry[2], David Carr[3], Marisela Mainegra Hing[2], and Ward G.M. Vanlaar[2]

[1]Traffic Injury Research Foundation USA, Inc. (TIRF USA)

[2]Traffic Injury Research Foundation (TIRF)

[3]Washington University School of Medicine

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

Financial support for this study has been received by TIRF USA from the US Food and Drug Administration (FDA). Ethical approval has been obtained from the New England Independent Review Board (IRB#: 120160541). The research team would like to acknowledge the contributions of Kara Morris, Tara Casanova Powell and Devon Valentine who contributed to the introductory literature review. Tara Casanova Powell contributed to the data collection of the focus groups in July 2017. In addition, the research team acknowledges the staff at The Rehabilitation Institute of St. Louis (TRISL) for their assistance with patient recruitment.

1. INTRODUCTION

In recent years the issue of drug-impaired driving has garnered increased attention. However, greater focus has been placed on illegal drugs as compared to medicinal drugs despite the fact that numerous medications have been identified as having the potential to impair driving. These include but are not limited to; benzodiazepines, antidepressants, antihistamines and prescription pain medications such as opioids (Emich, van dijk, & Monteiro, 2014; Smyth, Sheehan, Siskind, Mercier-Guyon, & Mallaret, 2013a; Rudisill, Zhu, Kelley, Pilkerton, & Rudisill, 2016). While many studies have examined the effects of benzodiazepines and antihistamines with respect to driving, pain medications including opioid analgesics have not received similar attention (Smyth, Sheehan, Siskind, 2013b).

In the late 1990s, laws governing opioid prescribing for the treatment of chronic pain were relaxed by American state medical boards. Machikanti et al. (2012b) argue this coincided with a "dramatic increase" in the use of opioid analgesics by Health Care Practitioners (HCPs). Between 2001 and 2005, the use of several major opioid analgesics including codeine, hydrocodone, morphine, oxycodone and methadone increased 38% (Dubois, Bédard, & Weaver, 2010). Examining data from the National Hospital Ambulatory Medical Care Survey from 2001 to 2010, Mazer-Amirshahi, Mullins, Rasooly, van den Anker and Pines (2014), found the number of emergency department visits resulting in an opioid analgesic prescription increased from 20.8% to 31.0%. Further, Chihuri and Li (2017) showed the prevalence of prescription opioids detected in fatally injured drivers had increased in the past two decades. All of these studies highlight a need to assess the effect of increased prescription opioid use on traffic safety.

There were 238 million opioid prescriptions filled by American pharmacies in 2011 (Mazer-Amirshahi et al., 2014); and in 2012 there were 135.5 million prescriptions written for hydrocodone, the most frequently prescribed opioid in the United States (Kaye, Kaye, & Lofton, 2013). Opioid use in the United States has been on the rise and addressing opioid abuse and misuse has been identified as a priority by the United States Government (Dubois et al., 2010). There has also been a recent surge in older adults seeking treatment for opioid use disorder, indicating specialized research about this population is critically needed (Huhn, Strain, Tompkins, & Dunn, 2018).

Efforts to curb accidental deaths due to opioid misuse and the rising rates of opioid dependence and abuse have driven the development of more comprehensive guidelines on opioid prescribing practices by HCPs. These guidelines provide recommendations on how to manage and monitor opioid use by patients and how to assess and reduce the risk of opioid misuse and abuse. However, less frequently addressed is the potential risk posed by opioid use and driving. A small body of research has begun to examine how HCPs and patients communicate about pain management, but data on the topic is still very limited (Matthias, Krebs, Collins, Bregman, Coffing, & Bair, 2013). The existing literature has emphasized the need to understand how HCPs and patients communicate about pain medication risks as essential for developing more effective tools and strategies. Several studies have examined poor risk communication and identified the

prevalence of miscommunication around pain medications, but few have explored how to improve communication (Matthias et al., 2013). Specifically, patients and physicians report communication about chronic pain and opioids is often challenging. Unfortunately, there is little empirical research on whether patient-physician communication about pain affects visit experience for patients and physicians. Recent research has indicated training programs focused on improving communication skills including responding to patient requests for more opioids, have potential to improve visit experience ratings for both patients and physicians (Henry, Bell, Fenton, & Kravitz, 2018).

In light of the above, this review provides a comprehensive summary of the existing academic literature on:

- The prevalence of medication-impaired driving in the United States, notably with respect to pain medications;
- The side effects of pain medications that may impair driving;
- The elevated crash risk associated with pain medication use by drivers;
- The experimental studies on the impact of pain medication on opioid-naïve and opioid-maintained patients;
- Several clinical guidelines which have been developed to inform opioid prescription practices, specifically as they relate to informing patients about driving abilities;
- Current methods of risk communication between HCPs and patients, including verbal communication, written information, medication inserts and both text-based and pictorial-based medication warning labels.

Included in this last area of focus is a discussion on medication warning labels specifically designed to inform patients about the risks posed to their driving. Two European countries have legally mandated the use of these warnings on all driving-impairing medications and recent efforts have been undertaken to standardize labelling techniques in Europe.

1.1 Impacts of prescription pain medication on driving ability

The most common side effects of prescribed opioid analgesics for pain relief include nausea, constipation, drowsiness, sedation, dizziness, dry and itchy skin and vomiting (Kahan, Mailis-Gagnon, Wilson, & Srivastava, 2011; Kaye et al., 2013). Other patients report mood changes, mental clouding and impaired motor skills (Wilhelmi & Cohen, 2012). The more common opioids used to treat pain include codeine, hydrocodone, oxycodone, methadone and morphine; hydrocodone and oxycodone have also been shown to impact critical thinking skills (Dubois et al., 2010; Wilson, Stimpson, & Pagán, 2014). Tramadol, an opioid commonly prescribed for pain management, can produce many of the same side effects, including dizziness, nausea, vomiting, headaches, sweating, drowsiness and in more extreme cases, seizures (Clarkson, Lacy, Flinger et al., 2004; Kaye et al., 2013).

Approximately 20% to 60% of patients initiating opioid treatment or with dose increases experience sedation or drowsiness. (Cherny et al., 2001; Schisler, Groninger, & Rosielle, 2012). Patients on stable doses generally develop a tolerance for the side effects of the drug within the first several weeks of use, but variations in the time it takes for this tolerance to develop have been reported (Kaye et al., 2013). Side effects may return when opioids are combined with other

medications, illicit drugs, or alcohol (Chou et al., 2009). Research has shown a 30% increase in dose can result in some degree of cognitive impairment in patients on stable opioid treatment who have otherwise developed a tolerance to the side effects (Benzon et al., 2013).

The side effects listed above pose a serious concern for the skills required to drive safely, as they can impact psychomotor skills, cognitive function, decision-making, eyesight, attention to detail and alertness (Kaye et al., 2013; Webster, Dickson, Mannan, & Staton, 2018). The potential for impairment is more acute in opioid-naïve patients (those initiating opioid treatment), but may also be present in opioid-maintained patients (those on long-term stable doses who have generally become tolerant of negative side effects) receiving an increase in dose, or combining their pain medication with other drugs or alcohol.

Only a few studies have examined the impact of pain medication on driving. In general, research has focused on the issues of alcohol and illegal drug-impaired driving and when medication impaired driving is explored, drugs such as benzodiazepines, antihistamines and hypnotics are principally studied (Bezemer, Smink, van Maanen, Verschraagen, & de Gier, 2014). Conversely, other medications, including opioids and antidepressants, have not received as much attention despite their prevalent use by drivers and there is a lack of comprehensive studies on the topic (Orriols et al., 2010; Wilson et al., 2014; Zacny, 1996).

Additionally, existing research on opioids and driving has revealed mixed results. Epidemiological studies have demonstrated opioids are prevalent in American drivers, as well as in other countries. Many have found a significant relationship between the presence of opioids in drivers and an elevated crash and culpability risk (Leung, 2011; Duren, Ehsani, Grant, & Fowler, 2019). Alternatively, experimental studies have often failed to find significant impairment as a result of opioid use in opioid-maintained patients; however, some studies have shown impairment amongst opioid-naïve patients and those who are combining several medications (Fishbain, Cutler, Rosomoff and Rosomoff, 2003; Strand, Fjeld, Arnestad and Mørland, 2013).

While the side effects of pain medication may impair driving, it is noted the use of pain medication can improve driving abilities in certain situations (Beirness, Cumming, Hughes, Zobeck, & Griffiths, 2012; Wilhelmi & Cohen, 2012). Specifically, the use of prescribed pain medication can help alleviate the impairing symptoms of underlying medical conditions (Benzon et al., 2013). Extreme pain can in itself be debilitating and, if left untreated, can directly impair driving, or cause secondary conditions, such as sleep disorders that can impair driving. Therefore, a balanced approach is required when assessing possible impairment related to pain medication, with an understanding that pain left untreated can also pose a threat to safe driving.

1.1.1 Epidemiological studies

Epidemiological studies in the United States have reported high numbers of opioids in drivers involved in fatal car crashes and in the general driving population. Wilson et al. (2014), examined crash data from the Fatality Analysis Reporting System (FARS) database and found in 2010, 11.4% of all fatally injured drivers tested positive for drugs, of which 46.5% tested positive for prescription drugs. Of those who tested positive for prescription drugs, 10.2% tested positive for oxycodone

and 11.1% for hydrocodone, representing a marked increase from 1993 findings for both drugs (Wilson et al., 2014).

Results from the 2013-2014 National Roadside Survey, which collected oral fluid and blood samples from a random sample of American drivers from hundreds of sites through the United States, showed 10.3% of weekday daytime drivers and 7.3% of weekend night drivers, tested positive for prescription and over-the-counter medications (Berning, Compton and Wochinger, 2015). Furthermore, these numbers were for only those drivers testing positive for medications alone, thus it is possible a proportion of drivers testing positive for illegal drugs also had medications present in their systems and would not have been captured in these statistics.

Epidemiological studies have also assessed the crash and culpability risks associated with medication use and driving. Dubois et al. (2010), in a case control study examining FARS data for the period of 1993 to 2006, reported American drivers who tested positive for opioid analgesics were at a higher risk of being involved in a crash. This is especially the case in the presence of alcohol (Li and Chihuri, 2019). Specifically, drivers who tested positive for opioid analgesics had 32% more crashes, 38% more traffic convictions and 88% more license suspensions than other drivers (Dubois et al., 2010).

A French case control study, using data from the national health care insurance database, police reports and the national police database of injurious crashes, demonstrated drivers injured in vehicle crashes who tested positive for buprenorphine or methadone had an elevated risk of being responsible for the crash (Corsenac et al., 2012). A larger European case control study, using data from Belgium, Denmark, Finland, Italy, Lithuania and the Netherlands, examined the risk of severe injury accidents for ten substance groups. Drivers who used medicinal opioids were significantly more likely to be severely injured than drivers who tested positive for benzodiazepines (Hels, Lyckegaard, Wiese Simonsen, Steentoft, & Bernhoft, 2013).

Three Norwegian studies using data from three population-based registries (the Norwegian Prescription Database, the Norwegian Road Accident Registry and the Norwegian Central Population Registry) reported elevated crash risk for drivers positive for various pain medications. Engeland, Skurveit and Mørland (2007) found the risk of being involved in a vehicle crash was somewhat increased in the first seven days of prescribed drug use and that this risk was higher for users of opioid analgesics. Similarly, Bramness, Skurtveit, Mørland and Engleand (2007), showed individuals who were prescribed carisoprodol (a muscle relaxant used for acute lower back pain) had an elevated risk of being involved in a traffic crash in the first seven days after the medication was prescribed. Bachs, Engeland, Mørland and Skurtveit (2009) initially found a significant increased crash risk for drivers using codeine, however, when data on drivers exposed to codeine and another impairing drug were excluded (including other opioids, benzodiazepines, hypnotics), the relationship for codeine was no longer significant. In all, 98 of the 181 drivers positive for codeine were also positive for another impairing drug, suggesting that drug combinations were common and the use of codeine in conjunction with other medication did pose an elevated drug risk.

More recent research has supported these findings. For example, a meta-analysis conducted by Chihuri and Li analyzed 15 studies about the use of prescription opioids on driver behavior, specifically, examining crash risk. Across all studies examined, the existent epidemiologic evidence indicated that use of prescription opioids by drivers was associated with significantly increased risk of crash involvement and culpability (Chihuri & Li, 2017).

As evidenced above, epidemiological studies have reported a high prevalence of medicinal drugs and opioids in fatally injured drivers and the general driving population in the United States. Additionally, both American and European studies have found evidence for elevated crash and culpability risks associated with opioids and pain medication use by drivers. However, while these studies provide evidence for a relationship between opioid use and crash risk, it is not possible to definitively determine if opioid use causes impaired driving directly, as the impact of additional conditions and covariates (e.g., the use of other impairing drugs, combining opioids with alcohol, crash responsibility, etc.) are not always assessed (Leung, 2011).

1.1.2 Experimental studies

In contrast to epidemiological studies, experimental studies more directly examine the impact of medicinal drugs on driving impairment, while controlling for other influences. However, limited experimental studies have assessed the effects of pain medication on driving (Schisler et al., 2012). The existing literature focuses on two types of pain patients: (1) those who are opioid-naïve, including both patients who are initiating opioid treatment and healthy non-opioid using volunteers; and (2) opioid-maintained patients who are on long-term stable doses and have generally become tolerant to any negative side effects (Wilhelmi and Cohen, 2012). In general, studies have focused on the latter group and sought to address the question of whether opioid-maintained patients can safely drive (Borgeat, 2010).

Opioid-maintained patients. In a systematic review of experimental studies on the effects of opioids on opioid-maintained patients, Fishbain, Cutler, Rosomoff and Rosomoff (2003) reported there was "moderate, generally consistent evidence for no impairment of psychomotor abilities of opioid-maintained patients." Additional experimental case control studies examining the effects of methadone (Baewart, Gombas, Schindler, Peternell-Moelzer, Eder, Jagsch, & Fischer, 2007), codeine (Nilsen et al., 2011), transdermal buprenorphine (Dagtekin et al., 2007) and fentanyl (Menefee et al., 2004; Sabatowski et al., 2003) on long-term opioid-maintained patients generally did not find driving skills to be impaired.

Specifically, Baewart et al. (2007) examined the impact of peak (when the medication is at its highest concentration in the patient's body) and trough (when the medication is at its lowest concentration) levels of methadone in opioid-maintained patients. While there were some observed differences between the two groups – with patients at trough levels performing better than those at peak levels on reaction time tests, but worse on stress tolerance and visual abilities tests – only moderate deficits in driving skills were observed. Baewart et al. (2007) concluded opioid-maintained patients did not experience significant impairment related to driving abilities when administered methadone.

Using a video driving simulator test, Nilsen et al. (2011) did not find significant differences between long-term codeine users and chronic pain patients not using codeine. However, when compared to healthy controls, chronic pain patients not on codeine treatment did show poorer driving performance. Therefore, the authors concluded codeine did not impair long-term users over and above any impairment seen in chronic pain patients. Despite this finding, they still supported the recommendation that pain medication users refrain from driving two to four hours following use and further cautioned about generalizing the findings as only a driving simulator was used.

Sabatowski et al. (2003) assessed the effects of long-term fentanyl use by comparing the results of patients who had been on stable doses for at least two weeks to a group of healthy controls. Using a computerized test measuring attention, reaction times and other driving-related skills, researchers found no significant impairment due to fentanyl use. Similarly, Menefee et al. (2004) determined driving abilities of long-term fentanyl users on stable doses were not significantly impaired when compared to their pre-treatment results. The study did not assess driving abilities in the immediate period of time following the initiation of fentanyl treatment. Thus, the impact of the initial sedating effects of fentanyl was not evaluated. The authors concluded that the question remains as to how patients will be affected following initial use (Menefee et al., 2004). In addition, it is difficult to study the drug in typical patients with significant co-morbidities and polypharmacy.

Breivik (2006) argued cognitive and psychomotor abilities of opioid-maintained patients were not generally impacted in a way that would make it unsafe for them to drive, as they have generally become tolerant to the side effects first experienced. Borgeat (2010) also highlighted that as tolerance develops the sedating side effects of pain medication decrease. Tolerance, however, may be impacted by the ingesting of alcohol or other drugs and thus impact an opioid-maintained patient's ability to drive (Breivik, 2006).

The use of multiple medications has been identified as a risk factor for increasing the side effects of opioids that can impact driving (Benzon et al., 2013). According to Tan (2007), the use of other psychoactive drugs, including antidepressants, anticonvulsants and benzodiazepines, was common in patients taking pain medications. In a study by Sabatowski et al. (2003), 36% of the patients on pain medication were taking additional medications. The cognitive and psychomotor side effects resulting from these drugs had been shown to increase risks to driving. Tan (2007) argued the combined use of prescription medication may increase driving risks, even in opioid-maintained patients and highlighted that most studies recommend opioid-maintained patients prescribed other psychoactive drugs refrain from driving. This may be especially true in older adults with multi-morbidity.

Opioid-Naïve Patients. While fewer studies have explored the impacts of pain medication on opioid-naïve patients, existing research has found driving-related skills to be impaired when pain medication is first administered. Specifically, Corsenac et al. (2012) observed impairment of psychomotor skills and cognitive abilities in opioid naïve patients. Borgeat (2010) showed opioid-naïve patients experienced sedation, dizziness, decreased reaction times and impacted motor coordination following the administration of a single dose of an opioid. He concluded the driving abilities of opioid-naïve patients were impacted following the initial use of opioids. In a review of the existing literature Strand, Fjeld, Arnestad and Mørland (2013) found methadone and

buprenorphine had the potential to impair opioid-naïve patients. Bramness et al. (2011) reported methadone can impair psychomotor skills when administered to healthy opioid-naive individuals.

A case control study in which immediate-release oxycodone was administered to healthy adults who were not suffering from pain, showed significant declines in attention, working memory and verbal memory in the first hour following administration of the dose. The impairing effects did however dissipate with time and normal functioning generally returned within five hours of the dose (Cherrier, Amory, Ersek, Risler, & Shen, 2009).

Alternatively, Amato et al. (2013) did not find any significant impairment in driving ability, alertness, or psychomotor performance in healthy, young, opioid-naïve patients administered three doses of codeine. However, in a review of the existing literature, Amato et al. highlighted that about half of the studies did find impairing effects, often observed with higher doses (above 60mg). They further suggested additional research on how pain medications impact different populations, including the elderly, should be undertaken.

Breivik (2006) argued opioid-naïve patients will experience a period of "reduced cognitive functioning and slowing of psychomotor skills" when first prescribed opioid pain medication and depending on the dose prescribed, these effects may impact driving ability. Impairment may also be observed in patients who take opioids irregularly or in those taking high doses for "recreational use," to experience a high (Breivik, 2006).

The above review summarizes important findings. First, epidemiological studies revealed opioids to be prevalent amongst fatally injured drivers and in the general driving population; and opioid use was associated with elevated crash risks. Notably, a recent meta-analysis revealed opioid use was associated with increased motor vehicle crash risk and crash culpability (Chihuri and Li, 2017). Second, experimental studies have found inconsistent evidence as to whether opioids directly impaired driving abilities (Kelly, Darke, & Ross, 2004). In general, however, studies examining the effects on opioid-naïve patients revealed evidence of impairment after the initial use of opioids; and studies examining opioid-maintained patients have found no evidence of impairment, likely due to the tolerance to detrimental side effects which develops after long-term use (Ferriera, et al 2018). Finally, the combined use of other medications, drugs, or alcohol with long-term opioid use has been shown to cause side effects similar to those experienced by opioid-naïve patients and in turn may impair driving (Chihuri and Li, 2019; Li and Chihuri 2019).

1.2 Opioid guidelines

As previously discussed, efforts to standardize prescribing practices in order to increase patient safety have driven the development of more comprehensive guidelines. However, very few of these guidelines address the issue of driving specifically and those that do address it, do so in limited ways (Amato et al., 2013). Specifically, the vast majority of guidelines that address driving only include one or two recommendations, specifying HCPs should advise patients as to the potential side effects that could impact driving, and to refrain from driving during the initiation of treatment or dose titration.

The American Society of Interventional Pain Physicians' *Guidelines for Responsible Opioid Prescribing for Chronic Non-cancer Pain*, includes a set of recommendations designed to guide

opioid risk communication between patients and their doctors (Manchikanti et al., 2012a). The Guideline, last updated in 2012, recommends the use of a treatment agreement between the patient and doctor, which includes specific statements wherein the patient acknowledges they understand the risks posed by opioids. Specific to driving, the Guideline recommends the inclusion of the following statement as part of the treatment agreement:

> I understand that driving while under the influence of any substance, including a prescribed controlled substance or any combination of substances, which impairs my driving ability, may result in DUI charges.

Additionally, the Guidelines recommend doctors advise patients initiating opioid treatment to avoid driving a car until a stable dosage is established and until the patient is sure that they are not experiencing sedation (Manchikanti et al., 2012b).

The American Pain Society and the American Academy of Pain Medicine's *Clinical Guidelines for the use of Chronic Opioid Therapy in Chronic Non-cancer Pain* also provides several recommendations related to driving while on opioid therapy (Chou et al., 2009; McMullen & Howie, 2011). Specifically, the Guidelines recommend patients be advised of initial and lasting side effects which may impact their ability to drive or work safely, and patients be counseled not to drive if they experience these side effects. The Guidelines emphasize doctors should discuss these side effects when initiating treatment and when changing doses of opioids. The Guidelines inform HCPs they should be aware of additional regulations that patients in certain professions (e.g. bus drivers and pilots) may face if prescribed opioids. The Guidelines also recommend the use of a written treatment plan as a means of informing patients about the risks associated with opioid treatment.

The *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*, developed by the National Opioid Use Guideline Group, recommends physicians advise patients that "opioids cause cognitive effects that could impair their ability to drive," especially during initial treatment and when used in combination with alcohol, benzodiazepines, or other sedating drugs (NOUGG, 2018, p. 29). As part of a series of messages doctors should use to create patient education materials, the Guideline recommends including the statement:

> Opioids have risks – these can be managed by working cooperatively with your doctor. […] Do not drive while your dose is being gradually increased or if the medication is making you sleepy or confused.

Further, the Guideline recommends HCPs warn patients to avoid alcohol and sedating drugs while taking opioids and the common side effects of opioids include drowsiness and dizziness. Additionally, the Guideline recommends prescribing the weakest dose of opioid possible to treat the pain in question and monitoring and ensuring patient education when initiating treatment and when increasing the dose.

Despite the existence of several guidelines, there is no central authority on this topic. Additional issues surrounding differing opinions relating to dosage limits and what constitutes proper monitoring and patient risk management, further hinders a standardized approach to counseling patients on driving risks (Amato et al., 2013; Wilhelmi & Cohen, 2012; Herzig et al., 2018).

Failing to advise patients on the risks posed to driving or failing to monitor patients on opioid treatment can have legal consequences for HCPs (Collins & Jones, 2019). Wilhemi and Cohen (2012) referenced several court cases in the United States in which doctors have been held liable for their patients' driving actions when they failed to: "prescribe a specific and limited dosage in accordance with current guidelines; regularly examine the patient; disclose risks, including impaired driving; recognize and modify treatment for drug abusers; and monitor the patient properly." Additionally, as touched upon in the American Society of Interventional Pain Physicians' *Guidelines*, patients who drive while impaired by opioids can be charged with a driving under the influence offense. Providing information and discussing side effects allows patients to make informed decisions about their ability to drive; failing to do so could have legal implications for both HCPs and patients (Tan, 2007).

Pharmacists are also an important resource in our health care system and play a role in education of patients who are prescribed opioids and managing the opioid crisis (Barlas, 2019). Some studies have noted pharmacists may be missing important messaging regarding safe opioid use (Salinas et al., 2012). Similar to physician studies, pharmacists have stated they may lack time, knowledge, and confidence is communicating those risks (Hagemeier, Murawski, Lopez, Alamian, & Pack, 2014). Yet, there is evidence pharmacists play an important role in de-prescribing (Thakur, Frey, & Chewning, 2019). Although pill bottles filled with prescription opioids may provide warning on driving or using when operating heavy machinery, it is unknown how often pharmacists educate patients on this topic in general practice. There has been a call in the literature for pharmacists to address the risks of driving when they dispense opioids to their patients (Sigona & Williams, 2015).

While it is generally accepted HCPs should counsel their patients about the impacts of opioids on their driving – a recommendation reiterated throughout the guidelines – little information about effective ways in which to communicate these risks and ensure patient understanding and adherence, are provided. The limited research on risk communication between HCPs and patients is reviewed in the following section.

1.3 Methods of risk communication between HCPs and patients

The existing research on risk communication between HCPs and patients has examined the effectiveness of verbal and written communication, as well as medication inserts and medication warning labels. Within the American context, opioids tend to drive the push for increased medication risk communication, as evidenced by the push for more comprehensive guidelines (Brooks, 2014; Herzig et al., 2018).

While drugs are often classified dependent on their chemical composition, the literature explored in this review predominantly references classification systems that categorize drugs based on the side effects experienced by users. For example, Jonah (2012) summarized the literature regarding the effects of the major drug classes on the body, based on the Drug Evaluation Classification (DEC) program used by police services in the United States and Canada to detect drug-impaired drivers. Rather than relying on chemical composition, this system categorizes drugs based on the common side effects to the body (e.g., pupil dilation, heart rate, blood pressure, balance, etc.). These classes include: Cannabis; Central Nervous System Depressants; Central Nervous System Stimulants;

Hallucinogens; Dissociative Anesthetics; Narcotic Analgesics; and, Inhalants. Focusing on prescription medication, the European Driving under the Influence of Drugs, Alcohol and Medicines (DRUID) project developed a classification system categorizing medications based on their central nervous system side effects and their potential to impair driving. This classification system is discussed in more depth later in the report, as it has guided the development of more comprehensive medication warning labels concerning driving under the influence of medications.

1.3.1 Verbal and written risk communication

Existing research suggests some HCPs rely heavily on verbal counsel as a means of conveying information on the side effects associated with prescribed pain medications and the potential risks they may pose to a patient's driving abilities. A study by Benzon et al. (2013) surveyed over 400 physicians from three American pain societies about their pain mediation prescribing practices. Results showed 81% of physicians cautioned their patients about driving when first initiating opioid treatment and 75% cautioned their patients when increasing the dose. Alternatively, an Australian study examining older drivers' health literacy, found 85.7% of the 322 surveyed drivers reported not receiving information from their doctors about the impact of their medical condition and medications on their driving (Sargent-Cox, Windsor, Walker, & Anstey, 2010).

Kumar (2013) conducted a survey on doctor knowledge and adherence to the United Kingdom's Driver and Vehicle Licensing Agency's (DVLA) guidelines on fitness to drive, which are meant to help medical professionals inform patients about driving with certain conditions. Responses from 34 doctors showed that while all the doctors "were aware of the guidelines only 38% discussed them with their patients" (Kumar, 2013). Moreover, half of the surveyed doctors reported they did not routinely discuss medication effects, including impact on motor abilities, concentration and sedation with their patients (Kumar, 2013). Those that did counsel their patients on the effects of medications, generally only did so verbally without written documentation. A more recent UK study found that of the 33 cases analyzed, only 9% documented the patient was informed about the consequences of driving on opioids. The study noted that while the discussion did often occur, it was rarely accompanied by documentation in written format (Collins & Jones, 2019).

The effectiveness of relying on verbal counsel to convey risks associated with pain medication has been called into question, as research has shown that patients experience difficulty recalling verbal warnings and communication about medication risks (Smyth et al., 2013b). It also creates certain liability for the HCPs (Collins & Jones, 2019). Alternatively, the combined use of verbal counsel and written medication instructions has been shown to increase recall and medication adherence. Verbal and written information detailing the common side effects of pain medication, the potential risks posed to driving, as well as current legal regulations on driving while taking pain medication, can help patients make informed decisions (Breivik, 2006). Written instructions should inform patients that if they experience any of the side effects that could impact their cognitive and psychomotor abilities, such as sedation, dizziness, or confusion, they should refrain from driving and consult a doctor. Additionally, written medical instructions should warn patients about the adverse side effects they may experience if they use pain medication in combination with other medication, alcohol, or illegal drugs (Breivik, 2006).

As recommended by the *Clinical Guidelines for the use of Chronic Opioid Therapy in Chronic Non-cancer Pain*, a written opioid therapy management plan, or opioid contract, can help inform the patient, their family and any other doctors involved in treating the patient, about the potential side effects of their prescribed medication (Chou et al., 2009). Opioid agreements and contracts can also serve to remind patients of the risks, which can be important in long-term use situations where patients may not recall initial conversations with their HCPs.

1.3.2 Medication inserts and leaflets

Medication inserts and leaflets, typically produced by pharmaceutical companies and distributed to patients by pharmacists at the time of drug dispensing, also act as a written form of risk communication. It is mandatory for pharmaceutical companies in the European Union to provide inserts for medications with side effects that may pose a risk to driving (Fierro, Gómez-Talegón, & Alvarez, 2013). In addition to providing information on the common side effects and safe use of medications, these inserts also contain information about the possible side effects that may impact the patient's ability to drive. However, Fierro et al. (2013) noted several studies had shown that not all patients read these medical inserts and others found them difficult to understand. There are pamphlets and information available online that discuss the risks for driving with prescription medications (e.g., "Are Your Medicines Increasing Your Risk of a Fall or a Car Crash" CDC 2019). However, it is unknown how much these resources are utilized and/or their efficacy in decreasing risk for drug-impaired driving.

Within the American context, the Food and Drug Administration Amendments Act of 2007 mandated the development of Risk Evaluation and Mitigation Strategies (REMS) for numerous prescription medications as a means of reducing and managing drug risks. Changes in 2013 to REMS for long-acting and extended release opioids, including hydrocodone and oxycodone, resulted in them only being recommended for the management of severe pain where other measures have not been sufficient (Kaye et al., 2013).

As part of REMS, pharmaceutical companies must provide written medication guides with information about the safe use and side effects associated with their medication and this information must be targeted at both patients and HCPs (Wolf et al., 2012). However, a study assessing 185 medication guides found they were on average at a 10^{th}-11^{th} grade reading level with an average word count of 1,932 (Wolf et al., 2012). This finding calls into question the accessibility of medication guides for patients with limited or low literacy (i.e., lack in ability to understand written material).

The issue is broader than low literacy, as close to ninety million Americans have low levels of health literacy (i.e., lack of understanding health and medical information; Shiyanbola, Meyer, Locke, & Wettergreen, 2014). Low health literacy is associated with medication non-adherence, misuse and abuse (Shiyanbola et al., 2014). Research on whether REMS medication guides promote medication education and proper use is limited and the impact of such issues as low literacy have not been fully explored (Brooks, 2014). However, one study which did examine this topic found REMS patient materials fell short in terms of recommended reading level, stressing that developers of these materials should apply plain language to improve readability (Chan, Russell, & Smith, 2018).

While medication inserts and guides provide information on the common side effects of drugs, they do not always specifically address the issue of driving or contain sufficient advice to patients regarding their ability to drive (Legrand, Boets, Meesmann, & Verstraete, 2012). Only in a minority of cases are the package inserts consistently reviewed (Rowa'Al-Ramahi & Na'em Kettana, 2012). Additionally, when they do provide information related to driving, it is generally up to patients to self-assess for any impairment they may experience and to self-regulate their own driving behavior (Smyth et al., 2013b).

A case-control study by McCarthy et al. (2015) found that a group of American patients who were prescribed hydrocodone-acetaminophen and received an information sheet on the risk factors associated with use and driving, reported being less likely to drive within six hours of taking hydrocodone as compared to a control group. While the above study provides some examination of the impact of medication inserts and leaflets on patients' decisions to drive, research is still very limited, both in terms of the effectiveness of medication inserts and their use (Smyth et al., 2013b).

1.3.3 Medication warning labels

As most patients fail to read medication leaflets in any great depth, warning labels affixed to medication containers can allow for risk information to be more visible and accessible (Shiyanbola et al., 2014). HCPs often rely on bringing patients' attention to medication warning labels as a means of risk communication, yet few studies have examined patients' understanding of these warning labels or their impact on patients' driving behaviors (Smyth et al., 2013a; Veldhuijzen et al., 2006).

One study in the Netherlands surveyed patients prescribed medications with a text-based warning label related to driving risks and found that of the 58 participants with valid driver's licenses, 91% were aware of the warning labels yet 71% continued to drive while taking the medication. Despite a high number of participants continuing to drive, 38% did report not driving for a period of time because of the side effects they experienced from the medication, and 60% reported driving more carefully as a result of their medication use (Veldjuijzen et al., 2006). Of interest, 38% reported their HCP did not inform them of potential risks posed to their driving ability by their prescribed medication. Based on the results of the study, the researchers concluded warning labels did not have a significant impact on patient decisions to drive or not and experience of side effects was more likely to influence driving behaviors.

While warning labels increase the visibility of medication side effects, text-based labels do not necessarily overcome barriers to patient comprehension. Specifically, Davis et al. (2006) found one-third of the patients visiting the Louisiana State University Health Sciences Centre read at/or below a 6th grade level, and patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly. Examining the same group of patients, Wolf, Davis, Tilson, Bass and Parker (2006) reported less than half of patients reading at/or below a 6th grade level were able to correctly interpret medication warning labels.

Additional studies have shown certain labelling techniques were more effective than others in conveying risks posed to driving. Specifically, warning labels using pictorial aids, such as pictograms, in addition to print, were more likely to be interpreted correctly by patients with low

literacy (Fierro et al., 2013; Wolf et al., 2010; Wolf et al., 2006; Van Beusekom, Land-Zandstra, Bos, Van den Broek, & Guchelaar, 2017). Pharmaceutical pictograms are "standardized graphic images that help convey medication instructions, precautions and/or warnings to patients and consumers" (United States Pharmacopeia, 2015).

In a review of the existing literature on the use of pictorial aids, Katz, Kripalani and Weiss (2006) reported people had a preference for picture-based information as compared to text-based. Additionally, picture-based information has been shown to improve adherence, recall and comprehension of medication instructions (Choi, 2011; Dowse & Ehlers, 2004; Shiyanbola et al., 2014; Katz et al., 2006). Houts, Doak, Doak and Lascalzo (2006) found a similar consensus on the use of pictorial aids to promote improved patient comprehension and recall, noting the greatest benefits are found for patients with limited literacy.

Warning labels with pictograms used in combination with verbal counseling by HCPs showed greater levels of patient understanding as compared to either method in isolation (Emich et al., 2014; Kheir, Awaisu, Radoui, Badawi, Jean, Dowse, 2014; Del Re, Vaillancourt, Villarreal, & Pouliot, 2016). Specifically, when warning labels with pictograms were paired with HCP counseling of patients as to their meaning, studies revealed an increase in patients' recall of risks, medication adherence and proper medication use (Montagne, 2013; Shiyanbola et al., 2014). To this end, several European countries have developed and introduced pictograms on medication packaging as a means of communicating potential risk to driving abilities, and pictograms are required by law in France and Spain (Monteiro, Huiskes, van Dijk, van Weert, Geir, & 2013).

DRUID Pictograms. In 2005, the European Union recommended the development of a standardized approach to labeling driving impairing medications across Member States (Emich et al., 2014; Monterio et al., 2013). In response, a classification system of all driving-impairing medicines was developed as part of the Driving under the Influence of Drugs, Alcohol and Medicines (DRUID) project. Based on a review of the existing classification systems, experimental and epidemiological studies, 1,541 medicines on the European market were classified into four categories depending on the number of central nervous system side effects associated with use and the level of risk posed to users' driving abilities (Emich et al., 2014; Ravera et al., 2012):

- 50.3% fell under Category 0 as they had no impact on driving fitness;
- 26.0% were classified as Category I for having a minor influence on driving;
- 11.2% were classified as Category II for having a moderate influence;
- 5.8% were classified as Category III for having a severe influence; and,
- 6.7% fell into multiple categories or could be classified into different categories depending on which medications were combined.

The classification system developed under DRUID represents one of the most exhaustive and extensive categorizations of medications for their potential to impair driving in the world (Ravera et al., 2013).

This classification system was in turn used to develop a standardized pictogram warning label design. The DRUID pictogram includes a horizontal bar divided into four sections representing the four categories, color-coded to indicate the respective level of risk posed to driving:

- green for Category 0;
- yellow for Category I;
- orange for Category II; and,
- red for Category III.

A black car inside a triangle is situated in one section depending on the level of risk posed by that specific medication. Additionally, side text was developed to provide users with additional information about the level of risk associated with each category (Emich et al., 2014):

- Category I – "Be careful. Read the patient information leaflet before driving";
- Category II – "Be very careful! Don't drive without the advice of your GP or pharmacist"; and,
- Category III "Attention: Danger! Do not drive. Seek medical advice before driving again".

Recommendations were also developed for HCPs regarding topics to discuss with patients when prescribing medications at each risk level (Ravera et al., 2012):

- Category 0: Confirm that the medicine will be safe for driving, provided that combinations with alcohol and other psychotropic medicines are excluded.
- Category 1: Inform the patient that impairing side effects may occur especially during the first days and that they have a negative influence on his/her driving ability. Give the patient the advice not to drive if these side effects occur.
- Category 2: Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. Advise the patient not to drive during the first few days of the treatment. If possible, prescribe a safer medicine, if effective and acceptable to the patient.
- Category 3: Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. Urgently advise the patient not to drive. Consider prescribing a safer medicine, if acceptable to the patient.

Using a combined pictorial and text-based medication warning label with verbal risk communication recommendations, enhances the potential for patient comprehension of the driving risks associated with medication use (Sudore & Schillinger, 2009).

Emich et al. (2014) compared the existing Dutch text-based warning labels to those developed under the DRUID project. Patients presented with a variety of medications using the text-based label estimated similar levels of driving risks for all categories of medications, despite significant differences (Emich et al., 2014). Comparatively, respondents were more likely to accurately assess and distinguish the level of risk associated with medications when exposed to the DRUID pictograms with side text. While differences were evident in respondents' ability to distinguish levels of risk between the two pictogram methods, no significant differences were observed with respect to respondents' intention to change their driving behaviors.

French pictograms. The French pictogram labeling system is a three-tier model categorization of medications based on their potential to impair driving (Beirness et al., 2012).

- Category I medications have side effects which may result in minor influence on driving ability and are labeled with a car in a yellow triangle and text instructing the user to "Be careful. Read carefully the patient leaflet before driving."
- Category II medications may pose a moderate influence to driving ability and are labeled with an orange triangle and text reading "Be very careful. Take advice from a physician or a pharmacist before driving."
- Category III medications can have a major influence on driving ability and are labeled with a red triangle and text stating "Danger: do not drive. Seek medical advice before driving again."

A limitation of the French pictogram system is that not all three levels of risk are included in each label, leaving patients to evaluate their risk without reference of the different levels (Monteiro et al., 2013).

Comparing the French and DRUID pictograms, Monteiro et al. (2013) reported that respondents asked to interpret the pictograms with respect to the level of risk posed were significantly more likely to interpret the DRUID pictograms correctly. Additionally, with respect to medications classified as Category III (posing severe risk to driving abilities), respondents shown the DRUID pictograms reported significantly higher driving risk as compared to those shown a Category III French pictogram. Therefore, the inclusion of other categories on a graduated scale helped respondents correctly interpret the highest level of risk. Despite differences observed with respect to interpreting pictograms, Monterio et al. (2013) did not find a significant difference between respondents' intention to drive based on exposure to either set of pictograms. Specifically, 78.8% of all respondents indicated they were likely or very likely to change their driving behavior on account of the pictograms, demonstrating the effectiveness of medication labels which utilize graphics to convey risks.

Spanish pictograms. Legislative changes in Spain in 2007 resulted in the mandatory inclusion of warning symbols on medications that may impact fitness to drive or operation of dangerous machinery. This regulation came into effect in 2011 (Fierro et al., 2013). The Spanish pictogram, which includes a small black car inside a red triangle on a white background with the warning "Driving: See package insert," was designed to alert users to potential risk and encourage them to read the medication insert. Fierro et al. (2013) sought to evaluate patient comprehension of the pictogram and any resultant changes to driving behavior. Of the 1,363 people surveyed, 85.7% were able to correctly identify the pictogram meant that the medication in question could have an impact of driving. Additionally, 48.3% felt the pictogram indicated the medication posed a high risk, 33.9% a moderate risk and 4.5% a low risk to driving. In all, 83.9% of drivers reported they would reduce their driving frequency if prescribed a medication with the pictogram about driving on it (Fierro et al., 2013). The authors highlighted other studies showing an increased perception of risk was associated with a higher likelihood that patients would read medication inserts; however, as participants were encouraged to look at the pictogram as part of the survey, the authors were unable to determine the likelihood a user would notice the pictogram and in turn read the medication insert. Despite this limitation, Fierro et al. (2013) concluded that the Spanish pictogram

was an effective way to increase patients' awareness of risk and impact their attitudes towards driving while using potentially impairing medications.

Only a few studies have assessed risk communication related to medications and driving between HCPs and patients. The existing literature indicates many HCPs rely heavily on verbally counseling patients as to the risks, sometimes supplemented with written information, or on the belief that patients will self-inform through reading medication inserts or warning labels. Several studies assessing medication inserts and warning labels in the United States identified low health literacy as a barrier to comprehension. The literature discussed above demonstrates the combined use of verbal counseling with warning labels and medication inserts with pictorial aids, enhance patient understanding and can help improve medication adherence and proper use. In addition to the established forms of risk communication between HCPs and patients explored above, several organizations have begun to develop digital educational tools in an effort to increase awareness and improve road safety.

For example, a recent educational strategy is the American online interactive database, Roadwise Rx (www.roadwiserx.com), developed by the AAA Foundation for Traffic Safety. It communicates and encourages adherence to driving-related instructions to patients taking prescribed or over the counter (OTC) medications. Roadwise Rx provides customized feedback to drivers on the possible side effects they may experience when using their prescription and OTC medications, and how these side effects may affect their driving performance. While the educational tool helps increase patient knowledge, it does not suggest strategies for HCPs to effectively communicate with their patients about the effects of prescribed or OTC medications in relation to driving abilities. Additionally, as compared to the use of warning labels and other traditional risk communication strategies, the effectiveness of Roadwise Rx to improve patient knowledge and affect changes to driving behaviors has not been evaluated. A recent review of countermeasures to prescription and OTC drug-impaired driving concluded that even though countermeasures to reduce drug impaired driving could be identified, there was a lack of empirical support and published research showing efficacy (Smith, Turturici, & Camden, 2018).

1.3.4 Summary

The rising rate of opioid use in the United States, coupled with the results of epidemiological studies demonstrating elevated crash risks amongst opioid users, underscore the importance of implementing effective safety strategies to reduce the occurrence and risks of medication-impaired driving. Results from experimental studies assessing opioid-naïve patient have found evidence that the common side effects experienced during the initial period of opioid therapy may impair a patient's ability to drive safely. These side effects can also be experienced by opioid-maintained patients who have otherwise become tolerant after long-term stable doses, when they combine their pain medication with alcohol, illegal drugs, or other sedating medications.

Based on the available evidence, clinical guidelines have been developed in the United States and other jurisdictions, in an effort to standardize and improve how HCPs manage and monitor opioid use by patients. These guidelines often include one or two recommendations specifying HCPs should counsel their patients about the impacts of opioids on their driving, but provide very little

information about effective ways in which to communicate these risks to increase patient understanding and adherence.

A small body of literature has explored the effectiveness of several methods of risk communication strategies between HCPs and patients. Strategies that include both verbal counsel and written instructions show better patient understanding and medication adherence than either strategy in isolation (Haynes, McKibbon & Kanani, 1996; Vermeir et al., 2015). Additionally, medication leaflets or warning labels incorporating pictorial aids, such as pictograms, have been shown to overcome barriers to patient understanding, including low literacy. The use of pictograms on medication warning labels specific to driving-impairing medications has been introduced in several European countries. Studies have found pictograms are effective in terms of patient understanding and in influencing intentions to change driving behaviors.

Despite these recent efforts within the European context, limited work has been done to identify evidence-based strategies for HCPs to effectively communicate with their patients about the effects of prescribed pain medications on driving abilities in North America. In the absence of standardized regulations in the United States regarding the labelling of medications that potentially impair driving and a limited understanding of American patients' knowledge, attitudes and behaviors towards such methods of risk communications, American HCPs have little guidance regarding the types and content of messages about driving risk that have the greatest impact on patients. Additionally, modern communication tools that target patients, for example the online Roadwise Rx tool, have not been evaluated and there is a lack of evidence as to whether they improve patient understanding and encourage safer driving behaviors (e.g., refraining from driving, taking alternative medication). In light of the above, the objectives of this study were to develop an educational resource for HCPs to help them communicate effectively with their patients about the risks associated with the use of prescription pain medication when driving. The resource also included related materials for use with patients to encourage them to adopt protective behaviors with the ultimate goal to improve road safety and protect the public.

2. METHODS

2.1 Focus groups

Two focus groups with prescribing HCPs (N=27) were conducted in July 2017 on the Washington University (WU) at St. Louis, Missouri (MO) medical campus (see Appendix 1a for Discussion Guide). The first HCP focus group included WU faculty/attending pain management physicians, anesthesiologists, geriatricians, a pain management pharmacist, and pain management fellows (anesthesiology and/or psychiatry background). Participants in the second focus group were psychiatry faculty from WU, but also included a fellow, nurse practitioner, and Physical Medicine and Rehabilitation (PM&R) residents. Years of experience among participants varied from two to 30 years. Participants were recruited using snowball sampling from a pool of subjects that served as a captive audience. Saturation was reached.

Two focus groups with pain medication patients (N=16) at the Rehabilitation Institute of St. Louis (TRISL) in MO were conducted in July 2017 (see Appendix 1b for Discussion Guide). Participants were recruited from an inpatient rehabilitation facility (IRF) and were under the management of a physiatrist. They had been prescribed a variety of pain medications prior to and during their hospitalization. The sample included seven males, eight females and one patient with gender not specified. The age of patients in both groups ranged from 25 up to 84 years. Participants were recruited using snowball sampling from a pool of subjects that served as a captive audience. Saturation was reached.

2.2 Pilot-test

The findings from both focus groups were used to create the DiDRxChecker (i.e., Drug Impaired Driving Rx – or, medical prescription – Checker), a Smartphone App for HCPs. The beta version was pilot tested with HCPs (N=9) in August 2018 to obtain process evaluation information (see Appendix 2 for Discussion Guide). The focus groups and pilot test were organized and delivered according to Knowledge Translation (KT) theory to ensure necessary data would be obtained to inform the development of the App as to facilitate the efficient communication between HCPs and their patients. In particular, TIRF's KT model served as a guiding paradigm for this purpose (Robertson, 2013).

2.3 Outcome evaluation

2.3.1 Recruitment

Recruitment for the evaluation of the educational resource was conducted at TRISL from August 2018 to October 2019. HCPs (specifically physicians) were asked to identify patients under their care who may qualify to participate using a Screening Tool (see Appendix 3a). TRISL Case Managers approached these patients to inform them they had been selected to participate in a research study (see Appendix 3b). If patients were interested in receiving more information, they were visited by the Principal Investigator (PI) of the study to provide an in-person invitation (see Appendix 3c). After a period of 24 hours to enable consideration of benefits/risks of enrollment, the PI returned to the

patient and provided them with a consent form to complete if they agreed to participate (Appendix 3d).

2.3.2 Subjects

Different techniques were used to assess the sample size needed to find significant effects, including power analysis for two sample proportions test; power analysis for a Cochran-Mantel-Haenszel test; and, power analysis for matched case-control studies (StataCorp., 2015). In each power analysis the alpha was set at 0.05 for the significance level and power at 0.80.

A total of N=74 patients participated in this study. The sample consisted of N=39 males and N=35 females (table 1). Patients were at least 21 years of age, with a mode of 60 to 69 years old. Patients were compensated $25 for each outcome evaluation questionnaire they completed, for a total of $50 if both questionnaires were completed. There were 12 patients who did not complete the second outcome evaluation questionnaire.

All participants possessed a valid driver's license and had driven within the last 6 months prior to admission to TRISL. Patients were all taking prescribed pain medication under the supervision of an physician at TRISL. Patients in this sample did not have mental health issues which would interfere with their ability to participate, active substance abuse addiction (alcohol, illicit drugs, prescribed medication or over the counter (OTC) medication), diminished cognitive ability regarding mental disabilities and/or inability to give informed consent, and were not taking any medications which would prevent them from making an informed decision.

Table 1: Sample distribution (N=74)

	Age category	
	20-69	**70-90+**
Experimental		
Males	13	10
Females	16	4
Control		
Males	12	4
Females	11	4

2.3.3 Design

An experimental design was implemented to evaluate the educational resource. There were N=43 patients in the experimental group exposed to the intervention with the App and N=31 patients in the control group not exposed to the intervention.

For those subjects successfully recruited (N=74), experimental group and control group participants were administered the first in-person questionnaire (Appendix 4a). After this, patients in the experimental group were visited by the TRISL physician (DC) who exposed them to the App and provided them with educational handouts associated with the App (Appendix 4b). Patients in the control group were given the Centers for Disease Control (CDC) Opioid Patient Education handout (Appendix 4c) but received no intervention with, or about, the App. Both groups were then administered the second in-person questionnaire. The second questionnaire was similar for the

control group (Appendix 4d) and experimental group (Appendix 4e), however the experimental group questionnaire had an additional section to assess the usability of the App.

The outcome evaluation was used to assess if patients in the experimental group: (1) were better informed about impairing risks of their medication after the intervention; (2) demonstrated receptive attitudes and beliefs about the impairing risks of their medication after the intervention; and (3) planned to adapt their behavior in accordance with increased knowledge.

3. RESULTS

3.1 Focus groups

Focus groups with HCPs revealed that established operational practices for patient care did not facilitate discussion of the impairing effects of medication on driving. Notably, there was a considerable knowledge gap that impeded the ability of HCPs to determine the impairing effects of medication on the driving skills of individual patients. This gap reduced confidence among HCPs in identifying which patients required a conversation about this topic, key messages to include in the conversation, and strategies to conduct the conversation. Also, the main strategy followed by HCPs was to assist their patients to achieve the best outcomes and a return to baseline if possible, or to help them achieve a reasonable quality of life. In this regard, preventing them from driving or impeding their ability to drive was not perceived to be a realistic solution to manage health issues except in the most extreme circumstances.

Focus groups with patients revealed patients appeared to be most receptive to verbal information provided by physicians as well as other HCPs, and they were less likely to review written materials that exceed a page. The ability to personalize information was determined to be an essential requirement to increase usage of information by HCPs and patients. Further, results of the focus groups suggested that although HCPs may have explained some general impairing side effects related to prescription pain medication, rarely were the implications for driving skills explicitly highlighted. This was primarily due to the fact that HCPs assumed patients were able to extrapolate general information about impairing effects to a wide range of activities, notably driving, when in fact they were not. It may also be an indication that HCPs were less familiar with skills needed for driving, and the way these medications can contribute to unsafe driving. It could also be possible that HCPs assumed this content is covered by pharmacists.

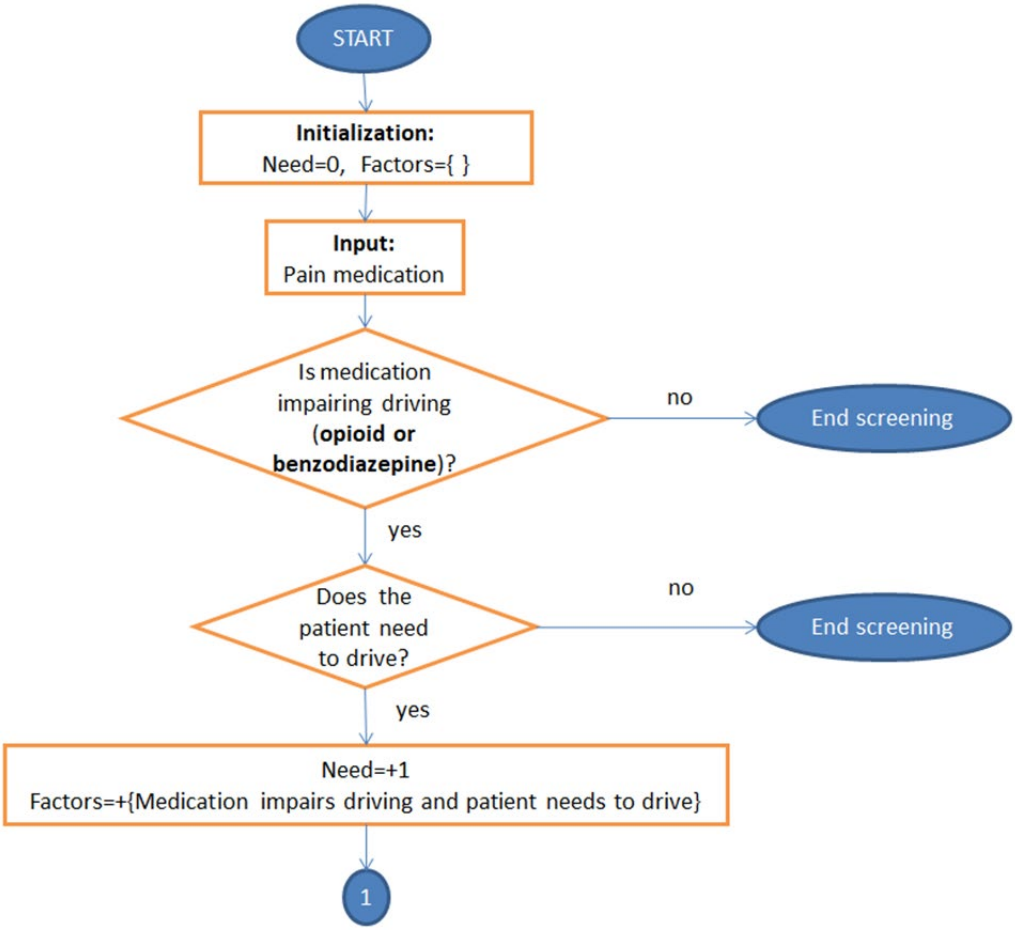
3.2 Pilot-test

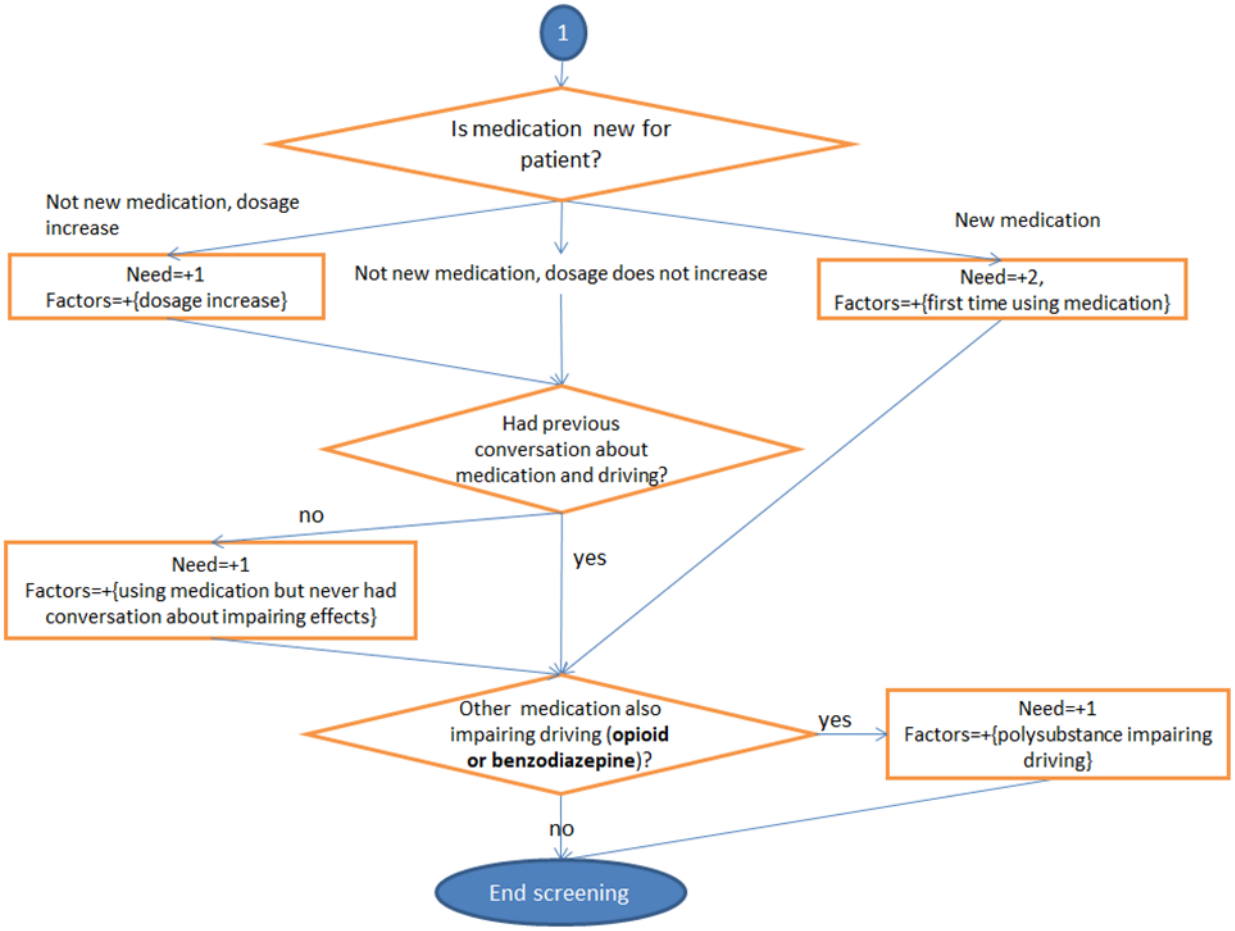
Based on the literature review and results from the focus groups, an online Application was built that HCPs can use to guide their conversation with their patients about the impairing risks of prescription pain medication. It was pilot tested with HCPs and further fine-tuned based on their feedback.

The App, called the DiDRxChecker (i.e., Drug Impaired Driving Rx – or, medical prescription – Checker), can be downloaded from the Apple App Store or Google Play Store. It consists of a user-friendly interface enabling HCPs to answer a few key questions about the patient to determine applicability of further discussion about impairing effects (e.g., types of medication prescribed; driving needs of patients; new medications; other prescribed medications; patient characteristics). Based on the answers, an indication of the level of risk and associated need for a conversation about impairing risks is provided (low need, moderate need, high need; see Figure 1 for an overview of the algorithm used by the App and Figure 2 for a screen caption of the App). Along with this indication, a series of resources are provided that can easily be forwarded to patients or printed if hard copies are preferred. Resources consist of a series of short, one-page documents

that provide information about the impairing effects of prescription medications, the impact on driving skills, and guidelines for effective communication (see appendix 5).

Figure 1: Graphical depiction of DiDRxChecker algorithm




1
Is medication new for patient?
Not new medication, dosage increase
Not new medication, dosage does not increase
New medication
Need=+1
Factors=+{dosage increase}
Need=+2,
Factors=+{first time using medication}
Had previous conversation about medication and driving?
no
yes
Need=+1
Factors=+{using medication but never had conversation about impairing effects}
Other medication also impairing driving (opioid or benzodiazepine)?
yes
Need=+1
Factors=+{polysubstance impairing driving}
no
End screening

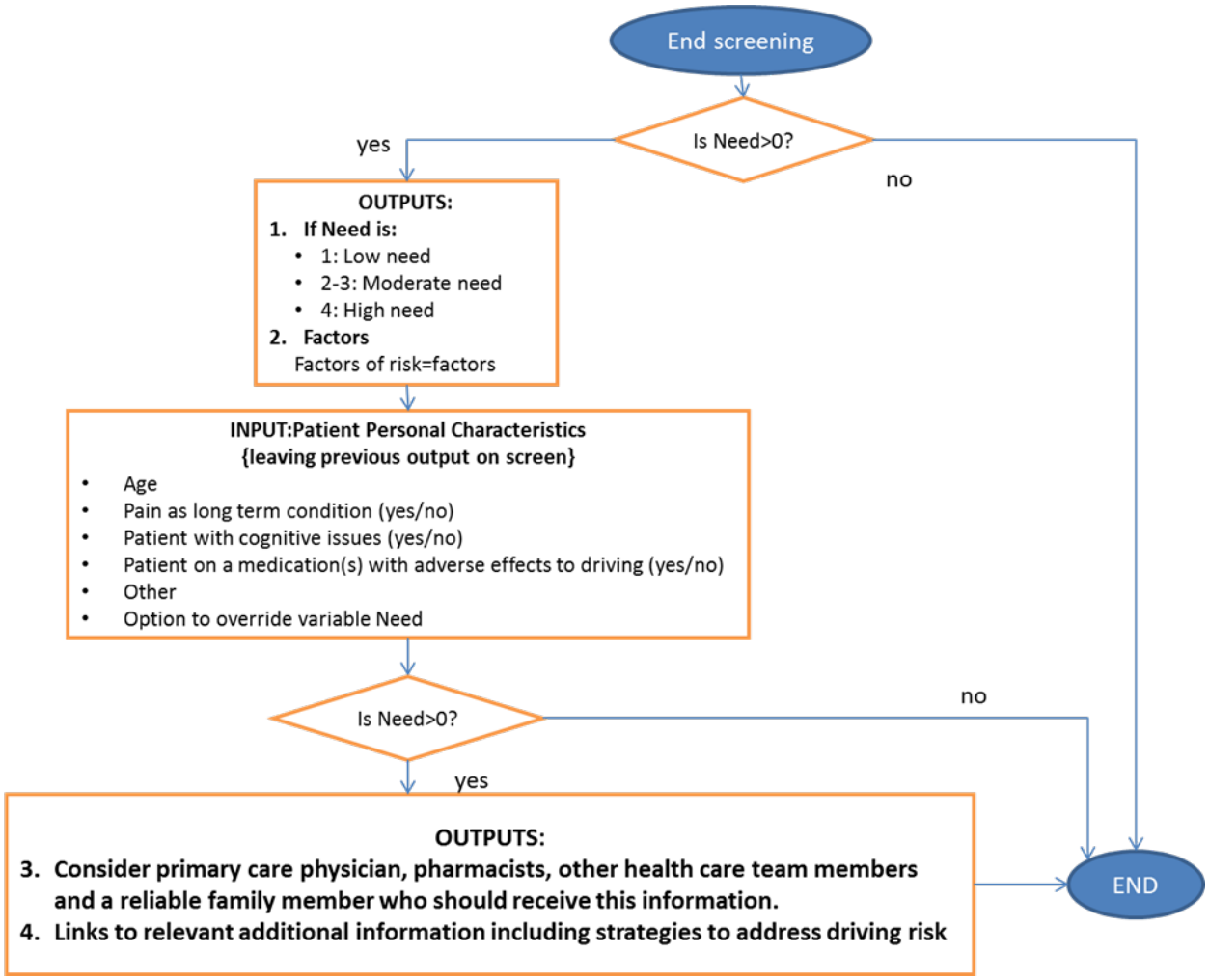
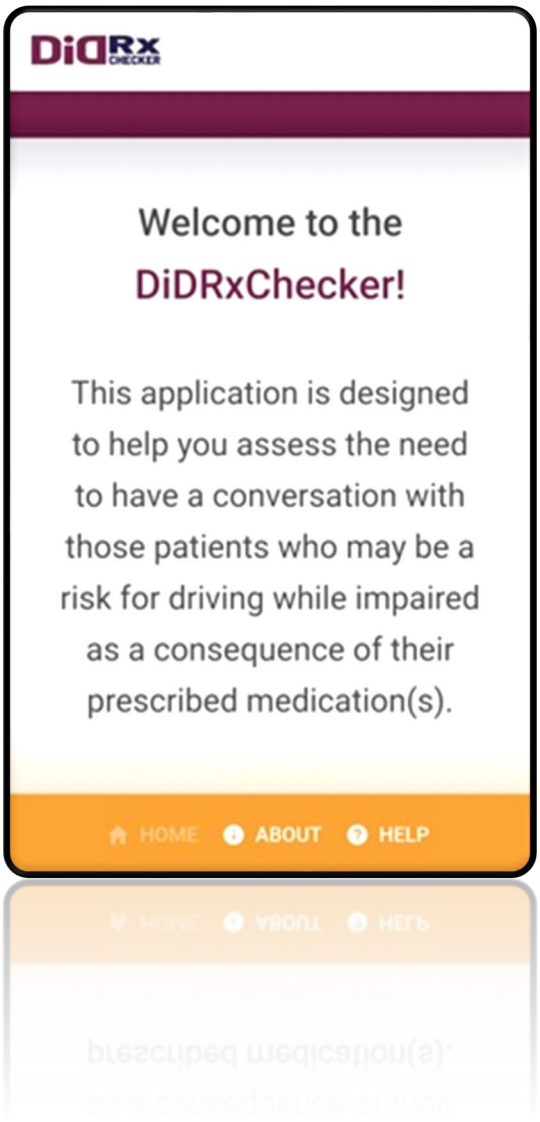

End screening
Is Need>0?
yes
no
OUTPUTS:
1. If Need is:
• 1: Low need
• 2-3: Moderate need
• 4: High need
2. Factors
Factors of risk=factors
INPUT:Patient Personal Characteristics
{leaving previous output on screen}
• Age
• Pain as long term condition (yes/no)
• Patient with cognitive issues (yes/no)
• Patient on a medication(s) with adverse effects to driving (yes/no)
• Other
• Option to override variable Need
Is Need>0?
no
yes
OUTPUTS:
3. Consider primary care physician, pharmacists, other health care team members and a reliable family member who should receive this information.
4. Links to relevant additional information including strategies to address driving risk
END

Figure 2: Screen caption of the DiDRxChecker App



3.3 Outcome evaluation

3.3.1 Knowledge

To evaluate if patients in the experimental group were better informed about impairing risks of their medication after the intervention, two knowledge-based questionnaire items were examined. The first item was "How informed do you think you are on the side effects of your prescribed pain medication that may impact your driving abilities?" (Table 2). An increase was observed from baseline to post-measurement in the frequency of experimental group participants who reported they were informed (36.59% to 46.88%). A small increase from baseline to post-measurement was also observed in the frequency of control group participants who reported they were informed (46.67% to 50.00%).

Table 2: Frequency table for the number of patients reporting they were informed on the side effects of the prescribed pain medication that may impact driving abilities from baseline to post measurement

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"How informed do you think you are on the side effects of your prescribed pain medication that may impact your driving abilities?"	Uninformed	16 **53.33 %**	26 **63.41 %**	42 **59.15 %**	13 **50 %**	17 **53.13 %**	30 **51.72 %**
	Informed	14 **46.67 %**	15 **36.59 %**	29 **40.85 %**	13 **50 %**	15 **46.88 %**	28 **48.28 %**
Total		30 **100 %**	41 **100 %**	71 **100 %**	26 **100 %**	32 **100 %**	58 **100 %**

Baseline Pearson chi2(1) = 0.7287 Pr = 0.393

Post-measurement Pearson chi2(1) = 0.0561 Pr = 0.813

To examine the odds of those in the experimental group reporting they were informed, a logistic regression analysis controlling for age and sex was conducted to examine the interaction effect of group by time (Figure 3). The interaction effect was not significant. However, it demonstrated that the odds of patients reporting they were informed on the side effects of their prescribed pain medication after receiving the intervention in the experimental group was 43% greater than participants in the control group (OR: 1.43 p=.62).

Figure 3: Logistic regression model for the likelihood of patients reporting they were informed on the side effects of the prescribed pain medication that may impact driving abilities, controlling for age and sex

```
Logistic regression                                 Number of obs     =        128
                                                    LR chi2(5)        =       2.88
                                                    Prob > chi2       =     0.7187
Log likelihood = -86.516264                         Pseudo R2         =     0.0164

------------------------------------------------------------------------------
      PK6arec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
--------------+---------------------------------------------------------------
        group |
            0 |          1  (base)
            1 |   .6702772    .329658    -0.81   0.416     .2556311      1.7575
              |
         time |
            0 |          1  (base)
            1 |   1.125765   .6068492     0.22   0.826     .3913843    3.238114
              |
   group#time |
        1 1   |   1.429576   1.039518     0.49   0.623     .3437601    5.945101
              |
          AGE |
    20 to 69  |          1  (base)
    70 to 90+ |   .6591644   .2780904    -0.99   0.323     .2883275    1.506959
              |
          SEX |   1.166812    .423059     0.43   0.670      .573291    2.374799
        _cons |   .7676637   .5071633    -0.40   0.689     .2102896    2.802362
------------------------------------------------------------------------------
```

The second item was "How likely do you think prescribed pain medication can impair someone's driving abilities?" (Table 3). An increase was observed from baseline to post-measurement in the frequency of experimental group participants who reported this was likely (56.1% to 78.13%). An increase from baseline to post-measurement was also observed in the frequency of control group participants who reported this was likely (72.41% to 92.86%).

Table 3: Frequency table for the number of patients reporting it was likely that prescribed pain medication can impair someone's driving abilities

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"How likely do you think prescribed pain medication can impair someone's driving abilities?"	unlikely	8 **27.59 %**	18 **43.90 %**	26 **37.14 %**	2 **7.14 %**	7 **21.88 %**	9 **15 %**
	likely	21 **72.41 %**	23 **56.10 %**	44 **62.86 %**	26 **92.86 %**	25 **78.13 %**	51 **85 %**
Total		29 **100 %**	41 **100 %**	70 **100 %**	28 **100 %**	32 **100 %**	60 **100 %**

Baseline Pearson chi2(1) = 1.9368 Pr = 0.164

Post-measurement Pearson chi2(1) = 2.5420 Pr = 0.111

To examine the odds of those in the experimental group reporting this was likely, a logistic regression analysis controlling for age and sex was conducted to examine the interaction effect of group by time (Figure 4). The interaction effect was not significant, however, it demonstrated that the odds of patients reporting it was likely that prescribed pain medication can impair driving ability after receiving the intervention in the experimental group decreased by 37.6% when compared to those in the control group (OR: 0.62 p=.65).

Figure 4: Logistic regression model for the likelihood of patients reporting it was likely that prescribed pain medication can impair someone's driving abilities, controlling for age and sex

```
Logistic regression                               Number of obs     =        129
                                                  LR chi2(5)        =      24.52
                                                  Prob > chi2       =     0.0002
Log likelihood = -62.139649                       Pseudo R2         =     0.1648

------------------------------------------------------------------------------
      PK2arec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
--------------+---------------------------------------------------------------
        group |
            0 |          1  (base)
            1 |   .4737999   .2614406    -1.35   0.176     .1606593    1.397282
              |
         time |
            0 |          1  (base)
            1 |   5.614175   4.891499     1.98   0.048      1.01778    30.96834
              |
   group#time |
          1 1 |   .6242197   .6520266    -0.45   0.652     .0805783    4.835676
              |
          AGE |
     20 to 69 |          1  (base)
     70 to 90+|   .2590203   .1219645    -2.87   0.004     .1029271    .6518352
              |
          SEX |   1.823805   .8188874     1.34   0.181     .7564661    4.397111
        _cons |   1.656605   1.289914     0.65   0.517      .360107    7.620903
------------------------------------------------------------------------------
```

3.3.2 Attitudes & beliefs

To evaluate if patients in the experimental group demonstrated receptive attitudes and beliefs about the impairing risks of their medication after the intervention, two attitude-based questionnaire items were examined. The first item was "It is safe to drive when first taking prescribed pain medication, as long as you feel fine" (Table 4). A decrease was observed from baseline to post-measurement in the frequency of experimental group participants who reported they agreed (14.29% to 6.25%). A minor increase from baseline to post-measurement was observed in the frequency of control group participants who reported they agreed (3.23% to 3.45%).

Table 4: Frequency table for the number of patients reporting they agreed it is safe to drive when first taking prescribed pain medication as long as you feel fine

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"It is safe to drive when first taking prescribed pain medication, as long as you feel fine."	disagree	30 **96.77 %**	36 **85.71 %**	66 **90.41 %**	28 **96.55 %**	30 **93.75 %**	58 **95.08 %**
	agree	1 **3.23 %**	6 **14.29 %**	7 **9.59 %**	1 **3.45 %**	2 **6.25 %**	3 **4.92 %**
Total		31 **100 %**	42 **100 %**	73 **100 %**	29 **100 %**	32 **100 %**	61 **100 %**

Baseline Pearson chi2(1) = 2.5165 Pr = 0.113
Post-measurement Pearson chi2(1) = 0.2554 Pr = 0.613

To examine the odds of those in the experimental group reporting they agree, a logistic regression analysis controlling for age and sex was conducted to examine the interaction effect of group by time (Figure 5). The interaction effect was not significant, however, it demonstrated the odds of patients agreeing it is safe to drive when first taking prescription pain medication after receiving the intervention in the experimental group decreased by 80% when compared to those in the control group (OR: 0.20 p=.38).

Figure 5: Logistic regression model for the likelihood of patients reporting they agreed it is safe to drive when first taking prescribed pain medication as long as you feel fine, controlling for age and sex

```
Logistic regression                               Number of obs     =        133
                                                  LR chi2(5)        =       6.05
                                                  Prob > chi2       =     0.3017
Log likelihood = -29.903106                       Pseudo R2         =     0.0918

------------------------------------------------------------------------------
      PBP1brec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------+--------------------------------------------------------------
         group |
             0 |          1  (base)
             1 |   5.008077   5.574082     1.45   0.148     .5652856    44.36843
               |
          time |
             0 |          1  (base)
             1 |   1.069414   1.541253     0.05   0.963     .0634429    18.02638
               |
    group#time |
           1 1 |   .1993226   .3629454    -0.89   0.376     .0056183    7.071387
               |
           AGE |
         20 to 69 |          1  (base)
       70 to 90 + |   1.081127   .8269368     0.10   0.919     .2414384    4.841135
               |
           SEX |     .48836   .3669405    -0.95   0.340     .1119877    2.129658
         _cons |   .0892095   .1300409    -1.66   0.097      .005124    1.553135
------------------------------------------------------------------------------
```

The second item was "My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities" (Table 5). An increase was observed from baseline to post-measurement in the frequency of experimental group participants who reported they agreed (52.38% to 59.38%). An increase from baseline to post-measurement was also observed in the frequency of control group participants who reported they agreed (48.39% to 56.67%).

Table 5: Frequency table for the number of patients reporting they agreed that their doctor should have provided more information on the possible impairing effects of their prescribed pain medication

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities."	disagree	16 **51.56 %**	20 **47.62 %**	36 **49.32 %**	13 **43.33 %**	13 **40.63 %**	26 **41.94 %**
	agree	15 **48.39 %**	22 **52.38 %**	37 **50.68 %**	17 **56.67 %**	19 **59.38 %**	36 **58.06 %**
Total		31 **100 %**	42 **100 %**	73 **100 %**	30 **100 %**	32 **100 %**	62 **100 %**

Baseline Pearson chi2(1) = 0.1138 Pr = 0.736

Post-Measurement Pearson chi2(1) = 0.0466 Pr = 0.829

To examine the odds of those in the experimental group reporting they agreed, a logistic regression analysis controlling for age and sex was conducted (Figure 6). The interaction effect was not significant. However, it demonstrated that the odds of patients reporting they agreed their doctor should have provided more information on the possible impairing effects of the prescribed pain medication on their driving abilities after receiving the intervention in the experimental group decreased by 4% when compared to those in the control group (OR: 0.96 p=.95).

Figure 6: Logistic regression model for the likelihood of patients reporting they agreed their doctor should have provided more information on the possible impairing effects of the prescribed pain medication(s) on their driving abilities, controlling for age and sex

```
Logistic regression                               Number of obs     =        134
                                                  LR chi2(5)        =       6.19
                                                  Prob > chi2       =     0.2885
Log likelihood = -89.415127                       Pseudo R2         =     0.0334

------------------------------------------------------------------------------
      PBP3drec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------+--------------------------------------------------------------
         group |
             0 |          1  (base)
             1 |   1.138467   .5513086     0.27   0.789     .4406781    2.941164
               |
          time |
             0 |          1  (base)
             1 |   1.417244   .7433319     0.66   0.506     .5069871    3.961797
               |
    group#time |
           1 1 |     .95958   .6876792    -0.06   0.954     .2355435    3.909231
               |
           AGE |
      20 to 69 |          1  (base)
     70 to 90+ |   1.940277   .7822781     1.64   0.100     .8803952    4.276121
               |
           SEX |   .5823189   .2078032    -1.52   0.130     .2893382    1.171969
         _cons |   1.761664    1.15109     0.87   0.386     .4894842    6.340265
------------------------------------------------------------------------------
```

3.3.3 Behavior

To evaluate whether patients in the experimental group planned to adapt their behavior in accordance with increased knowledge after the intervention, two behavior-based questionnaire items were examined. The first item was "I will drive within two hours of taking my prescribed pain medication" (Table 6). A decrease was observed from baseline to post-measurement in the frequency of experimental group participants who reported this behavior was likely (37.21% to 21.88%). A small decrease was also observed from baseline to post-measurement in the frequency of control group participants who reported this behavior was likely (26.67% to 24.14%).

Table 6: Frequency table for the number of patients reporting it is likely they will drive within two hours of taking their prescribed pain medication

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"I will drive within two hours of taking my prescribed pain medication."	unlikely	22 **73.33 %**	27 **62.79 %**	49 **67.12 %**	22 **75.86 5**	25 **78.13 %**	47 **77.05 %**
	likely	8 **26.67 %**	16 **37.21 %**	24 **32.88 %**	7 **24.14 %**	7 **21.88 %**	14 **22.95 %**
Total		30 **100 %**	43 **100 %**	73 **100 %**	29 **100 %**	32 **100 %**	61 **100 %**

Baseline Pearson chi2(1) = 0.8900 Pr = 0.345

Post-measurement Pearson chi2(1) = 0.0441 Pr = 0.834

To examine the odds of those in the experimental group reporting this was likely, a logistic regression analysis controlling for age and sex was conducted (Figure 7). The interaction effect was not significant, however, it demonstrated that the odds of patients reporting they are likely to drive within two hours of taking their prescribed pain medication after receiving the intervention in the experimental group decreased by 42% when compared to those in the control group (OR: .58 p=.50).

Figure 7: Logistic regression model for the likelihood of patients reporting it is likely they will drive within two hours of taking their prescribed pain medication, controlling for age and sex

```
Logistic regression                                 Number of obs     =        133
                                                    LR chi2(5)        =       8.08
                                                    Prob > chi2       =     0.1519
Log likelihood = -75.529677                         Pseudo R2         =     0.0508

------------------------------------------------------------------------------
      PB7arec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
--------------+---------------------------------------------------------------
        group |
            0 |          1  (base)
            1 |    1.56218   .8313453     0.84   0.402     .5504869    4.433176
              |
         time |
            0 |          1  (base)
            1 |   .8623402   .5275525    -0.24   0.809     .2599803    2.860335
              |
   group#time |
        1 1   |   .5782551   .4743953    -0.67   0.504     .1158248    2.886939
              |
          AGE |
    20 to 69  |          1  (base)
    70 to 90+ |    2.64032   1.091265     2.35   0.019     1.174487    5.935602
              |
          SEX |   .9266738   .3707036    -0.19   0.849     .4230727    2.029732
        _cons |   .3022181   .2284708    -1.58   0.113     .0686798    1.329877
------------------------------------------------------------------------------
```

The second item was "I will not drive within the first 2 weeks that I am taking prescribed pain medication(s)" (Table 7). An increase was observed from baseline to post-measurement in the frequency of experimental group participants who reported it was likely they would not drive

within the first two weeks of taking their prescribed pain medication (69.05% to 74.19%). A small increase was also observed from baseline to post-measurement in the frequency of control group participants who reported this was likely (77.42% to 78.57%).

Table 7: Frequency table for the number of patients reporting it is likely they will not drive within the first two weeks that they are taking prescribed pain medication(s)

		Baseline		Total	Post-measurement		Total
		Control	Experimental		Control	Experimental	
"I will not drive within the first 2 weeks that I am taking prescribed pain medication(s)."	unlikely	7 **22.58 %**	13 **30.95 %**	20 **27.40 %**	6 **21.43 %**	8 **25.81 %**	14 **23.73 %**
	Likely	24 **77.42 %**	29 **69.05 %**	53 **72.60 %**	22 **78.57 %**	23 **74.19 %**	45 **76.27 %**
Total		31 **100 %**	42 **100 %**	73 **100 %**	28 **100 %**	31 **100 %**	59 **100 %**

Baseline Pearson chi2(1) = 0.6284 Pr = 0.428
Post-measurement Pearson chi2(1) = 0.1558 Pr = 0.693

To examine the odds of those in the experimental group reporting that this was likely, a logistic regression analysis controlling for age and sex was conducted (Figure 8). The interaction effect was not significant, however, it demonstrated that the odds of patients reporting it is likely they will not drive within the first two weeks of taking prescribed pain medication after receiving the intervention in the experimental group was 5% greater than participants in the control group (OR: 1.05 p=.96).

Figure 8: Logistic regression model for the likelihood of patients reporting it is likely they will not drive within the first two weeks of taking prescription pain medication, controlling for age and sex

```
Logistic regression                               Number of obs     =        131
                                                  LR chi2(5)        =      13.54
                                                  Prob > chi2       =     0.0188
Log likelihood =  -68.23746                       Pseudo R2         =     0.0903

------------------------------------------------------------------------------
       PB7frec | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------+--------------------------------------------------------------
         group |
             0 |          1  (base)
             1 |   .6875686   .3939022    -0.65   0.513      .223702    2.113305
               |
          time |
             0 |          1  (base)
             1 |   1.062011   .7001049     0.09   0.927     .2917394     3.86601
               |
    group#time |
           1 1 |   1.046126   .9073732     0.05   0.959      .191109    5.726465
               |
           AGE |
      20 to 69 |          1  (base)
     70 to 90+ |   .2581804    .111985    -3.12   0.002      .110336    .6041287
               |
           SEX |   1.770817   .7575118     1.34   0.182     .7656861    4.095404
         _cons |   2.324327    1.80938     1.08   0.279     .5054484    10.68852
------------------------------------------------------------------------------
```

3.4 Power analysis

A power analysis was conducted to estimate the sample size needed to find significant effects given the distribution of the preliminary results. The different analyses combined revealed the sample size should be N>105. As our sample (N=74) was smaller than this, the lack of power in our sample may have impacted our ability to demonstrate significant effects.

4. DISCUSSION

Results from the focus group with HCPs demonstrated that operational practices for patient care did not facilitate discussion of the impairing effects of medication on driving. Moreover, there was a considerable knowledge gap that impeded the ability of HCPs to determine the impairing effects of medication on the driving skills of individual patients, reducing confidence among HCPs regarding whether and in what instances such conversations may be appropriate. This was consistent across all disciplines and training levels.

Results from the focus groups with patients demonstrated patients appeared to be most receptive to verbal information provided by HCPs, and they were less likely to review written materials exceeding a page in length. The ability to personalize information was determined to be an essential requirement to increase usage of information by HCPs and patients. Further, results of the focus groups suggested that although HCPs may have explained some general impairing side effects related to prescription pain medication, rarely were the implications for driving skills explicitly highlighted. Both groups appeared receptive to obtaining information via smartphone and/or the Internet.

Data from these focus groups demonstrated there is a need for HCPs and patients to be better informed about the impairing effects of prescription medication on driving. It also demonstrated HCPs and patients were receptive to using an educational tool. HCPs were supportive of tools to help them guide their conversation with patients about this issue to positively influence patient care. Patients were supportive of tools that would be beneficial to help them understand important information regarding the impairing effects of pain medications on driving. These results in combination with existing literature were used to inform the development of an educational resource, the DIDRxChecker, which was pilot tested with HCPs and further fine-tuned based on their feedback.

Results from the outcome evaluation are described below. The observed effects of the intervention in the experimental group are promising. Evaluations demonstrated that after being exposed to the App, patients in the experimental group were better informed about impairing risks of their medication, demonstrated receptive attitudes and beliefs about the impairing risks of their medication, and planned to adapt their behavior in accordance with increased knowledge. It is worth mentioning that some positive changes were also observed in the control group. Even though they were not exposed to the App, they received a "Patient Opioid Education" handout from the Center for Disease Control (CDC). When comparing the two groups, the effects observed in the experimental group may have been diminished as a result of the positive impact that the handout may have had on the control group and reduced our ability to assess the full efficacy of the App. However, even though patients often do not receive any information about this, it was not deemed ethical in our study to truly not provide any information at all to control group patients on possible impairing effects given the important nature of the issue.

The outcome evaluation of the DIDRxChecker demonstrated there was an increase in the percentage of patients who reported being informed about the side effects of their prescribed pain

medication which may impact driving abilities after being exposed to the App (36.59% to 46.88%). Logistic regression revealed a non-significant effect, however, the relationship suggested the odds of experimental group patients reporting they were informed increased by 43% after the intervention when compared to control group patients. These results indicate the App provided patients with helpful information about the effect of their prescribed pain medication on driving abilities, and that the App facilitated the ability of HCPs to communicate the impairing risks of pain medications on driving.

Additionally, when asked "How likely do you think prescribed pain medication can impair someone's driving abilities?", there was an increase in the percentage of experimental group patients who indicated this was likely after being exposed to the App (56.1% to 78.13%). These results demonstrated the App equipped patients with helpful information about the impairing risks of prescription pain medication. Logistic regression revealed a non-significant effect, however, the relationship suggested that the odds of experimental group patients indicating this was likely decreased by 37.6% after receiving the intervention when compared to those in the control group (OR: 0.62 p=.65).

When assessing the impact of the App on the attitudes and beliefs of patients, a decrease was observed in the percentage of experimental group patients who reported they agree with the statement "It is safe to drive when first taking prescribed pain medication, as long as you feel fine" (14.29% to 6.25%). Logistic regression revealed a non-significant effect, however, the relationship revealed the odds of experimental group patients indicating they agree with the statement after the intervention with the App decreased by 80% when compared to those in the control group. These results suggest the intervention with the App positively altered the attitudes and beliefs of patients regarding the impairing effects of prescription pain medications.

Attitudes and beliefs about the information provided to patients were also assessed. The percentage of patients in the experimental group that agreed with the statement "My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities" increased after the intervention with the App (52.38% to 59.38%). Although the logistic regression analysis revealed that the odds of experimental group patients indicating they agree with this statement decreased by 4% after receiving the intervention when compared to the control group, these results may suggest the information provided to patients through the intervention with the App could be further fine-tuned and tailored to patients. It is worth nothing this statement lacked precision as it did not specify which doctor the statement was referring to and may have caused confusion among subjects. In future research this item will have to be better formulated.

Finally, the impact of the App on behavior was assessed to evaluate if patients in the experimental group planned to adapt their behavior in accordance with increased knowledge after the intervention. There was a decrease in the percentage of experimental group patients who indicated they would likely drive within two hours of taking their prescribed pain medication after receiving the intervention (37.21% to 21.88%). Logistic regression revealed a non-significant effect, however, the relationship suggested that the odds of experimental group patients reporting they

are likely to drive within two hours of taking their prescribed pain medication decreased by 42% after receiving the intervention compared to the control group.

Similarly, there was an increase in the percentage of experimental group patients who reported they would likely not drive within the first two weeks while taking prescribed pain medication (69.05% to 74.19%). The logistic regression results suggested the odds of experimental group patients reporting this after receiving the intervention was 5% greater compared to patients in the control group. Overall, these findings indicate that exposure to the App incited experimental group patients to positively adapt their behavior in accordance with the knowledge they acquired from the intervention. These findings are in line with existing literature that demonstrates strategies including both verbal counsel and written instructions show better patient understanding and medication adherence than either strategy in isolation (Collins & Jones, 2019; Smyth et al., 2013b; Breivik, 2006).

There were several limitations to this study. The health professionals recruited in the focus groups were from an academic institution and may not reflect the opinions or behaviors of community HCPs. The majority of the responses in the HCP focus group was from physicians, whereas a group of pharmacists may have had other input or suggestions in shaping the intervention. Conversely, unlike the wider array of HCPs involved in the focus groups, the outcome evaluation with the App was only conducted with physicians. Future studies should therefore conduct the evaluation with other HCPs involved in the communication of the risks of prescribed pain medication.

The DIDRxChecker algorithm answer categories allowed for the input of two types of drugs, opioids or benzodiazepines (see Figure 1). However, approximately less than 5% of the sample were prescribed benzodiazepines. Future samples should include a wider variety of prescribed pain medications, as the current sample consisted primarily of patients being prescribed opioids.

Moreover, the inpatient rehabilitation facility (IRF) presented many recruitment challenges. It is important to note there was significant pressure on referring hospitals and physiatrists to reduce opioid prescribing during the course of this initiative, resulting in fewer patients on opioids in the available recruitment pool during the final phases of recruitment. In addition, the facility required case workers to first approach patients and this often resulted in a delay in our enrollment team approaching them and a loss of potential subjects.

Finally, patients in IRFs often have stroke, brain injury and cognitive impairment and many were excluded due to neurological illness and inability to either return to active driving or inability to give consent. Also, approximately 15% of IRF patients were sent back to the hospital due to acute care transfers and the average length of stay for an IRF patient was two weeks.

However, recruiting through an IRF also offers several benefits. IRF patients typically have acute and/or chronic pain and are often prescribed opioids. Physiatrists are usually called into pain management and are required to either initiate or continue opioid use in these populations. The lack of continuity of care of different primary care providers as patients transition from the acute hospital setting to inpatient rehabilitation and then on to home is a reality of patient care in the U.S. As difficult as it may have been to recruit, this setting was real-world and underlies the

challenges of studying the outcomes of educational interventions where they are most needed and possibly most beneficial.

5. CONCLUSION & RECOMMENDATIONS

In conclusion, the focus groups and questionnaire data demonstrated there is a need among HCPs and patients to be better informed about the impairing effects of prescription medication on driving. It also demonstrated HCPs and patients were receptive to using supporting tools to help them guide their conversation with patients about this issue to positively influence patient care. Based on the literature and input from HCPs and patients, such an educational tool was developed, and pilot-tested. The tool is called the DiDRxChecker and is available as an App. It is easy to use and supports HCPs to have a meaningful conversation with patients who take potentially impairing medications and are driving. It also provides easy access to short documents (available electronically or for printing) that can be shared with patients to better inform them.

Results from the outcome evaluation suggested patients exposed to the resource feel better informed, have receptive attitudes and health beliefs about the potentially impairing effects of prescription pain medication on driving, and are more inclined to adopt protective behaviors compared to patients not exposed to the App. However, these findings did not reach significance, potentially due to a lack of power in our sample. In light of this, the effects found are promising and require further investigation as they suggest the DIDRxChecker may help facilitate the communication of risk between HCPs and patients on the potential impairing effects of prescribed pain medication.

These results are important as this study represents some of the first findings to inform evidence-based strategies for HCPs to effectively communicate with their patients about the effects of prescribed medications on driving abilities. These results are in response to the lack of resources for HCPs in the U.S. about the impact of prescription drugs on driving abilities and road safety as well as effective ways to communicate these risks to patients. Therefore, future research should focus on implementing the intervention with the App with a variety of HCPs in a larger sample of patients who have been prescribed pain medication and are driving.

Additionally, this research should be conducted with patients being prescribed pain medication other than opioids or benzodiazepines. The current study examined these two types of pain medication because the App was designed to accept these two response categories. However, expanding the types of prescribed pain medication in future samples may help provide a more profound perspective of how risk is communicated to patients under varied pain treatment circumstances.

REFERENCES

AAA Foundation for Traffic Safety. (2015). *Roadwise RX*. Found: http://www.roadwiserx.com/

Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). (2005). *Mise au point: Médicaments et conduit automobile.* Retrieved from: http://ansm.sante.fr/var/ansm_site/storage/original/application/faff1e402339cd443a9894792f20d31d.pdf

Agencia Española de Medicamentos y Productos Sanitarios. (2010). *El Pictograma*. Retrieved from: http://www.aemps.gob.es/industria/etiquetado/conduccion/pictograma.htm

Alberta College of Pharmacists. (2013). *Medication-assisted treatment for opioid dependence: Guidelines for pharmacists and pharmacy technicians*. Retrieved from: https://pharmacists.ab.ca/system/files/ODTGuidelines.pdf

Alvarez, J.F., de Gier, J.J., Christophersen, A.S., Del Rio, M.C., Donelson, A.C., Karlovsek, M.Z…, Walsh, J.M. (2001). *Prescribing and dispensing guidelines for medicinal drugs affecting driving performance*. International Council on Alcohol, Drugs and Traffic Safety. Retrieved from: http://www.icadts.nl/reports/ICADTSpresguiderpt.pdf

American College of Occupational Environmental Medicine. (2011). *Guidelines for the chronic use of opioids.* Retrieved from: https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf

American Family Physician. (2009). *Practice guidelines: Guidelines for the use of opioid therapy in patients with chronic noncancer pain.* Retrieved from: http://www.aafp.org/afp/2009/1201/p1315.html

American Medical Association and the National Highway Traffic Safety Administration. (2010). *Physicians' Guide to Assessing and Counseling Older Drivers.* Retrieved from: www.nhtsa.gov/staticfiles/nti/older_drivers/pdf/811298.pdf

Aronoff, G.M., Erdil, M., Hartenbaum, N. (2005). Medication's, driving, and work. In: Talmage JB, Melhorn JM, eds. *A Physician's Guide to Return to Work*. Chicago, Illinois; 133-48.

Barlas, S. (2015). Pharmacists step up efforts to combat opioid abuse: the CDC and congress are trying to pitch in. Pharmacy and Therapeutics, 40(6), 369.

CARRS-Q. (2015). *State of the road: Medications & driving fact sheet*. Retrieved from: http://www.carrsq.qut.edu.au/publications/corporate/medication_and_driving_fs.pdf

Cherny, N., Ripamonti, C., Pereira, J., Davis, C., Fallon, M., McQuay, H., ... & Expert Working Group of the European Association of Palliative Care Network. (2001). Strategies to manage the adverse effects of oral morphine: an evidence-based report. Journal of Clinical Oncology, 19(9), 2542-2554.

Chihuri, S., & Li, G. (2017). Use of prescription opioids and motor vehicle crashes: a meta analysis. Accident Analysis & Prevention, 109, 123-131.

Chihuri, S., & Li, G. (2019). Use of prescription opioids and initiation of fatal 2-vehicle crashes. *JAMA network open*, *2*(2), e188081-e188081.

Chou, R., Fanciullo, G.J., Fine, P.G., Adler, J.A., Ballantyne, J.C., Davies, P., … Miaskowski, C. (2009). Clinical Guidelines for the use of chronic opioid therapy in chronic noncancer pain. *Journal of Pain*, 10(2): 113-130.

de Gier, H., Heissing, M., Alvarez, J., & Tant, M. (2006). *Recommendations for improving medical guidelines for assessing fitness to drive in patients who use psychotropic medicines*. DRUID Deliverable D.7.2.1. Retrieved from: http://www.druid-project.eu/Druid/EN/deliverales-list/downloads/Deliverable_7_2_1.pdf?__blob=publicationFile&v=1

Department for Transport. (2015). *New drug driving rules*. Retrieved from: http://www.unimed.co.uk/pdfs/Drug%20Driving%20Rules%20Leaflet.pdf

Drug and Alcohol Services South Australia. (2008). *Opioid prescription in chronic pain conditions. Guidelines for South Australian general practitioners.* Retrieved from: http://www.sahealth.sa.gov.au/wps/wcm/connect/7b1378004ddce5e2965efe6d722e1562/Opioid_prescription_chronic_pain_guidelines_for_SA_GPs_ALL.PDF?MOD=AJPERES&CACHEID=7b1378004ddce5e2965efe6d722e1562

Drug and Alcohol Services South Australia. (2010). *Methadone and buprenorphine guidelines for pharmacists in South Australia*. Retrieved from: http://www.sahealth.sa.gov.au/wps/wcm/connect/8875c9804008e393b7ffbf4826472d56/Methadone+and+Buprenorphine+Guidelines+for+Pharmacists+in+SA-DASSA-April2014.pdf?MOD=AJPERES&CACHEID=8875c9804008e393b7ffbf4826472d56

Emich, B., van Dijk, L., & Monteiro, S. P. (2014). A study comparing the effectiveness of three warning labels on the package of driving-impairing medicines. *International Journal of Clinical Pharmacology,* 36: 1152-1159.

Engeland, A., Skurtveit, S., Morland, J. (2007). Risk of road traffic accidents associated with the prescription of drugs: a registry-based cohort study. *Annals of Epidemiology*, 17(8):597-602.

Federation of State Medical Boards. (2013). *Model policy on the use of opioid analgesics in the treatment of chronic pain.* Retrieved from: http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf

Ferreira, D. H., Boland, J. W., Phillips, J. L., Lam, L., & Currow, D. C. (2018). The impact of therapeutic opioid agonists on driving-related psychomotor skills assessed by a driving simulator or an on-road driving task: a systematic review. Palliative medicine, 32(4), 786-803.

Fierro, I., Gómez-Talegón, T., Alverez, F.J. (2013). The Spanish pictogram on medicines and driving: The population's comprehension of and attitudes towards its use on medication packaging. *Accident Analysis and Prevention*, 50: 1056-1061.

Fishbain, D.A., Cutler, R.B., Rosomoff, H.L., Rosomoff, R.S. (2003). Are opioid-dependent/tolerant patients impaired in driving-related skills? A structured evidence-based review. *Journal of Pain and Symptom Management*, 25(6):559-77.

Group Health Cooperative. (2014). *Chronic opioid therapy safety guideline for patients with chronic non-cancer pain.* Retrieved from: https://www.ghc.org/all-sites/guidelines/chronicOpioid.pdf

Hagemeier, N. E., Murawski, M. M., Lopez, N. C., Alamian, A., & Pack, R. P. (2014). Theoretical exploration of Tennessee community pharmacists' perceptions regarding opioid pain reliever abuse communication. Research in Social and Administrative Pharmacy, 10(3), 562-575.

Haynes, R. B., McKibbon, K. A., & Kanani, R. (1996). Systematic review of randomised trials of interventions to assist patients to follow prescriptions for medications. The Lancet, 348(9024), 383-386.

Holtom, N. (2015). *Information on driving whilst taking certain medications*. Norfolk and Norwich University Hospitals. Retrieved from: www.nnuh.nhs.uk/publication/.../driving-and-your-medication-24-0-15/

Li, G., & Chihuri, S. (2019). Prescription opioids, alcohol and fatal motor vehicle crashes: a population-based case-control study. Injury epidemiology, 6(1), 11.

Lococo, K., & Tyree, R. (2010). *Medication-related impaired driving*. Medscape Education Pharmacists. Retrieved from: http://www.medscape.org/viewprogram/31244

Manchikanti, L., Abdi, S., Atluri, S., Balog, C.C., Benyamin, R.M., Boswell, M.V., … Wargo, B.W. (2012a). American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 1 – evidence assessment. *Pain Physician*, 15: 1-66.

Manchikanti, L., Abdi, S., Atluri, S., Balog, C.C., Benyamin, R.M., Boswell, M.V., … Wargo, B.W. (2012b). American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2 – guidance. *Pain Physician*, 15: 67-116.

Massachusetts Medical Society. (2015). *Massachusetts Medical Society Opioid Therapy and Physician Communication Guidelines.* Retrieved from: http://www.massmed.org/opioid-guidelines/#.Vh6cm_lViko

Medical Board of California. (2014). *Guidelines for prescribing controlled substances for pain*. Retrieved from: http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

Monteiro, S.P., & de Gier, H. (2011). *Guidelines and Professional Standards.* DRUID Deliverable 7.2.2. Retrieved from: http://www.druid-project.eu/Druid/EN/deliverales-list/downloads/Deliverable_7_2_2.pdf?__blob=publicationFile&v=1

Monteiro, S.P., Huiskes, R., van Dijk, L., van Weert, J.C.M., & Geir, J.J. (2013). How effective are pictograms in communicating risk about driving-impairing medicines? *Traffic Injury Prevention*, 14: 299-308.

Pennsylvania Medical Society. (2014). *Pennsylvania guidelines on the use of opioids to treat chronic noncancer pain.* Retrieved from: http://www.pamedsoc.org/DocumentVault/VaultPDFs/PatientcarePDFs/opioid-guidelines-PDF.html

Ravera, S., Monteiro, S.P., de Gier, J.J., van der Linden, T., Gómez-Talegón, T., & Álvarez, F.J. (2012). A European approach to categorizing medicines for fitness to drive: Outcomes of the DRUID project. *British Journal of Clinical Pharmacology*, 74(6): 920-931.

Rowa'Al-Ramahi, A. N. Z., & Na'em Kettana, W. S. (2012). Attitudes of consumers and healthcare professionals towards the patient package inserts-a study in Palestine. Pharmacy practice, 10(1), 57.

Salinas, G. D., Susalka, D., B Stephen Burton, M. S., Nancy Roepke, M. B. A., Evanyo, K., Biondi, D., & Nicholson, S. (2012). Risk assessment and counseling behaviors of healthcare professionals managing patients with chronic pain: a national multifaceted assessment of physicians, pharmacists, and their patients. Journal of opioid management, 8(5), 273-284.

Sigona, N., & Williams, K. G. (2015). Driving under the influence, public policy, and pharmacy practice. Journal of pharmacy practice, 28(1), 119-123.

Smith, R. C., Turturici, M., & Camden, M. C. (2018). Countermeasures Against Prescription and Over-the-Counter Drug-Impaired Driving (October 2018).

Smyth, T. (2012). *Hospital outpatient response to potential driving impairment due to prescribed medications.* (Unpublished doctoral dissertation). Queensland University of Technology, Queensland Australia. Retrieved from: http://eprints.qut.edu.au/51095/1/Tanya_Smyth_Thesis.pdf

Smyth, T., Sheehan, M., Siskind, V., Mercier-Guyon, C., & Mallaret, M. (2013). Consumer perceptions of medication warnings about driving: A comparison of French and Australian Labels. *Traffic Injury Prevention*, 14: 557-564.

StataCorp. (2015). Stata Statistical Software: Release 14. College Station, TX: StataCorp LP.

State of California, Department of Industrial Relations. (2015). *Medical treatment utilization schedule (MTUS). Opioids treatment guidelines. Part 1: Executive summary, introduction and recommendations.* Retrieved from: https://www.dir.ca.gov/dwc/DWCPropRegs/MTUS-Opioids-ChronicPain/Opioids-Guidelines.pdf

Sudore, R. L., & Schillinger, D. (2009). Interventions to improve care for patients with limited health literacy. Journal of clinical outcomes management: JCOM, 16(1), 20.

Sundwall, D.N., Rolfs, R.T., & Johnson, E. (2009). *Utah clinical guidelines on prescribing opioids for treatment of pain.* Utah Department of Health. Retrieved from: http://health.utah.gov/prescription/pdf/guidelines/final.04.09opioidGuidlines.pdf

Thakur, T., Frey, M., & Chewning, B. (2019). Pharmacist services in the opioid crisis: current practices and scope in the United States. Pharmacy, 7(2), 60.

The National Opioid Use Guideline Group. (2010). *Canadian guideline for safe and effective use of opioids for chronic non-cancer pain. Part B: Recommendations for practice.* National Pain Centre, McMaster University. Retrieved from: http://nationalpaincentre.mcmaster.ca/documents/opioid_guideline_part_b_v5_6.pdf

The Pain Society. (2004). *Recommendations for the appropriate use of opioids for persistent non-cancer pain.* The Pain Society, the Royal College of Anesthetists, the Royal College of General

Practitioners and the Royal College of Psychiatrists. Retrieved from: http://www.anaesthesiauk.com/documents/opioids_doc_2004.pdf

United Kingdom – Department of Transport. (2014). *Guidance for healthcare professionals on drug driving*. Retrieved from: https://www.rcpsych.ac.uk/pdf/healthcare-profs-drug-driving.pdf

United States Food and Drug Administration. (2008). *Some medications and driving don't mix*. Retrieved from: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107894.htm

United States Food and Drug Administration. (2014). *FDA basics webinar: Over-the-counter medicines and driving*. Retrieved from: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm402791.htm

United States Food and Drug Administration. (2015). Driving when using medicine. Retrieved from: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/DrivingWhenYouAreUsingMedicine/default.htm

Veldhuijzen, D.S., van Wijck, A.J.M., Verster, J.C., Kalkman, C.J., Kenemans, J.L., Olivier, B., & Volkerts, E.R. (2006). The impact of chronic pain patients' psychotropic drug knowledge and warning labels on the decision whether to drive a car or not. *Traffic Injury Prevention*, 7: 360-364.

Vermeir, P., Vandijck, D., Degroote, S., Peleman, R., Verhaeghe, R., Mortier, E., ... & Vogelaers, D. (2015). Communication in healthcare: a narrative review of the literature and practical recommendations. International journal of clinical practice, 69(11), 1257-1267.

APPENDIX 1A: HCP FOCUS GROUP DISCUSSION GUIDE

Focus Group Discussion Guide – Health Care Practitioners

Introduction

The Traffic Injury Research Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and the Rehabilitation Institute of Saint Louis (TRISL), is conducting a study in order to develop and evaluate an educational resource to improve communication between health care professionals (HCPs) and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This study is funded by the U.S. Food & Drug Administration (FDA).

The focus group that you are participating in today will be a discussion about your perceptions and experiences in relation to communication with patients about the impairing effects of prescribed pain medication while driving. The focus group should take approximately two hours. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond. The study Principal Investigator will summarize the discussion so that we can gather the different perspectives that are shared.

Before the focus group discussion begins we would ask you to complete a confidential questionnaire that will help us to better understand more about the focus group participants.

The study team will keep the information you provide confidential at all times. You will be identified via a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals. There is some risk regarding confidentiality of study participant information that is discussed during the focus group, since the project team does not have oversight of what other study participants may divulge from the focus group discussion once the focus group has ended. For this reason, you are advised not to discuss information from this study with anyone outside the study. You are reminded to keep confidential what is discussed during group discussions and not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

The information and comments you provide us with today will help inform the educational resource we will develop to improve communication between HCPs and their patients.

We would like to thank you for participating in this focus group today.

Common Prescribed Pain Medications

1. What are the most common prescribed pain medications your patients are prescribed?
2. What are the common side effects of these medications?
3. Are there side effects that would impact your patient's driving abilities (i.e., drowsiness, confusion, delayed reaction times, etc.)?
4. Do you feel well-informed about the possible driving-risks posed by prescribed pain medication side effects, to discuss them with your patients?

Communication Training

1. Did you receive any training on how to communicate prescribed pain medication risks to your patients?
2. What kind of training did you receive?
3. If you did not receive formal training, what has informed your approach to discussing prescribed pain medication-risks with patients?
4. Are there any resources available to help guide you when discussing prescribed pain medication-risks with patients?
5. Is there a need for resources and training to improve prescribed pain medication-risk communication?

Risk Communication

1. Do you inform your patients about the possible driving-risks associated with their prescription prescribed pain medication?
    a. If yes:
        i. How do you inform your patients about prescribed pain medication risks?
            1. Do you have a verbal conversation about the risks?
            2. Do you provide written material to your patients about these risks?
                a. If yes, what kind of written materials do you provide (i.e. pamphlets, warning labels, etc.)?
        ii. What do you tell them?
            1. What side effects do you highlight?
            2. Do you advise them to refrain from driving, or change their driving behaviors?
            3. Do you advise them to refrain from drinking or taking other medications?
        iii. When do you inform your patients of the risks?
            1. Do you advise them when first prescribing prescribed pain medications?
            2. Do you remind patients of the risks at follow up appointments?
        iv. How do you ensure that your patients understand the driving-risks associated with their prescribed pain medications?
        v. What issues may prevent or impede patients from understanding either what you tell them or the written material you provide them (i.e., low health literacy, language barriers, physical and psychological conditions, age, etc.)?
        vi. How do patients generally react to this information? Are they resistant to changing their driving habits/behaviors?

vii. Do you follow up with your patients to ensure they understand the risks and have changed their driving behaviours accordingly?

b. If no:
   i. Why do you not inform your patients of the possible driving-risks associated with their prescription prescribed pain medication?

Educational Resource

1. What educational resource, currently available, best conveys information about the risks associated with prescribed pain medication and driving abilities?
   a. What makes this resource useful?
   b. What elements of it work best (images, content, language, etc.)?
   c. What aspects do not work?
   d. Do you use this resource?

2. If a new educational resource was developed to help you convey this information better, what are important features/aspects that should be included or considered?
   a. What content should it include?
   b. Should it include pictorial aids/graphics?
   c. What are your thoughts about an online tool, accessible through a computer, tablet or mobile phone?
      i. Do you think an online tool would be helpful to your patients?
      ii. Do you see any limitations that may impact patient understanding if an online tool was used?

3. What would make you more likely to use an educational resource when informing your patients about driving-risks associated with prescribed pain medications?

APPENDIX 1B: PAIN MEDICATION PATIENTS FOCUS GROUP DISCUSSION GUIDE

Focus Group Discussion Guide

Introduction

The Traffic Injury Research Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and the Rehabilitation Institute of Saint Louis (TRISL), is conducting a study in order to develop and evaluate an educational resource to improve communication between health care professionals (HCPs) and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This study is funded by the U.S. Food & Drug Administration (FDA).

The focus group that you are participating in today will be a discussion about your perceptions and experiences in relation to communication with HCPs about the impairing effects of prescribed pain medication while driving. The focus group should take approximately two hours. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond. The study Principal Investigator will summarize the discussion so that we can gather the different perspectives that are shared.

Before the focus group discussion begins we would ask you to complete a confidential questionnaire that will help us to better understand more about the focus group participants.

The study team will keep the information you provide confidential at all times. You will be identified via a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals, including your doctor or family members, and will not affect your medical care in any way. There is some risk regarding confidentiality of study participant information that is discussed during the focus group, since the project team does not have oversight of what other study participants may divulge from the focus group discussion once the focus group has ended. For this reason, you are advised not to discuss information from this study with anyone outside the study. You are reminded to keep confidential what is discussed during group discussions and not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

The information and comments you provide us with today will help inform the educational resource we will develop to improve communication between HCPs and their patients.

We would like to thank you for participating in this focus group today.

Risk Knowledge and Communication

1. Do you know of any risks associated with your prescribed pain medication and your ability to drive?
   d. How did you learn about these risks?
   e. Have you experienced any impairing side effects from your prescribed pain medication (i.e., drowsiness, mental clouding, confusion, delayed reaction times, etc.)?

2. Did your doctor/HCP discuss any general risks associated with your prescribed pain medication?

3. Did your doctor/HCP discuss any risks specific to your ability to drive associated with your prescribed pain medication?
   a. If yes:
      iii. What risks did your doctor or HCP tell you about?
      iv. How did they tell you? Did they have a conversation with you or provide you with written educational material (i.e., leaflets, brochures, posters in HCP's office, inserts in medication packages, warning labels affixed to the prescribed pain medication, etc.)
      v. If Verbal Conversation:
         1. Did you understand the information your doctor/HCP told you?
         2. Did your doctor/HCP use language you understood – did they use a lot of medical terminology that you did not understand?
         3. Were you able to ask questions and have a discussion with your doctor/HCP about these risks?
      vi. If written information provided:
         1. Did you read the material your doctor/HCP gave you?
         2. Did you understand the written material? Did it contain a lot of medical terminology you didn't understand?
         3. Were there pictures or graphics in the written information?
            a. If yes, what did the images look like?
            b. Did they help you understand the material?
            c. Would additional pictures have been useful? If so, what type of pictures and what information should they have conveyed?
         4. Did you have questions about the information?
            a. Were you able to follow up with your doctor/HCP and get answers?
      vii. Did you change your driving behaviors/habits because of the information your doctor/HCP told/gave you?
         1. If yes – how did you change your driving habits?
         2. If no – why did you not change your driving habits?
      viii. Did your doctor/HCP follow up about these risks or your experiences when you had a follow up appointment with them, or by phone at a later date?
         1. What did they ask you?
         2. Did they give you any additional recommendations about driving?

ix. Did your pharmacist discuss any risks associated with your prescribed pain medication and driving when you filled your prescription?
3. What risks did your pharmacists tell you about?
4. Did you receive any educational material from your HCP or doctor that discussed the risks posed to your driving abilities by your prescribed pain medication – i.e. leaflets, brochures, inserts in medication packages, warning labels affixed to medication.

b. If participant did not receive information from their doctor/HCP:
i. Did you learn about any risks associated with your prescribed pain medication and driving from another source (i.e., friends/family, the internet, based on your own personal experience of driving impairment, etc.)?
1. If yes:
a. What did you find out?
b. Did you seek out additional information?
c. Did you change your driving behaviors/habits because of this information?
d. Did you discuss what you learned with your doctor/HCP?

Development of an educational resource

1. What information did you receive about driving risks when you were first prescribed pain medication that was most helpful?

2. What information would you have wanted to receive, but did not?

3. What is the best way to receive information about prescribed medication risks?
   a. Verbal conversation with doctor/HCP;
   b. Written information (i.e. medication leaflet or medication warning labels);
   c. Online tool – accessible through a computer, tablet or mobile phone; or
   d. Combination of the above.

4. If a new educational resource was developed to help patients better understand the risks associated with driving while taking prescribed pain medication, what are important features/aspects that should be included or considered?
   a. What type of language should be used?
   b. Should pictures/graphics be used? What kind?
   c. Should the resource be customized to the patient?
   d. Should the resource be discussed with the doctor/HCP or should it be for the patient to review independently?

APPENDIX 2: PILOT-TEST FOCUS GROUP DISCUSSION GUIDE

Pilot Test Group Interview Discussion Guide – Health Care Practitioners

Introduction

The Traffic Injury Research Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and the Rehabilitation Institute of Saint Louis (TRISL), is conducting a study to develop and evaluate an educational resource to improve communication between health care professionals (HCPs) and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This study is funded by the U.S. Food & Drug Administration (FDA).

The pilot test group interview that you are participating in today will be a discussion about your thoughts and opinions concerning the educational resource that has been developed as part of this study. Specifically, we would like you to consider whether you believe the resource would help HCPs and patients communicate about the possible impairing side effects of prescribed pain medication on a patient's driving abilities. Additionally, we would like you to consider if this tool would help improve patient knowledge and change patients' driving behaviours. The interview should take approximately 45 minutes to an hour. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond. The study Principal Investigator will summarize the discussion so that we can gather the different perspectives that are shared.

The study team will keep the information you provide confidential at all times. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals.

There is some risk regarding confidentiality of study participant information that is discussed during the pilot test group discussion, since the project team does not have oversight of what other study participants may divulge from the pilot test group discussion once the pilot test group has ended. For this reason, you are advised not to discuss information from this study with anyone outside the study. You are reminded to keep confidential what is discussed during group discussions and caution the study participants not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

The information and comments you provide us with today will help enhance the educational resource we are developing to improve communication between HCPs and their patients. We would like to thank you for participating in this interview today.

Interview Questions

1. What type of material do you currently provide to your patients to help them understand the risks associated with their prescribed pain medication? Does this material address driving-related risks?

2. What are your general thoughts about this educational resource that we have developed?

3. What information does it tell you? Please explain to me in your own words what the resource tells you?

4. Is it easy to understand?
   a. If no, what part is difficult to understand?

5. Are there any words or terms you do not understand?
   a. If yes, which words or terms do you not understand?

6. Is any of the information confusing or vague?
   a. If yes, what information is confusing or vague? How could this be clarified?

7. Do you have questions after reading it?
   a. If yes, what are your questions?

8. Do you like the layout of it?
   a. If yes, what aspects do you like?
   b. If no, what aspects do you not like?

9. Is the layout easy to follow?
   a. If no, which aspect is not easy to follow?

10. Does the resource grab your attention?
    a. If yes, which aspects in particular?
    b. If no, how could the tool be more engaging?

11. What do the images/graphics tell you?

12. What do you like most about it?

13. What do you like least about it?

14. Do you have any suggestions on how to improve either the layout or the content of the educational resource?

15. Do you think this educational resource would help you discuss medication risks with your patients as they relate to driving?

16. Would you see yourself using this tool with your patients?

a. If no, why not? Is there an aspect that could be changed that would make you more likely to use it with your patients?

17. How do you see yourself using this tool?
    a. Would you go over it and discuss it with your patients?
    b. Would you provide a copy to your patient and advise them to follow up with you if they had questions?
    c. Other?

18. Is there anything else you would like to add?

APPENDIX 3A: HCP SCREENING TOOL

Script to Request HCPs to Select Patient Study Participants for Outcome Evaluation

To HCP selected to identify potential outcome evaluation patient participants

It is requested that you identify patients under your care who may qualify to participate in a research study. The purpose of this study is to develop and evaluate an educational resource to improve communication between HCPs and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This study is funded by the U.S. Food & Drug Administration. This study is being conducted by the Traffic Injury Research Foundation, USA (TIRF USA). TIRF USA is a U.S. registered non-profit research organization. TIRF USA focuses on the human causes and effects of road crashes and provides objective, independent and evidence-based research to support the development, implementation and evaluation of road safety programs, effective advocacy and consultation.

This study is for research purposes only. If you agree you will be provided with a Screening Tool Checklist to identify and select potential patient participants at least 48 hours prior to the outcome evaluation. The Outcome Evaluation includes two individual surveys which will ask participants questions about the care they received during their treatment. The surveys are about participant's perceptions and experiences in relation to communication with HCPs.

Eligibility criteria for patient study participants will be determined through your review of the patient's medical records and discussions with your patients.

Eligibility criteria for patient study participation includes:

- must be at least 21 years of age;
- must possess a valid driver's license;
- must have driven within the last 6 months prior to their admission to the rehabilitation institute and;
- must be currently taking prescribed pain medication under your supervision at TRISL.

Exclusionary criteria for patient study participants include:

- those patients with mental health issues which interfere with the patient's ability to participate in this study as determined by either your professional medical opinion, or previously diagnosed and recorded in the patient's medical records by a licensed medical professional (if applicable);
- those patients with substance abuse addiction (alcohol, illicit drugs, prescribed medication or over the counter (OTC) medication), which may interfere with the patient's ability to participate in this study as determined by either your professional medical opinion, or previously diagnosed and recorded in the patient's medical records by a licensed medical professional (if applicable);

- those patients with diminished cognitive ability regarding mental disabilities as determined by either your professional medical opinion, or previously diagnosed and recorded in the patient's medical records by a licensed medical professional (if applicable);
- those patients currently taking any medications which prevents the potential participant from making an informed decision; either OTC or prescribed medications, taken by the patient prior to or while being prescribed pain medication at TRISL as determined by either your professional medical opinion, or previously diagnosed and recorded in the patient's medical records by a licensed medical professional (if applicable).

You will use the Screening Tool to identify potential patients who qualify and may be willing to participate in the outcome evaluation. You will then give the TRISL Case Manager a list of names of patients that qualify for the study.

The TRISL Case Manager who is also an employee at TRISL, will approach these patients to inform the patient they have been selected to participate in a research study, and if the patient is interested in receiving more information, the Principal Investigator of the study will visit with them for an in-person invitation.

Some of your participating patients may be selected to receive the Educational Resource that you will distribute to your patient once your patient has participated in the first evaluation survey. You may or may not agree to distribute the Educational Resource. If you do not agree to distribute the Educational Resource to your patients, you will not be included in this study, nor will your patients. The Educational Resource will be distributed to patient study participants within three days of taking the first outcome evaluation survey while the study participant remains a patient at TRISL. After you distribute the Educational Resource to your designated patients your involvement with your patient with regard to this study will be completed.

Thank you very much for your consideration. If you have any further questions, please contact Robyn Robertson, the Principal Investigator at TIRF USA at robynr@tirf.us or 613-986-7632.

APPENDIX 3B: BEDSIDE DISCUSSION LETTER

To potential outcome evaluation survey participant:

You are invited to participate in a research study because you have been identified by your health care professional (HCP) at The Rehabilitation Institute at Saint Louis (TRISL) as a potential participant who is currently taking prescribed pain medication under your HCP's direction. The case manager for TRISL has spoken with you about this study and you communicated to the case manager that you would like to discuss further information regarding this study, which I will provide to you.

The purpose of the study is to develop and evaluate an educational resource to improve communication between HCPs and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This study is funded by the U.S. Food & Drug Administration. This study is being conducted by the Traffic Injury Research Foundation, USA (TIRF USA). I represent TIRF USA. TIRF USA is a U.S. registered non-profit research organization. TIRF USA focuses on the human causes and effects of road crashes and provides objective, independent and evidence-based research to support the development, implementation and evaluation of road safety programs, effective advocacy and consultation.

This study is for research purposes only. Your participation in this research study is voluntary and will have no influence on your current treatment. This study is separate from the care you are currently receiving at TRISL. To qualify you must have a current valid driver license. It is also required that you have driven within the last 6 months prior to your admission to TRISL and being prescribed pain medication.

If you agree to participate, we would like you to participate in two surveys which will ask you questions about the care you received during your treatment. The surveys are about your perceptions and experiences in relation to communication HCPs. The first survey will be an in-person survey taken here at TRISL. Instructions for taking the second survey at a later date will be given to you after you have completed the first survey. The second survey will either be sent to you by email or you will be given instructions to take the survey online. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond.

The study team will keep the information you provide confidential. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your confidentiality. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. If we write a report about this study, we will do so in such a way that you cannot be identified. There is some risk regarding confidentiality of study participant information that may be discussed by participants, since the project team does not have oversight of what other study participants may divulge once the study task has ended. For this reason, you are advised not to discuss information from this study with

anyone outside the study. You are also advised to keep confidential what is discussed during group discussions and not to reveal anything about yourselves you do not want repeated outside of the project discussions, particularly personal information.

You will not have any costs for being in this research study. You will be paid $25 in the form of cash immediately after completing the first questionnaire and again after the second questionnaire has been completed and received. The second payment of $25 will be sent to you by mail.

This study will involve Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained in this letter. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect records pertaining to the research. This could include government representatives, (including the U.S. FDA who is sponsoring this project) to complete federal or state responsibilities. Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

If you have questions or concerns about your privacy and the use of your PHI, please contact the TRISL Medical Director, Dr. David Carr at 314-286-2706. Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your HCP.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. You will be given an Informed Consent Form which will be explained to you by the study Principal Investigator. This consent form will explain in detail the use of PHI and privacy issues regarding this study.

Please see the documents for further information. I will go over these documents with you in detail.

Thank you very much for your consideration. If you have any further questions, please contact Robyn Robertson, the Principal Investigator at TIRF USA at robynr@tirf.us or 613-986-7632. The survey will be held at XXXXX. Please arrive at XXXXX.

APPENDIX 3C: BEDSIDE INFORMATION LETTER

Dear potential outcome evaluation survey participant:

You are invited to participate in a research study. You have been selected because you have been identified by your health care professional (HCP) and case manager at The Rehabilitation Institute at Saint Louis (TRISL) as a potential study participant who is currently taking prescribed pain medication under your HCP's direction. It was indicated to the study Principal Investigator by the case manager at TRISL that you agreed to receive more information regarding this research study.

The purpose of the study is to develop and evaluate an educational resource to improve communication between HCPs and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals. This research study is funded by the U.S. Food & Drug Administration. This study is being conducted by the Traffic Injury Research Foundation, USA (TIRF USA). TIRF USA is a US registered non-profit research organization. TIRF USA focuses on the human causes and effects of road crashes and provides objective, independent and evidence-based research to support the development, implementation and evaluation of road safety programs, effective advocacy and consultation. This study is for research purposes only. Your participation in this research study is completely voluntary and will have no influence on your current treatment. This study is separate from the care you are currently receiving at TRISL. To qualify you must have a current valid driver license. It is also required that you have driven recently (within the last 6 months prior to their admission to TRISL) prior to being prescribed pain medication.

If you agree to participate, we would like you to participate in two individual surveys which will ask you questions about the care you received during your treatment. The surveys are about your perceptions and experiences in relation to communication with HCPs. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond. Depending on the method of delivery you select, the second survey will be sent either through mail delivered by the U.S. Postal Service, or delivered online through email by the Task Facilitator or a survey website.

The study team will keep the information you provide confidential. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your confidentiality. Your name or other identifiable information will not be included in any publications or presentations that result from this

research project. If we write a report about this study, we will do so in such a way that you cannot be identified.

There is some risk regarding confidentiality of study participant information that may be discussed after the outcome evaluation survey has been completed, since it is possible that study participants may discuss their answers to survey questions with others or each other once the outcome evaluation has ended. For this reason, you are advised not to discuss your survey answers or your personal information with anyone.

You will not have any costs for being in this research study. You will be paid for your participation $25 in the form of cash immediately following completion of the first outcome evaluation survey and again once the second outcome evaluation survey has been received.

This study will involve Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained in this letter. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect records pertaining to the research. This could include government representatives, (including the U.S. FDA who is sponsoring this project) to complete federal or state responsibilities. Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

If you have questions or concerns about your privacy and the use of your PHI, please contact the TRISL Medical Director, Dr. David Carr at 314-286-2706. Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your HCP.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. You will be given an Informed Consent Form which will be explained to you by the study Principal Investigator. This consent form will explain in detail the use of PHI and privacy issues regarding this study.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Robyn Robertson, Principal Investigator, Traffic Injury Research Foundation, USA (TIRF USA), 613-986-7632, or email robynr@tirf.us

Thank you very much for your consideration.

Sincerely,

Robyn Robertson
Principal Investigator
TIRF USA

APPENDIX 3D: INFORMED CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Educational Resource for the Effective Communication between Health Care Professionals and Patients about Impairing Risks of Medication in Relation to Driving

INVESTIGATOR: Robyn Robertson, President and CEO, Traffic Injury Research Foundation USA, Inc.

PHONE NUMBER: 613-986-7632

SPONSOR: U.S. Food and Drug Administration (FDA)

You have been asked to participate in this research study because you have been identified by your health care professional (HCP) at the Rehabilitation Institute of Saint Louis (TRISL) as a potential participant possessing the following qualifications:

- you are at least 21 years old;
- you possess a valid driver's license;
- you have driven within the last 6 months prior to your admission to TRISL; and,
- you are currently taking prescribed pain medication under the supervision of your HCP who is reviewing and selecting patient study participants at TRISL.

What is the purpose of this form?

You are being asked to participate in a research study. It is important that you read the following explanation of the proposed procedures. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes your right to withdraw from the study at any time. The study Principal Investigator will read through the consent form with you and discuss all the information. When you think you understand the study, you will then be asked if you agree to participate. If you agree, you are asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep.

You may show this consent form to family, your HCP other doctors, and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study. If you don't know another doctor, but want a second opinion about this study, please ask. The Principal Investigator will give you the name of another doctor that you can talk to. You will have time to discuss this study with your HCP at TRISL prior to this study if requested.

Why is this study being done?

The purpose of the study is to develop and evaluate an educational resource to improve communication between HCPs and their patients. The specific focus is on prescribed pain medications and how certain side effects can impair driving ability in some individuals.

What do I need to know about this study?

This study is for research purposes only. The Traffic Injury Research Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada, has been contracted by the US Food and Drug Administration (FDA) to conduct this research study. TIRF USA is a registered non-profit research organization in the U.S.

At the end of the study, we hope to gain a better understanding of HCPs' and their patients knowledge, opinions and behaviors in relation to driving while taking prescribed pain medication. In addition, we hope the study will help identify the type of information that is discussed between HCPs and their patients. This information will help create an educational resource that can be used by HCPs' when educating patients about the effects of driving when taking prescription pain medication.

What will happen during this study?

If you agree to participate, we would like you to participate in two outcome evaluation surveys which will ask you questions about the care you received during your treatment and your perceptions and experiences in relation to communication with HCPs. The first survey will be distributed in person at TRISL by the Principal Investigator. The second survey will be sent to you at a later date. The total time of the visit for the first survey should take approximately 90 minutes. The survey will be contained within a survey booklet in addition to a brief reminder about the goals of the research study and who is conducting and funding the study. You are free to skip any questions that you prefer not to answer. If you prefer not to answer a question or not to participate in any part of the discussion, you may decline to answer or otherwise not respond.

You will be asked to provide your contact information (including mailing address, email and phone number), so that the second survey and financial compensation can be sent to you by the study Principal Investigator. You will be given several options as to how you want to receive and complete the second survey. These options will include a survey sent to you through the mail, email, or administered and completed online through a survey website. At the completion of the second survey your participation in this study will be completed.

What are the potential risks of being in the study?

There is a possible risk of loss of confidentiality for this study. As a study participant, there is some risk regarding confidentiality of information that may be discussed during your participation in the study or by fellow participants. For this reason, you are advised not to discuss any personal information or information discussed during this study with anyone outside the study. However, every effort will be made to reduce the risk of loss of confidentiality by the project team.

You will be identified by a code number, and your name and other personal identifiers will be kept separate from your recorded responses to protect your confidentiality. The project team will not publish or disclose personal information to third parties. Your name or other identifiable information will not be included in any publications or presentations that result from this project. All documents containing protected health information (PHI) will be kept and stored safely and securely using modern, pass-word protected computers avoiding unauthorized access. Paper copies

of such PHI will be stored securely by the Principal Investigator in locked cabinets in locked offices at the TIRF USA office. PHI will be destroyed and/or purged immediately at the end of this study.

There are no other known risks from being in this study.

Will I be informed of new information relating to the study?

All new findings discovered during this research study that may reasonably influence your decision to continue to participate in this study will be provided to you by the Principal Investigator as such information becomes available.

Does being in this study provide any benefit?

Participating in this study will not provide a direct benefit to you.

Who do I contact in the event of an emergency?

In the event of an emergency during the study, you should immediately contact Dr. David Carr who is the Medical Director at TRISL. Dr. David Carr can be contacted at 314-286-2706.

What happens if I have a research related injury?

It is not expected that you will suffer a physical injury because of your participation in this study. No funds have been provided to cover injury during the study. If you are injured during the study, you will receive medical care, however you and your insurance company will be responsible for any costs. In the unlikely event that you do suffer a physical injury because of your participation in this study please contact the Medical Director at TRISL, Dr. David Carr at 314-286-2706.

Will it cost me anything to be in this study?

You will not have any costs for participating in this research study.

Will I be paid for being in this study?

You will be paid for your participation in the amount of $25 in the form of cash immediately in person after completing the first outcome evaluation survey. Once the second survey has been submitted to TIRF USA, you will be mailed an additional $25 in the form of cash upon receipt of the second survey.

Do I have to be in this study?

Your participation in this study is completely voluntary. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. Your participation in this research study will have no influence on your current treatment. This study is separate from the care you are currently receiving at TRISL.

Can I be removed from the study without my permission?

There is no reason why you should be removed from this study without your permission unless the study is terminated by TIRF USA or the U.S. FDA.

Who will have access to my study and/or medical information?

Records of your participation in this study will be held confidential so far as permitted by law. We will keep the information you provide confidential as described in the "potential risks" section of this consent form.

Federal regulatory agencies may inspect and copy records pertaining to this research. The study doctor, the sponsor or its designee and, under certain circumstances, the FDA and New England Institutional Review Board (IRB) will be able to inspect and have access to confidential data that identifies you by name. NEIRB is the agency who provided approval for this study regarding human research protection. NEIRB is an Independent Review Board (IRB) accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). By signing this consent form, you authorize the study doctor to release your medical records to the sponsor, the FDA, and NEIRB.

Who do I contact if I have questions about the study?

We encourage you to ask questions. If you have any questions about the research study itself, please contact the research study Principal Investigator: Robyn Robertson, Principal Investigator, Traffic Injury Research Foundation (TIRF) USA, Inc. (Tel.: 613-986-7632 or email: robynr@tirf.ca).

If you have questions about your rights as a research subject, or other concerns about the research, you can contact NEIRB at 1-800-232-9570.

VOLUNTEER'S STATEMENT

I agree that I have been given a chance to ask questions about this research study. Any questions I had have been answered to my satisfaction. I may contact the Principal Investigator *Robyn Robertson* if I have any more questions about taking part in this study.

I understand that my participation in this research project is voluntary. I also understand that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I understand the U.S. FDA or TIRF USA may terminate this study at any time.

If I have any questions about my rights as a research subject in this study I may contact:

New England Independent Review Board

Telephone: 1-800-232-9570

By signing this form, I have not waived any of my legal rights.

I agree to participate in this study. I will be given a copy of this signed and dated form for my own records.

_____ _____

Study Participant (signature) Date

_____

Print Participant's Name

_____ _____

Person who explained this study (signature) Date

APPENDIX 4A: BASELINE OUTCOME EVALUATION QUESTIONNAIRE

Outcome Evaluation Survey - Survey Part I

Dear outcome evaluation survey participant,

You have been identified through a recommendation from your health care professional (HCP) and the case manager at The Rehabilitation Institute at Saint Louis (TRISL) as a potential study participant currently taking prescribed pain medication under the direction of your HCP. We are inviting you to complete a two-part survey in support of a research study currently being conducted by the Traffic Research Injury Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and TRISL. This study is funded by the U.S. Food & Drug Administration (FDA).

The first survey is provided below and is designed to gauge your perceptions and experiences in relation to communication with your HCP, and to assess the care you have received during your treatment. The second survey will be a follow-up survey that will be administered in the near future. If you choose to participate in this two-part survey you will receive $25.00 (cash) immediately upon completing this first survey, and an additional $25 (cash) will be mailed to you after you finish the second survey. If you choose to participate in this two-part survey we would ask you to provide us with your contact information (in the space provided on the next page), so that we may send you the second survey and your compensation.

You are free to skip any questions that you would prefer not to answer. We will keep the information you provide confidential at all times. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals, including your doctor or family members, and will not affect your medical care in any way. There is some risk regarding confidentiality of study participant information that is discussed during the study, since the project team does not have oversight of what other study participants may divulge once the outcome evaluation has ended. For this reason, you are advised not to discuss information from this study with anyone. You are reminded to keep confidential what is discussed during group discussions and not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that are collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify. If you choose to participate and complete the below survey, the information you provide will help us develop and evaluate an

educational resource to improve communication between HCPs and their patients. We would like to thank you for participating in this survey today.

Sincerely,

Robyn Robertson
Principal Investigator
Traffic Injury Research Foundation USA Inc.
20 F Street
Washington, DC 20001
Tel.: 202-507-6334
Cell: 613-986-7632
Fax: 202-507-6101

Please provide your contact information:

Address:

Name: _____

Street Number: _____

Apartment Number _____

Street Name: _____

City: _____

State: _____

Zip Code: _____

Phone number: _____

Email address: _____

Patient Information

1. How old are you?
   - ☐ 18 – 19
   - ☐ 20 – 29
   - ☐ 30 – 39
   - ☐ 40 – 49
   - ☐ 50 – 59
   - ☐ 60 - 69
   - ☐ 70 - 79
   - ☐ 80 - 89
   - ☐ 90 and above
2. What is your sex?
   - ☐ Male
   - ☐ Female
3. Please list the prescription pain medication(s) you are currently taking:

   _____

   _____

   _____

   _____

4. How long have you been taking the above prescribed pain medication(s)?
   - ☐ 1-3 days
   - ☐ 4-7 days
   - ☐ 1-2 weeks
   - ☐ 3-4 weeks
   - ☐ More than 1 month but less than 3 months
   - ☐ More than 3 months

Patient Knowledge

1. What side effects do you think you may experience while taking your prescribed pain medication(s)? Please check all that apply:
   - ☐ Drowsiness
   - ☐ Constipation
   - ☐ Nausea or vomiting
   - ☐ Unclear thinking
   - ☐ Sleep disorders or disruptions
   - ☐ Fatigue
   - ☐ Confusion
   - ☐ Dizziness
   - ☐ Delayed Reaction Times
   - ☐ Disorientation
   - ☐ Headache
   - ☐ Light-headedness
   - ☐ Loss of appetite
   - ☐ Itching
   - ☐ Other: _____
2. How likely do you think prescribed pain medication can impair someone's driving abilities?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

3. How likely do you think consuming alcohol will increase the side effects of pain medication?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

4. Has your doctor discussed your ability to drive while taking your prescribed pain medication(s)?

☐ Yes ☐ No ☐ Not sure

5. How informed do you think you are on the side effects of your prescribed pain medication?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

6. How informed do you think you are on the side effects of your prescribed pain medication that may impact your driving abilities?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

7. How long do you think any side effects from your prescribed pain medication will last?

☐ 0 days
☐ 1-3 days
☐ 4-7 days
☐ 1-2 weeks
☐ 3-4 weeks
☐ More than 1 month but less than 3 months
☐ More than 3 months
☐ Not sure

8. How long do you think side effects from your prescribed pain medication that may impact your driving abilities will last?

☐ 0 days
☐ 1-3 days
☐ 4-7 days
☐ 1-2 weeks
☐ 3-4 weeks
☐ More than 1 month but less than 3 months
☐ More than 3 months
☐ Not sure

Patient Beliefs and Perceptions

1. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
It is safe to drive if you are taking prescribed pain medication as directed by a doctor.	☐	☐	☐	☐	☐	☐
It is safe to drive when first taking prescribed pain medication, as long as you feel fine.	☐	☐	☐	☐	☐	☐
It is safe to drive when you have been taking prescribed pain medication for a long time (i.e., 2 weeks or more).	☐	☐	☐	☐	☐	☐

1. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
People should refrain from driving if they are feeling drowsy or sleepy.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they consume illegal drugs.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they experience any impairing side effects from prescribed pain medication (e.g., drowsiness, dizziness, confusion, etc.).	☐	☐	☐	☐	☐	☐
People should refrain from driving if they are impaired by alcohol.	☐	☐	☐	☐	☐	☐

2. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
My doctor has provided me with information about the possible side effects I may experience while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I can make informed decisions about what I can and cannot do while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities.	☐	☐	☐	☐	☐	☐

Patient Behaviors

1. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will take my prescribed pain medication(s) as directed by my doctor (e.g., I will take the proper dose at the right time of day with/without food depending on instruction; I will not drive if instructed not to).	☐	☐	☐	☐	☐	☐
I will read the medication inserts that come in my prescribed pain medication(s) packages.	☐	☐	☐	☐	☐	☐
I will read any warning labels affixed to my prescribed pain medication(s) packages or bottles.	☐	☐	☐	☐	☐	☐
When filling my prescription I will request consultation from my pharmacist.	☐	☐	☐	☐	☐	☐
I will seek out additional information about my prescribed pain medication(s) and any side effects that may impact my driving abilities from my pharmacist or on the internet.	☐	☐	☐	☐	☐	☐

2. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will consume alcohol while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume illegal drugs while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume marijuana while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume other prescription medication(s) or over-the-counter medication(s) while taking my current prescribed pain medication(s).	☐	☐	☐	☐	☐	☐

3. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will adjust my prescribed pain medication(s) dose(s) if I experience any negative side effects when driving.	☐	☐	☐	☐	☐	☐
I will inform my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐
I will seek out alternative medication(s) from my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐

4. How frequently did you drive prior to being prescribed pain medication? Please check the answer that best applies to you:
   - ☐ Did not drive at all
   - ☐ Less than once per week
   - ☐ Once or twice per week
   - ☐ Several times per week
   - ☐ Everyday

5. How frequently do you anticipate driving while taking prescribed pain medication? Please check the answer that best applies to you:
   - ☐ Will not drive at all
   - ☐ Less than once per week
   - ☐ Once or twice per week
   - ☐ Several times per week
   - ☐ Everyday

6. Please indicate how strongly you agree or disagree with the following statements:

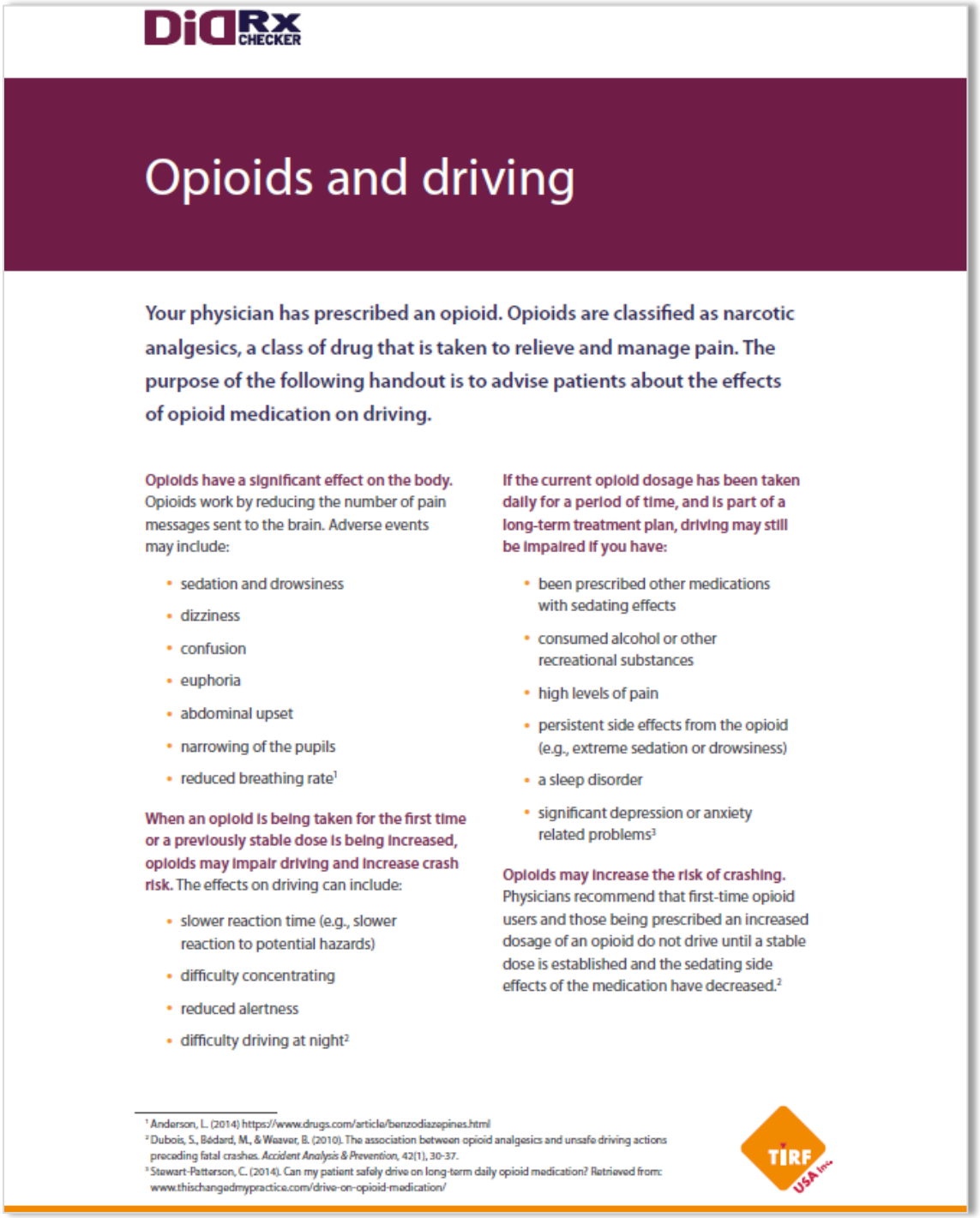
	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I need to drive in order to get to my work.	☐	☐	☐	☐	☐	☐
I need to drive as part of my work.	☐	☐	☐	☐	☐	☐
I need to drive in order to fulfil family obligations (e.g., dropping off/picking up my children from school, visiting family, etc.).	☐	☐	☐	☐	☐	☐

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I need to drive in order to fulfil life necessities (e.g., to get groceries, to make it to medical appointments, to go to the pharmacy, etc.).	☐	☐	☐	☐	☐	☐
I have friends/family members who I can call on to drive me to work or appointments if I felt I couldn't drive.	☐	☐	☐	☐	☐	☐
I am the only one in my family who can drive.	☐	☐	☐	☐	☐	☐
Public transportation (e.g., busses, metros, etc.) is available in my area.	☐	☐	☐	☐	☐	☐
I am willing to take public transportation.	☐	☐	☐	☐	☐	☐

7. Please indicate how likely or unlikely you are to do the following:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will drive within 2 hours of taking my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after consuming alcohol in combination with my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after taking other prescribed medication(s) or over-the-counter medication(s) in combination with my prescription pain medication.	☐	☐	☐	☐	☐	☐
I will not drive if I experience any negative side effects from my prescribed pain medication(s) (e.g. confusion, drowsiness, dizziness, etc.).	☐	☐	☐	☐	☐	☐
I will not drive if my doctor advises me to do so.	☐	☐	☐	☐	☐	☐
I will not drive during the first 2 weeks that I am taking prescribed pain medication(s)	☐	☐	☐	☐	☐	☐

APPENDIX 4B: DIDRXCHECKER APP HANDOUTS



DiDRx CHECKER

Opioids and driving

Your physician has prescribed an opioid. Opioids are classified as narcotic analgesics, a class of drug that is taken to relieve and manage pain. The purpose of the following handout is to advise patients about the effects of opioid medication on driving.

Opioids have a significant effect on the body. Opioids work by reducing the number of pain messages sent to the brain. Adverse events may include:

- sedation and drowsiness
- dizziness
- confusion
- euphoria
- abdominal upset
- narrowing of the pupils
- reduced breathing rate[1]

When an opioid is being taken for the first time or a previously stable dose is being increased, opioids may impair driving and increase crash risk. The effects on driving can include:

- slower reaction time (e.g., slower reaction to potential hazards)
- difficulty concentrating
- reduced alertness
- difficulty driving at night[2]

If the current opioid dosage has been taken daily for a period of time, and is part of a long-term treatment plan, driving may still be impaired if you have:

- been prescribed other medications with sedating effects
- consumed alcohol or other recreational substances
- high levels of pain
- persistent side effects from the opioid (e.g., extreme sedation or drowsiness)
- a sleep disorder
- significant depression or anxiety related problems[3]

Opioids may increase the risk of crashing. Physicians recommend that first-time opioid users and those being prescribed an increased dosage of an opioid do not drive until a stable dose is established and the sedating side effects of the medication have decreased.[2]

[1] Anderson, L. (2014) https://www.drugs.com/article/benzodiazepines.html
[2] Dubois, S., Bédard, M., & Weaver, B. (2010). The association between opioid analgesics and unsafe driving actions preceding fatal crashes. *Accident Analysis & Prevention*, 42(1), 30-37.
[3] Stewart-Patterson, C. (2014). Can my patient safely drive on long-term daily opioid medication? Retrieved from: www.thischangedmypractice.com/drive-on-opioid-medication/

DiDRx CHECKER

Benzodiazepines and driving

Your physician has prescribed a benzodiazepine (also referred to as benzo). Benzos are classified as a central nervous system (CNS) depressant, a class of drugs that slow down the activity of the brain. These are medications typically given for anxiety and/or muscle spasm. The following handout provides information on the risks of operating a motor vehicle while taking benzos and its adverse effects on driving.

Benzos have significant effects on the body. By sedating the body and brain functions, benzos can cause:

- drowsiness or lack of alertness
- impaired coordination
- slow reaction time
- impaired judgement

The effects of benzos may start within an hour of ingesting the drug, and can last anywhere from 2½ to several hours, depending on whether they are short, intermediate or long acting benzos (in some instances with long acting benzos, the effect can last up to 160 hours).[1]

Benzos can impair driving ability. The effects on driving often include:

- increased lane weaving (e.g., swerving)
- slower reaction time (e.g., slower reaction to potential hazards)
- reduced ability to perform multiple tasks (e.g., speaking with a passenger and paying attention to the road)
- falling asleep behind the wheel

Benzos can increase the risk of crashing. The greatest increase in risk occurs when:

- benzos are being used for the first time
- when there is a sleep disorder
- a previously stable dose is being increased
- when taken with alcohol or other sedating drugs

Also, long acting benzos present the greatest crash risk, since there is not enough time between doses for the effects to wear off, creating an accumulation of the impairing effects listed above.[2]

Benzos are the most detected CNS depressant in fatal or serious injury crashes. Aside from alcohol, benzos are the most frequently detected CNS depressant in fatal or serious injury crashes. The use of benzodiazepines in combination with another sedating substance (e.g., alcohol) is hazardous and can amplify the impairing effects of benzos alone.[3]

[1] Anderson, L. (2014) https://www.drugs.com/article/benzodiazepines.html
[2] OECD (2010) Drugs and Driving Detection and Deterrence: Detection and Deterrence. OECD Publishing.
[3] Verstraete, A. G., et al. (2014). *Drug use, impaired driving and traffic accidents.* Publications Office of the European Union.

DiDRx CHECKER

Transportation alternatives

Available to all public

- OATS Transit
  Phone: (314) 888-6720
- Metro Transit St. Louis
  (Metro Bus, Metro Link, Metro Call-A-Ride)
- Mobility for U
  Phone: (314) 873-6814
  Service area: St. Louis area—including entire Metro St. Louis Area and neighboring Illinois counties.
- Express Medical Transporters
  Phone: (314) 781-6400
  Service area: Greater St. Louis

Available to seniors

- Aging Ahead
  Phone: (636) 207-0847
  Toll Free: 1-(800)-AGE-6060
  Service area: Missouri
- County Older Resident Programs
  Phone: (314) 615-4516
- City Seniors Inc.
  Phone: (314) 352-0141
  Service area: St. Louis city limits
- Comfort Keepers St. Louis
  Phone: (314) 576-7000
  Service area: Metro St. Louis
- Continuum Care
  Phone: (314) 863-9912
  Service area: St. Louis and St. Charles
- Help at Home St. Louis
  Phone: (314) 569-5036
  Service area: St. Louis
- Home Instead St. Louis
  Phone: (314) 862-4663
  Service area: St. Louis
- Homewatch Caregivers
  Phone: (314) 963-1100
  Service area: St. Louis County
- INTGateway
  Phone: (636) 329-0888
  Service area: 15 mile radius from St. Charles
- Maxim Healthcare St. Louis
  Phone: (314) 569-3935
  Service area: St. Louis
- St. Louis Area Agency on Aging
  Phone: (314) 612-5918
  Service area: St. Louis city limits
- ZipCare Transportation
  Phone: (314)-292-7302
  Service area: St. Louis and surrounding communities

APPENDIX 4C: CONTROL GROUP HANDOUT CDC OPIOID PATIENT EDUCATION

PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW

Prescription opioids can be used to help relieve moderate-to-severe pain and are often prescribed following a surgery or injury, or for certain health conditions. These medications can be an important part of treatment but also come with serious risks. It is important to work with your health care provider to make sure you are getting the safest, most effective care.

WHAT ARE THE RISKS AND SIDE EFFECTS OF OPIOID USE?

Prescription opioids carry serious risks of addiction and overdose, especially with prolonged use. An opioid overdose, often marked by slowed breathing, can cause sudden death. The use of prescription opioids can have a number of side effects as well, even when taken as directed:

- Tolerance—meaning you might need to take more of a medication for the same pain relief
- Physical dependence—meaning you have symptoms of withdrawal when a medication is stopped
- Increased sensitivity to pain
- Constipation
- Nausea, vomiting, and dry mouth
- Sleepiness and dizziness
- Confusion
- Depression
- Low levels of testosterone that can result in lower sex drive, energy, and strength
- Itching and sweating

As many as **1 in 4** PEOPLE*

receiving prescription opioids long term in a primary care setting struggles with addiction.

* Findings from one study

RISKS ARE GREATER WITH:

- History of drug misuse, substance use disorder, or overdose
- Mental health conditions (such as depression or anxiety)
- Sleep apnea
- Older age (65 years or older)
- Pregnancy

Avoid alcohol while taking prescription opioids. Also, unless specifically advised by your health care provider, medications to avoid include:

- Benzodiazepines (such as Xanax or Valium)
- Muscle relaxants (such as Soma or Flexeril)
- Hypnotics (such as Ambien or Lunesta)
- Other prescription opioids

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

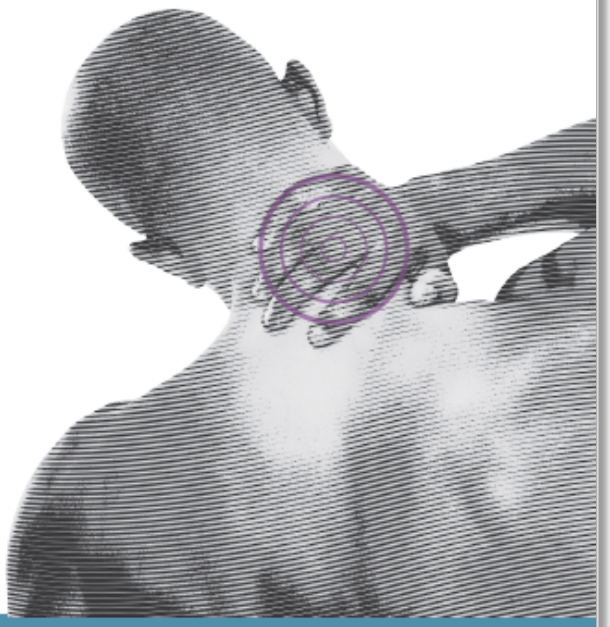
American Hospital Association

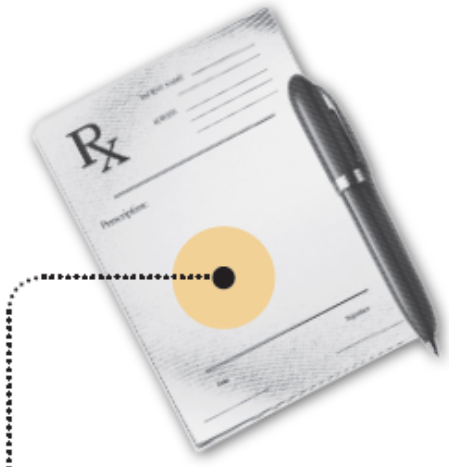
CS264107C May 9, 2016

KNOW YOUR OPTIONS

Talk to your health care provider about ways to manage your pain that don't involve prescription opioids. Some of these options **may actually work better** and have fewer risks and side effects. Options may include:

- Pain relievers such as acetaminophen, ibuprofen, and naproxen
- Some medications that are also used for depression or seizures
- Physical therapy and exercise
- Cognitive behavioral therapy, a psychological, goal-directed approach, in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress.





Be Informed!

Make sure you know the name of your medication, how much and how often to take it, and its potential risks & side effects.

IF YOU ARE PRESCRIBED OPIOIDS FOR PAIN:

- Never take opioids in greater amounts or more often than prescribed.
- Follow up with your primary health care provider within ____ days.
  - Work together to create a plan on how to manage your pain.
  - Talk about ways to help manage your pain that don't involve prescription opioids.
  - Talk about any and all concerns and side effects.
- Help prevent misuse and abuse.
  - Never sell or share prescription opioids.
  - Never use another person's prescription opioids.
- Store prescription opioids in a secure place and out of reach of others (this may include visitors, children, friends, and family).
- Safely dispose of unused prescription opioids: Find your community drug take-back program or your pharmacy mail-back program, or flush them down the toilet, following guidance from the Food and Drug Administration (www.fda.gov/Drugs/ResourcesForYou).
- Visit www.cdc.gov/drugoverdose to learn about the risks of opioid abuse and overdose.
- If you believe you may be struggling with addiction, tell your health care provider and ask for guidance or call SAMHSA's National Helpline at 1-800-662-HELP.

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

APPENDIX 4D: POST OUTCOME EVALUATION QUESTIONNAIRE FOR EXPERIMENTAL GROUP

Outcome Evaluation Survey - Survey Part II

Dear outcome evaluation survey participant,

You have identified as a potential study participant who has completed part one of our two-part survey in support of a research study currently being conducted by the Traffic Research Injury Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and the Rehabilitation Institute of Saint Louis (TRISL). This study is funded by the U.S. Food & Drug Administration (FDA).

The second survey is provided below and is intended to be a follow-up survey. If you choose to complete this second survey and return it to us, you will receive $25.00 (cash) to compensate you for your time which will be provided to you through the mail once your survey is received. In order to receive this compensation please confirm your contact information in the space provided on the next page.

You are free to skip any questions that you would prefer not to answer. We will keep the information you provide confidential at all times. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals, including your doctor or family members, and will not affect your medical care in any way. There is some risk regarding confidentiality of study participant information that is discussed during the study, since The project team does not have oversight of what other study participants may divulge once the outcome evaluation has ended. For this reason, you are advised not to discuss information from this study with anyone. You are reminded to keep confidential what is discussed during group discussions and not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that are collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify.

If you choose to participate and complete the below survey, the information you provide will help us develop and evaluate an educational resource to improve communication between HCPs and their patients. We would like to thank you for participating in this survey today.

Sincerely,

Robyn Robertson
Principal Investigator
Traffic Injury Research Foundation USA Inc.
20 F Street
Washington, DC 20001
Tel.: 202-507-6334
Cell: 613-986-7632
Fax: 202-507-6101

Please provide your contact information:

Address:

Name: _____

Street Number: _____

Apartment Number _____

Street Name: _____

City: _____

State: _____

Zip Code: _____

Phone number: _____

Email address: _____

Patient Information

5. How old are you?
   - ☐ 18 – 19
   - ☐ 20 – 29
   - ☐ 30 – 39
   - ☐ 40 – 49
   - ☐ 50 – 59
   - ☐ 60 - 69
   - ☐ 70 - 79
   - ☐ 80 - 89
   - ☐ 90 and above

6. What is your sex?
   - ☐ Male
   - ☐ Female

7. Are you currently in out-patient treatment or in-patient treatment?
   - ☐ Out-patient treatment
   - ☐ In-patient treatment

8. Are you currently taking prescription pain medication(s)?
   - ☐ Yes
   - ☐ No

If you are currently taking prescribed pain medication(s) please answer the below questions and then proceed to the next section (entitled Patient Knowledge on page 4). If you are not currently taking prescription pain medication(s) please skip to the next section (entitled Patient Knowledge on page 4).

9. Please list the prescribed pain medication(s) you are currently taking:

   _____

   _____

   _____

   _____

10. How long have you been taking the above prescribed pain medication(s)?
    - ☐ 1-3 days
    - ☐ 4-7 days
    - ☐ 1-2 weeks
    - ☐ 3-4 weeks
    - ☐ More than 1 month but less than 3 months
    - ☐ More than 3 months

Patient Knowledge

9. What side effects do you think you may experience while taking your prescribed pain medication(s)? Please check all that apply:

☐ Drowsiness ☐ Fatigue ☐ Headache

☐ Constipation ☐ Confusion ☐ Light-headedness

☐ Nausea or vomiting ☐ Dizziness ☐ Loss of appetite

☐ Unclear thinking ☐ Delayed Reaction Times ☐ Itching

☐ Sleep disorders or disruptions ☐ Disorientation

☐ Other: _____

10. How likely do you think prescribed pain medication can impair someone's driving abilities?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

3. How likely do you think consuming alcohol will increase the side effects of prescribed pain medication?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

4. Has your doctor discussed your ability to drive while taking your prescribed pain medication(s)?

☐ Yes ☐ No ☐ Not sure

5. How informed do you think you are on the side effects of your prescribed pain medication?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

6. How informed do you think you are on the side effects of your prescribed pain medication that may impact your driving abilities?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

7. How long do you think any side effects from your prescribed pain medication will last?

- ☐ 0 days
- ☐ 1-3 days
- ☐ 4-7 days
- ☐ 1-2 weeks
- ☐ 3-4 weeks
- ☐ More than 1 month but less than 3 months
- ☐ More than 3 months
- ☐ Not sure

8. How long do you think side effects from your prescribed pain medication that may impact your driving abilities will last?

- ☐ 0 days
- ☐ 1-3 days
- ☐ 4-7 days
- ☐ 1-2 weeks
- ☐ 3-4 weeks
- ☐ More than 1 month but less than 3 months
- ☐ More than 3 months
- ☐ Not sure

Patient Beliefs and Perceptions

3. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
It is safe to drive if you are taking prescribed pain medication as directed by a doctor.	☐	☐	☐	☐	☐	☐
It is safe to drive when first taking prescribed pain medication, as long as you feel fine.	☐	☐	☐	☐	☐	☐
It is safe to drive when you have been taking prescribed pain medication for a long time (i.e., 2 weeks or more).	☐	☐	☐	☐	☐	☐

4. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
People should refrain from driving if they are feeling drowsy or sleepy.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they consume illegal drugs.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they experience any impairing side effects from prescribed pain medication (e.g., drowsiness, dizziness, confusion, etc.).	☐	☐	☐	☐	☐	☐
People should refrain from driving if they are impaired by alcohol.	☐	☐	☐	☐	☐	☐

5. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
My doctor has provided me with information about the possible side effects I may experience while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I can make informed decisions about what I can and cannot do while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities.	☐	☐	☐	☐	☐	☐

Patient Behaviors

8. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will take my prescribed pain medication(s) as directed by my doctor (e.g., I will take the proper dose at the right time of day with/without food depending on instruction; I will not drive if instructed not to).	☐	☐	☐	☐	☐	☐
I will read the medication inserts that come in my prescribed pain medication(s) packages.	☐	☐	☐	☐	☐	☐
I will read any warning labels affixed to my prescribed pain medication(s) packages or bottles.	☐	☐	☐	☐	☐	☐
When filling my prescription I will request consultation from my pharmacist.	☐	☐	☐	☐	☐	☐
I will seek out additional information about my prescribed pain medication(s) and any side effects that may impact my driving abilities from my pharmacist or on the internet.	☐	☐	☐	☐	☐	☐

9. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will consume alcohol while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume illegal drugs while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume marijuana while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume other prescribed medication(s) or over-the-counter medication(s) while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐

10. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will adjust my prescribed pain medication(s) dose(s) if I experience any negative side effects when driving.	☐	☐	☐	☐	☐	☐
I will inform my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐
I will seek out alternative medication(s) from my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐

11. How frequently did you drive prior to being prescribed pain medication? Please check the answer that best applies to you:
    - ☐ Did not drive at all
    - ☐ Less than once per week
    - ☐ Once or twice per week
    - ☐ Several times per week
    - ☐ Everyday

12. How frequently do you anticipate driving while taking prescribed pain medication? Please check the answer that best applies to you:
    - ☐ Will not drive at all
    - ☐ Less than once per week

☐ Once or twice per week
☐ Several times per week
☐ Everyday

13. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I need to drive in order to get to my work.	☐	☐	☐	☐	☐	☐
I need to drive as part of my work.	☐	☐	☐	☐	☐	☐
I need to drive in order to fulfil family obligations (e.g., dropping off/picking up my children from school, visiting family, etc.).	☐	☐	☐	☐	☐	☐
I need to drive in order to fulfil life necessities (e.g., to get groceries, to make it to medical appointments, to go to the pharmacy, etc.).	☐	☐	☐	☐	☐	☐
I have friends/family members who I can call on to drive me to work or appointments if I felt I couldn't drive.	☐	☐	☐	☐	☐	☐
I am the only one in my family who can drive.	☐	☐	☐	☐	☐	☐
Public transportation (e.g., busses, metros, etc.) is available in my area.	☐	☐	☐	☐	☐	☐
I am willing to take public transportation.	☐	☐	☐	☐	☐	☐

14. Please indicate how likely or unlikely you are to do the following:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will drive within 2 hours of taking my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after consuming alcohol in combination with my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after taking other prescribed medication(s) or over-the-counter medication(s) in combination with my current prescription pain medication.	☐	☐	☐	☐	☐	☐
I will not drive if I experience any negative side effects from my prescription pain medication(s) (e.g. confusion, drowsiness, dizziness, etc.).	☐	☐	☐	☐	☐	☐

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will not drive if my doctor advises me to do so.	☐	☐	☐	☐	☐	☐
I will not drive during the first 2 weeks that I am taking prescription pain medication(s)	☐	☐	☐	☐	☐	☐

Educational Resource

1. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I used the educational resource recommended to me by my doctor.	☐	☐	☐	☐	☐	☐
I was able to review the information in the educational resource with my doctor.	☐	☐	☐	☐	☐	☐
I found the educational resource easy to navigate.	☐	☐	☐	☐	☐	☐
I understood the information included in the educational resource.	☐	☐	☐	☐	☐	☐
I found the pictures and graphics helped me better understand the information in the educational resource.	☐	☐	☐	☐	☐	☐
I found the educational resource interesting.	☐	☐	☐	☐	☐	☐
I enjoyed using the educational resource.	☐	☐	☐	☐	☐	☐
I would recommend the educational resource to other people who are being prescribed pain medications.	☐	☐	☐	☐	☐	☐
I would use a similar educational resource if I was prescribed other types of medication.	☐	☐	☐	☐	☐	☐

2. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I learned new things about my prescribed pain medication(s) from using the educational resource.	☐	☐	☐	☐	☐	☐
After using the educational resource I have a better understanding of the side effects of my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐

After using the educational resource I have a better understanding of how the possible side effects my prescribed pain medication(s) can impact my driving abilities.	☐	☐	☐	☐	☐	☐
After using the educational resource I am better able to recognize if I am experiencing any side effects from my prescribed pain medication(s) that may impact my driving abilities.	☐	☐	☐	☐	☐	☐
I have discussed what I learned from the educational resource with my doctor and/or pharmacist	☐	☐	☐	☐	☐	☐
I have discussed what I learned from the educational resource with my family and/or friends.	☐	☐	☐	☐	☐	☐
I have adjusted my driving behaviors/habits because of what I learned from the educational resource.	☐	☐	☐	☐	☐	☐
I feel I am making safer decisions about whether I can drive or not based on what I learned from the educational resource.	☐	☐	☐	☐	☐	☐

3. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree	Not Applicable
It was easy to download the educational resource onto my home computer or tablet.	☐	☐	☐	☐	☐	☐	☐
It was easy to download the educational resource onto my mobile phone.	☐	☐	☐	☐	☐	☐	☐
It was easy to use the educational resource on my home computer or tablet.	☐	☐	☐	☐	☐	☐	☐
It was easy to use the educational resource on my mobile phone.	☐	☐	☐	☐	☐	☐	☐

4. What features or aspects of the educational resource did you find most helpful?

_____

_____

5. What features or aspects of the educational resource did you find most frustrating to use?

_____

_____

6. What would you change about the educational resource to make it more helpful for patients?

APPENDIX 4E: POST OUTCOME EVALUATION QUESTIONNAIRE FOR CONTROL GROUP

Outcome Evaluation Survey - Survey Part II

Dear outcome evaluation survey participant,

You have identified as a potential study participant who has completed part one of our two-part survey in support of a research study currently being conducted by the Traffic Research Injury Foundation USA, Inc. (TIRF USA), in partnership with TIRF in Canada and the Rehabilitation Institute of Saint Louis (TRISL). This study is funded by the U.S. Food & Drug Administration (FDA).

The second survey is provided below and is intended to be a follow-up survey. If you choose to complete this second survey and return it to us, you will receive $25.00 (cash) to compensate you for your time which will be provided to you through the mail once your survey is received. In order to receive this compensation please confirm your contact information in the space provided on the next page.

You are free to skip any questions that you would prefer not to answer. We will keep the information you provide confidential at all times. You will be identified by a code number, and your name and other personal identifiers will be kept separate from your responses to protect your identity and any information you provide. Your name or other identifiable information will not be included in any publications or presentations that result from this research project. The information you provide will not be shared with any individuals, including your doctor or family members, and will not affect your medical care in any way. There is some risk regarding confidentiality of study participant information that is discussed during the study, since the project team does not have oversight of what other study participants may divulge once the outcome evaluation has ended. For this reason, you are advised not to discuss information from this study with anyone. You are reminded to keep confidential what is discussed during group discussions and not to reveal anything about yourself you do not want repeated outside of the project discussions, particularly personal information.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that are collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify.

If you choose to participate and complete the below survey, the information you provide will help us develop and evaluate an educational resource to improve communication between HCPs and their patients. We would like to thank you for participating in this survey today.

Sincerely,

Robyn Robertson
Principal Investigator
Traffic Injury Research Foundation USA Inc.
20 F Street
Washington, DC 20001
Tel.: 202-507-6334
Cell: 613-986-7632
Fax: 202-507-6101

Please provide your contact information:

Address:

Name: _____

Street Number: _____

Apartment Number _____

Street Name: _____

City: _____

State: _____

Zip Code: _____

Phone number: _____

Email address: _____

Patient Information

11. How old are you?

☐ 18 – 19
☐ 20 – 29
☐ 30 – 39
☐ 40 – 49
☐ 50 – 59
☐ 60 - 69
☐ 70 - 79
☐ 80 - 89
☐ 90 and above

12. What is your sex?

☐ Male
☐ Female

13. Are you currently in out-patient treatment or in-patient treatment?

☐ Out-patient treatment
☐ In-patient treatment

14. Are you currently taking prescription pain medication(s)?

☐ Yes
☐ No

If you are currently taking prescribed pain medication(s) please answer the below questions and then proceed to the next section (entitled Patient Knowledge on page 4). If you are not currently taking prescription pain medication(s) please skip to the next section (entitled Patient Knowledge on page 4).

15. Please list the prescribed pain medication(s) you are currently taking:

_____

_____

_____

_____

16. How long have you been taking the above prescribed pain medication(s)?

☐ 1-3 days
☐ 4-7 days
☐ 1-2 weeks
☐ 3-4 weeks
☐ More than 1 month but less than 3 months
☐ More than 3 months

Patient Knowledge

11. What side effects do you think you may experience while taking your prescribed pain medication(s)? Please check all that apply:

☐ Drowsiness	☐ Fatigue	☐ Headache
☐ Constipation	☐ Confusion	☐ Light-headedness
☐ Nausea or vomiting	☐ Dizziness	☐ Loss of appetite
☐ Unclear thinking	☐ Delayed Reaction Times	☐ Itching
☐ Sleep disorders or disruptions	☐ Disorientation	
☐ Other: _____		

12. How likely do you think prescribed pain medication can impair someone's driving abilities?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

9. How likely do you think consuming alcohol will increase the side effects of prescribed pain medication?

Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely	Not Sure
☐	☐	☐	☐	☐	☐	☐

10. Has your doctor discussed your ability to drive while taking your prescribed pain medication(s)?

☐ Yes ☐ No ☐ Not sure

11. How informed do you think you are on the side effects of your prescribed pain medication?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

12. How informed do you think you are on the side effects of your prescribed pain medication that may impact your driving abilities?

Very Uninformed	Uninformed	Somewhat Uninformed	Somewhat Informed	Informed	Very Informed	Not Sure
☐	☐	☐	☐	☐	☐	☐

13. How long do you think any side effects from your prescribed pain medication will last?

- ☐ 0 days
- ☐ 1-3 days
- ☐ 4-7 days
- ☐ 1-2 weeks
- ☐ 3-4 weeks
- ☐ More than 1 month but less than 3 months
- ☐ More than 3 months
- ☐ Not sure

14. How long do you think side effects from your prescribed pain medication that may impact your driving abilities will last?

- ☐ 0 days
- ☐ 1-3 days
- ☐ 4-7 days
- ☐ 1-2 weeks
- ☐ 3-4 weeks
- ☐ More than 1 month but less than 3 months
- ☐ More than 3 months
- ☐ Not sure

Patient Beliefs and Perceptions

6. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
It is safe to drive if you are taking prescribed pain medication as directed by a doctor.	☐	☐	☐	☐	☐	☐
It is safe to drive when first taking prescribed pain medication, as long as you feel fine.	☐	☐	☐	☐	☐	☐
It is safe to drive when you have been taking prescribed pain medication for a long time (i.e., 2 weeks or more).	☐	☐	☐	☐	☐	☐

7. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
People should refrain from driving if they are feeling drowsy or sleepy.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they consume illegal drugs.	☐	☐	☐	☐	☐	☐
People should refrain from driving if they experience any impairing side effects from prescribed pain medication (e.g., drowsiness, dizziness, confusion, etc.).	☐	☐	☐	☐	☐	☐
People should refrain from driving if they are impaired by alcohol.	☐	☐	☐	☐	☐	☐

8. Please indicate how strongly you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
My doctor has provided me with information about the possible side effects I may experience while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I can make informed decisions about what I can and cannot do while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
My doctor should have provided me with more information on the possible impairing effects of my prescribed pain medication(s) on my driving abilities.	☐	☐	☐	☐	☐	☐

Patient Behaviors

15. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will take my prescribed pain medication(s) as directed by my doctor (e.g., I will take the proper dose at the right time of day with/without food depending on instruction; I will not drive if instructed not to).	☐	☐	☐	☐	☐	☐
I will read the medication inserts that come in my prescribed pain medication(s) packages.	☐	☐	☐	☐	☐	☐
I will read any warning labels affixed to my prescribed pain medication(s) packages or bottles.	☐	☐	☐	☐	☐	☐
When filling my prescription, I will request consultation from my pharmacist.	☐	☐	☐	☐	☐	☐
I will seek out additional information about my prescribed pain medication(s) and any side effects that may impact my driving abilities from my pharmacist or on the internet.	☐	☐	☐	☐	☐	☐

16. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will consume alcohol while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume illegal drugs while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume marijuana while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐
I will consume other prescribed medication(s) or over-the-counter medication(s) while taking my prescribed pain medication(s).	☐	☐	☐	☐	☐	☐

17. Please indicate how likely or unlikely you are to do the following once you receive a prescription from your doctor for pain medication:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will adjust my prescribed pain medication(s) dose(s) if I experience any negative side effects when driving.	☐	☐	☐	☐	☐	☐
I will inform my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐
I will seek out alternative medication(s) from my doctor if I experience any negative side effects from my prescribed pain medication(s) when driving.	☐	☐	☐	☐	☐	☐

18. How frequently did you drive prior to being prescribed pain medication? Please check the answer that best applies to you:
    - ☐ Did not drive at all
    - ☐ Less than once per week
    - ☐ Once or twice per week
    - ☐ Several times per week
    - ☐ Everyday

19. How frequently do you anticipate driving while taking prescribed pain medication? Please check the answer that best applies to you:
    - ☐ Will not drive at all
    - ☐ Less than once per week

☐ Once or twice per week
☐ Several times per week
☐ Everyday

20. Please indicate how strongly you agree or disagree with the following statements:

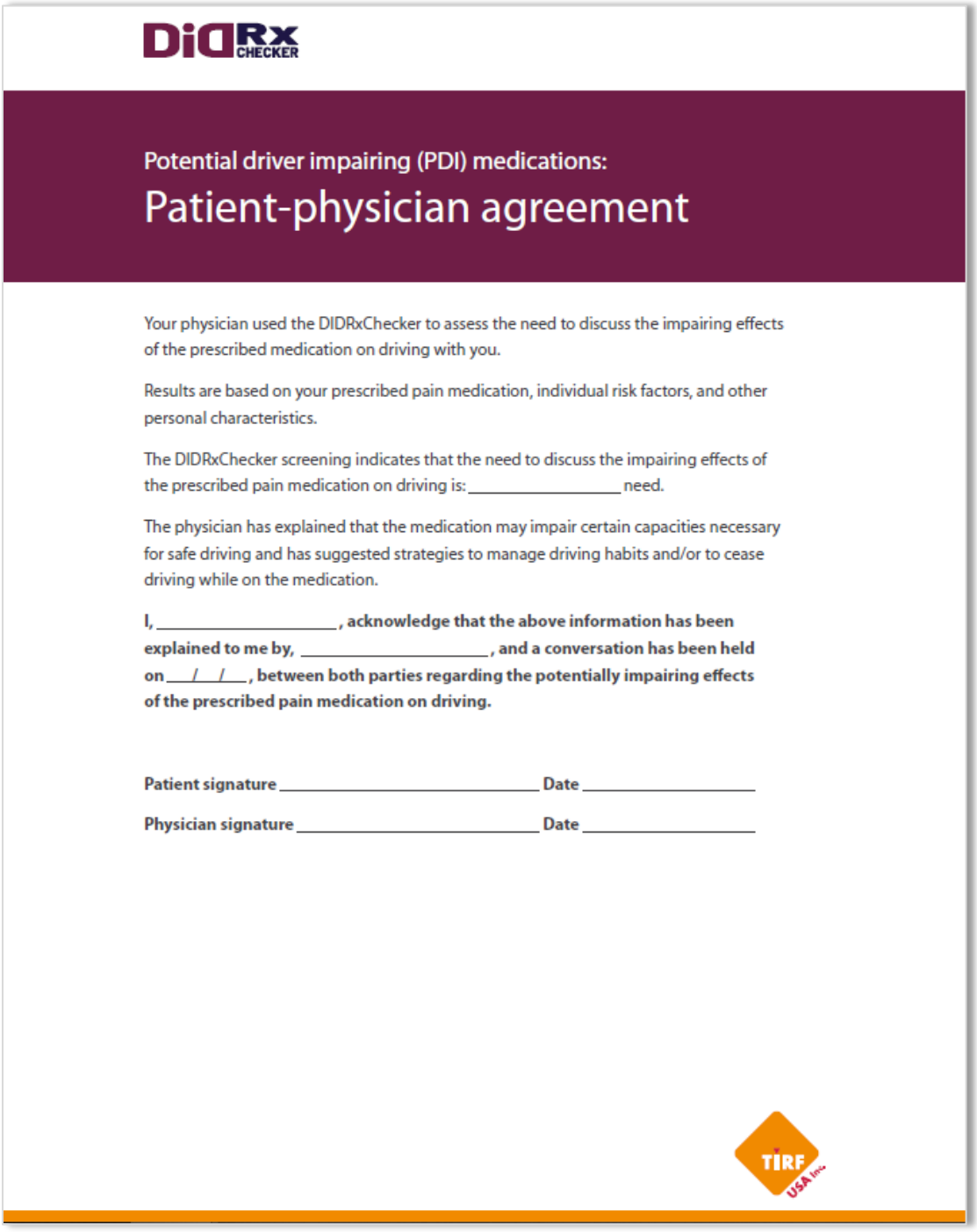
	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I need to drive in order to get to my work.	☐	☐	☐	☐	☐	☐
I need to drive as part of my work.	☐	☐	☐	☐	☐	☐
I need to drive in order to fulfil family obligations (e.g., dropping off/picking up my children from school, visiting family, etc.).	☐	☐	☐	☐	☐	☐
I need to drive in order to fulfil life necessities (e.g., to get groceries, to make it to medical appointments, to go to the pharmacy, etc.).	☐	☐	☐	☐	☐	☐
I have friends/family members who I can call on to drive me to work or appointments if I felt I couldn't drive.	☐	☐	☐	☐	☐	☐
I am the only one in my family who can drive.	☐	☐	☐	☐	☐	☐
Public transportation (e.g., busses, metros, etc.) is available in my area.	☐	☐	☐	☐	☐	☐
I am willing to take public transportation.	☐	☐	☐	☐	☐	☐

21. Please indicate how likely or unlikely you are to do the following:

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will drive within 2 hours of taking my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after consuming alcohol in combination with my prescribed pain medication.	☐	☐	☐	☐	☐	☐
I will drive after taking other prescribed medication(s) or over-the-counter medication(s) in combination with my current prescription pain medication.	☐	☐	☐	☐	☐	☐
I will not drive if I experience any negative side effects from my prescription pain medication(s) (e.g. confusion, drowsiness, dizziness, etc.).	☐	☐	☐	☐	☐	☐
I will not drive if my doctor advises me to do so.	☐	☐	☐	☐	☐	☐

	Very Unlikely	Unlikely	Somewhat Unlikely	Somewhat Likely	Likely	Very Likely
I will not drive during the first 2 weeks that I am taking prescription pain medication(s)	☐	☐	☐	☐	☐	☐

APPENDIX 5: DIDRXCHECKER APP RESOURCES



DiDRx CHECKER

Potential driver impairing (PDI) medications:

Patient-physician agreement

Your physician used the DIDRxChecker to assess the need to discuss the impairing effects of the prescribed medication on driving with you.

Results are based on your prescribed pain medication, individual risk factors, and other personal characteristics.

The DIDRxChecker screening indicates that the need to discuss the impairing effects of the prescribed pain medication on driving is: _____ need.

The physician has explained that the medication may impair certain capacities necessary for safe driving and has suggested strategies to manage driving habits and/or to cease driving while on the medication.

I, _____, acknowledge that the above information has been explained to me by, _____, and a conversation has been held on ___/___/___, between both parties regarding the potentially impairing effects of the prescribed pain medication on driving.

Patient signature _____ **Date** _____

Physician signature _____ **Date** _____

DiDRx CHECKER

Skills for safe driving

Driving is a divided attention task that requires three different types of skills: visual/auditory abilities, cognitive processing abilities, and motor abilities. Prescribed pain medications are often associated with side effects that may include impairments in relation to one or more of these skills. Research shows that drivers who have impairments related to one or more of these skills are more likely to be involved in road crashes.

While it can be difficult to predict how potential driver impairing (PDI) medications may affect individual patients, it is important they are informed about the potentially impairing effects of the medication, and understand how these medications can interfere with driving skills. Notably, the impairing effects of prescribed medication can be significant, regardless of age. In addition, older drivers who are crash-involved are at increased risk for injury and death because of their frailty. Discussing the potentially impairing effects of pain medications can help patients protect their health, and avoid injuring or killing themselves or other persons on the road.

This fact sheet describes the range of visual, cognitive, and motor skills necessary for safe driving,[1] and the consequences of impairments. It was designed to increase awareness among prescribing health care practitioners about these topics to facilitate discussion with patients about protecting their health and safety.

It is organized by the following sections: visual/auditory skills, cognitive skills, and motor skills. Definitions are provided for each type of driving skill. Specific examples are included to help patients understand how driving skills can be affected, and the importance of managing their driving and their use of prescribed medications to avoid driving while impaired.

Visual/auditory skills

There are four types of visual/auditory skills essential for driving:

- **Visual acuity:** The ability to resolve detail at a given distance according to a set standard.
  - **Driving example:** Driving requires the ability to discern objects in the environment with a certain level of acuity. Impairments in visual acuity may result in blurred vision, where the driver experiences a loss of visual detail or sharpness, and therefore may not be able to focus while driving.

[1] University of Calgary (March 2014). Functions needed for driving. Retrieved from http://www.ucalgary.ca/FTWguidelines/content/functions-needed-driving

DiDRx CHECKER

- **Contrast sensitivity:** The ability to perceive the changes in contrast between an object and its background.
  - **Driving example:** Driving requires the ability to perceive an object that may be similar to or blend into the background, and this happens when there is low contrast between the object and background. If a driver's ability to perceive contrast was impaired, they might have difficulties detecting objects of similar contrast in the roadway, such as a pedestrian in dark clothing crossing the road at night or driving through a tunnel.
- **Glare recovery:** The ability of the eye to recover after exposure to bright lights.
  - **Driving example:** Driving requires adequate glare recovery when exposed to bright sunlight or oncoming headlights at night. If a driver's ability to recover from glare was impaired, they might feel extremely sensitive to bright lights and experience temporary visual disruptions lasting much longer than usual.
- **Auditory perception:** The ability to perceive sound.
  - **Driving example:** Driving requires the ability to perceive a variety of auditory stimuli, which helps the driver understand the surrounding environment. If hearing was impaired, the driver may not be able to detect important sounds that provide key information about objects and their location in the driving environment, such as the sound of a honking horn from an oncoming vehicle.

Cognitive skills

There are numerous types of cognitive skills essential for driving:

- **Information processing:** The ability to comprehend and interpret incoming information and develop an appropriate response for the context.
  - **Driving example:** Driving requires the processing of incoming visual and auditory information such as a pedestrian waiting at a crosswalk, or a car that honks at you. Information processing is a cognitive skill that helps recognize, interpret and formulate an action in response to this information. If information processing was impaired, the driver may not effectively process that a pedestrian has begun crossing, and may have trouble formulating the appropriate response to slow down or stop to give the right of way.
- **Sustained and selective attention:** Sustained attention allows you to remain attentive to a task for an extended period of time, and selective attention allows you to attend to important facets of that task while filtering out all irrelevant information.
  - **Driving example:** Driving requires the ability to attend to the roadway environment for a prolonged period of time and focus on the pertinent elements of the driving experience while filtering out the rest. If sustained attention was impaired, the driver may be inattentive and have trouble maintaining alertness on the road. If selective attention was impaired, the driver may not be able to focus or concentrate and may become overwhelmed by the task.

DiDRx CHECKER

- **Divided attention:** The ability to pay attention two or more different stimuli concurrently.
  - **Driving example:** Driving requires the ability to attend to many stimuli at the same time. If divided attention was impaired, the driver may have difficulties paying attention to the roadway ahead while also attending and maintaining the posted speed limit or observing distractions along the route.
- **Hazard perception:** The ability to detect a potential hazard and make the cognitive estimation to determine whether the potential hazard requires evasive action.
  - **Driving example:** Driving requires the ability to detect, assess and potentially respond to hazards in the roadway. If hazard detection was impaired, the driver may have difficulties identifying a potential hazard as a threat to their safety and fail to respond appropriately.
- **Reaction time:** The length of time it takes to respond to a stimulus.
  - **Driving example:** Reaction time dictates how quickly a driver will respond to an event. If a driver's reaction time was impaired, the driver may be slower to engage the brakes or make an evasive action in the event of a roadway hazard.
- **Short-term and working memory:** Short-term memory holds information for short periods of time, and working memory uses this information to manage, maintain and update the input to allow for more complex processes such as reasoning and understanding.
  - **Driving example:** Driving requires the ability to recall, retain and manipulate information in memory so that appropriate action can be taken. If short-term or working memory was impaired, the driver may not remember that they just saw a sign indicating the beginning of a construction zone, as a result they may neglect to reduce their speed and could have trouble interpreting and navigating the complexities of a construction zone. They may also forget routes and have difficulty with geographic disorientation.
- **Long-term memory:** The ability to store information for long periods of time.
  - **Driving example:** Driving requires the ability to call upon pre-existing knowledge such as the rules of the road or the route to a familiar location. If long-term memory was impaired, the driver may have difficulties remembering some aspects of their daily route.

Motor skills

There are two types of motor skills essential for driving:

- **Coordination:** The ability to execute physical movements in a controlled, smooth and efficient manner.
  - **Driving example:** Driving requires the coordination of motor actions to execute driving maneuvers and retain control of the vehicle. If coordination was impaired, the driver may experience difficulty executing a variety of vehicle maneuvers such as turns, reversing, or shifting gears.
- **Gross motor abilities:** the strength and range of motion and coordination of upper and lower limbs.
  - **Driving example:** Driving requires the continual use of upper and lower extremities to maintain vehicular control. If gross motor abilities were impaired, the driver may experience difficulties executing movements with as much force or control as usual, which could affect lane and/or speed maintenance through loss of control over steering, braking, and/or accelerating.

DID Rx CHECKER

General communication tips for healthcare practitioners

Now that you have determined the need to have a conversation with your patient regarding the impairing effects of their prescribed medication on driving, here are a few tips to facilitate the conversation.

- **Use terms that are familiar to the patient.** Remember to always speak with a patient using lay-terms that can be easily understood by all. For example, when explaining how driving may be impaired by a certain medication, it is important to give concrete examples of how driving is affected (instead of stating that the medication reduces reaction time, explain this effect using a real-world example such as having slower responses to stopping at an intersection).
- **Pay attention to non-verbal communication.** Sometimes there are non-verbal cues that will provide further insight into how the patient is feeling. These non-verbal cues, or body language, can include facial expressions, body movement and gestures, eye contact, posture, or tone of voice. You can also ensure that your body language is positive and receptive; this will make the patient more at ease. For example, when recommending that the patient cease driving for a certain period of time due to the prescribed medication, ensure that you make eye contact with the patient and keep an upright posture to demonstrate the importance of your recommendation.
- **Have a balanced conversation.** Effective communication should be a two-way, dynamic interaction that is less focused on talking and more focused on listening to what the patient is saying. For example, when conducting a conversation with the patient, ensure that you allow the patient to speak his/her mind and avoid interrupting or speaking over the patient.
- **Practice engaged listening.** Instead of simply hearing what the patient is saying, really listen to what they are trying to convey by taking the information in and relaying it back to them to ensure that you understand fully. For example, when a patient has shared a thought or concern, paraphrase what they have shared in order to verify that you understand it fully.
- **Practice empathy.** Empathy is crucial to a conversation, and showing that you can understand your patient's feelings by putting them into words will establish a strong rapport with your patient. For example, if a patient begins to show extreme concern or worry about the recommendations that you have made, ensure that you are empathetic to their concerns and can understand how they might feel.
- **Engage a family member.** Involving a family member will help to produce better long-term outcomes for the patient. This can include better physical and emotional health,[1] as well as greater adherence and maintenance of treatment plans.[2]

[1] Stewart, M.A., et al., (2000). The Impact of Patient-Centered Care on Outcomes. The Journal of family practice. 49. 796-804.
[2] Haynes, R. B., et al., (2002). Helping patients follow prescribed treatment: clinical applications. *Jama*, 288(22), 2880-2883.

DiDRx CHECKER

Potential driver impairing (PDI) medications:

Advice for an informed conversation with patients

Health care practitioners play a key role in preparing their patients to make the responsible decision to find alternate means of transportation when taking potential driver impairing (PDI) medications. This information can help guide the conversation, so that you can convey to your patient why they should not drive or be cautious when operating a motor vehicle. It provides four consecutive building blocks to inform the conversation with patients as well as concrete examples to illustrate risks, consequences and alternative solutions.

1. **Acknowledge their concern.** Advising your patient that their driving may be impacted by the medication and result in them having to make changes to manage their driving and/or cease to drive while on the medication may be devastating to the patient, especially because personal vehicles serve as the primary form of transportation for most individuals. Your patient may express concern at this recommendation, and therefore it is essential to acknowledge their feelings and reassure them that you have their best interests in mind. Although you may be concerned about damaging the relationship and trust that has already been established with your patient, remind them that this recommendation is just like any other health advice or course of treatment that you have given them in the past. Because your patient may not only be putting themselves at risk, but may also endanger others on the road, a higher level of concern is raised with these circumstances.

2. **Explain how the ability to operate a vehicle safely can be affected.** You will need to provide your patient with a solid understanding of how driving may be affected when taking a PDI medication, by using concrete examples. Some of the ways that prescription drugs can impair driving are lane maintenance, speed maintenance, hazard perception, reaction time, divided attention, and information processing.

   - *Impaired lane maintenance* can be described as deviating unintentionally from a lane (e.g., swerving or drifting off to the side of the road).
   - *Impaired speed maintenance* is described as the inability to keep a safe and constant speed relative to the roadway (e.g., driving too fast or too slow).
   - *Impaired hazard perception* affects your ability to recognize an object in the roadway as a potential hazard (e.g., child running out onto the road).

DID Rx CHECKER

- *Impaired reaction time* increases the time that it takes to react to a potential hazard (e.g., slower reaction to breaking and avoiding the child that ran onto the road).
- *Impaired divided attention* reduces the driver's ability to perform multiple tasks (e.g., hold a conversation with a passenger and pay attention to the road).
- *Impaired information* processing reduces the speed of processing for visual and cognitive information (e.g., identifying traffic or road signs).

3. Describe the risk and potential consequences.
Now that the patient is aware that their driving skills can be impaired while taking the prescribed medication, explain that they may have a substantially increased crash risk when taking a PDI medication. Because certain driving skills may be impaired by the medication, their risk of crashing can be much greater than an average driver who is unimpaired. Describe the potential consequences by illustrating that they could be seriously injured or killed in a motor vehicle crash, especially if they are of advanced age, since older drivers are less likely to survive a crash. Finally, ask the patient to reflect on how they might feel if they ended up hurting or killing others as a result of their impaired driving.

4. Propose alternative means of transportation.
It is important to reassure the patient that their decision to stop driving while taking the prescribed medication does not mean that they will be stuck without means of transportation. Make sure to convey to the patient that there are many alternative options available to them, including family, friends, religious communities, public transit (in St. Louis: MetroBus, MetroLink, Metro Call-A-Ride), and community clubs (Rotary Club, Lions Club, Knights of Columbus) for those living in areas not serviced by transit systems. There are also more personalized transportation options such as taxis, Uber or Lyft.

If the patient chooses to drive against what you have advised, then it is important to provide patients with ways to manage their driving to minimize risk. This includes advising patients to avoid driving during high traffic times, during the evening and nighttime, as well as to avoid driving on freeways or roads where speeds are upwards of 40 mph. Other ways to mitigate risks are to shorten trips, avoid inclement weather, and to wait until the effects of the medications are gone.

DID Rx CHECKER

Opioids and driving

Your physician has prescribed an opioid. Opioids are classified as narcotic analgesics, a class of drug that is taken to relieve and manage pain. The purpose of the following handout is to advise patients about the effects of opioid medication on driving.

Opioids have a significant effect on the body. Opioids work by reducing the number of pain messages sent to the brain. Adverse events may include:

- sedation and drowsiness
- dizziness
- confusion
- euphoria
- abdominal upset
- narrowing of the pupils
- reduced breathing rate[1]

When an opioid is being taken for the first time or a previously stable dose is being increased, opioids may impair driving and increase crash risk. The effects on driving can include:

- slower reaction time (e.g., slower reaction to potential hazards)
- difficulty concentrating
- reduced alertness
- difficulty driving at night[2]

If the current opioid dosage has been taken daily for a period of time, and is part of a long-term treatment plan, driving may still be impaired if you have:

- been prescribed other medications with sedating effects
- consumed alcohol or other recreational substances
- high levels of pain
- persistent side effects from the opioid (e.g., extreme sedation or drowsiness)
- a sleep disorder
- significant depression or anxiety related problems[3]

Opioids may increase the risk of crashing. Physicians recommend that first-time opioid users and those being prescribed an increased dosage of an opioid do not drive until a stable dose is established and the sedating side effects of the medication have decreased.[2]

[1] Anderson, L. (2014) https://www.drugs.com/article/benzodiazepines.html
[2] Dubois, S., Bédard, M., & Weaver, B. (2010). The association between opioid analgesics and unsafe driving actions preceding fatal crashes. *Accident Analysis & Prevention*, 42(1), 30-37.
[3] Stewart-Patterson, C. (2014). Can my patient safely drive on long-term daily opioid medication? Retrieved from: www.thischangedmypractice.com/drive-on-opioid-medication/

DiDRx CHECKER

Benzodiazepines and driving

Your physician has prescribed a benzodiazepine (also referred to as benzo). Benzos are classified as a central nervous system (CNS) depressant, a class of drugs that slow down the activity of the brain. These are medications typically given for anxiety and/or muscle spasm. The following handout provides information on the risks of operating a motor vehicle while taking benzos and its adverse effects on driving.

Benzos have significant effects on the body. By sedating the body and brain functions, benzos can cause:

- drowsiness or lack of alertness
- impaired coordination
- slow reaction time
- impaired judgement

The effects of benzos may start within an hour of ingesting the drug, and can last anywhere from 2½ to several hours, depending on whether they are short, intermediate or long acting benzos (in some instances with long acting benzos, the effect can last up to 160 hours).[1]

Benzos can impair driving ability. The effects on driving often include:

- increased lane weaving (e.g., swerving)
- slower reaction time (e.g., slower reaction to potential hazards)
- reduced ability to perform multiple tasks (e.g., speaking with a passenger and paying attention to the road)
- falling asleep behind the wheel

Benzos can increase the risk of crashing. The greatest increase in risk occurs when:

- benzos are being used for the first time
- when there is a sleep disorder
- a previously stable dose is being increased
- when taken with alcohol or other sedating drugs

Also, long acting benzos present the greatest crash risk, since there is not enough time between doses for the effects to wear off, creating an accumulation of the impairing effects listed above.[2]

Benzos are the most detected CNS depressant in fatal or serious injury crashes. Aside from alcohol, benzos are the most frequently detected CNS depressant in fatal or serious injury crashes. The use of benzodiazepines in combination with another sedating substance (e.g., alcohol) is hazardous and can amplify the impairing effects of benzos alone.[3]

[1] Anderson, L. (2014) https://www.drugs.com/article/benzodiazepines.html
[2] OECD (2010) Drugs and Driving Detection and Deterrence: Detection and Deterrence. OECD Publishing.
[3] Verstraete, A. G., et al. (2014). *Drug use, impaired driving and traffic accidents.* Publications Office of the European Union.

DiDRx CHECKER

Transportation alternatives

Available to all public

- OATS Transit
  Phone: (314) 888-6720
- Metro Transit St. Louis
  (Metro Bus, Metro Link, Metro Call-A-Ride)
- Mobility for U
  Phone: (314) 873-6814
  Service area: St. Louis area—including entire Metro St. Louis Area and neighboring Illinois counties.
- Express Medical Transporters
  Phone: (314) 781-6400
  Service area: Greater St. Louis

Available to seniors

- Aging Ahead
  Phone: (636) 207-0847
  Toll Free: 1-(800)-AGE-6060
  Service area: Missouri
- County Older Resident Programs
  Phone: (314) 615-4516
- City Seniors Inc.
  Phone: (314) 352-0141
  Service area: St. Louis city limits
- Comfort Keepers St. Louis
  Phone: (314) 576-7000
  Service area: Metro St. Louis
- Continuum Care
  Phone: (314) 863-9912
  Service area: St. Louis and St. Charles
- Help at Home St. Louis
  Phone: (314) 569-5036
  Service area: St. Louis
- Home Instead St. Louis
  Phone: (314) 862-4663
  Service area: St. Louis
- Homewatch Caregivers
  Phone: (314) 963-1100
  Service area: St. Louis County
- INTGateway
  Phone: (636) 329-0888
  Service area: 15 mile radius from St. Charles
- Maxim Healthcare St. Louis
  Phone: (314) 569-3935
  Service area: St. Louis
- St. Louis Area Agency on Aging
  Phone: (314) 612-5918
  Service area: St. Louis city limits
- ZipCare Transportation
  Phone: (314)-292-7302
  Service area: St. Louis and surrounding communities

Traffic Injury Research Foundation, USA Inc.

Corporate Office
20 F Street, 7th Floor
Washington, DC 20001

www.tirf.us
Email: tirf@tirf.us