

The Canadian Safe Driving Study – phase I pilot: Examining potential logistical barriers to the full cohort study

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This work was funded by the Canadian Institutes of Health Research (grant 54024).

Running title: Logistical barriers to cohort study

## Abstract

Multiple organizations and task forces have called for a reliable and valid method to identify older drivers who are medically unfit to drive. The development of a clinical decision rule for this type of screening requires data from a longitudinal prospective cohort of older drivers. The aim of this article is to identify and examine potential barriers to such studies based on an analysis of the Canadian Safe Driving Study – phase I pilot (Candrive I). A convenience sample of 100 active older drivers aged 70 years or more was recruited through the aid of a seniors' organization, 94 of whom completed the full study (retention rate 94%). Data were collected over the course of 1 year on various driving behaviours, as well as on cognitive, physical and mental functioning. Driving patterns were recorded using driving diaries, logs and electronic devices. Driving records from the Ministry of Transportation of Ontario (MTO) were obtained for the 3-year period preceding the study initiation and up to 1 year following study completion. An increased burden of illness was observed as the number of medical diagnoses and medication use increased over the study period. Study participants were involved in a total of five motor vehicle collisions identified through MTO records, which was comparable to the Ontario annual collision rate of 4.1% for drivers aged 75 years or older. The results support the feasibility of completing a large prospective cohort study of older drivers and indicate that successful recruitment and retention is possible with endorsement from recognized organizations representing older adults.

Keywords: Older drivers; Crash rates; Driving patterns; Pilot study

## 1.0 Introduction

Persons over the age of 65 years represent the fastest-growing segment of the Canadian population (Bell et al., 2011; Bongaarts, 2009; Smith and Tayman, 2003); likewise, the absolute number and proportion of older persons holding a driver's licence is increasing rapidly (Dobbs, 2008; Lyman et al., 2002). Chronic impairments associated with aging can lead to impaired driving ability (Man-Son-Hing et al., 2007; Marshall, 2008). This, in turn, can threaten the safety of older drivers and put others at risk. In many jurisdictions, clinicians are legally obligated to identify persons who are medically unfit to drive (Eby and Molnar, 2010; Fox et al., 1992; Miller and Morley, 1993; Nouri, 1988; Parnes and Sindwani, 1997), but there is no validated tool for doing so. Consequently, the objective determination of an older adult's medical fitness to drive is an increasingly important issue in health care.

Determining driving risk is complex, as driving is an overlearned skill involving the integration of multiple factors including physical, cognitive and perceptual faculties that are influenced by driving experiences, attitudes and behaviour (Anstey et al., 2005; Galski et al., 1992; George and Smiley, 1999; Simms, 1985). For instance, younger inexperienced drivers (15–24 years of age) typically exhibit unsafe driving behaviours such as speeding and driving while under the influence of alcohol in addition to their lack of experience behind the wheel (National Highway Traffic Safety Administration). Older drivers, on the other hand, are experienced and less likely to engage in unsafe driving behaviours (National Highway Traffic Safety Administration). Surprisingly, older drivers have one of the highest rates of collision per mile driven (Braver and Trempel, 2004;

Daigneault et al., 2002b; Di Stefano and Macdonald, 2003). One explanation for increased collision risk in this age group is a characterized low mileage bias (Gallo et al., 1999; Kostyniuk et al., 2000). Using distance as a model for determining driving risk, anyone who travels shorter distances would present a greater risk of crash, artificially inflating collision rates (Langford et al., 2006). Accordingly, more accurate models of assessing driving risk are required to determine what factors influence older persons' collision risk (Jang et al., 2007; Voelker, 1999). Conducting a naturalistic study of older drivers could aid in the development of more accurate predictors of crash risk. However, this type of research can present many challenges, such as recruiting a large representative sample of older drivers, minimizing attrition over a longer term, conducting appropriate medical and cognitive assessments and collecting valid naturalistic driving data.

In this paper we describe our experience in conducting a prospective feasibility pilot study, the Canadian Safe Driving Study – phase I pilot (Candrive I). Outcomes from this pilot study have provided valuable information for planning a larger longitudinal study of older drivers.

## **2.0 Potential barriers in cohort research of older drivers**

### *2.1 Barriers related to study design*

A study attempting to identify predictors of crash risk among older drivers who may be unsafe to drive should be prospective and longitudinal, so as to permit

examination of driving behaviour based on medical and functional fitness over time. Previous work relating to medical fitness and driving in older adults has been largely retrospective or cross-sectional (Marottoli and Richardson, 1998; Sims et al., 1998; Songer et al, 1993; Stutts et al., 1998; Vernon et al., 2002), collecting health and driving data through surveys (Ivers et al., 1999), questionnaires (Daigneault et al. 2002a) and driving institution records, such as driver's licence applications (Vernon et al., 2002), state/provincial citations (Ball et al., 1993; Stutts et al., 1998) and on-road tests (Vernon et al., 2002; McKnight and McKnight, 1999). The challenge of using retrospective and cross-sectional designs is that they are limited by the information collected or conveniently available, and many factors cannot be taken into account or adjusted for when trying to determine valid predictors of crash risk. Retrospective state/provincial reports of crashes are also limited because other serious driving events such as poor driving and near misses as well as less serious driving incidents such as unreported collisions are not recorded. These limitations could be best addressed through prospective follow-up with participants, in which assessments of their health, driving exposure and driving outcomes could occur.

## *2.2 Barriers related to sampling*

### *2.2.1 Sample size*

Recruiting a sufficient number of participants is another principal barrier to longitudinal research involving older drivers. In order to ensure external validity and

adequate power, the sample size should exceed at least 200 participants (<200 = poor, 200–1000 = good, >1000 = excellent) (Anstey et al., 2005). Of the few prospective studies that have explored predictors of crash risk, several had relatively small samples (e.g.,  $n < 300$ ) (Owsley et al., 1998, 2001; Staplin et al., 2003). A number of factors can affect recruitment, including lack of trust on the part of potential participants since driving is a privilege that could potentially be threatened with heightened observation, the arduousness of the study procedures and participants' unwillingness to travel to the study centre. Staplin et al. (2003) attained a sample of 1,876 licensed drivers aged 55 years or older by recruiting and testing their participants at the offices of the Maryland Motor Vehicle Administration. Participants' potential hesitations about taking part in the study may have been alleviated by the fact that recruitment and testing were conducted at credible state offices. While this study provided valuable insight into the construction of a prospective cohort of older drivers, it had important limitations: drivers were screened only at baseline, participant-reported driving exposure data were found to be highly unreliable, and the researchers were unable to determine at-fault crash status. Collectively, these limitations suggest that a more inclusive prospective cohort study of older drivers must still be conducted in order to accurately identify older drivers at risk.

### 2.2.2 Attrition and retention rate

Even if a sufficient sample is recruited, its validity and representativeness can be compromised if the rate of attrition is large over the long term. Participants who drop out of the study may have different characteristics than those who remain in the study,

particularly when participant health is a primary reason for withdrawal (Mody et al., 2008). Conclusions drawn from studies with high attrition rates may then be questionable (Robinson et al., 2007). Maintaining participants' dedication to the study is a vital component in achieving an appropriate retention rate. Aptly designed protocols can minimize exclusion and ensure the representativeness of a sample by avoiding tasks that are daunting or too time-consuming (Mody et al., 2008). Regular reevaluation of data collection procedures based on participants' feedback as well as repeated contact with subjects may aid in ensuring their satisfaction with participation (Robinson et al., 2007). Other ways of reducing the participants' burden and increasing contentment may include reimbursing expenses and distributing small gifts (Desmond et al., 1995; Hellard et al., 2001).

### 2.2.3 Representativeness of the sample

Dissemination to the general population is of particular importance for studies that aim to develop clinical decision tools for health care professionals and consumers. A number of previous studies that attempted to identify older drivers at risk used secondary analyses of data from large cohort studies. The former had primary objectives that were unrelated to the investigation of driving, including the effects of aging (Ahlgren et al., 2003; Margolis et al., 2002; Rosenwasser, 1995), or used a convenience sampling technique rather than random sampling (Ahlgren et al., 2003; De Raedt and Ponjaert-Kristoffersen, 2000; McKnight and McKnight, 1999). Such studies are subject to self-selection bias in that participants who are recruited for a study unrelated to driving but

who then voluntarily agree to participate in a driving substudy may have different characteristics than the general population, which could affect the external validity of the obtained results. For example, volunteers may represent drivers who are healthier than drivers in the general population. However, if study participants were to be monitored longitudinally, the initial differences between study drivers and drivers in the general population might disappear with time, as the health status of the older driver sample population declined.

### *2.3 Barriers related to data collection*

#### 2.3.1 Appropriateness of assessments

The primary limiting factor in research efforts examining older drivers thus far is that no study has attempted to assess multiple concurrent factors associated with driving. Previous efforts to develop research around fitness to drive have focused on medical history, given that the presence of multiple chronic conditions is associated with increased collision rates and reduced ability to drive (Ahlgren et al., 2003; Ball et al., 1998; Charlton et al., 2004; Dischinger et al., 2000; Koepsell et al., 1994; Marshall and Man-Son-Hing, 2011; Vernon et al., 2002). However, inherent variability within and between conditions (e.g., level of severity, degree of instability) can result in endless permutations of potential effects on driving ability. Therefore, the use of multiple diagnoses exclusively as a predictive tool for assessing medical fitness to drive is fundamentally flawed. Instead, a comprehensive battery of reliable, valid assessments of health and of physical and cognitive functioning should be administered in a timely manner and on multiple occasions to fully capture changes in participants' health-related functioning and link those changes chronologically to driving risk.

#### 2.3.2 Length and location of assessments

Another challenge for researchers is to choose the best assessment tools currently available, while minimizing the administration process to reduce burden on the

participants. Collecting too many measures of potential relevance can result in an assessment battery of exceeding length, risking higher participant dissatisfaction and dropout rates and the erroneous identification of risk factors. Thus, it should be feasible to administer all of the tests in one session within a reasonable amount of time, as determined by participants' levels of fatigue and willingness to continue.

Researchers also have to choose whether to conduct the assessments in participants' homes or in a clinic. In doing so, it is important to determine whether assessing participants in their own homes reduces the rate of attrition. If location is not important to participants, a research team can save considerable resources by assessing participants in the clinic, thereby avoiding personnel travelling costs.

### 2.3.3 Method of collecting driving data

Attempts to record and measure driving exposure accurately in older populations have been made in previous research (e.g., telephone [DeCarlo et al., 2003; Owsley et al., 1999], paper [Kiernan et al., 1999] and computer [Wolf et al., 2000] surveys), although the accuracy and validity of these methods have yet to be confirmed. Driving diaries are less preferable than electronic devices as they are more onerous on the participant (Marshall et al., 2007) and may lead to high dropout rates if the study duration is long. The information recorded in driving diaries is also likely to be incomplete. Older drivers' self-reported driving distances are inaccurate compared to data obtained with electronic devices with global positioning system capability (Blanchard et al., 2010; Huebner et al., 2006), since driving frequency, habits and behaviours are often not recorded or are done

so unreliably (Marshall et al., 2007). Driving data could be enhanced if the data collected using diaries and/or electronic devices were supplemented by official records of participants' traffic violations and collisions.

#### *2.4 Summary*

To summarize, the principal challenges in cohort research of older drivers include various issues related to study design, participant sampling and data collection. Through an analysis of Candrive I we investigate these barriers, followed by a description of how these challenges unfolded over the course of the study. Specifically, the primary objectives of the Candrive I study were to: 1) determine participant recruitment yield by method of recruitment and identify reasons for nonparticipation, with the intent of refining methods to maximize recruitment, 2) determine participant dropout rate and explore the reasons for dropping out, in order to optimize retention and 3) determine whether it is possible to obtain a comprehensive collection of driving data (e.g., self-reported data and ministry of transportation records) and link it with study participants' clinical data.

The secondary objectives of Candrive I were to: 1) determine the compliance and satisfaction of participants regarding the study protocol and the use of measures such as driving diaries and monthly telephone follow-up interviews, 2) explore the best method of determining driving exposure (characteristics of driving patterns including mileage, driving environment, time of day and road conditions), 3) compare the methods of identifying crashes and traffic violations (e.g. driving diary, telephone interview, ministry

of transportation driving record) and 4) determine the acceptability and feasibility of specific assessment measures in a battery of tests to measure changes in participants' health.

### **3.0 Methods**

#### *3.1 Study design*

The initial data were collected by two research nurses at an in-home baseline assessment. Subsequent in-home assessments took place 6 months and 1 year later. Participants also authorized the retrieval of their driving data from the Ministry of Transportation of Ontario (MTO) for the 3 years before their baseline assessment and up to 1 year after their last follow-up interview. Monthly telephone calls were made by the two nurses to collect self-reported driving incidents as well as to encourage compliance with the study. Feedback was collected using a structured questionnaire. Participants who had ceased driving during the study were also asked to complete a structured interview to explore their reasons for driving cessation. After the study was completed the participants were surveyed anonymously using an exit questionnaire about their perceptions of the study protocol and factors that would affect future participation in similar types of research. A feedback session was also held following study completion. Data from the exit questionnaire and feedback session were used to determine participant satisfaction.

#### *3.2 Sampling*

The study was conducted in the Eastern Ontario region (Ottawa and surrounding area) with residents residing primarily in urban locations. To be eligible, participants had to meet the following criteria: 1) have a valid Ontario class G driver's licence and have been driving actively during the 3 years preceding the study, 2) own a vehicle or have regular (full-time) access to a vehicle that they could drive, 3) be an active driver (defined as a person who drives at least weekly during all seasons), 4) reside in the local Ottawa area for 10 months or more per year, 5) consent to release their driving record information from the MTO, 6) be aged 70 years or greater, 7) have a family physician and 8) be fluent in French or English. Participants who planned to stop or interrupt their driving or who planned to move out of the Ottawa region during the course of the study were excluded, as were those who had an absolute contraindication to driving identified on screening, including blindness, an uncontrolled seizure disorder or uncontrolled arrhythmia (Canadian Medical Association, 2000).

Participants were recruited through their membership with the Federal Superannuates National Association (FSNA), an organization representing the interests of retired federal government employees (including police, civil servants and military) with a national membership of approximately 120,000 and a local Ottawa membership of approximately 20,000. Study information was posted on the FSNA website, and letters were sent to randomly selected association members through the FSNA office requesting potential participants to contact the study coordinators. Two mail-outs were sent 4 weeks apart, each consisting of 500 letters. The names of the FSNA members contacted were never made available to the study investigators. People who expressed interest in

participating were screened for eligibility over the telephone. People who called to decline participation were asked to take part in a brief telephone interview to determine the reason for nonparticipation.

### *3.3 Data collection*

The primary goal in selecting the battery of tests was to assemble a set of reliable, valid assessment tools that could evaluate aspects of mental and physical health that may be associated with driving ability, along with indicators of driving behaviours. The assessment battery was seen as invaluable in identifying declines in driving capacity that may be associated with changes in health and functioning. Accordingly, instruments were selected to gather information on sensory, physical and cognitive function, as well as information about driving habits and behaviours, health status and psychological factors, all of which can affect or predict driving risk (Table 1). All measures used in this study were also chosen on the premise that they could be administered in a timely fashion within a front-line clinical setting.

#### *3.3.1 Driving data*

A daily driving log documenting the date, time, distance and location driven was to be filled out by participants each time the vehicle was used. At the monthly telephone calls the research nurses collected self-reported driving incidents, including near-misses, traffic violations and crashes. For some participants who volunteered and had vehicles of

the 1996 or more recent model years the CarChip electronic recording device (Davis Instruments Corp., Hayward, Calif.) was simultaneously used to track driving data passively (Marshall, Wilson et al., 2007). The CarChip is a commercially available electronic device that can be installed into the onboard diagnostic port of vehicles made after 1996. It records up to 75 hours of data on driving date, time, distance and speed, in addition to instances of hard or soft braking and acceleration. For participants who used the CarChip, driving exposure data were compiled for 3 months, and participants were asked to record when other people drove the vehicle in order to ensure that all electronic driving data corresponded with the study participant only.

The Candrive I study also assessed the feasibility of collaboration between the research centre and the MTO. A request was made to the MTO to obtain the driving records of participants for the year of the study and the 3 preceding years.

### *3.4 Statistical analysis*

All analyses were performed using SPSS version 20.0 (SPSS Inc., Chicago, Ill.). Relative frequency distributions were used to report qualitative variables, and quantitative variables were expressed as a mean and standard deviation (SD). Chronic conditions, medication history, driving behaviours and assessment measures at baseline and follow-up were compared using paired-sample *t*-tests, with  $p < 0.05$  reported as statistically significant. Binary logistic regression analysis was used to identify assessment measures with collision predictive qualities. Given that this was a pilot,

feasibility study, analyses were exploratory, and sample size was not believed to be sufficient to adequately address these questions.

## **4.0 Results**

### *4.1 Recruitment and retention*

We received responses from 87 people to the initial posting of the study advertisement on the FSNA website. Of the 87, 54 met the inclusion criteria and were enrolled in the study. The first mail-out produced 61 inquiries, with 41 participants enrolled, and the second produced 5 participants. Thus, a total of 100 participants were enrolled. The mean age was 78.6 (SD 4.8) years (range 70–93 years) (Table 2). The majority of the participants were men (68%), lived in urban areas (97%) and had only one vehicle (86%). Drivers never or rarely used taxis (86%) or public transportation (68%) or relied on family or friends to drive them (70%).

During the course of the study, six participants dropped out. Three participants dropped out by 3 months, one because of a stroke, one at his wife's request, and one owing to cognitive difficulties and subsequent reporting to his family physician. Two participants dropped out at 5 months, owing to death in one case and unstable atrial fibrillation in the other. The sixth participant dropped out at 7 months because of a stroke.

### *4.2 Health and functioning*

As would be expected with an older population, participants in this sample had a number of chronic medical conditions and problems at baseline, including arthritis (41.0%), hypertension (35.0%), hearing problems, (35.0%) pain (35.0%) and cataracts (26.0%) (Table 3). Seventy-two percent reported three or more chronic medical conditions at baseline; this proportion was significantly higher at 1 year (76.6%;  $p < 0.001$ ). The proportions with cataracts and glaucoma also increased significantly from baseline (26.0% vs. 39.4% and 7.0% vs. 12.8%, respectively;  $p < 0.05$ ). Antihypertensive (35.0%) and cardiac (18.0%) medications were the most commonly taken medications at baseline and 1 year; the proportions of participants taking these medications were significantly higher at 1 year (36.2% and 24.5%, respectively;  $p < 0.05$ ) (Table 3). Most participants reported taking over-the-counter medications (81.0% at baseline and 79.8% at 1 year). There was a trend toward an increase in the mean total number of medications taken over the study period (3.29 [SD 2.83] vs. 4.10 [SD 2.87];  $p = 0.062$ ).

For the most part, participants scored relatively highly on both the cognitive and physical assessments. The mean scores at baseline of 29.0 (SD 1.0) (out of 30) for the Mini-Mental Status Examination (MMSE) total and 96.0 (SD 3.8) (out of 100) for the modified Mini-Mental State Examination (3MS) total illustrate that overall the participants possessed good cognitive capabilities (Table 4). The mean activities of daily living total score of 14.9 (SD 0.4) (out of 15) at baseline shows that they were very independent. Overall, outcomes for cognitive and physical measures remained relatively stable over the study period; in particular, there were no significant changes in the mean MMSE or 3MS scores. However, the mean scores for the clock drawing test, backward digit span, Timed Up & Go test, American Medical Association screening questions and

traffic sign recognition test all improved ( $p < 0.05$ ). This result may be reflective of practice effect on these measures, which had been assessed or repeated at 6 months.

### *4.3 Driving exposure*

#### 4.3.1 Driving diaries and logs

Daily diaries proved to be too much of a burden for participants, and the frequency was reduced to a quarterly driving summary log (for a total of five times). At baseline, most of the participants reported driving at night (86.0%), on the highway (97.0%), in wet weather (99.0%) and during rush hour (87.0%). All participants regularly drove outside of their neighbourhoods, and/or in the winter and/or alone. As expected, high proportions reported driving with distractions, including listening to the radio (94.0%) or to music (58.0%) or talking with passengers (82.0%). Very few participants (6.0%) had spoken to their physician regarding their driving safety; however, more than one-fourth had spoken to a family member about this issue. Fewer than half (37.0%) had attended a driver refresher course. Driving patterns from baseline to 1 year remained relatively unchanged.

#### 4.3.2 Ministry of Transportation records

Collaboration with the MTO was successful. A collaboration agreement was obtained and signed detailing the disclosure and confidentiality of the transportation data

with respect to the requirements of the study. Transportation records were then obtained from the MTO. Records provided participants' collision involvement and all traffic violations committed during the requested period. In particular, electronic driving record data and hard copy police collision reports were received within 2 weeks of a formal request from the MTO, including collision records and driving-related offences for all participants. Baseline driving data (Table 5) for the 3 years preceding the study were obtained for 99 participants (1 participant withdrew from the study before the information was requested from the MTO). Following completion of the study, updated information for the driving record was obtained for 97 participants (2 other participants who withdrew from the study also withdrew permission to access their driving record).

Nine motor vehicle collisions (both major and minor) were documented during the study period. The MTO data revealed five collisions, all by different drivers, and six convictions over the study period. Two of the drivers with collisions had had a previous collision in the 3 years before the study. Self-report data identified eight of the collisions, four of which matched the MTO collision data. One collision identified by the MTO data was not self-reported. In the self-report interview, five participants indicated police attendance at the collision; however, only four incidents were recorded by the MTO. Binary logistic regression analysis did not reveal any specific factor predictive of collisions identified in MTO data or when all collisions (self-reported included) were considered.

## **5.0 Discussion**

### *5.1 Study design*

Successful completion of this prospective longitudinal pilot study affirms the possibility of empirically linking crash risk to physical, cognitive and driving behavioural factors over a longer term. This, in turn, demonstrates that a more definitive multicentre prospective cohort study of older drivers is achievable. Specifically, results from the Candrive I study demonstrate the feasibility of analysing health, functioning and driving exposure data over an extended period and linking the data to administrative data from a provincial driver registry. Technically, therefore, it should be possible to use this approach to derive a clinical decision rule to identify older drivers who may be medically at risk to drive and require further assessment or intervention.

### 5.1.1 Sampling

*Sample size.* A previous effort by our group to directly recruit older drivers in the emergency department who had been involved in motor vehicle collisions had failed, as participants feared that their recent involvement in a collision along with the study results could result in their licence being revoked (Molnar et al., 2007). In the Candrive I study, recruitment occurred through support from a known institution (FSNA), which played a positive role in the recruitment. In particular, posting advertisements on the FSNA website and in their newsletter turned out to be the most efficient method of recruitment, with more than half of the participants enrolling through this approach. Mailing out letters was less valuable, especially following the second wave of letters to the same population. Accordingly, with future studies investigators should consider devoting resources to recruitment strategies other than mailing out letters, such as website and newsletter postings supported and endorsed by a credible organization.

In summary, our successful enrolment of 100 drivers aged 70 years or older emphasizes the importance of encouraging stakeholder and community involvement, as it appears to play a significant role in maximizing participant enrolment, especially for intensive prospective research. In fact, poststudy interviews revealed that only 8% of participants would have enrolled in the study if contacted via an unsolicited and unexpected phone call. Our enrolment rate from a single source also indicates that an adequate sample size could be achieved for a multicentre prospective cohort study if several reliable supporting organizations were identified and utilized.

*Attrition and retention rate.* A notable success of this pilot study was the high retention rate: 94% of the participants completed the final assessment. There were only six dropouts over the course of a year's follow-up, three of which were due to unforeseeable health-related issues. This finding is corroborated by high levels of compliance and satisfaction associated with participation, as reported by participants at the end of the study. Specifically, participants' feedback revealed that high satisfaction was attributed to the positive interactions between the participants and the research nurses, highlighting the critical importance of selecting engaging, highly motivated research personnel. Participants were also appreciative of the convenience of the home assessments, as many indicated they did not find the assessments too time consuming and they would be willing to participate again. Nevertheless, they also indicated that driving to an assessment centre would not deter them from participating. These study design matters are noteworthy points to consider for future research, if it is desired to keep participants engaged for the entire study duration.

*Representativeness of the sample.* A clear but necessary bias exists in recruiting through an organization such as the FSNA, since the characteristics of this group may not be representative of all older drivers in a general population. For instance, it may be expected that FSNA members are more affluent, more educated and healthier given that they are retired federal government employees receiving a pension. However, in a randomized prospective cohort study of older persons in Australia, Anstey et al. (2005) found that a sample of older drivers from the general population are likewise more likely to be male, married, more educated and healthier than older nondrivers. Thus there are

reasons to believe that our participant group may be a somewhat representative sample of the older driver population.

Another common concern for studies that use a convenience sampling procedure is that volunteers who self-select for a driving study are healthier than drivers in the general population. Nevertheless, for studies of a longitudinal nature, this concern may be alleviated by the fact that participants' state of health is likely to change over time, particularly for older persons. Indeed, the Canadian Study of Health and Aging demonstrated that 15% of participants who initially had no cognitive impairments had a diagnosis of dementia by the 5-year follow-up, and the annual incidence rates of dementia and mild cognitive impairment for those over age 65 were 2% and 4%, respectively (Tuokko et al., 2003). Likewise, in the Candrive I study the proportion of participants with several chronic medical conditions increased significantly over 1 year ( $p < 0.001$ ). There was also a trend toward an increase in the mean number of medications taken ( $p = 0.062$ ). Consequently, even if participants are healthier than the general population at the time of recruitment, these health differences likely diminish as study duration increases. Changes like these are likely to be even more pronounced in studies of longer duration.

## *5.2 Data collection*

### *5.2.1 Appropriateness of assessments*

Given that there is a demonstrated association between the presence of multiple conditions and increased collision rates and reduced ability to drive (Ahlgren et al., 2003; Ball et al., 1998; Charlton et al., 2004; Dischinger et al., 2000; Koepsell et al., 1994; Marshall and Man-Son-Hing, 2011; Vernon et al., 2002), increasing prevalence rates of chronic conditions could affect driving ability and should be documented accordingly.

Conducting three in-home assessments and monthly follow-up calls for all participants was feasible with two full-time research nurses. The average length (3 hours) of the assessments and their location within their home setting was also well tolerated by participants. In particular, most participants appreciated the convenience of being assessed in their own homes, although their feedback indicated that this was not a decisive factor for their participation (i.e., travelling to a clinic for the assessments would be acceptable). It is anticipated that home visits might become more important to retention as participants' health and driving confidence deteriorate over time. Since the measures assessed were aimed at being completed in a clinic setting, this was transferrable to the home setting, but would result in some variability. For instance, measures such as the Timed Up & Go test (Podsiadlo and Richardson, 1991) and Functional Acuity Contrast Test (Ginsburg, 1984) required some specific accommodations in the home setting.

### 5.2.2 Method of collecting driving data

The results from the Candrive I study suggest that daily driving logs may not be practical for data collection, since participants' compliance with the logs became

problematic. Their feedback suggested that the daily driving logs were too time-consuming and easy to forget. Future driving studies should use daily driving diaries with caution, and only over short periods. In fact, the duration for which information was collected in this manner was markedly shortened within the first month of the pilot study due to participant feedback.

On the other hand, the validity of driving data is likely to be improved with the use of electronic devices rather than daily driving diaries. Indeed, a substudy within our pilot study showed that the CarChip was the preferred method for collecting driving pattern information (Marshall et al., 2007). Electronic data logging devices such as the CarChip are reliable and objectively measure driving exposure. Furthermore, adding global positioning system technology may aid in providing additional information about driving patterns unique to older drivers. Future research should investigate these methods on a larger scale in order to better capture a detailed and accurate representation of naturalistic driving in older driving populations.

The Candrive I study also confirmed that collaboration with the MTO is feasible and efficient. In fact, the rate of reported collisions in our study, 5%, was consistent with the collision rate of 4.1% for Ontario drivers aged 75 years or older (Ontario Ministry of Transportation, 2012). This supports the supposition that recruitment indirectly through a seniors' organization does not lower the chances of accruing outcomes. With the consent of all participants at study enrolment to release driving record information from the MTO, there was a smooth and timely receipt of driving record information over the course of the study. For every collision, the data received from the MTO required more labour-intensive hand extraction versus receiving a directly extractible format;

nevertheless, this method of data collection would still be feasible even for much larger studies, since collisions and traffic violations are relatively rare events.

The discrepancies between self-reported and MTO collision data further support the need for formal administrative records, since there is potential to miss collisions even with periodic interviews. Using collision records documented by police also allows the standard for collision severity and at-fault status to be met consistently. For instance, minor, less significant collisions are attained through self-report, whereas a formal police report serves as an indicator of a significant collision where there was significant vehicle damage or injury. In some jurisdictions police reports may also assign at-fault status. On the other hand, in one instance a participant did not admit to having had a collision, even though the MTO record indicated that he/she did, further indicating the need to capture all collisions from both administrative databases and self-report. Accordingly, both methods of collecting collision and conviction data should be implemented, as either method by itself is likely to underestimate the number of collisions and convictions experienced by participants.

### 5.3 *Study limitations*

As a feasibility pilot study, the Candrive I study has many limitations, particularly the inability to determine at-fault status. Although the primary purpose of this study was to determine the feasibility of recruitment, comprehensive assessment, follow-up and record linkage, the need to identify responsibility for collision will be important for future studies as an outcome of interest. Based on the information available to us through this feasibility study, it appears possible to assign expert collision evaluators to independently assign at-fault status based on the review of police accident reports (Marshall et al., 2002; Owsley et al., 2001) that can be obtained from licensing authority (e.g., MTO) records. While this feasibility study highlights many aspects of a prospective study that can be accounted for, such as the ability to recruit participants and retain them as anticipated, a continuing limitation would be the need to use a convenience versus random sample, since participant feedback among even this volunteer group suggests an unwillingness to participate without the advance endorsement of a recognized organization. We were able to monitor naturalistic driving patterns with written record diaries, but it is evident that an electronic means of monitoring will be necessary in future studies. A significant limitation is the inability of technological monitoring to identify the driver, particularly in instances in which vehicles are shared. These limitations notwithstanding, many of the barriers to a prospective naturalistic driving study appear surmountable.

## **6.0 Conclusions**

In summary, the Candrive I pilot study met its primary and secondary objectives. Therefore, many of the relevant logistical and practical barriers to studying a large sample of older drivers longitudinally have been shown to be addressable. While there will be further challenges and potential barriers in expanding a study beyond a local context, this pilot study confirms the feasibility of a successful, naturalistic prospective of older drivers with the aim of deriving a validated decision rule to identify medically at risk older drivers.

**Acknowledgements:** We thank research nurses Jennifer Biggs and Anita Jessup for their commitment and contributions to launching and modifying the pilot study, and Gloria Baker for editing the manuscript. We acknowledge with thanks Candrive I's key partner, the Federal Superannuates National Association. We also thank the older driver participants, without whose valuable contribution this research would not have been possible.

This work was funded by the Canadian Institutes of Health Research (grant 54024).

**Table 1**

Measures administered at baseline, 6 months and 1 year.

General health
Cumulative Illness Rating Scale (modified) (Hudon et al., 2007)
Medication list
American Medical Association screening questions (American Medical Association, 2010) <sup>a</sup>
Instrumental Activities of Daily Living (Doble and Fisher 1998)
Health and physical measures
Hearing (Macphee et al., 1988)
Joint range of motion (American Medical Association, 2010)
Manual test of motor strength (American Medical Association, 2010)
Testing for balance (tandem gait)
Coordination
Timed Up & Go test (Podsiadlo and Richardson, 1991)
Sleep Impairment Index (Morin, 1993)
Vision/visuospatial measures
Visual fields (Myers et al., 2008)
Peripheral vision to confrontation (Myers et al., 2008)
Functional Acuity Contrast Test instrument (Ginsburg, 1984)
Mood
15-item Geriatric Depression Scale (Yesavage et al., 1982)
Individual factors/environment
Demographic factors
Historical driving factors
Vehicle factors
Current driving factors
Winter driving factors
Online Accident Reporting System
Driver Behaviour Questionnaire (Obriot-Claudet and Gabaude, 2004)
Cognition
Mini-Mental Status Examination (Davey and Jamieson, 2004; Teng and Chui, 1987)
Modified Mini-Mental State Examination (Teng and Chui, 1987)
Test for perseveration (ramparts)
Clock drawing (Freund et al., 2005)
Trail Making Test A and B (Moses, 2004)
Ottawa Driving Toolkit (Byszewski et al., 2003)
Traffic sign recognition test <sup>a</sup>
Digit span (Weschler, 1981)
Psychosocial measures
Driving habits and intentions (Lindstrom-Forneri et al., 2007)

<sup>a</sup> Not administered at baseline.

**Table 2**

Demographic characteristics and transportation status of the 100 study participants at baseline.

Variable	% of participants
Gender	
Male	68.0
Female	32.0
Marital status	
Married	60.0
Widowed	33.0
Other	7.0
Spouse licensed	
Yes	46.0
No	15.0
NA	39.0
Location of residence	
Urban	97.0
Rural	3.0
Retired	97.0
Highest-level licence class G	99.0
Owens more than 1 car	19.0
Other person(s) drives participant's vehicle	44.0
Automatic transmission	93.0
Uses taxis never/rarely	86.0
Uses public transportation never/rarely	68.0
Family/friends drive participant never/rarely	70.0

NA = not applicable.

**Table 3**

Medication use and chronic medical conditions at baseline and 1 year.

Measure of health	No. (and %) of participants	
	Baseline (n = 100)	1 year (n = 94)
<b>Medication</b>		
Cardiac	18 (18.0)	23 (24.5) <sup>a</sup>
Antihypertensive	35 (35.0)	34 (36.2) <sup>a</sup>
Anti-inflammatory	16 (16.0)	14 (14.9)
Benzodiazepine	12 (12.0)	12 (12.8)
Narcotic	2 (2.0)	1 (1.1)
Antidepressant	7 (7.0)	5 (5.3)
Other prescribed medication(s)	10 (10.0)	10 (10.6)
Over-the-counter medication	81 (81.0)	75 (79.8)
≥ 3 prescribed medications	64 (64.0)	60 (63.8)
<b>Diagnosis</b>		
Hypertension	35 (35.0)	37 (39.4)
Angina	19 (19.0)	23 (24.5)
Congestive heart failure	7 (7.0)	5 (5.3)
Palpitations	12 (12.0)	3 (3.2)
Atrial fibrillation	11 (11.0)	8 (8.5)
Arthritis	41 (41.0)	40 (42.6)
Cancer	17 (17.0)	20 (21.3)
Cataracts	26 (26.0)	37 (39.4) <sup>a</sup>
Glaucoma	7 (7.0)	12 (12.8) <sup>a</sup>
Macular degeneration	5 (5.0)	6 (6.4)
Diabetes mellitus type I or II	7 (7.0)	5 (5.3)
Kidney disease	5 (5.0)	5 (5.3)
Progressively worsening memory loss	5 (5.0)	4 (4.3)
Epilepsy	0 (0.0)	1 (1.1)
Parkinson's disease	1 (1.0)	1 (1.1)
Osteoporosis	16 (16.0)	18 (19.1)
Stroke	6 (6.0)	7 (7.4)
Dizziness/fainting	5 (5.0)	6 (6.4)
Dizziness/vertigo	3 (3.0)	3 (3.2)
Localized weakness	2 (2.0)	7 (7.4)
Hearing problems	35 (35.0)	36 (38.3)
Tremors	6 (6.0)	6 (6.4)
Pain	35 (35.0)	35 (37.2)
Asthma/emphysema	13 (13.0)	15 (16.0)
Depression	6 (6.0)	5 (5.3)
Anxiety	2 (2.0)	0 (0.0)
Thyroid problems	10 (10.0)	9 (9.6)
≥ 3 conditions	72 (72.0)	72 (76.6) <sup>a</sup>

<sup>a</sup>  $p < 0.05$ .

**Table 4**

Mean assessment results at baseline and 1 year.

Measure	Mean (and SD)		<i>p</i>
	Baseline ( <i>n</i> = 100)	1 year ( <i>n</i> = 94)	
Mini-Mental Status Examination total score	29.0 (1.0)	29.1 (1.1)	0.75
Modified Mini-Mental State Examination total score	96.0 (3.8)	96.5 (4.0)	0.26
Trail making test B (sec)	10.4 (7.8)	9.1 (5.7)	0.11
Clock drawing test total score	12.7 (0.5)	12.9 (0.4)	0.001
Digit span: backward total score	5.0 (1.3)	5.3 (1.2)	0.03
Geriatric Depression Scale total score	1.1 (1.5)	1.3 (1.5)	0.21
Ottawa Driving Toolkit Questionnaire total score	9.6 (0.7)	9.4 (1.3)	0.27
Timed Up and Go test score (sec)	10.1 (1.6)	9.2 (1.5)	<0.001
Activities of Daily Living total score	14.9 (0.4)	14.8 (0.5)	0.06
American Medical Association screening questions total score	17.6 (2.7) <sup>a</sup>	18.1 (1.8)	0.04
Traffic sign recognition test spontaneous answer total score	9.3 (4.0) <sup>a</sup>	10.6 (2.2)	0.001

<sup>a</sup> Results at 6-month assessment (not administered at baseline).

**Table 5**

Data on collisions, convictions and demerit points from Ministry of Transportation of Ontario driving records.

Variable	Before study					During study		
	No. of collisions in 3 years preceding study	No. of convictions in 3 years preceding study	No. of demerit points total record	No. of convictions total record	No. of collisions total record	No. of collisions	No. of convictions	No. of demerit points
Total	11	21	20	117	56	5	6	22
Average per participant	0.11	0.22	0.20	1.18	0.57	0.05	0.06	0.23
Maximum per participant	1	3	4	8	4	1	1	6
Minimum per participant	0	0	0	0	0	0	0	0
No. of drivers involved	11	16	6	58	39	5	6	6

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