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INVESTIGATION OF COMMERCIAL MOTOR VEHICLE DRIVER CUMULATIVE FATIGUE RECOVERY PERIODS: PHASE II

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INVESTIGATION OF COMMERCIAL MOTOR VEHICLE DRIVER CUMULATIVE FATIGUE RECOVERY PERIODS: PHASE II

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16. Abstract

Governments and the trucking industry would like to provide an optimal regulatory and operating framework within which commercial motor vehicle (CMV) driver fatigue can be better managed to reduce its contribution to collisions. There is insufficient scientific information concerning the length of time required for drivers to recover from various types of work schedules, particularly night schedules.

The goals of Phase I of the Investigation of Commercial Motor Vehicle Driver Cumulative Fatigue Recovery Periods were to review literature related to recovery, and to develop experimental protocols to examine driver recovery needs. The goals of Phase II were to collect survey data on typical CMV driver schedules; to refine the Phase I protocols based on the survey results; and to review and revise the proposed protocol options in a workshop with experts and stakeholders.

Nine protocol options are proposed: six field studies involving CMV drivers on typical schedules before and after recovery periods of various lengths; two laboratory studies to investigate individual differences, sleep fragmentation and recovery; and an epidemiological study of crash risk in relation to recovery periods.

Details are given regarding general research ethics considerations. Specific ethics considerations associated with each of the proposed protocol options are addressed.

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16. Résumé

Les gouvernements et l'industrie du camionnage souhaitent optimiser l'encadrement réglementaire du transport routier pour mieux combattre la fatigue chez les conducteurs de véhicules utilitaires et réduire le rôle de celle-ci dans les accidents. Il existe peu de données scientifiques concernant le temps de repos nécessaire aux conducteurs pour se remettre de la fatigue accumulée à la suite de divers types d'horaires de travail, en particulier d'horaires de nuit.

La phase I de *l'Étude des périodes de récupération chez les conducteurs de véhicules utilitaires* poursuivait deux objectifs : recenser la littérature sur la récupération et élaborer des protocoles expérimentaux pour étudier le temps nécessaire aux conducteurs pour récupérer. La phase II avait pour objectifs de recueillir, au moyen d'un questionnaire, des données sur les horaires types des conducteurs de véhicules utilitaires, de perfectionner les protocoles élaborés au cours de la phase I, à la lumière des réponses au questionnaire, et de revoir les protocoles, et les modifier au besoin, au cours d'un atelier réunissant experts et intervenants clés.

Neuf protocoles sont proposés : six études sur le terrain de conducteurs de véhicules utilitaires affectés à des horaires types, avant et après des périodes de récupération de durées variées; deux études en laboratoire portant sur les différences individuelles, le morcellement du sommeil et la récupération; et une étude épidémiologique de la relation entre le risque d'accident et les périodes de récupération.

Le rapport traite en outre de l'éthique de la recherche en général, et des enjeux éthiques propres aux protocoles proposés.

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SUMMARY

Governments and the trucking industry would like to provide an optimal regulatory and operating framework within which commercial motor vehicle (CMV) driver fatigue can be better managed to reduce its contribution to collisions. There is insufficient scientific information concerning the length of time required for drivers to recover from various types of work schedules, particularly night schedules. The goal of Phase I of the Investigation of Commercial Motor Vehicle Driver Cumulative Fatigue Recovery Periods was two-fold: first to review literature related to recovery, and second to develop experimental protocols to examine driver recovery needs. The goal of Phase II was three-fold: first to collect data on typical CMV driver schedules through a questionnaire survey; second to refine the protocols developed in Phase I based on the survey results; and third to review and revise the proposed protocol options by means of a consultation workshop with key experts and stakeholders.

Experimental Protocol Options to Examine Driver Recovery Needs

The fundamental goal of the field and laboratory study options was to determine how long a period of time off is required for drivers to recover to their rested state after a sustained period of work. Studies would be carried out within the current applicable laws and hours of service regulations. Nine protocol options were developed. The protocols are divided into field, laboratory and epidemiological studies. While a variety of approaches to assessing recovery are possible, it is clear from the literature review and the project team's knowledge concerning the acceptability of research findings by the industry and by regulators that field assessments of drivers must be the primary focus of the assessment. The most influential studies in the past have been field studies. For this reason the core study is a field study. Five options involving variations on parameters within this core field study are addressed following a description of this fundamental study. It is important to note that the proposed field study protocols were designed with the goal of examining typical rather than extreme schedules so as to encourage the involvement of trucking companies in potential field studies. As a result, whenever possible, the protocols reflect the results of the hours-of-service and fatigue survey.

In addition to the six proposed field study options, two laboratory study options are described. While laboratory studies have the advantage of rigor and control over a wide variety of factors that can confound or otherwise influence the outcomes, they are necessarily artificial with regard to stressors that exist in the commercial motor carrier environment. Nevertheless, laboratory experiments that clarify field-oriented questions are scientifically valuable and can positively impact the design of key field experiments. Therefore, our approach has been to consider the laboratory studies as either answering specific questions that need more rigorous control or establishing individual subject differences that may be predictors of recovery in field settings. The laboratory studies deal with issues of individual differences (self-perceived difficulty with night driving and measured recovery) and with the impact of consolidated versus fragmented sleep on length of recovery.

The final study proposed is a case-control epidemiological study on the impact of a schedule and recovery period on crash risk.

Research Ethics Considerations for Driver Recovery Studies Involving Driver Schedules that Induce Fatigue

The research ethics section begins with a rationale for adhering to ethical standards, a brief history of the development of current standards, a review of current ethics regulations in the U.S. and Canada, and a “lessons learned” review of a fatigue and driving protocol. Specific ethics considerations associated with each of the nine proposed protocol options are then addressed. The discussion focuses on the need for naturalistic driving, full and frank disclosure to drivers, the amount of rest prior to beginning the study, daily sleep requirements, driver selection criteria, recommended performance measures, and assurances that must be made to drivers who are employed in the study.

Most of the studies proposed involve naturalistic driving on operational revenue-generating routes. In this circumstance it is important to ensure that these routes are indeed typical, operational, and revenue-generating routes so that the fatigue that results from driving will be at a level consistent with drivers’ everyday experience. In order for the results to be generalizable and pragmatic, normal routines must be considered unless there are specific experimental concerns that override these issues. The second reason to keep the driving conditions as operational as possible is to limit the liability and responsibility of the investigators and the sponsors.

One of the primary requirements of investigators and sponsors is to fully and frankly disclose to drivers the potential risks associated with their participation in the study and the expectations of them through the informed consent process. This is a continuous process that begins when a driver is recruited and does not end until his or her relationship with the study is completed.

The discussion of ethics considerations includes recommendations regarding the minimum amount of rest required before beginning any of the proposed driving schedules. From an ethics perspective, the decision was made to conform to normal operations. The discussion also includes recommendations regarding the amount of daily sleep required for the proposed protocol options. Few restrictions are placed on daily sleep; however, it is recommended that there be a minimum daily amount of sleep. Since these protocols are intended to be as naturalistic as possible, the lack of restriction on daily sleep is intended to keep the driving/sleeping schedules as naturalistic as possible.

With respect to driver selection criteria, it was decided to select any driver who passed the company physical in order to adhere to current standards and to minimize the risk to drivers, investigators and sponsors associated with the discovery of unknown medical conditions. No other restrictions on drivers are recommended in order to have the driver samples as representative as possible.

Various subjective and objective behavioural probes are recommended for these protocol options. From an ethics perspective, it must be disclosed to drivers that the measures obtained in the study may be subpoenaed under the law in the event of an accident or incident. Investigators must also assure drivers of: a) the procedures to be employed in the study, b) the confidentiality of the information collected in the study, c) the voluntary nature of their participation, and d) their freedom to withdraw from the study for any reason at any time without the need for justifying their decision. In order to make such assurances feasible and ethically acceptable, the appropriate representatives of the company, their dispatchers and perhaps specific shippers must agree to the conditions of the study.

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GLOSSARY

ANOVA	Analysis of Variance
CMV	Commercial Motor Vehicle
EB	Ethics Board
EC	Ethics Committee (European Union)
EEG	Electroencephalogram
ICH	International Conference on Harmonization
IRB	Institutional Review Board (U.S.)
OHRP	Office of Human Research Protection
OSPAT	Occupational Safety Performance Assessment Test
PERCLOS	Percentage of Eyelid Closure
PI	Principal Investigator
PIPEDA	Personal Information Protection and Electronic Documents Act
PVT	Psychomotor Vigilance Test
REB	Research Ethics Board (Canada)
TCPS	Tri-Council Policy Statement

1 INTRODUCTION

Governments and the trucking industry would like to provide an optimal regulatory and operating framework within which commercial motor vehicle (CMV) driver fatigue can be better managed to reduce its contribution to collisions. In both Canada and the U.S., the current hours-of-service regulations do not specifically include an extended off-duty recovery period to reduce the "sleep debt" acquired by drivers after cumulative periods of sleep restriction or loss over multiple work shifts. This is only addressed indirectly by specification of maximum on-duty hours over a cumulative period such as, for example, over seven days. There is little scientific information concerning the length of time required for drivers to recover from various types of work schedules. Developing a scientific basis for minimum recovery periods is important from the safety perspective as well as for maximizing driver operational efficiency and quality of life.

To develop a scientific basis for minimum recovery, Transport Canada, in collaboration with the U.S. Federal Motor Carrier Safety Administration (FMCSA), tendered bids for a multi-phase project that could directly address the length of time required for drivers to recover from various types of work schedules. The first phase of this project involved a review of the literature on the shiftwork and recovery aspects for CMV driving (Smiley, Boivin, Heslegrave, & Davis, 2003). Based on the findings of the literature review, experimental protocol options were developed. The intent of these protocols is to further our understanding of the minimum duration of off-duty periods required for CMV drivers to recover, from a road safety perspective, from the effects of cumulative fatigue resulting from various shiftwork conditions involving multiple days and/or nights.

To reflect common current operational situations in the trucking industry, these experimental protocols were revised in Phase II, based on the findings of an hours-of-service and fatigue survey conducted with 150 long-haul truck drivers in Ontario, Quebec, and Alberta. To conclude this second phase of the project, a Fatigue and Recovery Consultation Workshop was held in Montreal (September 2003) with key experts and stakeholders. The goal of the workshop was to review and revise the proposed protocol options with a specific focus on the field studies so that they answer relevant research questions using practical and realistic schedules that encourage the participation of drivers and trucking companies. The workshop participants reviewed the scientific and pragmatic aspects of each of the proposed options and suggested revisions. This document contains these revised protocol options as well as the workshop participants' suggestions for additional protocol options. The protocols have been divided into field, laboratory and epidemiological studies. Upon completion of Phase II, Transport Canada, in collaboration with the U.S. FMCSA and other potential sponsors and stakeholders, will consider tendering a bid for a project to implement some of the recommended protocol options.

Appendix A provides the results of the driver survey, Appendix B describes the factors to be considered in experimental protocols, Appendix C contains a summary of the Phase I literature review, and Appendix D reviews various measures of driver response and related measurement technologies.

2 EXPERIMENTAL PROTOCOLS AND ASSUMPTIONS

The fundamental goal of the field and laboratory study options is to determine how long a period of time off is required for drivers to recover to their rested state after a sustained period of work. The goal of the epidemiological option is to determine the relationship between crash risk and recovery period. Field and laboratory studies would be carried out within the current applicable laws and hours of service regulations. A driver is considered recovered when the following criteria are equivalent to (or at least not significantly different from) when the driver has been off work for several days:

- Quality and length of sleep
- Driving performance
- Subjective alertness

Because performance and alertness vary depending on time of day, a driver is considered recovered when performance and alertness are equivalent to rested performance and alertness measured at the same time of day.

In the literature review it was determined that 1) circadian factors and consecutive driving days/nights are the primary factors that affect fatigue, and 2) age is the primary individual difference variable that may influence fatigue and subsequent recovery. Clearly all test conditions must induce some degree of fatigue and then establish the effectiveness of recovery options based on the degree of fatigue. Both fatigue and recovery are influenced by circadian rhythms so this factor is key to the design of studies. Since age is a critical individual variable, each study should include sufficient numbers of subjects to make comparisons on the basis of age. Recent studies of fatigue – e.g., Wylie et al.'s U.S./Canada study (Wylie, Shultz, Miller, Mitler, & Mackie, 1997) and the Development of a North American Fatigue Management Program for Commercial Motor Carriers, being conducted by Transport Canada in collaboration with other sponsors and stakeholders – have used 20 to 24 subjects per condition.

A number of experimental protocols are outlined in Section 3. The experimental protocols include laboratory, field and epidemiological studies. Having noted that a variety of approaches to assessing recovery are possible, it is clear from the literature review and the project team's knowledge concerning the acceptability of research findings by the industry and by regulators that field assessments of drivers must be the primary focus of the assessment. The most influential studies in the past have been field studies. While laboratory studies have the advantage of rigor and control over a wide variety of factors that can confound or otherwise influence the outcomes, they are necessarily artificial with regard to stressors that exist in the commercial motor carrier environment – notably the hazards associated with the real task of driving and controlling a tractor-trailer for long periods over many days and attempting to recover from that task in the face of family and social obligations. Nevertheless, laboratory experiments that clarify field-oriented questions are scientifically valuable and can positively impact the design of key field experiments. Therefore, our approach has been to consider the laboratory studies as either answering specific questions that need more rigorous control or establishing individual subject differences that may be predictors of recovery in field settings. The importance of those factors would then be validated in field studies. For this reason the core study is a field study, and this is described first. Options involving variations on parameters within this core field study are addressed following an understanding of this fundamental study.

It is important to note that the proposed field study protocols were designed with the goal of examining typical rather than extreme schedules so as to encourage the involvement of trucking companies in potential field studies. As a result, whenever possible, the protocols reflect the results of the hours-of-service and fatigue survey.

3 EXPERIMENTAL PROTOCOL OPTIONS

3.1 Experimental Parameters

The following experimental parameters are relevant to the proposed experimental protocol options.

3.1.1 Baseline Period

To ensure that drivers begin the study in a well-rested condition, they will be required to have had a minimum of 60 hours off immediately before the described work period (drivers must not work more than five days prior to this baseline period). Workshop participants chose 60 hours as the minimum amount of time off as it allows participants to have two nights off and return to their regular shift. According to workshop participants this is a common rest period for drivers and as a result would facilitate recruitment and provide face validity for the proposed protocols. However, subjects who have two nights off (i.e., 60 hours) may not be as well rested as those with three nights off (i.e., 84 hours) and may start the study with lower performance than would be possible if they had had many nights of rest before entering the study. As a result, if 60 hours is used as the minimum baseline, researchers should consider adding a third recovery condition of three nights (i.e., 84 hours) to Option 1. This would allow an examination of whether or not time off beyond 60 hours results in measurably improved recovery, without unnecessarily restricting entrance to the study to only those drivers who have had 84 hours off.

During this baseline period of non-driving, drivers would be trained on performance measures and other assessments (e.g., en route subjective measures). Also the quantity of sleep (using actigraphy) in the period immediately before driving would be recorded. During the 60 hour baseline period, drivers would be required to sleep at night, that is, at a minimum during the 24:00 to 06:00 period.

3.1.2 Drivers

3.1.2.1 Night Driving

Night driving is defined as driving at least two hours between 24:00 and 06:00. Thus, for example, drivers who work from 12:00 to 02:00, or from 04:00 to 18:00, would be considered to be driving at night. Subjects driving at night should have a minimum amount of five hours of core sleep (in addition to naps) a day. A suggestion was made at the workshop to define those who drive at night as those participants who sleep during the day (e.g., 50 percent or more of their rest period occurs between 06:00 and 23:00). However, this suggestion was rejected as the researchers felt it was important to define night driving in terms of participants' driving behaviour rather than their sleeping behaviour.

3.1.2.2 Day Driving

Day driving is defined as *not* driving between 23:00 and 06:00 on any of the shifts worked, and driving at least eight hours each shift.

3.1.3 Individual Differences: Age

While age is an important individual difference variable, it will be used as a covariate rather than a control variable. It would be unrealistic to use age as a control variable given the numbers of subjects that have been required per condition in recent fatigue studies (e.g., 20 to 24 subjects per condition). Using age as a control variable would require 20 subjects per age group per condition, which is an unrealistically large sample size. Instead, a sufficient distribution reflective of the trucking population should be employed. We suggest using the same distribution as we found in our survey of driver schedules. In this survey, one third of the subjects were under 40, one third were between 40 and 50 years of age, and one third were over 50 years of age.

3.1.4 Number of Subjects

As this study proposes similar field measures (e.g., lane tracking, PVT, subjective scales) as recent fatigue studies (e.g., Wylie et al., 1997; Development of a North American Fatigue Management Program for Commercial Motor Carriers, Transport Canada), we propose a similar number of drivers per condition (i.e., 20 to 24 subjects).

3.1.5 Measures

Subjective and objective behavioural probe measures and driving measures are possible in these studies. Appendix D reviews a considerable number of physiological and behavioural measures, sleep indices, and driving simulator and vehicle-based performance technologies that may be used in the experimental protocols to be developed. At a minimum, subjective and objective measures of fatigue and sleep are required.

Both fatigue (disinclination to continue working) as well as drowsiness (potential for falling asleep) will be measured. Subjective assessments of fatigue and drowsiness will be carried out using standard rating scales; the quantity and quality of sleep will be recorded using logbooks. All sleep periods, including short naps, will be recorded.

A variety of scales, such as the Standard Shiftwork Index and the Epworth Sleepiness Scale should be used to assess individual differences such as morningness and eveningness as well as susceptibility to fatigue to allow researchers to examine their predictive value with respect to recovery.

Objective measures of drowsiness should minimally include an actigraphy assessment to assess sleep/wake patterns. Actigraphy could be collected over the entire protocol duration.

Behavioural assessments should include the psychomotor vigilance task (PVT) as this test has been used in numerous previous studies and will be used in the study "Evaluation of a North American Fatigue Management Program for Commercial Motor Carriers". In addition, a computerized test called the Occupational Safety Performance Assessment Test (OSPAT) should be considered. This test was used in an Australian train driver study of napping and is a simple random visual-motor tracking task that requires hand-eye coordination and measures reaction time and vigilance. It requires the subjects to return a randomly moving cursor to the centre of a circular target. Both of these behavioural tasks should be administered at the same time on each shift as the fatigue and drowsiness assessments.

This study should also incorporate driving performance measures. The objective performance measure that has been most reliably shown to be affected by drowsiness is the standard deviation of lane position. The main concern with this measure is that it is affected by road geometry and vehicle type. In the U.S./Canada study by Wylie et al. (Wylie, Shultz, Miller, Mitler, & Mackie, 1996), the comparisons of U.S. and Canadian shift lengths (10 vs. 13 hours) were confounded by differences in routes and in vehicle types, which were likely responsible for unexpected findings associated with lane tracking. In the study being proposed, this would not be a concern, as long as drivers were on the same routes, and within subject comparisons can be made with regard to whether full recovery has occurred, after a specific recovery period.

Other driver performance measures that have high face validity and have been used in previous on-road studies (Hanowski, Wierwille, Gellatly, Early, & Dingus, 2000) involve analysis of videotapes of the three minute intervals preceding the start of critical incidents. An incident was defined as a control movement exceeding a threshold, based on driver or analyst input. Analysts recorded eye transitions and the proportion of time that the driver's eyes were closed/nearly closed or off the road during these three minute intervals. Since critical incidents in which the drivers were at fault averaged only 1.8 per driver over two weeks of driving, more continuous measures of driving performance, such as lane position variability, will be required.

During the recovery periods subjective and objective behavioural assessments should be measured. The measures should occur at the same time of day as was the case during the driving days, with the exception of the 02:00 to 05:00 test time where drivers will be sleeping on their recovery days.

Physiological measures are more cumbersome and we do not recommend them for the field studies. There are three main reasons for not recommending physiological measures with regard to measuring the key parameters of circadian rhythms and alertness/drowsiness. First, collecting these measures can be operationally difficult. For instance, core body temperature is viewed as a very robust measure of circadian rhythm but is difficult to obtain in an operational setting in a reliable, unobtrusive, and continuous manner (i.e., use of probes or repeated measurements). EEG measures to assess drowsiness are also difficult to obtain in operational settings. Second, many measures of circadian rhythm and alertness (oral or tympanic temperature, melatonin, cortisol, etc.) can be masked by environmental changes such as light exposure, exercise, stress, food intake, and types of physical and mental activity. Finally, many of these measures are labour-intensive in terms of analysis and interpretation. For instance, the EEG or eye closure (PERCLOS) information to measure alertness, or body temperature, melatonin, or cortisol measures to measure circadian rhythms are extremely resource-intensive with respect to data reduction (scoring, quantification, assays, etc.) and subsequent analyses.

3.1.6 Analysis

In addition to descriptive statistics, analysis of covariance will be conducted using age and self-perception of fatigue as covariates. Linear or logistic regression (e.g., napping/no napping; age; self-perception of fatigue) may also be used to predict recovery.

3.2 Field Options

3.2.1 Option 1: Core Field Study for Night Driving

The assumption behind this core field study is that the impact of different recovery time periods should be assessed following a common, yet challenging, night work schedule (described in Section 3.1.2.1).

3.2.1.1 Experimental Design

The basic experimental design will be a two group repeated measures design where two groups of subjects who typically drive at night (as defined in Section 3.1.2.1) are monitored for fatigue over consecutive shifts of night driving followed by two different recovery opportunities. (As discussed in Section 3.1.1, if it seems that subjects will typically enter the study after only 60 hours off, a third 84 hour recovery period should be considered.) A work period will follow the recovery period.

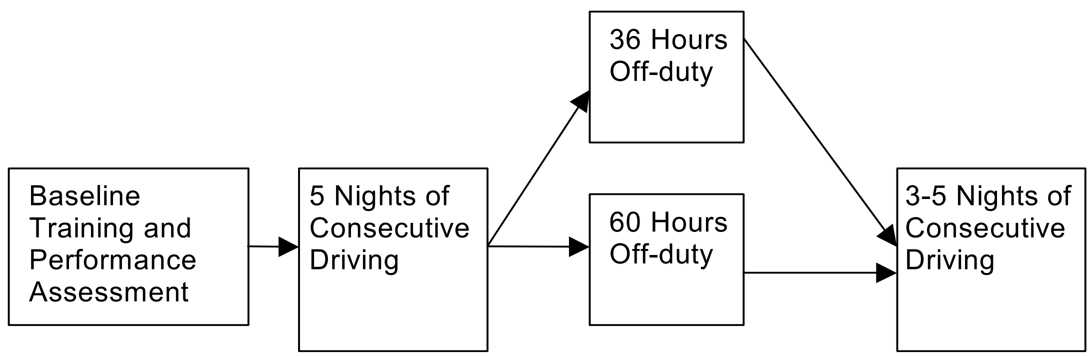

Figure 1 Option 1: Core Field Study for Night Drivers

3.2.1.2 Design and Parameter Rationale

The recovery time available to drivers is systematically manipulated. This variable recovery period is followed by a subsequent work period to assess adequacy of the recovery period. For recovery periods where full recovery occurs, the decline in performance seen over the second period of work should be similar to that seen over the initial period of work. If recovery is incomplete following the recovery opportunity, it would be expected that performance across consecutive driving periods would decline earlier than in the first set of night driving periods and that the decline would likely be of greater magnitude.

The basic design shown in Figure 1 begins with a baseline training period (described in Section 3.1.1) to enable drivers to familiarize themselves with and develop skill on the performance assessment tools (described in Section 3.1.5).

A driver would be considered acceptable for participation in the night driving condition as long as he or she worked a minimum of two hours between 24:00 and 06:00 on four out of five sequential shifts. Drivers must be on-duty for a minimum of nine hours per night for four of the five nights. Our hours-of-service and fatigue survey showed that only 22 percent (7/32) of "mainly night" drivers recorded working less than nine hours on average in their three previous shifts. None of these five nights of driving can consist of less than six hours of on-duty time. Five nights of driving was chosen because it is a relatively common occurrence. However, it is likely to maximize the fatigue that would develop under normal operational conditions. In addition, five nights of driving (assuming some 10 to 12 hours per night) would be consistent with the current Canadian Hours of Service regulations.

Following their five nights of driving, half of the drivers will receive 36 hours (+/- 4 hours) off-duty and the other half will receive 60 hours (+/- 4 hours) off-duty. The allowance for 32 to 40 hours (or 56 to 64 hours) off-duty will enable more drivers to participate in the study, without compromising the distinction between off-duty periods of different lengths.

If a baseline of two nights (i.e., 60 hours) is chosen rather than three nights (i.e., 84 hours), an additional off-duty condition of 84 hours (+/- 4 hours) should be added to allow researchers to look at recovery associated with three nights of sleep (as it is obtained by the majority of the working population that has a weekend off). The groups will be counterbalanced to control for relevant variables such as the percent of time spent working within the 24:00 to 06:00 time zone as well as age.

The recovery periods are intended to cover a normal range of off-duty time. The 36 hours (+/- 4 hours) off-duty after the finish of a final night of driving would allow drivers to obtain both some day sleep as well as some night sleep in that 36 hour (+/- 4 hours) period and then return to the same night driving schedule as they worked earlier. This 36 hour (+/- 4 hours) recovery period was also chosen because this is the minimum recovery period recommended under the proposed Hours of Service regulations. The 60 (+/- 4 hours) hours of time off would allow an additional one night for sleep before returning to night driving. Thus, drivers in this study would obtain one or two night sleep opportunities.

The subsequent work period is suggested to be a minimum of three nights and a maximum of five nights. For recovery periods where full recovery occurs, the decline in performance seen over the second set of five night shifts should be similar to that seen over the initial five nights. When full recovery occurs, a shorter period of three nights may be sufficient to document similar declines in function in the first and second set of night shifts. Similarly, if full recovery is not evident, less subsequent driving will be required to demonstrate that only partial recovery has occurred. Ideally, the subsequent driving period should be five nights, but it is recognized that if recovery is incomplete then driving may be hazardous if prolonged and this three to five night window allows and encourages drivers to withdraw from the study if fatigue becomes a safety issue.

In this and in all other study options, safety of drivers is paramount. From an ethical perspective, the informed consent process will make it clear to drivers that they are free to deviate or withdraw from the study at any time. Their safety must be the paramount factor in making driving/resting decisions.

3.2.1.3 Drivers

The participants eligible for Option 1 are described in Sections 3.1.2 and 3.1.3. Eligible participants would be those drivers engaged in "night driving" according to the operational definition given in Section 3.1.2.1.

3.2.1.4 MEASURES

The possible subjective and objective behavioural probe and driving measures for this field study are described in Section 3.1.5. The following information describes possible timing for measurements for the night driving involved in Option 1. This information also applies to the other field options that focus on night driving (see Sections 3.2.2, 3.2.3, 3.2.4 and 3.2.6).

Since the drivers in this option will be night driving, fatigue and drowsiness will be assessed at the beginning, middle and end of each shift. To ensure that time of day is taken into account, two hour time windows will likely be defined where the beginning of night driving should ideally be rated. These two hour windows will be separated from each other by two to three hours. This separation ensures that measurements taken one minute apart are not allocated to different circadian periods, but are clearly separated. The time periods will be the same for all options, to allow comparability, and measurements will be made only in those time periods when drivers are awake. The time periods used will be 03:00-05:00 (early morning and circadian nadir), 09:00-11:00 (mid-morning), 13:00-15:00 (post-lunch dip), 18:00-20:00 (circadian peak) and 22:00-24:00 (late evening). Depending on the driver's schedule, he or she may be asleep during one or more of these time periods, in which case a measurement will not be recorded.

3.2.2 Option 2: Option 1 Plus Four Night Work Period

In addition to a five night work period followed by 36 (+/- 4 hours) and 60 hours (+/- 4 hours) off, a four night work period (a minimum of 8 hours of driving per shift) followed by 36 hours (+/- 4 hours) off could also be examined (see Figure 2). In the latter case, a driver would be considered acceptable for participation as a "night" driver as long as he or she worked a minimum of two hours between 24:00 and 06:00 on three out of four sequential shifts.

Option 2, with the additional four night condition, would allow the researchers to determine whether those subjects who work four nights and have 36 hours (+/- 4 hours) off recover better than those who work five nights and have 60 hours (+/- 4 hours) off. The four night shift schedule followed by 36 hours off (+/- 4 hours) results in more productivity than a five night schedule followed by 60 hours (+/- 4 hours) off and could be advantageous to companies.

The subsequent work period is the same as described for Option 1.

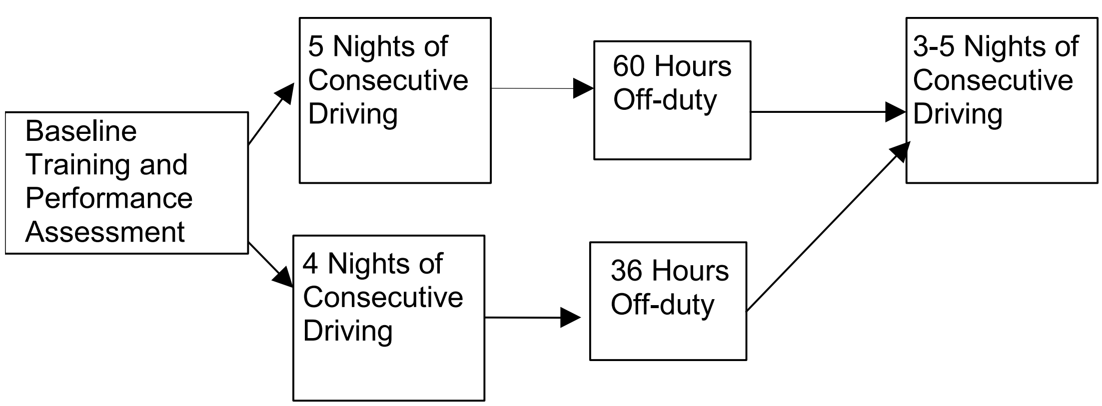

Figure 2 Option 2: Option 1 Plus Four Night Work Period

3.2.3 Option 3: Option 1 Plus Day Driving Group

This option is almost identical to Option 1 but has the addition of a comparison day driving group. Option 3 and Option 1 cannot both be chosen because Option 1 is a subset of Option 3. If the resources are available, Option 3 should be chosen as it provides additional information. A driver would be eligible for participation as a “day” driver as long as he or she does *not* drive between 23:00 and 06:00, and is on-duty for at least nine hours on four of five days.

3.2.3.1 Experimental Design

The same basic study design from Option 1 is proposed with the addition of a day driving group (defined in Section 3.1.2) in a two group repeated measures design where two groups of drivers are monitored for fatigue over consecutive shifts of day/night driving followed by two different recovery opportunities of 36 (+/- 4 hours) and 60 (+/- 4 hours) hours (see Figure 3). A work period of three to five days/nights will follow the recovery period.

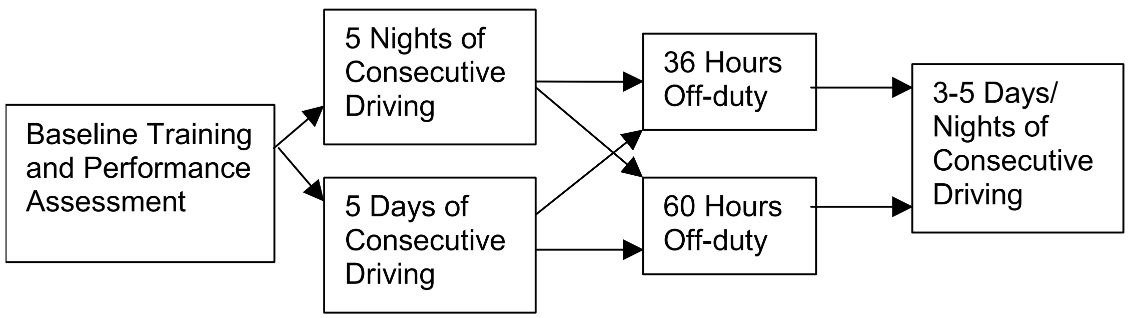

Figure 3 Option 3: Recovery after Day Driving vs. Recovery after Night Driving

3.2.3.2 Design and Parameter Rationale

This study will allow the researchers to compare the recovery of drivers on night shifts to the recovery of drivers on day shifts. It will reveal whether day and night drivers experience a similar decline in performance over five shifts and whether they need the same amount of recovery time to return to their baseline performance.

3.2.3.3 Drivers

The driver characteristics are the same as Option 1, with the addition of day shift drivers.

3.2.3.4 Measures

Subjective and objective behavioural probe measures are the same as in Option 1 with the following exception: subjective and behavioural measures will be collected at the beginning, middle and end of the day driving shifts at windows 09:00-11:00, 13:00-15:00 and 18:00-20:00, where possible.

3.2.4 Option 4: Field Study Variant – Nappers vs. Non-Nappers Before and After Fatigue Management Suggestions

The focus of this study is the effect of fatigue management suggestions on the recovery of nappers vs. non-nappers. The basic assumptions behind this study are essentially the same as those of Option 1.

In our survey of hours of service and fatigue only 1/3 of the drivers reported typical hours napping during the workday. Drivers reported that they typically napped during the daytime (22 percent), waiting to load (20 percent), while loading or unloading (13 percent), and during rush hours (12 percent). Only four percent of those surveyed reported napping between 24:00 and 06:00. Thirty-five percent of the drivers reported that they never nap during their shift.

3.2.4.1 Experimental Design

The basic experimental design will consist of the best shift and recovery time determined from the outcome of field study Option 2. For example, if it is determined that four nights followed by 36 hours off leads to better recovery than five nights and 60 hours off, then the former will be used as the basic schedule for this design. Nappers and non-nappers will then participate in this optimal schedule two consecutive times (see Figure 4). After their first work period they will be given some basic fatigue management suggestions before running through the schedule a second time.

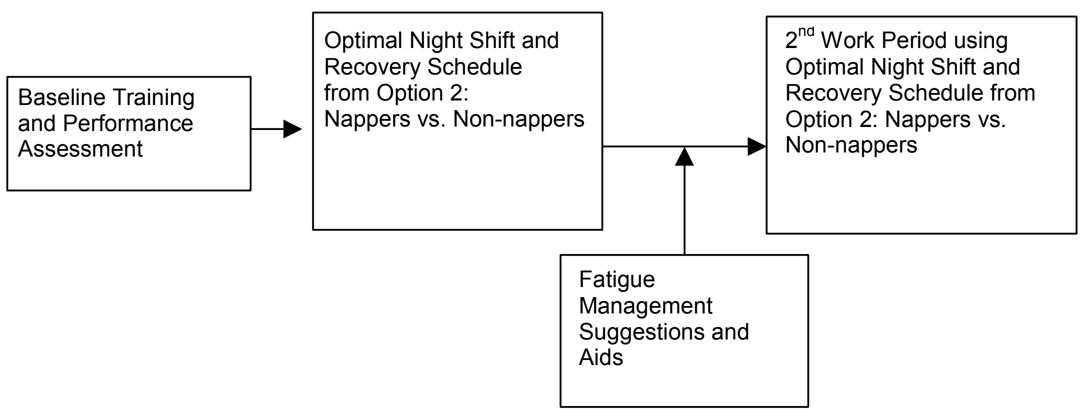

Figure 4 Option 4: Field Study Variant – Nappers vs. Non-Nappers Before and After Fatigue Management Suggestions

3.2.4.2 Design and Parameter Rationale

Participants will be screened prior to participating in the study to determine whether they are nappers or non-nappers. All participants will then participate in the optimal night shift and recovery schedule (determined in Option 2). The results will be examined to ascertain whether the recovery of non-nappers differs from the recovery of nappers. Following this, all subjects will receive a number of basic fatigue management suggestions such as minimum (i.e., 20 minutes) and maximum (i.e., 60 minutes) nap durations, the maximum amount of total nap time per day (i.e., no more than two hours), and suggestions for potential nap opportunities (e.g., waiting to unload). In addition, subjects will receive devices to aid napping (e.g., eye mask, alarm clock).

After receiving the fatigue management suggestions and aids, the subjects will participate in a repeat of their first shift and recovery schedule. This second work period will allow researchers to compare recovery for participants before and after the fatigue management suggestions and aids. In addition, it will allow researchers to examine the sleeping/napping habits of nappers and non-nappers following the fatigue management suggestions. Given that enthusiasm for using fatigue management suggestions may wane over time, it is proposed that the sleeping/napping habits of the subjects be re-examined again in several weeks, and perhaps several months, after the fatigue management training.

3.2.4.3 DRIVERS

Driver characteristics will be as described for Option 1, with the exception that drivers will be screened prior to beginning the study to identify nappers and non-nappers.

3.2.4.4 MEASURES

Subjective and objective behavioural probe measures and driving measures will be similar to those described for Option 1.

3.2.5 Option 5: Field Study – Consolidated Sleep vs. Split Sleep

This field study is based on Option 1. However, in contrast to Option 1, this option will look at drivers who typically take split sleep versus those who take consolidated sleep. One consolidated sleep period is a maximum of 10 hours total or 8 hours of sleep with additional naps (no longer than a half hour). Split sleep periods consist of two sleep periods, each of which is two hours or longer (e.g., 2 + 8 hours, 4 + 6 hours, 5 + 5 hours) which follow current regulations. Subjects will have a minimum of 10 hours off-duty. Sleep cannot total more than 14 hours in any 24 hour period. Split sleep drivers must have sleeper berths. Due to safety concerns split sleep drivers should be selected from drivers who typically sleep in this manner, rather than from those individuals who typically get seven or eight hours of sleep in a consolidated manner.

3.2.6 Option 6: Field Study – Self-Perception of Fatigue

Option 6 consists of two options, Option 6A and Option 6B. Only one of these two options can be chosen.

3.2.6.1 OPTION 6A

Option 6A involves incorporating self-perception of fatigue into Option 1 as a covariate, to see to what degree recovery and fatigue can be predicted by it. A questionnaire developed and validated in Option 7, a lab study, will be used to select and/or classify subjects according to their degree of susceptibility to fatigue or drowsiness while driving at night.

3.2.6.2 OPTION 6B

Option 6B involves using self-perception of fatigue as a condition rather than a covariate. There are two groups for this condition, those who are seriously affected by fatigue and drowsiness while driving at night and those who do not feel affected. Subjects will be selected for either group using the questionnaire that assesses their degree of susceptibility to fatigue while driving. The two groups will participate in each recovery condition in Option 1 (i.e., 36 or 60 +/- 4 hours off) to compare their degree of deterioration and their rapidity of recovery. It will be important to ensure that these two groups are equivalent in terms of their individual differences (e.g., years of experience night driving). The drawback of this option as compared to Option 6A is that it may take a considerable amount of time to accumulate the study population.

An additional field study focusing on driver's time off was also suggested at the workshop. However, this study was rejected due to the ethical implications in proposing how drivers should spend their time off.

3.3 Laboratory Studies

3.3.1 Option 7: Laboratory Study of Individual Differences: Quantitative Assessment of Recovery in Relation to Qualitative Perception of Recovery

While we know that fatigue and recovery are experienced very differently from one individual to another, the susceptibility to circadian rhythm effects is subjective based on self-report. We do not have evidence that this self-perception is accurate with respect to performance deterioration or subjective sleepiness. (Note: The workshop participants had varied opinions with respect to the value of these self-perceptions and suggested eliminating this option; however, Transport Canada felt this was a worthwhile option to explore.) This option first involves developing a questionnaire to assess driver self-perceived susceptibility to fatigue and drowsiness driving. The questionnaire would be used to select and/or classify subjects according to their degree of susceptibility. The validity of this self-perception would then be tested in a laboratory study. Using night driving as an example, the questionnaire might use the following criteria:

Self-perception of night driving:

- Little problem with night driving
- A lot of problems with night driving

Self-perception of recovery:

- Little problem with recovery after night driving
- A lot of problems with recovery after night driving

Self-perception can also be assessed with respect to problems associated with long driving or recovery need after designated work periods.

In all options self-perception of fatigue and recovery should be assessed so that groups can be appropriately balanced. This variable can also serve as a covariate in the examination of the impact of the various recovery periods, as in Option 6A.

Ideally this laboratory study would be conducted prior to any field studies focusing on self-perception of fatigue (e.g., Option 6). It is substantially more cost effective to assess whether self-perception of fatigue has any predictive power using a lab study rather than a field study. This lab study would allow researchers to develop and validate the questionnaire before it is used in the field. It could then serve as an objective measure of susceptibility to circadian rhythm impairment and degree of recovery from sleep, and subjects could be screened or classified according to this susceptibility, using screening criteria shown to be predictive of performance.

3.3.1.1 EXPERIMENTAL DESIGN

In the laboratory study outlined in Section 3.3.1.2, drivers would arrive after a normal day of activity on a day off and be trained on the tasks that will be used in the subsequent laboratory study. They would then be kept awake for a single night of sleep deprivation during which their fatigue and performance levels would be recorded on an hourly basis to assess the relationship between self-perceived difficulty in night driving and recovery and measured recovery.

To assess individual differences in the recuperative power of sleep, it is proposed that drivers be given an opportunity to sleep after the night of sleep deprivation and then enter a continuous assessment period where the degree of recovery in performance is assessed as well as the sustainability of that performance (see Figure 5).

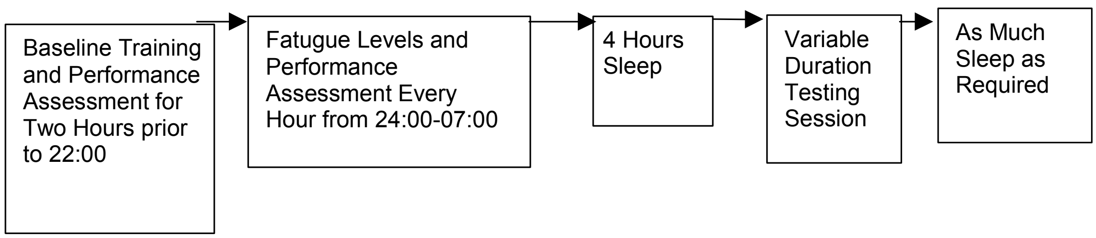

Figure 5 **Option 7: Laboratory Study of Individual Differences: Quantitative Assessment of Recovery in Relation to Qualitative Perception of Recovery**

3.3.1.2 DESIGN AND PARAMETER RATIONALE

Given that previous trucking studies have indicated that truckers obtain only about four to five hours sleep during night driving, it is proposed that an initial assessment of the capacity for recovery is made by waking drivers after four hours of sleep. It is further proposed that this sleep period be followed by a continuous assessment period to assess fatigue and performance (similar to the hourly testing during the first night of sleep deprivation). This second assessment period of fatigue and performance could last for perhaps as long as another 24 hours.

It is proposed that this testing session be variable in duration and be terminated based on the degree of performance impairment on standardized measures. It is proposed that the recovery portion of the study be terminated when a 20 percent decline in performance, an amount typically used as a threshold in clinical trials, occurs compared to the performance at the beginning of the study. Thereafter, drivers will be sent home by an appropriate method to obtain as much sleep as needed.

To account for learning effects that may well be present even after extensive training, performance after sleep will be compared to the best performance before sleep, even if that best performance is not the initial performance. Furthermore, the threshold used for optimum performance should be sustained across more than one measurement period, to avoid an artificially high statistical “blip” in performance.

Such a study would serve to characterize the drivers by way of the impact of circadian rhythms on their performance as well as the ability of drivers to recover quickly from periods of sleep deprivation. Such data would be very useful to assist researchers in more objectively defining the susceptibility of drivers to circadian and recovery factors. This study should therefore be carried out prior to any full studies.

3.3.1.3 Drivers

Driver characteristics will be as described for Option 1. However, drivers may be selected according to extremes of self-perceived susceptibility to fatigue during driving.

3.3.1.4 Measures

Performance measures would include those objective measures to be used in field studies (described in Section 3.1.5) as well as standardized laboratory tests assessing cognition and attention.

In addition to the above measures and the subjective and objective measures (e.g., actigraphy) of fatigue and sleep described in Section 3.1.5, physiological measures are recommended. As this study will be conducted in a laboratory, the “gold standard” measures of circadian rhythm and sleep – core body temperature, hormone collection and polysomnographic recordings – can be collected. The phase of the endogenous circadian pacemaker can be assessed with hormone collection by withdrawing blood. While subjects are asleep, blood can be collected using an in-dwelling catheter to assess hormone levels such as Plasma Melatonin or Plasma Cortisol. In addition, urine can also be used to measure the content in 6-sulphatoxymelatonin. Core body temperature can be taken with a rectal sensor every minute throughout the protocol. These physiological measures allow the researchers to capture important data on recovery sleep; however, they are more intrusive and more expensive than measures such as actigraphy.

Driving simulator performance measures could also be included, with test periods of 20 to 30 minutes every 90 minutes, to assess performance over time. In this manner susceptibility to circadian variation would be objectively defined.

3.3.2 Option 8: Laboratory Study of Impact of Consolidated vs. Fragmented Sleep on Recovery

The focus of this study is advice proposed as an element of Fatigue Management Plans. This advice is to encourage consolidated as opposed to fragmented sleep. While studies have suggested that consolidating sleep is beneficial, no studies have examined this issue with respect to recovery. The purpose of this option is to determine whether consolidated sleep reduces the required recovery period. This information will also be helpful in evaluating recent recommendations to allow drivers to split their 10 hour off-duty requirement into two periods. Under the recently revised U.S. regulations (49 CFR Parts 385, 390, and 395, April 28, 2003; and technical amendment final rule issued September 30, 2003), single drivers may accumulate the equivalent of 10 consecutive hours off-duty by taking two periods of rest in a sleeper berth, provided neither period is less than two hours. A recent Canadian Expert Panel on Sleeper Berth Split Rest (George, Laberge-Nadeau, Moldofsky, Rhodes, & Vespa, 2003) made a similar recommendation to allow single drivers to split the 10 hour off-duty requirement into two periods, neither of which could be less than two hours.

This study will help determine whether one consolidated sleep opportunity of eight hours, at an inappropriate time (falls at wrong circadian phase), results in less recovery than two four-hour recovery sleep opportunities falling at a good circadian phase. In addition, it will help determine whether one consolidated sleep opportunity of eight hours, falling at a good circadian phase, results in more recovery than two periods of four-hour recovery sleep also falling at a good circadian phase. The proposed focus on an eight hour sleep opportunity will allow researchers to examine the most extreme conditions that drivers might experience. However, to better reflect recent recommendations regarding sleeper berth split rest time, researchers could increase the total sleep opportunity to 10 hours (i.e., consolidated sleep opportunity of 10 hours; fragmented sleep of two periods, neither of which could be less than two hours, totalling 10 hours).

3.3.2.1 EXPERIMENTAL DESIGN

The experimental design will be a mixed 2 (sleep conditions: fragmented or consolidated) x 2 (sleep times: good or bad) x 3 (recovery period) groups repeated measures design where three groups of drivers are monitored over five days/nights of driving followed by three different recovery opportunities (i.e., 36, 60 or 84 hours off-duty) (see Figure 6). A driving period of three to five days/nights will follow the recovery period.

Comparisons that can be made are the impact of consolidated sleep vs. fragmented sleep on recovery from night driving, and the impact of consolidated sleep vs. fragmented sleep on recovery from day driving.

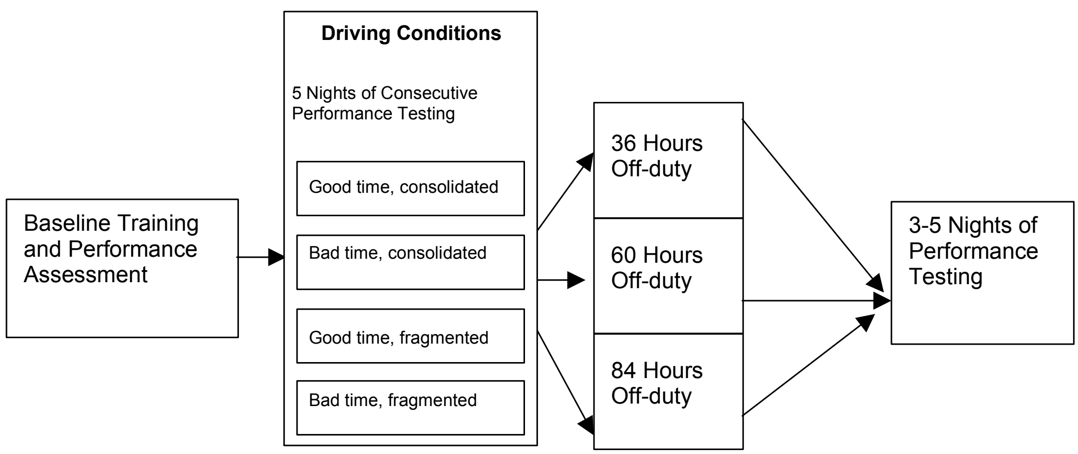

Figure 6 Option 8: Laboratory Study of Impact of Consolidated vs. Fragmented Sleep on Recovery

3.3.2.2 DESIGN AND PARAMETER RATIONALE

The design is a mixed repeated measure design. Sleep time and type (i.e., adequate or inappropriate scheduling), and driving times will be manipulated as well as the amount of recovery time available to drivers. The four sleep conditions will include combinations of good and bad sleep times and good and bad sleep types (consolidated vs. fragmented). Condition 1 is an optimal sleep time and a consolidated sleep. Condition 2 has an optimal sleep time but sleep is fragmented. Condition 3 is a "bad" sleep time but is consolidated. Finally, Condition 4 is at a bad sleep time and is also fragmented. Whenever feasible, the same methods to measure performance as those proposed for field studies will be used.

Drivers will participate in 12 hours of "driving time" (a mix of time in a driving simulator as well as participation in subjective and objective measures of fatigue) for each of the five days. To ensure that the study is not confounded by differential sleep times, each of the four conditions will involve the same amount of time in bed (maximum of eight hours) for each of the five days of the driving conditions. The drivers will have a *total* of 12 hours off (including eight hours in bed) each of the five days. The drivers' total rest times as well as their sleep and drive times are shown in Table 1. If the total sleep opportunity is extended to 10 hours (i.e., consolidated sleep opportunity of 10 hours; fragmented sleep of two periods, neither of which could be less than two hours, totalling 10 hours), then the rest times would start one hour before and end one hour after the times indicated in Table 1.

Table 1 Sleep, Drive and Rest Times for Option 8

	Condition 1: Good sleep time – Consolidated	**Condition 2: Good sleep time – Fragmented**	**Condition 3: Bad sleep time – Consolidated**	**Condition 4: Bad sleep time – Fragmented**
Total Off-duty Times (includes Sleep Times)	22:00 – 10:00	01:00 – 07:00 13:00 – 19:00	09:00 – 21:00	10:00 – 16:00 20:00 – 02:00
Sleep Times (*max. 8 hours*)	24:00 – 08:00	02:00 – 06:00 14:00 – 18:00	11:00 – 19:00	11:00 – 15:00 21:00 – 01:00
Drive Times (*12 hours*)	10:00 – 22:00	07:00 – 13:00 19:00 – 02:00	21:00 – 09:00	16:00 – 21:00 02:00 – 10:00

It is important to note that the times in Table 1 apply to subjects who typically sleep from 24:00 to 08:00. These times can be modified for subjects who are morning type ("larks") and evening type ("owls") individuals. For example, a subject who typically sleeps from 22:00 to 06:00 could have a sleep schedule that starts two hours earlier than the one in Table 1. Similarly, a subject who typically sleeps from 02:00 to 10:00 could have a schedule that starts two hours later.

The drivers in each condition will be given a 36 hour, 60 hour, or an 84 hour recovery time. This will be followed by a subsequent work period of a minimum of three nights and a maximum of five nights.

3.3.2.3 Drivers

Driver characteristics will be as described for Option 1.

3.3.2.4 Measures

The subjective and objective behavioural probe measures used in Options 1-4 will also be used for this study. This study will also incorporate driving simulator performance measures. These measures will be determined in part by the measures available in the chosen driving simulator. Ideally, the performance measure used in Options 1-4, standard deviation of lane position, which has been shown most reliably to be affected by drowsiness, should be used. In addition, as in Options 1-4, the analysis of video of the three minute interval preceding the start of a critical incident may also be used.

In addition to the above measures, the physiological measures described in Option 7 are recommended.

3.4 Epidemiological Studies

3.4.1 Option 9: Epidemiological Study of Impact of Schedule and Recovery Period on Crash Risk

The final study proposed is a case-control epidemiological study similar to that of a study done in 1987 (Jones & Stein, 1987). Data on schedules will be collected for several hundred drivers of trucks involved in crashes, as well as for a control sample of equal size. The number of drivers would be determined based on the degree of accuracy desired in predicting changes in crash risk. The schedule data will include:

- Days worked in a sequence since last period of at least 24 hours off
- Work hours since last period of at least 24 hours off
- Work hours since last period of 7 hours of sleep
- Total hours since last period of at least 24 hours off
- Total hours since last period of 7 hours of sleep
- Number of shifts that included at least 2 hours of work between 24:00 and 06:00
- Percent of work hours since last period of at least 24 hours off that were worked between 24:00 and 06:00
- Length of most recent recovery period (minimum 24 hours)

A control driver will be selected for each crash-involved driver. Controls will be drivers of trucks of a similar type (e.g., tractor-trailer, single unit), on the same section of roadway, on the same day of the week, and during the same two hour time period as the time of the crash. Multiple regression analysis will be used to determine the relationship between work hours since last 24 hour off period, between percent night hours and between the length of the most recent recovery period and crash risk.

In addition, the schedules used in crashes will be input into several of the fatigue models to determine whether the schedule would have predicted a fatigue-related accident. Specifically, the models proposed by Akerstedt (Akerstedt & Folkard, 1995; Akerstedt & Folkard, 1997), Balkin (Balkin, Thome, Sing, Thomas, Redmond, Wesensten, Williams, Hall, & Belenky, 2000), and Dawson and Fletcher (Dawson & Fletcher, 2001) will be evaluated to determine the predictive value of these models. With good predictive value, schedules susceptible to fatigue will be validated by crash data.

4. RESEARCH ETHICS ISSUES

The purpose of this section of the report is to provide future investigators who may implement any of the proposed recovery protocols with the knowledge of research ethics issues so that they can develop a research protocol that is comprehensive and in compliance with current ethical standards. This section begins by providing the rationale for the need to adhere to appropriate ethical conduct and is followed in Section 4.2 by a brief history of the development of current ethical practices. This history is followed by a review of the current ethics regulations in Canada and the U.S. in Section 4.3 and a description of the ethics review process by ethics boards in both countries in Section 4.4. In Section 4.5, a concrete example, based on an earlier study of driver fatigue and its ethical review, is provided. Lessons learned from that process are highlighted in order to provide future investigators with insights in terms of what pitfalls to avoid and what areas to highlight in both the research protocol and the consent form. Following this section, in Section 4.6, specific comments are made with regard to the protocol options proposed in this report and a template consent form for Protocol Option 1 is provided. Finally, guidelines for writing research protocols and consent forms are provided along with a generic template consent form that could be modified by future investigators for application to a final fatigue-recovery research protocol. It is hoped that the discussion of background knowledge, specific regulatory requirements in Canada and the U.S., specific problems associated with previous research protocols in this area, specific issues for some of the proposed protocols in this report, and guidelines for constructing research protocols and consent forms will assist future investigators in developing ethically sound research that protects the safety, dignity and autonomy of their study participants.

4.1 Rationale for Research Ethics

In order to conduct research on commercial motor vehicle driver recovery following fatigue-inducing work schedules, future investigators and sponsors (those financially supporting the project) will need a full understanding of the ethical principles that underpin any responsible research project. This understanding is imperative given the changing ethical climate for research and the adoption of privacy legislation at the federal (Personal Information Protection and Electronic Documents Act – PIPEDA) and the provincial level (e.g., Ontario’s new Bill 31, The Health Information Protection Act, 2003) in Canada.

More importantly, this understanding is necessary to safeguard drivers against potential risks that might be associated with the study. If the investigators keep the safety of drivers paramount then they indirectly protect their supervisors, employers and, indeed, the sponsors of such research by ensuring that this research was carried out in a manner that is consistent with the highest ethical standards expected in research today. If investigators fail to appreciate the ethics involved in research and thereby fail to discharge due diligence in this regard, they fail to protect the subjects of experiments. While it is inevitable that there are unexpected adverse events that can occur in any research study, the evaluation of such events by regulators, courts and the public typically begins with two questions: a) was due diligence carried out prior to any such adverse event? and b) was prompt corrective action taken by the investigator and sponsor?

In general, according to today's ethical expectations regarding the conduct of research, investigators and sponsors have a responsibility to safeguard the interests of subjects in the context of the experimental protocol. In this context, the investigators have a responsibility to disclose to subjects in these studies (commercial drivers) the real and expected or anticipated risks associated with their involvement in the research study. In addition, in such applied research carried out under naturalistic and realistic conditions, the Principal Investigator (PI) of the study as well as the sponsor of the study have the more difficult responsibility to ensure that others involved with the subjects in the studies are: a) aware of appropriate ethical behaviour with regard to the study procedures, b) have committed to the study expectations, and c) can separate these research expectations from other normal job-related expectations within the working environment. If all conditions (especially the latter condition) cannot be met, then the research cannot be conducted.

Another limiting characteristic under current ethical guidelines is that it is unethical to expose individuals to any degree of risk (physical, emotional, privacy, administrative) in research if the science of that research is of questionable merit or if the research is not feasible. Critical to entering subjects in any research is the requirement that the scientific question being asked is deemed worth investigating, and that the question can be answered by their participation (a valid question and a feasible study as noted above). If the science is questionable or cannot be reasonably expected to be achieved by the study proposed, then the study cannot be conducted ethically.

Failure to carry out these duties and responsibilities on the part of the PI and sponsor has consequences. In most jurisdictions, failure to carry out ethical research carries penalties such as the withdrawal of funding for the research as well as potential legal and/or professional action to seek damages or remove professional licensure. In all jurisdictions, the recognition of failing to protect research subjects results in societal censure and a failure of individuals to remain involved in research. In some jurisdictions, such a failure is a violation of law and carries with it those penalties prescribed in the relevant law.

4.2 Evolution of Current Research Ethics Policies and Law

4.2.1 Cruelty to Animals

The modern protection of species from cruelty by humans was evident as early as 1822 in the United Kingdom but it covered only the protection of animals from cruelty. The protection of human beings from cruelty would not follow for more than a century in earnest and some would argue that we are not yet there. Animal experimentation in the United Kingdom was controlled by the provisions of the Cruelty to Animals Act of 1876 based on the work by the Society for the Prevention of Cruelty to Animals. It was not until after the Second World War that such a code was put into place for human subjects in research – some 71 years or several generations after such principles were in force for animals.

4.2.2 Nuremberg Code

The protection of humans in experimentation came about as a result of the Nuremberg trials of Nazi war criminals who conducted medical experiments on those whom they held captive. The Nuremberg Code that resulted in 1947 outlined the types of experiments that could be performed on human subjects, the ethical constraints on those experiments, and the need for strong ethical oversight of experiments on human beings. The Nuremberg Code of 1947 under the section of "Permissible Medical Experiments" (though it generally applies to all experimentation on human beings) states the following:

> The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:
>
> 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
>   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
>
> 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
>
> 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
>
> 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
>
> 5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
>
> 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

(Vollmann, Winau, Proctor, Hanauske-Abel, Seidelman, Weindling, Brentlinger, & Barnouti, 1996)

The Nuremberg Code was significant in establishing the principles of ethics as they applied to research subjects in medical experiments. Although these principles are general in nature, they have been accepted with limited revision by investigators conducting medical and non-medical research since they constitute the fundamental ethical principles that apply to human rights when conducting research.

4.2.3 Belmont Report in the U.S.

Other important initiatives followed, such as the Belmont Report in the U.S. entitled *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* President Nixon proclaimed during the establishment of the Belmont Commission that this would be the greatest export of intellectual wealth from the United States, presumably because it fortified the rights of individuals in their own dignity with regard to their participation in research.

This report was federally commissioned by The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research on April 18, 1979, within the Department of Health, Education, and Welfare. One of the charges to the Commission was "to identify the basic ethical principles that should underlie the conduct of biomedical and **behavioural** [emphasis added] research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioural research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

The Belmont Report summarizes the basic ethical principles identified by the Commission in the course of its deliberations. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. The Belmont Report did not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare at the time but the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. It was later adopted, with minor modifications, into law and has become the basic fundamental document of U.S. policy in this regard.

4.2.4 Tuskegee Experiment

Despite such codes, vulnerable populations continued to be used for research purposes, including prisoners, patients in mental institutions, and, perhaps most importantly, the unsuspecting public. With regard to the last group, perhaps the most notable vulnerable population were those that participated in the Tuskegee syphilis trial carried out by the U.S. Public Health Department. In this trial, the government investigators continued to carry out the naturalistic observation of syphilis in southern, black, primarily sharecropper subjects in the U.S. for decades after effective treatments were available. The infamous Tuskegee Syphilis Study (in which 401 African American men in Alabama were not told they were being "studied" by the Public Health Service for 40 years for "untreated" syphilis) is often cited as the reason African Americans do not trust the health care system and refuse to participate in clinical trials. The Tuskegee Syphilis Study is more generally cited as one of the worst violations of medical [research] ethics and has helped to lead to the legal oversight of Institutional Review Boards and the need for a properly constructed Informed Consent process. The impact of the Tuskegee experiment is often seen, retrospectively, as the American equivalent of the Nazi medical experiments. However, it must be remembered that this study continued in the U.S. after the adoption of the Belmont report and after the Nuremberg Code. Tuskegee was not an isolated example and numerous other examples exist. This fact highlights the need to keep ethical principles paramount and the protection of our subjects in research studies at the leading edge of our deliberations and thoughts.

4.2.5 Contemporary Ethics Expectations

While such examples are rare today, the U.S. established an Office of Human Research Protection (OHRP) in 1998 to monitor adherence to research ethics principles. Since that time, there have been findings by OHRP that have closed research operations at the Children's Hospital in Los Angeles, Duke University (a pre-eminent medical university in the U.S.) and Johns Hopkins University (the largest federally funded research organization in the U.S.). Canada does not have such a powerful oversight body and does not have a broadly based oversight body enshrined in law. In 2001, however, Health Canada enshrined in law the need for ethics oversight (Research Ethics Boards) for all clinical trials conducted in Canada. In addition, some provincial legislatures have either enacted privacy legislation or are in the process thereof (e.g., Bill 31 in Ontario) to ensure that the confidentiality of subjects of research are protected from the inappropriate collection, use and disclosure of their personal information. Neither Canada nor the U.S. has comprehensive legislation to enshrine the rights of individuals who participate in research in general. However, in terms of a project supported by federal departments in Canada and the U.S., there is such protection for subjects. In Canada, all federal departments are expected to adhere to the Tri-Council Policy Statement (TCPS) governing research that is supported by public funding at the federal level. Similarly, the U.S. federal departments are expected to adhere to the law that governs the federal distribution of funds for research purposes in the U.S. Thus, in the specific case of such research under consideration in this report, there is an expectation that all relevant ethical principles adopted at the federal level will be adhered to by government departments, contractors, and investigators.

It is generally recognized in the ethics community that more strict adherence to such ethical principles is needed so that we do not, for the best of scientific and societal reasons, embark on research studies that cannot be supported by the highest ethical principles. Moreover, since experiments on motor carrier issues have often involved Canadian and U.S. drivers, there is an obligation that the laws, regulations and guidelines put in place at the federal level in both countries be vigorously enforced by sponsors of contractors and investigators (and the businesses from which they accrue drivers to studies) to meet current ethical standards.

4.3 Current Research Ethics Regulations in Canada and the U.S.

As this project is currently conceived as a Canadian project, it must conform to the Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans (1998). The TCPS is not enshrined in law in Canada for all research except as it applies to clinical drug trials as outlined in the Food and Drug Act Division 5 that became law in 2001 (see Gazette Part II 2001). Even if the TCPS is only enshrined in law for clinical trials, it is expected that all federal government departments comply with the TCPS. Moreover, as this is the ethics policy of the land, it is expected that all research investigators and their sponsors comply with this policy. All universities, research institutes, and research-oriented companies (biomedical, pharmaceutical, etc.) have accepted the TCPS as their code of conduct with regard to ethics. Finally, if such research involves clinical trials (i.e., that type of research involving the assessment and evaluation of new pharmacological agents or investigative devices for health research), as of 2001, new Health Canada regulations require, under law, compliance with the TCPS. In addition, such regulations for health research also fall under the international treaty of the International Committee on Harmonization: Good Clinical Practices, of which Canada is now a signatory for such medical clinical practices.

While there can be arguments in Canada with regard to whether the TCPS applies to specific research in studies that are not clinical trials and do not receive any federal or provincial funding (such as private research institutes and corporations), it is clear that the review of research protocols by duly constituted review boards (known in Canada as a Research Ethics Board (REB) and in the U.S. as an Institutional Review Board (IRB)) is necessary and constitutes the only argument acceptable in the court of public opinion (much less a court of law).

As this study is likely to be carried out under U.S. jurisdiction as well, it should be noted that the REB/IRB, investigators and sponsors also need to meet the U.S. regulations outlined in Title 45 – Code of Federal Regulations Part 46 – Protection of Human Subjects and current requirements by the Office of Human Research Protection under the Department of Health and Human Services. Such U.S. regulations have weight in law.

As a general rule all research carried out on human subjects in North America is expected to follow the regulations and principles stated in:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canada)
- Health Canada Food and Drug Act Division 5 (Canada)
- Title 45 – Code of Federal Regulations Part 46 – Protection of Human Subjects (U.S.)
- Title 21 – Code of Federal Regulations Part 56 – Guidance for Institutional Review Boards and Clinical Investigators (U.S.)
- International Conference on Harmonization (ICH)/World Health Organization Good Clinical Practice (unified standard for the European Union (EU), Japan, and the United States, based on current good clinical practices of those countries as well as those of Australia, Canada, the Nordic countries and the World Health Organization)
- Declaration of Helsinki – Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (International)
- Requirements as determined by the Office of Human Research Protection under the Department of Health and Human Services (U.S.)

4.4 Common Ethical Principles and the Ethics Review Process

The guidelines, regulations and laws listed in Section 4.3 are codified and updated applications of earlier statements from the Nuremberg Code and the Belmont Report. However, in general, ethics refers to the principles of right conduct guiding “what ought to be done”. The TCPS refers to the following ethical principles that are commonly held and valued across diverse research disciplines:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits

In all the guidelines an independent REB (Canada), IRB (U.S.) or Ethics Committee (European Union) is responsible for ensuring that all research carried out on human subjects is reviewed for both the scientific value of the study as well as the adherence of investigators to the ethical guidelines already outlined. Under regulations in Canada/U.S., the REB/IRB is composed of at least five members from the following broad areas:

- At least two members who have broad expertise in the scientific methodology, and research in an appropriate area of study (i.e., fatigue and transportation in this case)
- At least one member who is knowledgeable in ethics
- At least one member who is knowledgeable in relevant law
- At least one member who represents the community and society’s perspective

Most review boards have eight to twelve members (though medical review boards often have 12 to 20 members or more due to the complexity of the trials and risks) so that multiple and diverse perspectives are represented.

The REB/IRB is responsible for reviewing the science and the ethics of proposed research involving human subjects. The REB/IRB is not only responsible for providing the initial approval of such research but also for ongoing monitoring of that research until its conclusion. All changes to the protocol or the consent form must be reported to the REB/IRB and cannot be implemented until approval is granted. Moreover, all unexpected and serious adverse events that might arise from the research (such as an accident or incident that may have a possible relationship to the procedures in the study) must be reported to the REB/IRB. The REB/IRB has the authority to withdraw its approval and thereby put the continuation of the study on hold or direct the investigators/sponsors to stop the study prematurely and perhaps permanently.

In general, the ethics review process first must determine that the proposed protocol (in this case for the assessment of driver recovery following fatigue) is acceptable from a scientific perspective. From an ethical perspective, bad science is bad ethics. If the question being asked by the protocol cannot be answered scientifically by the proposed methodology, it is unethical to expose subjects (drivers) to the experimental procedures. Similarly, if the study is not sufficiently funded to be completed then it would be unethical to enrol subjects in the study.

Once the science has been deemed to be acceptable and the funding is sufficient to make the study feasible, the REB/IRB can deliberate the ethical issues that might be involved in the protocol. These issues include, but are not limited to, the following and investigators should address these issues in their initial submission to the REB/IRB:

- Who are the subjects for the study?
- Where is the study carried out (jurisdiction)?
- How will potential subjects be identified and recruited?
- How much time will subjects be given to review the consent form and make an informed decision concerning their participation?
- Is there any relationship between the investigator and research subjects?
- Is there any relationship between the study sponsor and research subjects?
- Are there any special considerations with regard to the study subjects that would make them more vulnerable (employees, health risks, etc.)?
- Is there any remuneration involved and is it sufficient to induce the study subjects to remain in the study against their better judgment?
- How will confidentiality be protected?
- Are there any conflicts of interest?
- How do the requirements of this study differ from the normal requirements of this study population?

Once the scientific and ethical issues have been addressed with regard to the research protocol itself, the REB/IRB must review and approve the informed consent form. Two issues are paramount regarding the consenting of subjects for research studies. The first issue for investigators to understand is that the informed consent process is a process that starts when subjects are initially considered and approached for a research study and does not end until the subject is no longer involved in the study. It is an ongoing process and any changes that might be pertinent to the subject's decision to continue to participate in the study must be disclosed so that the study subject can decide whether or not it is in his or her best interests to remain in the study. The informed consent process is not simply the signing of a piece of paper. The informed consent process stresses the ongoing relationship between the investigator and the study subject that is intended to protect the rights, safety and dignity of the study subject. It is the continuing obligation and responsibility of the investigator to ensure ongoing, knowledgeable and informed consent.

The second issue is that the investigator must fully disclose to the study subjects the nature and the purpose of the study, the procedures that will be employed in the study, the risks associated with the study, the voluntary nature of their participation, their right to withdraw from the study at any time, and the contact information for further questions. While there is more detail in the template consent form provided in Section 4.6.4, consent forms should include at least the following sections:

- Title describing the purpose of the study
- Identification of investigators and sponsors with contact information
- Background and study purpose in lay terms
- Expectation of participants
- Procedures and possible adverse events
- Risk (e.g., loss of licence due to medical screening, increased risk of accidents, unknown risk associated with driving)/benefits
- Alternatives to participation
- Voluntariness of participation
- Confidentiality protection
- Compensation, remuneration, or expected costs for participants
- Non-waiver clause indicating that signing the consent does not constitute waiving any legal rights
- Contact information to withdraw or to seek advice from an independent third party

All of this information must be in a form and language that allows for full comprehension by the study subject. If the subject cannot understand the consent form then there is not full disclosure and the subject is not fully informed. Any decision made by the subject that is not based on full disclosure does not constitute a free and informed choice by the subject.

4.5 Insights from Previous Commercial Motor Vehicle Protocol Submission

Numerous studies on driver fatigue have been conducted over the years, although only some of those studies were reviewed by ethics review boards. This section is intended to provide a “lessons learned” example of the pitfalls that a previous study confronted when seeking ethics approval for a driver fatigue study. For reasons of confidentiality, the study details will not be revealed nor the study exposed. Moreover, it is unnecessary. The purpose here is to provide a concrete example of issues raised in the review of the study and to provide guidance to future investigators who might carry out the recovery project that evolves from this report. Details that could identify the study specifically by the public are eliminated to protect the confidentiality of reviewers, investigators and sponsors. Having said this, this was a study examining fatigue in commercial drivers.

The review process was conducted in two separate jurisdictions, each operating under its own guidelines and laws. In one jurisdiction, the review board was an IRB and in the other, it was an *ad hoc* ethics board (EB) created to review this protocol, that remained in force through the duration of the protocol. In this way the EB remained in force to monitor the project, review amendments to the protocol or consent form, and review any serious adverse events. Each board was constituted according to its own local regulations.

The fundamental issues, summarized here for guidance purposes only, were the following:

- From a scientific and ethical perspective, the EB felt that the project had scientific merit and was well designed overall. Moreover, the EB considered this study to be important from a societal perspective with regard to developing methods of reducing fatigue.
- The IRB and the EB concurred that the study should be considered minimal risk, given that the drivers were professional, were going to be selected on the basis of a safe driving record and would not deviate from current accepted standards regarding hours-of-service regulations.
- Concern was raised with regard to the potential of a motor vehicle accident, which is always present in such studies and which demonstrates the need for vigilance and critical review of details.

In terms of specific concerns the following issues emerged:

- The protocol was submitted prematurely and appeared to be more of a work in progress than a final document. This submission left the EB in a position of uncertainty with regard to what it was potentially approving. This was an untenable position for the EB. The fundamental ethical principles of Respect for the Autonomy and Dignity of Persons, Justice and Beneficence were potentially jeopardized since the EB could not properly assess the disclosure in the consent form. Without assurances from the protocol itself, the EB would have no choice but to await a further submission for review. In summary, future investigators should ensure that the document is complete. Guidelines for writing a complete protocol document are given in Section 4.8.
- The concern was raised as to whether the study was sufficiently “naturalistic” as to yield information that was generalizable to the “real” working environment. In this respect, the concern was raised as to whether, given the conspicuousness of the study for the industry, companies could realistically commit in the study to comply with existing regulations or prompt dispatchers to put participating drivers on less time-sensitive routes or “non-naturalistic” (less demanding) schedules. It was questioned whether economic and industry demands would allow the company to fulfill its ethical obligations. Future investigators should comment in their submissions on the steps taken to maximize the representativeness of the study procedures, the possibility of generalizing the results and their expectations of industry compliance with the obligations of the study.
- Not all instruments of assessment were included. Again the EB did not have complete information on what it was approving. Future investigators should ensure the completeness of the study.
- There were inconsistencies between the protocol and the consent form. Full disclosure could not be guaranteed in an environment of ambiguity.

- The budget was not included with the study so the feasibility of the study could not be assessed. Future investigators should submit, in confidence, the study budget in order to demonstrate the feasibility of the study and assure an REB/IRB that incentive payments do not exist.
- The EB noted that unique questionnaires were included in the study but there was no information concerning the validation of those questionnaires. Future investigators should ensure that all relevant materials are submitted to the EB.
- Some of the auxiliary interventions (e.g., educational material, training material, company documents) were not included for review. Again, this reflected a lack of completeness.
- There was a reference to a jurisdictional requirement from one EB that was directly in opposition to the jurisdictional approach of the other EB. Future investigators should be sufficiently aware of jurisdictional differences to elaborate for each review board procedures that may be different in order to accommodate jurisdictional difference.
- The EB was concerned about certain procedural issues that potentially limited the discretion of individual drivers or may have been potentially coercive. Drivers need to be free to make their own safety decisions with regard to driving and need to make these decisions without potential coercion. In this regard, the EB noted that the drivers were not explicitly held accountable, based on their own best judgment under normal circumstances, for their own best practice. The consent form needed to be modified in this regard. Future investigators should include sufficient detail to convince the EB that no coercion exists and that subjects have sufficient autonomy to make informed choices throughout the study. Procedures that reflect the preservation of subject rights need to be included.
- The EB questioned whether drivers would realistically have the opportunity to make such individual decisions based on the fact that the routes were revenue-generating routes. In addition, it was questioned whether the trainers were qualified to deliver the training, whether the training was sufficient for the trainees and whether the training would be retained by the trainees. Future investigators should detail the reliability and validity of their procedures.
- From a privacy and confidentiality perspective, the EB questioned how the drivers would be allowed to implement decisions that they felt would be safety sensitive. This question again reflected the lack of detail in the submission and future investigators should be aware of the need for detailed *a priori* procedures to ensure the safety of participants.
- The EB noted that some of the inclusion/exclusion criteria were neither defined nor feasible. Future investigators should precisely define the inclusion/exclusion criteria and document how these criteria will be satisfied.
- The EB noted that there were no stopping rules for the study. The question was asked "at what point, and using what monitoring criteria, would drivers be withdrawn from the study for safety reasons. If they are withdrawn from the study, how are they protected from their employer? Even if they are not withdrawn, what are the protections from the employer with regard to not following the company requirements for the delivery schedules? Will disciplinary procedures be suspended for the duration of the study (except for safety violations)?" Such questions should be addressed by future investigators.
- The EB was concerned about protection of drivers from third parties who might have knowledge of the data being collected in the study, but not be party to the confidentiality protection. The EB was concerned that the collection of objective data on performance and state of alertness from this study could expose drivers to

legal consequences beyond their normal exposure, particularly in the event of a crash. Future investigators should have explicit plans to protect the safety and confidentiality of study participants. Where participants are potentially at greater risk through their participation in the study, this risk needs to be disclosed in the consenting process to drivers.

Finally, the consent form needed to be revised in the following areas:

- The details of the consent form needed to reflect the time frame, details and protocol specifications of the final protocol.
- A non-waiver clause for protection of adverse events should have been included (e.g., "By signing this consent form, you are in no way waiving your legal rights nor releasing any of the investigators on this study from the professional responsibilities or liabilities").
- What was covered and not covered by insurance needed to be specified.
- How long the data would be kept should have been stated if the data was to be kept with identifiers. If not, it was not necessary.
- The informed consent should have been on the investigator's letterhead.
- Standard sections of consent forms should have been utilized (Introduction, Purpose, Procedures, Risk/Benefits, Alternatives (i.e., not participating), Confidentiality, Compensation, Voluntariness, Contact Information, etc.).

These are but some of the changes that could be required as part of the review process. It is anticipated that this example will provide insight for future investigators so that the pitfalls of earlier investigators can be avoided.

4.6 Ethical Guidance for Proposed Fatigue Recovery Protocol Options

This section of the report discusses, from a research ethics perspective, the primary experimental protocol options identified in Section 3. For the most part, similar issues arise in the options provided so they can be discussed somewhat generically.

4.6.1 Naturalistic/Operational Commercial Driving

Most of the studies proposed involve naturalistic driving on operational revenue-generating routes. In this circumstance it is important to ensure that these routes are indeed typical, operational, and revenue-generating routes so that the fatigue that results from driving will be at a level consistent with drivers' everyday experience. Investigators are cautioned about manipulating the driving conditions to enhance fatigue for two reasons. First, the purpose of the proposed studies is to examine driver fatigue in the most naturalistic, operational setting as possible in order to make the results most generalizable. While artificial driving scenarios may lead to greater experimental effects, such results ultimately do not garner support from the industry or commercial drivers. Questions can be asked such as "how does this work apply to me or my industry?" In order for the results to be generalizable and pragmatic, normal routines must be considered unless there are specific experimental concerns that override these issues. In short, if the protocols selected do not represent commercially viable routes to many in the industry, and to drivers in particular, then the results are likely to be questioned and rejected.

The second reason to keep the driving conditions as operational as possible is to limit the liability and responsibility of the investigators and the sponsors. Both the law and guiding ethical principles do not normally expect or require investigators or their sponsors to accept responsibility or liability in terms of the normal day-to-day activity of research subjects. However, there is an obligation to accept the responsibility and liability associated with practices that require research subjects to extend their duties or risk beyond that which is normally acceptable in their day-to-day activities. In the same way that if a driver is asked to accept additional work that might generate fatigue and result in an accident for which the driver and company may be liable, so too is the investigator and sponsor additionally equally responsible in the case of a research study.

While some responsibility and liability are acceptable to investigators and sponsors in order to get answers to their experimental questions, it is recommended that, in the area of driver fatigue, the risks be kept to a minimum. By keeping driving schedules to operational revenue-generating routes that also conform to the legal hours-of-service regulations, increased risk will be minimized and generalizability will be maximized.

The proposed experimental protocols are designed to use driving schedules typical of normal revenue-generating schedules as much as possible so the deviation from normal commercial operations is minimized. In this way driver schedules (day or night driving) yield maximally generalizable results and minimize the risk exposure of drivers, investigators and sponsors.

4.6.2 Full and Frank Disclosure to Drivers

One of the primary requirements of investigators and sponsors is to fully and frankly disclose to drivers the potential risks associated with their participation in the study and the expectations of them as participants in the study. The way in which this is done is known as the informed consent process. This process is a continuous process and not just a form describing all aspects of the study. The informed consent process begins when a driver is recruited and does not end until his or her relationship with the study is completed. The investigator and sponsor have the obligation to keep this as a dynamic process in which any changes to the study, following the initial agreement by the driver, are relayed to the driver if it might substantively affect the decision to remain a participant in the study.

In the field protocols proposed, it is important that the major risks to the driver are disclosed. For instance, if exposure to the study will result in video-recording of a driver’s face, potentially providing evidence of sleepiness, such a recording could be subpoenaed in the event of a crash and used to prove that the driver was at fault. This is a real possibility and must be disclosed as a risk to drivers.

4.6.3 Specific Aspects of the Proposed Protocol Options

4.6.3.1 Rest Prior to Beginning of the Study

It is recommended that drivers be given at least 60 hours of rest immediately before beginning any driving schedule. From an ethics perspective, the decision was made to conform to normal operations. Based on expert advice at the 2003 Workshop in Montreal and data from the questionnaire, it appeared that most drivers would have at least one and probably two days off before beginning a long period of work. Minimizing the time off prior to starting the driving schedule (one day), as well as maximizing the time off (three to four days), were considered. It was decided that minimizing the time off could result in greater fatigue and affect driver recovery measures; moreover, it was felt that minimizing the time off would be somewhat artificial and expose drivers, investigators and sponsors to increased risk. Maximizing time off would result in well-rested drivers; however, it was felt that this was not representative of drivers' normal schedules and could minimize the impact on driver recovery since drivers would begin the fatiguing driving schedules more rested than would normally be the case. A compromise to mirror the usual driving schedules, as far as could be determined, was the choice for the baseline rest period.

4.6.3.2 Daily Sleep

Few restrictions are placed on daily sleep in the recommended protocol options. It is recommended that there be a minimum daily sleep of five hours but there is no restriction on how or when that sleep is obtained. It is assumed that all drivers will operate with the hours-of-service regulations that require more off-duty time than five hours so this recommended minimum is well within the expectation under current regulations. Again, since these protocols are intended to be as naturalistic as possible, the lack of restriction on daily sleep is intended to keep the driving/sleeping schedules as naturalistic as possible. One caution to this naturalistic approach concerns changes that can occur in local regulations. For instance, since the hours-of-service regulations are likely to change in Canada and have changed in the U.S., daily sleep requirements will be dictated by local regulations within jurisdictions. This may change the acceptable practice in local jurisdictions, and experimental parameters may need to be adjusted.

4.6.3.3 Driving/Drivers

In determining driving schedules and driver selection criteria, our goal was generalizability based on our survey of driver schedules. For purposes of classifying the type of shift worked by the drivers, "mainly day driving" was defined as no driving between 24:00 and 06:00 hours; "day driving with some night driving" was defined as no more than two hours driving between 24:00 and 06:00, and "mainly night driving" was defined as two hours or more driving between 24:00 and 06:00. With respect to night driving, 19 percent of drivers stated that all of their shifts involved driving two or more hours between 24:00 and 06:00. Thirty-six percent of drivers would be considered day drivers since they said that none of their shifts involved driving two or more hours during this time period. The remaining 45 percent of drivers would be considered drivers who did day with some night driving. The results from the questionnaire also indicated that if driving schedules included day with some night driving, fatigue was greater than day driving and even greater than only night driving.

Since the survey was carried out between 07:45 and 22:00, the actual percentage of night drivers so defined is likely higher. Given the distribution between the three types, with substantial numbers in each group, it seems a reasonable categorization to use for the protocols.

With respect to driver selection criteria, it was decided to select any driver who passed the company physical in order to adhere to current standards and to minimize the risk to drivers, investigators and sponsors associated with the discovery of unknown medical conditions. No other restrictions on drivers are recommended in order to have the driver samples as representative as possible.

4.6.3.4 Performance Measures

Various subjective and objective behavioural probes are recommended for these protocol options. With one exception, these measures are not directly related to driving performance and it would be difficult to argue, in the event of an incident, that such measures would accurately reflect momentary driving performance. The exception is lane tracking, which could be more convincingly argued to be related to driving performance.

From an ethics perspective, it must be disclosed to drivers that the measures obtained in the study may be subpoenaed under the law in the event of an accident or incident.

4.6.3.5 Company/Dispatcher/Shipper Agreement

From an ethics perspective, the investigators need to assure drivers of: a) the procedures to be employed in the study, b) the confidentiality of the information collected in the study, c) the voluntary nature of their participation, and d) their freedom to withdraw from the study for any reason at any time without the need for justifying their decision. In order to make such assurances feasible and ethically acceptable, the appropriate representatives of the company, their dispatchers and perhaps specific shippers must agree to the conditions of the study. An investigator cannot make such a commitment to a driver through an informed consent process without the commitment of these other parties. Therefore, all participants involved in the study should be committed to the ethical aspects of the study, including protecting the rights of the driver as outlined in the informed consent.

4.6.4 Field Protocol Options 1 – 3: Ethics Considerations

The general ethics considerations related to the primary field study protocol options are outlined in Section 4.6.3. Essentially, drivers need to be informed of the procedures to be carried out in the study, that their participation is voluntary, and of the risks associated with the study. Drivers need to be informed of these considerations in a way that is understandable and non-coercive. A template informed consent form is offered for protocol Option 1. This template will need to be changed and adjusted as the details of the experimental design are finalized. The other proposed protocol options will need revisions in the rationale for the study and the procedures based on the differences between the protocols.

While a specific consent form is provided below for the Field Protocol Option 1, the changes are relatively minor for Options 2 and 3. For Option 2 the four consecutive night conditions would need to be described, including the information that drivers will be randomized to either four or five consecutive nights of driving rather than to different recovery conditions. There are no other ethical issues involved with this option. For Option 3, only the day driving condition needs to be described, but otherwise this option is very similar to Option 1. Perhaps the only ethical issue that needs to be addressed is that it would be expected that those assigned to the night driving may experience more fatigue than those assigned to day driving. Thus, relative to the day driving condition, the night driving condition may lead to greater fatigue but that fatigue is within the normal expectation of drivers.

(Letterhead)

TEMPLATE CONSENT FORM FOR PROTOCOL OPTION 1

INVESTIGATOR:
Dr. X. Y. Smith
Director of the Research Institute
Address
Phone

TITLE: A Randomized Field Study on Driver Fatigue and Recovery: Comparing the Effects of 36 and 60 Hours Off-Duty Following Five Consecutive Nights of 9 to 12 Hours of Commercial Motor Carrier Driving

SPONSOR:
Transportation Development Centre, Transport Canada
Montreal, Quebec

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

Purpose

Fatigue in commercial drivers has been of concern for some time and has prompted the development of new regulations to minimize fatigue. One of the questions that needs to be resolved in the area of driver fatigue is how much recovery time is needed following a fatigue-inducing work schedule to again drive safely. You have been asked to participate in a study that is designed to help find out how much recovery time is needed for drivers, who are driving normal revenue-generating routes within the hours-of-service regulations of the appropriate jurisdictions, to drive safely. This information will help our understanding of fatigue and recovery and may influence policy makers in the future with regard to driving regulations.

This is a randomized study with two recovery conditions. In this study you will be randomly assigned (by a process like the flipping of a coin) to either a 36-hour or 60-hour recovery period. It is expected that 24 commercial drivers will be assigned to each condition. Your participation is entirely voluntary and you can withdraw from the study for any reason and at any time without it affecting your employment.

Procedures

The study will begin with an assessment of whether you are eligible for the study. You are eligible for the study as long as you are medically fit as determined by your company and are willing to participate in this study voluntarily. To get other basic information about you and your driving, we would like your permission to review and collect information about your previous driving experience and health problems from the company's employment information. Once it is determined that you are eligible, you will be familiarized with the requirements of the study and trained on any equipment or tests, such as the reaction time test, that are required in the study.

In this study you will be asked to drive a normal revenue-generating route within the applicable hours-of-service regulations in the jurisdictions in which you will be driving. You will be asked to drive five consecutive nights where at least two hours of that driving occurs between 24:00 and 06:00 on at least four out of five nights. It is also expected that your normal daily driving schedule will require 9 to 12 hours of driving. Following this driving routine you will asked to take 36 or 60 (+/- 4) hours off to recover from this work schedule. You will then be asked to return to work for at least three but not more than five consecutive nights of driving similar or identical to the routes driven during the first set of five nights. At all times in this study, you should always exercise your own judgment with regard to your ability to drive and only drive if you feel that you can drive safely.

The study will involve measuring your perception of fatigue and sleepiness during periods of driving as well as collecting more objective measures of reaction time. You will be asked to complete several brief questionnaires related to fatigue and sleepiness (less than ten minutes total each time) and do a reaction time test (called the Psychomotor Vigilance Test, which takes about ten minutes to complete) at the beginning, middle and end of each night's driving. Depending on when you start and end the night driving period, we will ask you to complete the questionnaires and do the reaction time test within three of the following two-hour windows that best estimate the beginning, middle and end of each driving day: 09:00-11:00, 13:00-15:00, 18:00-20:00, 22:00-24:00 or 03:00-05:00. Depending on your schedule, you may be asleep during one or more of these windows. You do not need to complete the testing if you are sleeping.

In this study, your sleep will be assessed using an Actigraph. An Actigraph is a wristwatch device that records arm movements and allows the study investigators to determine whether you are awake or asleep over the many days. You will be asked to wear this device for the entire time you are in the study (apart from showering).

In addition, your vehicle will be fitted with instrumentation that will allow lane-tracking measures of your vehicle to be collected. These data will be used to assess how your driving changes during this study.

Risks

There are no serious anticipated risks with this study because the driving that you will be doing will be normal operational driving for you. You will not be asked to operate outside of your normal driving schedules or outside of the driving regulations in the jurisdiction that you are driving. None of the testing procedures carry any inherent risk or interfere with your ability to operate the vehicle.

While every precaution is being taken to try and ensure that this study is naturalistic and only involves experiences that you have on a regular basis, it is possible that by participating in this study you may experience greater levels of fatigue than you normally experience. If this is the case, you should use your best judgment with regard to handling fatigue during this study. Your safety is our first concern and you should feel free to change any aspects of this study to ensure your safety, including withdrawing your participation in this study.

In the unlikely event that an incident or accident occurs during this study, information gathered about your fatigue and performance levels will be kept confidential unless otherwise required under law. There is a risk that these research records could be subpoenaed under law.

Benefits

The study may not benefit you directly. The results, however, may advance our understanding of fatigue and recovery and may influence future policy decisions.

Confidentiality

All information obtained during the study will be held in strict confidence unless required by law. No information will be released to the company, sponsor or any regulatory authority unless all identifying information is removed. No names or identifying information will be used in any publication or presentations.

Participation

Your participation in this study is voluntary. Your can choose not to participate or you may withdraw at any time without affecting your status as a driver. If you choose to withdraw from the study, you do not have to provide a reason for that decision.

Compensation

If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. [This statement will need to be adjusted according to the jurisdiction and relevant laws.] The reasonable costs of such treatment beyond that provided by your insurance will be provided by the investigator and sponsor for any injury or illness that is directly a result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

Questions

If you have any questions about the study, please call Dr. X. Y. Smith at phone number. If you have any questions about your rights as a research subject, please call Dr. Ethics, Chair of the Ethics Board that reviewed this study, at phone number. This person is not involved in the study.

Consent

I have had the opportunity to review and discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study with the understanding that I may withdraw at any time without affecting my status with the company or as a driver. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

Subject's Name (Please Print) Signature Date

I confirm that I have explained the nature and purpose of the study to the subject named above. I have answered all questions to be best of my ability.

Name of Person Obtaining Consent Signature Date

4.6.5 Field Protocols Options 4 – 6: Ethics Considerations

The only additional ethical considerations in Options 4, 5, and 6 are related to individual differences. These options describe protocols that are based fundamentally on either Option 1 or 2 but add to that recovery protocol the selection and assignment of specific types of drivers to the conditions.

In Option 4 drivers who are nappers and non-nappers will participate in the recovery study twice. The first time through the recovery protocol, the impact of their habitual napping or non-napping will be assessed in terms of whether different levels of fatigue develop and whether different amounts of recovery time are necessary. Prior to the second time through the recovery protocol, both nappers and non-nappers will be given strategic education to optimize their use of naps and the impact of this more strategic napping (for both groups) will be assessed in terms of recovery needs.

While protocol Option 4 involves the selection of specific drivers for the study, they are being selected on the basis of habitual napping patterns with regard to their normal driving routines. Thus, Option 4 remains a naturalistic study and there are no special ethical considerations. Moreover, there is no *a priori* reason to suspect that either habitual nappers or habitual non-nappers will be more at risk or receive more benefit from their napping ritual. It could be that the napping strategies are beneficial or it could be that these habits are simply individual differences. This study will help to sort out whether such differences between individuals are related to their preferences based on individual experience or simply a product of their individual biologies. In either case the consent forms would need to include a description of the rationale, the method of selection of these classes of drivers, and a description of the education requirement in terms of its content and effort.

Option 5 is similar to that of Option 4 except that drivers will be selected on the basis of whether they usually take consolidated or split sleep during the work schedule. Again no special ethical considerations present themselves and consent forms would need to be adjusted accordingly.

Option 6 consists of two options. Option 6A presents no special ethical consideration since the variable under study (i.e., self-perception of fatigue) will simply be used as a covariate. There are no changes in study procedures or the analysis.

Option 6B does require special ethical consideration. In this option, the driver's self-perception of fatigue will be used to assign him to her to an experimental condition. There are several considerations with regard to this option. First, this option relies on a laboratory study to validate a questionnaire that will validate drivers' self-perception of fatigue by experimentally inducing sleep deprivation effects. Second, to the extent that this assessment of increased risk of fatigue is true based on the results of the experimental study, more vulnerable drivers (i.e., those at higher risk for fatigue related to night driving) will be assigned to night driving conditions. This creates a potential for increased risk for these drivers. This risk must be disclosed to drivers and specific procedures should be in place for increased monitoring of these more vulnerable drivers. Given that this increased risk and vulnerability of some drivers is possible, an enhanced surveillance system is recommended for drivers in such a study. In addition, enhanced attention to this issue should be addressed in the submission to the ethics committee, which will review such a study since the potential vulnerabilities are clear.

It should be noted, however, that such questionnaires for selection (e.g., self-perceived fatigue) are rather inexact. In addition, other factors such as age, medical conditions etc. are known to create increased vulnerability, but with appropriate safeguards, such individuals are routinely invited to participate in studies. This study should be considered but with the enhanced precautions detailed.

4.6.6 Laboratory Protocol Options 7 – 8: Ethics Considerations

Options 7 and 8 are laboratory studies. As laboratory studies, risks are reduced relative to field studies where drivers are exposed to risks in a more vulnerable environment. Given that in these studies fatigue effects are likely to have little consequence, compared to field studies, the risk is reduced. Nonetheless, the need for full disclosure remains in force as does the need for monitoring by investigators.

Option 7 involves assessing the self-perceived susceptibility to fatigue and drowsiness while driving by developing a questionnaire, using that questionnaire to select and/or classify subjects according to their degree of susceptibility, and then testing the validity of the self-perception in a laboratory study. The validity of self-perception is tested by sleep depriving individual drivers to assess the fatigue levels overnight and then giving them a minimum sleep period to assess their recuperative abilities following such a fatiguing experience.

From an ethics perspective, this study involves fully informing drivers of these conditions and guaranteeing their confidentiality with regard to the results. These results are more likely to be kept confidential than would be the case in an on-road study since such results would not be acceptable as evidence in an unrelated civil action. Nonetheless, it remains a possibility that in the event of a participant being involved in an incident during his or her normal course of employment, such research records could be subpoenaed, though evidentiary value would be minimal. Nevertheless, with professional drivers such a minimal risk should be disclosed. This is not unlike some medical studies where the perforation of an artery during surgery may only occur at a rate of 1/10,000. Such a serious risk needs to be disclosed in order that the subject can decide whether to participate in the study.

The other risks in such a study relate to the collection of physiological measures. This is a usual risk in laboratory studies and the known risk ratios for the collection of certain common types of biochemical/physiological measures are well documented and only need to be documented in the consent form.

Option 8 is essentially another laboratory experiment. The same comments apply to this study as applied to Option 7. While the content is different, the same ethical principles apply.

4.6.7 Epidemiological Protocol Option 9: Ethics Considerations

The final Option 9 involves an epidemiological study where data will be collected for several hundred drivers of trucks involved in crashes and for a control sample of equal size.

Since this study does not involve the identification of individual drivers at risk of accidents, the risks are minimal. For drivers who have been involved in accidents, this is a matter of public record so the risk to these individuals is not increased by research into these incidents. However, without the protection of confidentiality, the risk of future consequences for these same drivers may be enhanced. Thus, this research proposal should consider the privacy rights of individuals already judged in the court of public or legal opinion. Drivers in the control group have not been involved in an incident so the risk is negligible.

Thus, Option 9 generally carries little risk for drivers who would participate. From an ethics perspective, the primary concerns would be around feasibility and confidentiality. For the experimental cohort involved in crashes, it would need to be determined whether there would be any need to contact these drivers to gather the fatigue-related information. If so, is a sample of several hundred drivers feasible since there could be some reluctance on the part of these drivers to cooperate with investigators? If the experimental cohort of drivers is not going to be contacted, how will such specific information be obtained? If such data is contained within the public record, such as through the judicial or police systems, then there is no ethical issue. However, if these specific data can only be gathered from private sources (company records, insurance records, government databases, etc.), then the question of confidentiality is raised. Given the new privacy legislation in Canada and other jurisdictions, obtaining such confidential information for research purposes may prove to be difficult. Investigators would need to make sure that their procedures are acceptable under the appropriate privacy legislation.

There is a need to protect absolute confidentiality by preserving complete anonymity in the collection of such data. If absolute confidentiality cannot be preserved then there is a risk of exposure for drivers. In this case, drivers must be informed of this risk and be willing to accept such risk, before such information is collected and used. It is recommended that only anonymous information be collected. If it is necessary that identified information be collected for research purposes, then the risk needs to be clearly understood by the drivers and the implications clearly stated. It should be noted that guaranteed anonymous data is likely to provide better estimates of circumstances under investigation than potentially identifiable data, which is not in the self-interest of drivers.

The question of confidentiality arises for both the experimental and control cohorts if these fatigue-related data were to be linked to other databases that exist. It is common in such studies to link data on individuals in one study to a myriad of data existing in other databases such as health databases or transportation databases. If such data linkage is possible, then particular attention must be paid to the confidentiality issue and how such data will be protected. Moreover, in some jurisdictions, explicit consent must be obtained from those involved in the study prior to the release of such data. If explicit consent is required, then the consent form must contain complete disclosure on the known and potential risks so that each driver can make an informed and autonomous choice regarding their participation. In this situation, the feasibility of the research may also be called into question.

4.7 Summary of Ethics Issues with Fatigue Recovery Projects

In this section the ethical considerations involved in these types of field studies of fatigue and recovery in commercial motor carriers were considered as well as any specific considerations regarding the nine protocol options discussed in Section 3. In general, three issues were identified: 1) ensuring that the study conditions can be met in an operational setting and that participants are protected from repercussions, 2) ensuring that full and complete disclosure to potential participants is achieved, and 3) ensuring that confidentiality is preserved to the greatest extent possible, but that the risk of disclosure under law in the event of an accident is clearly articulated. In general, the proposed protocol options 1-6 rest on the assumption that the study protocols are naturalistic observations made on drivers operating on their usual revenue-generating routes and within the regulations governing commercial motor carriers in the jurisdiction in which they are driving. Given the assumptions, the recommended protocols will maximize the generalizability of the results, minimize the risks to drivers, investigators and sponsors, and address a fundamentally unanswered scientific question of practical importance. Even though some of the protocols assign specific individuals to experimental groups, their assignment is based, in most cases, on their routine sleeping and napping behaviour so that they are not compromised beyond what would occur in everyday life. Only in Option 6B is there a chance of assigning individuals to experimental conditions that might put them at increased risk. However, if there is full disclosure to drivers concerning the potential for this risk, if drivers are required to use their own best judgment with regard to minimizing fatigue and maximizing safety regardless of the study objectives (as in all proposed studies), and if the investigators and companies support the driver in making safety decisions, then these risks are acceptable if drivers agree to participate. The risk in the laboratory studies (Options 7 and 8) and in the epidemiological study (Option 9) are minimal.

In summary, the ethical analysis of the protocols has identified areas that investigators need to consider prior to and during such study protocols. In addition, a specific template for an informed consent form is provided for Option 1 (see Section 4.6.4).

4.8 Guidelines for Writing Research Protocols

The following are some points that should be helpful in preparing a research protocol. While all points will not be applicable for every study, they represent some of the areas considered when reviewing a proposal.

Identification:	Title of project, principal investigator(s), sponsor, appropriate contact information
Background/rationale:	Review of current, relevant scientific data Rationale for the study Pros and cons of present standard situation
Purpose:	Hypothesis, objectives, research questions
Study population:	Description and reason for interest Inclusion/exclusion criteria Study design, e.g., groups and conditions Method of sample selection Sample size and power calculation
Procedure:	Description of procedures and information to be collected Procedures specifically for research purposes Study duration and testing duration

	Data sources apart from direct data collection (e.g., employee records)
Study intervention:	Study characteristics and schedule of activity Safety and risks Conditions for withdrawal Departure from usual working expectations Experimental aspects of the intervention
Tests, measurements:	Number and frequency Description of any risks Copy of instruments, questionnaires used
Risks and benefits:	Any risks from the study, study design and tests must be clearly stated without minimizing negative effects Benefits should not be exaggerated
Proposed and analysis:	Descriptive statistics, inferential statistics (e.g., means analysis of variance [ANOVA], correlations, regressions)
Implication of research:	How this will impact on subjects like themselves
Ethical issues/concerns:	Special population issues – competency, age Risks versus benefits Method of sample recruitment (free of coercion, written and verbal explanations, time to consider) Confidentiality safeguards Data security

4.9 Guidelines for Writing Informed Consent Forms

A consent form should provide, to the extent that it is possible, all the information needed for an individual to make an informed decision. Although written information is provided in the consent form, a verbal explanation should also be given. Participants should be given time to consider their decision and the opportunity to ask questions and seek clarification. The invitation to participate in a research study should be presented in a way that avoids coercion or undue influence.

The following outlines some points that may be considered when drafting a consent form.

Introduction:	An introductory statement regarding the consent process is recommended. The following statement is an example: “Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any

time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document."

Consent form should:	Be on letterhead Be in a language subject understands Use simple, clear language for technical and medical terms Define short forms and abbreviations Use meaningful comparisons to describe amounts or risks Use large print if older subjects are involved Be worded in the second person Identify consent by version date/or date
Identification:	Title of study, name of investigator and contact information/sponsor name and contact information
Rights as volunteer:	Participation is voluntary Refusal to participate does not affect the employment Right to withdraw without penalty and implications of refusal
Study description:	Description of study and purpose Why individual is asked to participate Number of participants Duration of study Current experience with experimental drug or treatment
Procedures:	Outline of steps in study Study design, e.g., random, groups – define terms
Intervention:	Description of intervention, conditions, expectations, etc.
Tests:	Procedures carried out for study versus normal working environment Description of tests or measurement Frequency and number Number of visits and time commitment
Eligibility:	Inclusion/exclusion criteria
Risks/inconvenience:	Must be clearly and fully detailed for treatments and tests Discomforts

	Estimate of the likelihood of the occurrence of any adverse events Who to call if an adverse event occurs
Benefits:	For subject, for society – do not exaggerate
Withdrawal:	Right to withdraw at any time. Guidelines for subject being withdrawn from study and implications of withdrawal Rules for stopping study
Confidentiality:	How data will be treated Possible access to records by sponsor or other bodies Sharing of the information with other investigators
Compensation:	If any and what it covers – in non-legal language
Non-waiver clause:	"In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities"
New findings:	Participant will be informed of any new findings that develop during the course of study that may relate to their willingness to continue in the study.
Questions/concerns:	Names of contacts and phone numbers. For any questions about rights as a research participant, name of REB/IRB Chair and contact information.
Consent:	The consent should be in the first person and repeat some of the key points that the subject should understand to participate. Statement should include that participation is voluntary and that they will receive a copy of the signed informed consent.
Signatures:	The consent should be signed and dated by the subject and by the person who has explained the study and obtained the consent. The person obtaining the consent may be one of the investigators or a designate. In addition, the person obtaining consent should: a) be knowledgeable about the study protocol in order to answer questions that the prospective participant may have, b) be able to obtain information from the investigators to address issues raised by the prospective participant, and c) ideally not be in a supervisory relationship with the prospective participant.
Date of consent:	The consent should be dated for easier tracking of future consent versions.

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APPENDIX A

FATIGUE AND RECOVERY COMMERCIAL DRIVER SURVEY RESULTS

1 INTRODUCTION

As part of Phase II of the Investigation of Commercial Motor Vehicle Driver Cumulative Fatigue Recovery Periods Project, 300 drivers at truck stops outside of Calgary, Toronto and Montreal were surveyed to obtain an understanding of typical CMV work-rest schedules and subjective impressions of fatigue after different amounts of time worked.

The survey included questions on demographics, experience and type of driving, hours per workday of work, driving, loading/unloading, waiting to load/unload, napping and sleeping, fatigue level at the end of the first, second, third and fourth day of driving, fatigue level after the maximum of 60 hours work, number of shifts worked before having 24, 36, 48 or 72 hours off, and average length of recovery time. Comparisons were made, among others, between drivers who worked mainly day shift, a mix of day and night shift and mainly night shift, between drivers indicating high and low levels of fatigue, between company and contractor drivers, and between drivers in Calgary, Toronto and Montreal.

The results from this survey were used to further refine the experimental protocols developed in Phase 1. This appendix describes the results of that survey.

2 METHODS

Two types of surveys were conducted: 1) a full 30 minute interview survey during which a research assistant asked questions and entered data on a laptop computer, and 2) a one page survey that included a subset of the questions in the full survey and was completed by drivers on their own. The one page survey required considerably less time commitment than the full survey. The purpose of the one page survey was to verify that a sample willing to participate in a 30-minute interview was representative of the majority of drivers. In addition, selected measures could be obtained inexpensively from a larger sample of drivers. A total of 300 drivers were interviewed, half with each type of survey, and one third in each of Calgary, Toronto and Montreal.

Surveys were conducted between March 3, 2003, and June 18, 2003, during weekdays between 07:45 and 22:00. Approximately 1/3 of interviews were conducted in the morning, 1/3 in the afternoon, and 1/3 in the evening. Since the average work time was anticipated to be 8 to 12 hours, these interview times were expected to encompass drivers on all types of schedules, including those driving mainly at night. Truck drivers were approached in rest stops near Calgary, Toronto and Montreal.

3 RESULTS

For ease of reference all tables of results are grouped at the end of this appendix in Appendix A1. The tables include the following results:

Table A1-1	Demographics
Table A1-2	Work Schedule Over the Last Year
Table A1-3	Work Schedule Over the Last Three Days
Table A1-4	Time of Driving
Table A1-5	Fatigue Ratings, Day Driving
Table A1-6	Fatigue Ratings, Day Driving with Some Night Driving

Table A1-7	Fatigue Ratings, Night Driving

Tables A1-8 through A1-15 show comparisons made between various groups. These are as follows:

Table A1-8	Mainly Day vs. Mainly Night vs. Night with Some Day Driving
Table A1-9	High Fatigue vs. Low Fatigue Rating
Table A1-10	Low Predictability vs. High Predictability
Table A1-11	Calgary vs. Toronto vs. Montreal
Table A1-12	Long Haul vs. Short Haul
Table A1-13	Company vs. Contractor Drivers
Table A1-14	Tanker vs. Non-tanker Drivers
Table A1-15	One Page vs. Full Survey

The findings pertaining to each table are summarized below.

With the exception of Table 15, all other tables, and their related sections below, refer to the results of the 30-minute interview unless specifically noted otherwise.

3.1 Response Rate

The percentage of drivers agreeing to participate in either the 30-minute interview or the one-page questionnaire was 70 percent (302/431). The rate of participation was the same for Calgary and Montreal (76 percent) and lower in Toronto (60 percent). Participation with respect to the type of survey was recorded only in Montreal and Toronto. In Montreal there was a higher participation in the interview, while in Toronto participation was higher for the one-page survey.

3.2 Demographics (Table A1-1)

The overwhelming majority of drivers were men (97 percent). Respondents had between 1 and 50 years of experience in the trucking industry, averaging 19 years (sd = 12, n = 150). Most drivers worked for a company (73 percent) and did long-haul driving (87 percent). Only 11 out of 150 (7 percent) of drivers interviewed were tank truck drivers.

Drivers were asked about their state of health and 97 percent said that it was “good” or better. Only three percent said “not good” or “poor”. Two thirds of drivers said that they would describe themselves as a “morning person” and the remaining one third, as an “evening person”. Five percent of drivers said they had been diagnosed with a sleeping disorder. Half of this group reported insomnia, and the other half, sleep apnea.

3.3 Work Schedule – Last Year (Table A1-2)

Drivers were asked to consider the last year and estimate the average hours they spent in a 24 hour period working (including driving, loading, inspections, etc.), driving, loading, waiting to load, napping and sleeping. The results are shown in Table A-1.

Table A-1. Work Schedule – Last Year

Question: B1-6	n	Mean Hours	Std Dev (sd)	Max	Min
Working	150	13.4	2.8	24	6
Driving	150	10.3	2.7	20	2
Loading	108	2.3	1.3	6	1
Waiting to load	89	2.0	0.9	5	1
Napping	55	1.8	0.8	4	1
Sleeping	149	6.9	1.6	12	2

The number of consecutive days or nights in the past year that drivers worked, on average, was 6.3 (sd = 2.4, n = 143). This average was multiplied by the average number of hours spent working in a day (13.4 h) to obtain an average of 84 hours worked before a recovery period was taken. Of the total, 29 drivers indicated that they typically worked more than seven days before taking at least one day off.

In addition to questions about typical work times, drivers were also asked about maximum work times. The mean maximum working hours per workday was reported to average 17.3 hours, with an average of 13.9 hours driving. The maximum number of consecutive shifts per work cycle was reported to be 8.5 days on average.

For purposes of classifying the type of shift worked by the drivers, "mainly day driving" was defined as no driving between 24:00 and 06:00; "day driving with some night driving" was defined as no more than two hours driving between 24:00 and 06:00, and "mainly night driving" was defined as two hours or more driving between 24:00 and 06:00. With respect to night driving, 29 drivers (19 percent) stated that all of their shifts involved driving two or more hours between 24:00 and 06:00. Fifty-four drivers (36 percent) would be considered day drivers since they said that none of their shifts involved driving two or more hours during this time period.

With respect to recovery time periods after an average work cycle, drivers said they took an average of two days off. In an average month, drivers said they take 6.5 days off. Drivers reported that they had on average 2.2 sleep periods before returning to work, and all sleep periods included sleeping between 24:00 and 06:00. Drivers were asked how many hours of sleep they typically got after the first, second and third days off. They reported 8.1 (n = 148), 7.8 (n = 126), and 7.8 (n = 53) hours, respectively. Note that only 1/3 of the sample reported hours during a third night of recovery.

When asked at what time of day they typically napped when on-duty, 35 percent of drivers reported that they never napped, 22 percent responded that they napped during the daytime, 20 percent while waiting to load, 13 percent while loading or unloading, and 12 percent during rush hours. Only four percent reported napping between 24:00 and 06:00. With respect to napping on days off to make up for lost sleep, 9 percent of drivers reported that they often did so, 17 percent sometimes, 24 percent rarely and 50 percent never did so.

With respect to driving after 24:00, 44 percent of drivers said that they never did so. For those drivers who did so, the most common reason was that they had to arrive at a set time for loading or unloading (46 percent); the next most common reason was that they were trying to avoid rush hour (35 percent). The majority of drivers (58 percent) said that if they wished to avoid driving between 24:00 and 06:00 they would not be able to arrange their schedule to do so.

Drivers were asked what hours they avoided in order to limit sleepiness. The greatest percent reported 05:00 to 05:59 (34 percent), followed by 04:00 to 04:59 (13 percent), 06:00 to 06:59 (11 percent) and 07:00 to 07:59 (eight percent). For each of the other hour periods, 5 percent or fewer drivers reported avoiding these.

With respect to the predictability of the hours for the next work schedule, on a scale of 1 (not at all predictable) to 7 (very predictable) the average rating was 4.3 (sd = 2.5).

3.4 Work Schedule – Last Three Days (Table A1-3)

Drivers were asked to report their work schedule over the last three days, including the current day. Data reported in this section are for the 150 drivers participating in the full interview (see Section 3.12 for comparison with drivers completing the one page survey). Drivers reporting hours for the current day estimated times for working, driving, etc. for the remainder of that day. Starting times were typically between 05:00 and 08:59 (57 percent of responses). Stopping times were more dispersed over the 24 hour day, with the most frequent periods being 24:00 to 00:59 (11 percent), 23:00 to 23:59 (10 percent), and 16:00 to 16:59 (8 percent).

Average hours reported for the three days were as follows:

- Working 11.4 (n = 382, sd = 4.2)
- Driving = 8.3 (n = 371, sd = 3.1)
- Sleeping = 7.3 (n = 372, sd = 1.8)
- Napping = 2.0 (n = 71, sd = 1.5)
- Loading/unloading = 2.6 (n = 222, sd = 2.6)

Note that napping hours were only indicated for 19 percent of the shifts, and loading hours for 58 percent.

To check the consistency of each driver's answers, the difference between "today's start time" and "yesterday's stop time" was calculated and compared to hours sleeping after yesterday's shift, with the following results:

Sample (n = 124)

- 7 percent (hours sleeping) > (time off)
- 29 percent (hours sleeping) = (time off)
- 18 percent (time off) - (hours sleeping) < 2 hours
- 46 percent (time off) – (hours sleeping) >= 2 hours

These data suggest that drivers tend to over-estimate either work time or sleep time.

Drivers were asked to estimate their fatigue level at the end of each day of driving on a scale of 1 to 7, with 1 indicating that they were not at all fatigued, and 7 indicating that they were severely fatigued. The average fatigue rating reported was 3.3 (n = 422, sd = 3.3).

Drivers were asked to estimate how many days it had been since they had had various recovery periods. Days worked before a recovery period were as follows:

- 24 hours off = 3.6 (n = 127, sd = 2.0)
- 36 hours off = 4.8 (n = 125, sd = 3.2)
- 48 hours off = 7.4 (n = 132, sd = 7.6)
- 72 hours off = 13.4 (n = 97, sd = 10)

3.5 Mainly Night vs. Mainly Day Driving vs. Day with Some Night (Tables A1-4, A1-5, A1-6, A1-7, and A1-8)

Table A1-4 shows the percentage of shifts in the last two months that were considered "mainly day driving", defined as no driving between 24:00 and 06:00, "day driving with some night driving", defined as no more than two hours driving between 24:00 and 06:00, and "mainly night driving", defined as two hours or more driving between 24:00 and 06:00.

Drivers who were classified as "mainly day" drivers are those who indicated that 75 percent or a greater percentage of shifts in the past two months were "mainly day driving" (n = 80). The same definition, but for night shifts, was used to classify drivers as "mainly night" (n = 25). The remaining drivers (n = 45) were "day with some night" drivers.

Tables A1-5, A1-6 and A1-7 show fatigue ratings for drivers in each of these three shift types. Drivers were asked to rate their fatigue after a shift of 10 to 13 hours of work. As shown in Table A-2, fatigue ratings were highest for "day with some night" drivers after four shifts.

Table A-2. Fatigue Ratings*

Question G/H/I, 2-5	After 1 shift	After 2 shifts	After 3 shifts	After 4 shifts
Day driving	2.9	2.9	3.1	3.5
Day with some night	3.4	3.5	3.9	4.2
Mostly night	3.1	3.3	3.4	3.6

* Fatigue (1 = not at all, 7 = very fatigued)

Table A1-8 shows a comparison in demographics and work-rest schedules for drivers on different shifts. These three categories of drivers were similar in demographic characteristics. There were also no differences in number of hours reported in the last year or in the past three days. However, the median number of shifts before 24 hours off was taken was shortest for the night drivers – three days – and longer for the other two groups – four days each.

3.6 High Fatigue vs. Low Fatigue Rating (Table A1-9)

Table A1-9 compares drivers with high versus low average ratings of fatigue for the past three days. The most fatigued (n = 45) drivers had an average fatigue rating > 4.0

(on a scale of 1-7, 7 being the most fatigued); the least fatigued (n = 40) had an average fatigue rating < 2.1. The numbers are unequal because all drivers with the same rating as the ratings used as the 25th and 75th percentile cutpoints are included in the comparison.

Drivers who experience the most fatigue:

- Have on average almost three years less experience than drivers who experience the least fatigue (17.8 vs. 20.7 years)
- Worked on average almost three hours more per day than drivers who experience the least fatigue (12.7 vs. 9.6 hours) in the last three days
- Slept on average ½ an hour less (7.2 vs. 7.7 hours) in the last three days
- Typically have fewer days off in an average month (6.0 vs. 6.6)
- Work more days before getting 24 (8.1 vs. 5.1 days), 36 (6.1 vs. 9.1 days), 48 (13.6 vs. 7.8 days) or 72 (29.1 vs. 17.6 days) hours off

3.7 Low Predictability vs. High Predictability (Table A1-10)

Table A1-10 compares drivers that gave low versus high average ratings for the predictability of the hours for their next work schedule. The drivers with the least predictable upcoming schedule (n=45) all had a predictability rating =1 (on a scale of 1-7, 1 being the least predictable); the drivers with the most predictable upcoming schedule (n=49) all had a predictability rating = 7.

With respect to the predictability of the hours for the next work schedule, on a scale of 1 (not at all predictable) to 7 (very predictable) the average rating was 4.3 (sd = 2.5).

The drivers who experience the least predictability:

- Had on average almost seven years less experience than drivers with a more predictable work schedule (15.9 vs. 22.6 years)
- Worked on average one and a half more hours per day than drivers with a more predictable work schedule (12.2 vs. 10.7 hours)
- Experienced a higher level of fatigue, on average (rating of 3.9 vs. 3.0 out of 7 – 7 being the most fatigue)

3.8 Results by Region – Calgary vs. Toronto vs. Montreal (Table A1-11)

Table A1-11 compares results by region. Demographic regional differences were as follows:

- Montreal drivers had five years less experience than the others, on average (16 vs. 21 years)
- More drivers interviewed in Montreal drove short haul (24 percent vs. 10 percent [Toronto] and 4 percent [Calgary])

Based on the last three days of driving, regional differences were as follows:

- Toronto drivers are more likely to stop before as opposed to after 24:00 than Calgary or Montreal drivers
- Calgary drivers work a total of two hours less per day, on average (9.9 vs. 12.0 [Toronto] and 12.1 [Montreal])

- Calgary drivers drive longest (Calgary = 8.7 h, Toronto = 8.4 h, Montreal = 7.8 h) but fewer report loading
- More Montreal drivers loaded in the past three days (n = 97 vs. n = 71 [Toronto] and 53 [Calgary]), and for the most amount of time (2.9 h vs. 2.3 and 2.2 h), only considering those drivers who reported loading
- Calgary drivers reported the highest number of hours waiting to load/unload (3.4 h vs. 1.8 h [Toronto] and 1.9 h [Montreal])
- More Montreal drivers napped in the past three days (n = 29 vs. n = 26 [Toronto] and 16 [Calgary]), but for the least amount of time (1.4 h vs. 2.3 h [Calgary] and 2.5 h [Toronto])
- Toronto drivers reported the highest level of fatigue on average (3.6) and Calgary the lowest (3.0)
- Calgary drivers took 36 hours off least frequently (median after six days vs. after four days for Toronto and Montreal)
- Calgary drivers took 48 hours off least frequently (median after seven days vs. after five days for Toronto and four days for Montreal)
- Montreal drivers took 72 hours off least frequently (median after 21 days vs. 14 days for Toronto and Calgary).

3.9 Long Haul vs. Short Haul (Table A1-12)

Most drivers were long-haul drivers (87 percent of the interview sample). Demographic differences between long- and short-haul drivers were as follows:

- Long-haul drivers are older (43 percent >50 years vs. 13 percent)
- Long-haul drivers have five more years of experience, on average

Based on the last three days of driving:

- Short-haul drivers are 60 percent more likely to start between 04:00 and 08:00 (71 percent vs. 44 percent)
- Short-haul drivers are most likely to complete their day between 16:00 and 20:00 (58 percent), while long-haul drivers are most likely to end their day between 20:00 and 24:00 (40 percent)
- Long-haul drivers spend two more hours per day driving (8.5 vs. 6.3 h), yet work the same amount of time per day (10.0 vs. 10.1 h)
- Short-haul drivers load for almost 1.5 hours more per day (3.4 vs. 2.0 h)
- Short-haul drivers report slightly higher levels of fatigue (3.7 vs. 3.5)
- Long-haul drivers take 36 and 48 hours off one day sooner
- Short-haul drivers take 72 hours off almost six days sooner
- Short-haul drivers have almost one more day off per month (7.7 vs. 6.9 days)

Table A-3 indicates start times for short-haul drivers are more concentrated – almost half of these drivers start the day between 05:00 and 07:00, whereas only one quarter of long-haul drivers start at this time.

Table A-3. Start Times for Long-Haul and Short-Haul Drivers

Start Time	Total (n = 400)	Long Haul (n = 350)	Short Haul (n = 50)
04:00-04:59	5%	5%	6%
05:00-05:59	11%	9%	24%
06:00-06:59	18%	17%	24%
07:00-07:59	14%	14%	12%
08:00-08:59	14%	15%	4%

3.10 Company vs. Contractor (Table A1-13)

With respect to demographic differences between company and contractor drivers, contractors have on average four more years of experience.

Based on the last three days of driving, contractors:

- Work over one more hour per day, on average (10.9 vs. 9.7 h)
- Spend over one more hour per day loading, on average (3.4 vs. 2.3 h)
- Have 72 hours off three days sooner, on average (7.3 vs. 10.2 days)
- Have almost one more day off per month, on average (7.8 vs. 7.0 days off)

3.11 Tanker vs. Non-Tanker (Table A1-14)

Tanker drivers comprised 7.3 percent of the interview sample. With respect to demographic differences between non-tanker and tanker drivers, the latter:

- Are three years older on average
- Nap for about an hour longer
- Are more likely to be short haul (36 percent vs. 9 percent)
- Have 48 hours off after a shorter amount of time (4.3 vs. 7.6 days)
- Have 72 hours off after a shorter period of time (7.6 vs. 14.0 days)
- Have almost two more days off per month (8.2 vs. 6.4 days)

3.12 One Page vs. Full Survey (Table A1-15)

The results for the one page and the full survey were compared for those items that were the same in each survey. Drivers completing the one-page survey were slightly older than those doing the full interview, were somewhat more likely to be short-haul drivers (29 percent vs. 13 percent long haul), worked on average 1.4 hours less per day, worked fewer days before getting 48 hours off (5.1 vs. 7.4 days), or 72 hours off (9.8 vs. 13.4 days), and took more time off in an average month (7.1 vs. 6.5 days).

4 DISCUSSION

4.1 Data Inconsistencies

Self-report data in the absence of records is bound to involve errors of recollection. There were a number of internal inconsistencies within the full interview results as well as discrepancies between the full interview and the one page survey. Based on recollections of driving over the past year, drivers reported 13.4 hours worked, whereas the reported schedule over the past three days indicated an average of 11.4 hours worked in the full interview, and 10.0 hours in the one page survey. As noted in Section 3.4, the time available for sleep was calculated using reported start and stop times. In 7 percent of the sample, the hours sleeping exceeded the time available; in 29 percent of the sample, the hours sleeping were equal to the time available. This suggests that drivers were overestimating either their work time or their sleep time. Future studies of hours of work should consider the use of diaries that are filled in on a daily basis, or black box recorders.

4.2 Fatigue Ratings

The highest fatigue ratings were reported by drivers who were classified as "day with some night" drivers. The lowest ratings were reported by day drivers. The three driver groups had similar demographic profiles. Night drivers worked an average of 0.5 hours longer, based on the previous three day schedule, as compared to day and day with some night drivers. The median number of shifts before 36 hours off was highest for day with some night drivers – 5 days as compared to 4 days for day drivers and 3.5 days for night drivers.

4.3 Parameters Related to High Fatigue Levels

The drivers reporting the highest levels of fatigue had on average almost three years less experience than drivers who experience the least fatigue. On average, those with the highest levels of fatigue reported, over the last three days, working almost three hours more (12.7 vs. 9.6 h), sleeping ½ hour less, and working more days before taking time off than drivers who experience the least fatigue. In particular these drivers worked, on average, 8.1 vs. 5.1 days before getting 24 hours off and 9.1 vs. 6.1 days before having 36 hours off. If the hours worked over the previous three days are multiplied by the average days worked before taking 24 hours off, this suggests that the high-fatigue drivers are working well beyond the hours of service limits – 103 hours – before 24 hours off. In contrast the same calculation for the low-fatigue drivers indicates a workweek less than half as lengthy: 49 hours before 24 hours off.

Interestingly, drivers reporting high levels of fatigue were of a similar age and more likely to be company drivers, as compared to drivers reporting low levels of fatigue.

4.4 Regional Differences

Based on the schedule for the last three days worked, Calgary drivers report working two hours less per day than Toronto or Montreal drivers but more of this is spent driving as opposed to loading. However, Calgary drivers report the fewest days off per month (every 5.9 days vs. 6.6 [Toronto] and 7.0 days [Montreal]).

4.5 Long-Haul vs. Short-Haul Driving

The majority of drivers interviewed were long-haul drivers; these drivers comprised 87 percent of the interview sample and 71 percent of the one page survey sample. The long-haul drivers reported the same amount of time working, but two more hours per day driving, and 1.5 hours less per day loading. Long-haul drivers reported taking 36 and 48 hours off one day sooner, but 72 hours off six days later than short-haul drivers. The short-haul drivers reported slightly higher levels of fatigue.

5 FINDINGS WITH IMPLICATIONS FOR PROTOCOLS

In designing the experimental protocols for the testing of required recovery time, it is important to ensure that the experimental designs reflect the reality of commercial driver work-rest schedules. Findings for the survey that have implications for the experimental protocols are discussed in Sections 5.1 to 5.5.

5.1 Working Hours

When drivers reported their typical schedule over the last year, they indicated that on average they worked 13.4 hours, with a standard deviation of 2.8 hours. When drivers reported their actual schedule for the day of the survey and two preceding days, average working hours reported were less: 11.4 hours (standard deviation 4.1) for drivers completing the 30 minute interview, and 10.0 hours for those completing the one page survey (standard deviation 4.0).

5.2 Number of Consecutive Shifts

When drivers reported their typical schedule over the last year, they indicated that on average 6.3 shifts were worked before at least one full day off was taken. When drivers were asked when they last took 24 hours off, the average value was 3.6 days, with a standard deviation of two days.

5.3 Timing of Shifts

In order to ensure all types of shifts were covered, survey times included the period 07:45 until 22:00. In our sample, 19 percent of the drivers stated that all their shifts involved driving two or more hours between 24:00 and 06:00. These drivers were classified as mainly night drivers. Of the total sample, 36 percent said none of their shifts involved driving during this period; these were classified as day drivers. With respect to driving after 24:00, 44 percent said they never did so; thus the majority of drivers do drive after 24:00 at least some of the time. If anything, because of the time period for the interviews, the survey is likely to underestimate the percentage of night drivers, and overestimate the percentage of day drivers.

5.4 Recovery Time

With respect to recovery periods, drivers reported an average of two days off. When asked about sleep after the third recovery day, only 1/3 of drivers responded.

5.5 Napping Practices

Only 1/3 of drivers reported hours napping during the workday. When asked at what time of day they typically napped, 35 percent of drivers reported that they never napped, 22 percent responded that they napped during the daytime, 20 percent while waiting to load, 13 percent while loading or unloading, and 12 percent during rush hours. Only 4 percent reported napping between 24:00 and 06:00.

APPENDIX A1

DETAILED RESULTS (TABLES A1-1 – A1-15)

Table A1-1. Demographics

Gender		
A2	Male	97%
	Female	3%
Age		
A3	Under 30	14%
	30-39	20%
	40-49	31%
	50-59	29%
	60 and over	6%
Employer		
A4	Company	73%
	Contractor	27%
Morningness/Eveningness		
A5	Morning person	67%
	Evening person	33%
Health status		
A6	Excellent	22%
	Very Good	37%
	Good	38%
	Not Good	2%
	Poor	1%
Sleep disorders		
A7	None	95%
	Insomnia	3%
	Sleep apnea	3%
Years in trucking industry		
A8	N	148
	Mean	18.9
	Std Dev	11.9
	Max	50
	Min	1
Type of driving		
A9	Long haul	87%
	Short haul	13%
Years in current type of driving		
A10	N	146
	Mean	14.5
	Std Dev	11.8
	Max	45
	Min	1
Tank-truck drivers		
A11	Yes	7%
	No	93%

Table A1-2. Work Schedule Over the Last Year

Average hours per workday working		
B1	N	150
	Mean	13.4
	Std Dev	2.8
	Max	24
	Min	6
Average hours per workday driving		
B2	N	150
	Mean	10.3
	Std Dev	2.7
	Max	20
	Min	2
Average hours per workday loading & unloading		
B3	N	108
	Mean	1.3
	Std Dev	1.3
	Max	6
* 41 responses = 0	Min	1
Average hours per workday waiting to load/unload		
B4	N	89
	Mean	2.0
	Std Dev	0.9
* 53 responses = 0	Max	5
** 7 responses > 3 std devs from mean	Min	1
Average hours per workday napping		
B5	N	55
	Mean	1.8
	Std Dev	0.8
	Max	4
* 94 responses = 0	Min	1
Average hours per workday sleeping		
B6	N	149
	Mean	6.9
	Std Dev	1.6
	Max	12
* 1 response > 3 std devs from mean	Min	2

No. of consecutive days/nights worked per week		
B7	N	143
	Mean	6.3
	Std Dev	2.4
	Max	14
	75th%-ile	7
	25th%-ile	5
* 7 responses > 3 std devs from mean	Min	2
Percentage of these shifts requiring driving 2 or more hours between 24:00 and 06:00		
B8	N	96
	Mean	53%
	Std Dev	38%
	Max	100%
* 54 responses = 0	Min	1%
No. of weeks worked per year		
B9	N	150
	Mean	48
	Std Dev	5.7
	Max	52
	Min	2
Maximum working hours per workday		
B10	N	149
	Mean	17.3
	Std Dev	4.4
	Max	30
* 1 response > 3std devs from mean	Min	6
Maximum driving hours per workday		
B11	N	150
	Mean	13.9
	Std Dev	4.5
	Max	24
	Min	4
Maximum No. of consecutive shifts per work cycle		
B12	N	136
	Mean	8.5
	Std Dev	4.7
	Max	22
* 14 responses > 3std devs from mean	Min	3

No. of days off after an average work cycle		
B13	N	144
	Mean	2.0
	Std Dev	0.76
* 2 responses = 0	Max	4
** 4 responses > 3 std devs from mean	Min	0.6
No. of days off during an average month		
B14	N	148
	Mean	6.5
	Std Dev	2.5
	Max	13
* 1 response > 3 std devs from mean	Min.	1
No. of sleep periods before returning to work after a long work cycle		
B15	N	143
	Mean	2.2
	Std Dev	0.75
* 1 response = 0	Max	4
** 4 responses > 3 std devs from mean	Min	1
No. of sleep periods that include sleeping between 24:00 and 06:00		
B16	N	142
	Mean	2.2
	Std Dev	0.78
* 3 responses = 0	Max	4
** 5 responses > 3 std devs from mean	Min	1
No. of hours of FIRST recovery sleep period		
B17	N	142
	Mean	2.2
	Std Dev	0.78
	Max	4
	Min	1
(continued from B15) **No. of hours of SECOND recovery sleep period**		
B18	N	126
	Mean	7.8
	Std Dev	1.4
	Max	12
	Min	4

No. of hours of THIRD recovery sleep period		
B19	N	53
	Mean	7.7
	Std Dev	1.3
	Max	10
	Min	5
Frequency of napping on days off to make up for lost sleep		
B20	N	149
	Often	9%
	Sometimes	17%
	Rarely	24%
	Never	50%
Typical naptime (all that apply)		
B21	24:00-06:00	4%
	Sunrise	8%
	Daytime	22%
	Rush hours	12%
	Sunset	2%
	Early evening	3%
	Late evening	3%
	Loading/unloading	13%
	Waiting for load	20%
	Rest stops during break	8%
	Other	5%
"Do you ever drive after midnight"		
C1	N	150
	Yes	56%
	No	44%
"If so, is it because:"		
C2	N	133
	Need to arrive at a set time for loading/unloading	46%
	Trying to avoid rush hour	35%
	Other	19%

(continued from C1) "If you wished to avoid driving between 24:00 and 06:00 would you be able to arrange your schedule to do so?"			
C3	N	84	
	Yes	42%	
	No	58%	
Reasons why not able to avoid driving between 24:00 and 06:00			
C4	- Prefer night driving, easiest time to drive - Customer demands, deadlines, appointment times, delivery time, scheduling, dispatches, time sensitive loads, load not ready, make up for lost time - Avoid traffic, too busy during day		
What hours are avoided to limit sleepiness			
C5, C6		**Starting from**	**Until**
	24:00-00:59	17%	3%
	01:00-01:59	3%	0%
	02:00-02:59	5%	2%
	03:00-03:59	13%	2%
	04:00-04:59	14%	2%
	05:00-05:59	9%	13%
	06:00-06:59	6%	33%
	07:00-07:59	0%	11%
	08:00-08:59	0%	7%
	09:00-09:59	0%	3%
	10:00-10:59	1%	1%
	11:00-11:59	2%	0%
	12:00-12:59	4%	2%
	13:00-13:59	4%	2%
	14:00-14:59	3%	0%
	15:00-15:59	3%	5%
	16:00-16:59	1%	5%
	17:00-17:59	0%	3%
	18:00-18:59	1%	2%

	19:00-19:59	0%	1%
	20:00-20:59	2%	2%
	21:00-21:59	1%	1%
	22:00-22:59	3%	0%
	23:00-23:59	8%	0%
Predictability of hours of work for next work cycle (1=not at all, 7=very predictable)			
C7	N	150	
	Mean	4.3	
	Std Dev	2.5	
	Max	7	
	Min	1	

Table A1-3. Work Schedule Over the Last Three Days

Start and stop times for the last 3 days			
D1, D2		**Start time**	**Stop time**
	24:00-00:59	2%	11%
	01:00-01:59	1%	5%
	02:00-02:59	1%	4%
	03:00-03:59	2%	2%
	04:00-04:59	5%	1%
	05:00-05:59	11%	1%
	06:00-06:59	18%	1%
	07:00-07:59	14%	1%
	08:00-08:59	14%	1%
	09:00-09:59	6%	2%
	10:00-10:59	5%	1%
	11:00-11:59	3%	1%
	12:00-12:59	5%	3%
	13:00-13:59	2%	1%
	14:00-14:59	3%	3%
	15:00-15:59	2%	4%
	16:00-16:59	1%	8%
	17:00-17:59	2%	5%
	18:00-18:59	2%	7%
	19:00-19:59	1%	5%
	20:00-20:59	2%	7%
	21:00-21:59	1%	6%
	22:00-22:59	1%	10%
	23:00-23:59	1%	12%

Hours worked in the last 3 days		
D3	N	382
	Mean	11.4
	Std Dev	4.2
* 8 responses = 0	Max	24
** 26% (99/392) of driver's shifts were shorter than 9 hours		
*** 45% (62/139) had 1 or more shift that was shorter than 9 hours		
Hours driving in the last 3 days		
D4	N	371
	Mean	8.3
* 2 responses = 0	Std Dev	3.1
** 2 responses > 3 std devs from mean	Max	16
Hours sleeping after each shift for the last 3 days		
D5	N	372
	Mean	7.3
	Std Dev	1.8
* 14 responses = 0	Max	13
** 1 response > 3 std devs from mean	Min	2
Hours napping during each shift for the last 3 days		
D6	N	71
	Mean	2.0
	Std Dev	1.5
	Max	7
* 321 responses = 0	Min	0.25
Hours loading/unloading during each shift for the last 3 days		
D7	N	222
	Mean	2.6
	Std Dev	1.8
	Max	8.5
* 161 responses = 0	Min	0.17
** 4 responses > 3 std devs from mean		
Fatigue level at the end of each day for the last 3 days		
D8	N	422
	Mean	3.3
	Std Dev	2.0
	Max	7
	Min	1

No. of days/nights since 24 hours off		
D25	N	127
	Mean	3.6
	Std Dev	2.0
* 5 responses = 0	Max	10
** 13 responses > 3 std devs from mean	Min	1
No. of days/nights since 36 hours off		
D26	N	125
	Mean	4.8
	Std Dev	3.2
* 3 responses = 0	Max	14
** 13 responses > 3 std devs from mean	Min	1
No. of days/nights since 48 hours off		
D27	N	132
	Mean	7.4
	Std Dev	7.6
	Max	30
	75^{th} percentile	10
* 2 responses = 0	25^{th} percentile	3
** 6 responses > 3 std devs from mean	Min	1
No. of days/nights since 72 hours off		
D28	N	97
	Mean	13.4
	Std Dev	10.0
* 1 response = 0	Max	40
** 28 responses > 3 std devs from mean	Min	1

Table A1-4. Time of Driving

Percentage of shifts in last two months defined as "mainly day driving"		
E2	N	150
	Mean	60%
	Std Dev	40%
	>75%	80
	>50%	97
Percentage of shifts in last two months defined as "day driving with some night driving"		
E3	N	149
	Mean	17%
	Std Dev	27%
	>75%	15
	>50%	21
Percentage of shifts in last two months defined as "mainly night driving"		
E4	N	149
	Mean	24%
	Std Dev	36%
	>75%	25
	>50%	39

Table A1-5. Fatigue Ratings, Day Driving

Day driving with no driving between 24:00 and 06:00						
G1	N	148				
	Mean	78%				
	Std Dev	22%				
Level of fatigue at the end of x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
G2 – G5	N	116	116	115	113	
	Mean	2.9	2.9	3.1	3.5	
	Std Dev	1.6	1.5	1.7	1.8	
	Max	7	7	7	7	
	Min	1	1	1	1	
Amount of sleep after x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
G7, G9, G11, G13	N	115	114	114	112	
	0-4 h	4%	3%	4%	4%	
	5 h	10%	11%	11%	13%	
	6 h	16%	18%	17%	17%	
	7 h	23%	23%	22%	20%	
	8 h	36%	37%	37%	36%	
	9 h	3%	3%	3%	3%	
	10 h	6%	5%	6%	7%	
	11 h	1%	1%	1%	1%	
Percent recovered after the sleep following x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
G8, G10, G12, G14	N	115	115	114	112	
	Mean	88%	89%	87%	84%	
	Std Dev	19%	16%	16%	21%	
	Max	95%	95%	100%	100%	
	Min	0%	0%	40%	0%	

How many hours off are needed after x days of driving to feel 100% fully recovered		**1st day**	**2nd day**	**3rd day**	**4th day**	**5th day**
G16-G20	N	114	114	113	111	111
	6 h	13%	13%	12%	14%	5%
	8 h	47%	45%	38%	34%	8%
	10 h	25%	26%	33%	32%	9%
	12 h	14%	14%	14%	13%	13%
	18 h			2%	1%	2%
	24 h	1%	2%	1%	3%	21%
	36 h					7%
	48 h				2%	24%
	More than 48 h				2%	12%

Table A1-6. Fatigue Ratings, Day Driving with Some Night Driving

Day driving with no driving between 24:00 and 06:00						
H1	N	138				
	Mean	43%				
	Std Dev	57%				
Level of fatigue at the end of x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
H2 – H5	N	55	54	53	53	
	Mean	3.4	3.5	3.9	4.2	
	Std Dev	1.6	1.7	1.7	1.8	
	Max	6	7	7	7	
	Min	1	1	1	1	
Amount of sleep after x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
H7, H9, H11, H13	N	55	54	53	53	
	0-4 h	7%	2%	4%	6%	
	5 h	11%	7%	9%	8%	
	6 h	31%	41%	34%	34%	
	7 h	20%	22%	25%	21%	
	8 h	27%	26%	23%	25%	
	9 h			2%	4%	
	10 h	4%	2%	4%	2%	
	11 h					
	12 h				2%	
Percent recovered after the sleep following x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
H8, H10, H12, H14	N	55	54	53	53	
	Mean	88%	86%	83%	80%	
	Std Dev	15%	12%	18%	20%	
	Max	100%	100%	100%	100%	
	Min	35%	50%	10%	0%	

How many hours off are needed after x days of driving to feel 100% fully recovered		**1st day**	**2nd day**	**3rd day**	**4th day**	**5th day**
H16-H20	N	55	54	53	53	
	6 h	15%	17%	13%	13%	4%
	8 h	45%	44%	38%	32%	8%
	10 h	24%	26%	32%	28%	15%
	12 h	9%	7%	9%	11%	6%
	18 h	2%	2%	4%	4%	
	24 h	5%	4%	4%	9%	36%
	36 h				2%	6%
	48 h					26%
	More than 48 h					

Table A1-7. Fatigue Ratings, Night Driving

Day driving with no driving between 24:00 and 06:00						
I1	N	132				
	Mean	43%				
	Std Dev	57%				
Level of fatigue at the end of x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
I2 – I5	N	57	55	54	54	
	Mean	3.1	3.3	3.3	3.6	
	Std Dev	1.9	1.9	2.0	2.0	
	Max	7	7	7	7	
	Min	1	1	1	1	
Amount of sleep after x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
I7, I9, I11, I13	N	57	55	54	53	
	0-4 h	18%	11%	11%	6%	
	5 h	18%	18%	17%	15%	
	6 h	23%	25%	28%	30%	
	7 h	11%	15%	15%	13%	
	8 h	26%	25%	22%	26%	
	9 h			2%	2%	
	10 h	4%	4%	4%	4%	
	11 h					
	12 h	2%	2%	2%	4%	
Percent recovered after the sleep following x days of driving		**1st day**	**2nd day**	**3rd day**	**4th day**	
I8, I10, I12, I14	N	57	55	54	53	
	Mean	83%	83%	82%	80%	
	Std Dev	23%	21%	19%	22%	
	Max	100%	100%	100%	100%	
	Min	0%	2%	30%	0%	

How many hours off are needed after x days of driving to feel 100% fully recovered		1st day	2nd day	3rd day	4th day	5th day
I16-I20	N	57	54	52	52	54
	6 h	25%	24%	15%	13%	7%
	8 h	44%	43%	38%	38%	11%
	10 h	21%	24%	33%	29%	11%
	12 h	5%	7%	8%	13%	7%
	18 h					2%
	24 h	4%	2%	2%	2%	30%
	36 h			2%		2%
	48 h			2%	2%	24%
	More than 48 h				2%	6%

Table A1-8. Mainly Day vs. Mainly Night vs. Night with Some Day Driving

		Day (n = 91)	Day w/night (n = 17)	Night (n = 32)	Totals (N = 150)
Gender					
A2	Male	97%	94%	100%	97%
	Female	3%	6%	0%	3%
Age					
A3	< 30	10%	18%	22%	14%
	30-39	19%	35%	13%	20%
	40-49	32%	18%	38%	31%
	50-59	30%	29%	28%	29%
	60 +	10%			6%
Employer					
A4	Company	77%	71%	72%	73%
	Independent	23%	29%	28%	27%
Years of Experience		n = 89	n = 17	n = 32	
A8	Mean	20.5	14.6	18.0	19 years
	Median				20 years
	Std Dev	12.4	7.9	11.4	12
	Max	50	32	42	50
	Min	1	4	2	1
Haul					
A9	Long	85%	82%	94%	87%
	Short	15%	18%	6%	13%

Past 3 days (combined)					
D1	Start time				n = 400
	24:00-03:59	4%	3%	6%	5%
	04:00-07:59	55%	45%	26%	47%
	08:00-11:59	27%	30%	15%	27%
	12:00-15:59	6%	6%	21%	11%
	16:00-19:59	6%	12%	11%	6%
	20:00-23:59	1%	3%	21%	4%
D2	Stop time				n = 386
	24:00-03:59	18%	30%	32%	22%
	04:00-07:59	2%	9%	13%	4%
	08:00-11:59	2%	0%	11%	5%
	12:00-15:59	10%	15%	4%	11%
	16:00-19:59	26%	15%	19%	24%
	20:00-23:59	42%	30%	21%	34%
		Day (n = 91)	**Day w/night (n = 17)**	**Night (n = 32)**	**Totals (N = 150)**
D3	Hrs working	237	44	76	n = 382
	Mean	11.4	11.8	11.6	11.4
	Median				12
	Std Dev	3.8	4.4	5.0	4.1
	Max	21	22	24	24
	Min	0 (n = 6)	2	0 (n = 1)	0 (n = 8)
D4	Hours driving	n = 231	n = 44	n = 75	n = 373
	Mean	8.0	8.6	9.1	8.3
	Median				8
	Std Dev	2.9	3.6	3.8	3.2
	Max	15	20	19	20
	Min	0 (n = 1)	2	1	0 (n = 2)
D5	Hours sleeping	n = 230	n = 45	n = 73	n = 373
	Mean	7.4	7.2	7.1	7.3
	Median				8
	Std Dev	1.7	1.5	2.4	1.9
	Max	13	10	15	15
	Min	0(n = 10)	4	0 (n = 3)	0 (n = 14)
D6	Hours napping	n = 52	N = 3	n = 13	n = 71
	Mean	1.9	0.9	2.5	2.0
	Median				2
	Std Dev	1.6	0.1	1.5	1.5
	Max	7	1	6	7
	Min	0 (n = 190)	0 (n = 45)	0 (n = 63)	0 (n = 321, 82%)

		Day (n = 91)	Day w/night (n = 17)	Night (n = 32)	Totals (N = 150)
D7	Hours loading	n = 140	n = 30	n = 38	n = 221
	Mean	2.6	2.7	2.6	2.6
	Median				2
	Std Dev	1.7	1.7	2.1	1.7
	Max	8	8	7.25	8
	Min	0 (n = 95)	0 (n = 14)	0 (n = 39)	0 (n = 161, 42%)
	> 3 sd	5			5
D8	Fatigue	n = 252	n = 51	n = 89	n = 422
	Mean	3.4	3.5	3.5	3.3
	Median				3
	Std Dev	2.0	1.9	2.1	2.0
	Max	7	7	7	7
	Min	1	1	1	1
How many nights since					
D25	24 hours off	n = 76	n = 16	n = 29	n = 127
	Mean	3.7	3.6	4.2	3.6
	Median				4
	Std Dev	1.9	2.3	4.3	2.0
	Max	8	10	17	10
	Min	0 (n = 3)	1	0 (n = 2)	0 (n = 5)
	> 3 sd	8	1		14
D26	36 hours off	n = 76	n = 16	n = 29	n = 125
	Mean	4.6	5.4	7.8	4.8
	Median				4
	Std Dev	3.2	2.9	7.8	3.2
	Max	14	11	30	14
	Min	0 (n = 2)	1	0 (n = 1)	0 (n = 3)
	> 3 sd	7	1		16
D27	48 hours off	n = 69	n = 16	n = 29	n = 132
	Mean	4.6	6.2	9.3	7.4
	Median				4
	Std Dev	3.0	4.1	9.3	7.6
	Max	14	17	30	30
	Min	0 (n = 2)	1	1	0 (n = 2)
	> 3 sd	13	1	1	7

		Day (n = 91)	Day w/night (n = 17)	Night (n = 32)	Totals (N = 150)
D28	72 hours off	n = 69	n = 14	n = 27	n = 97
	Mean	23.0	36.6	43.7	13.4
	Median				14
	Std Dev	27.5	46.6	50.8	10
	Max	100	160	180	40
	Min	0 (n = 1)	3	1	0 (n = 1)
	> 3 sd	6			30
Number of days off after an average workweek		n = 88	n = 17	n = 31	n = 144
B13	Mean	2.0	2.2	1.8	2.0
	Median				2
	Std Dev	0.8	0.8	0.8	0.8
	Max	5	4	4	4
	Min	0 (n = 1)	1	1	0 (n = 2)
	> 3 sd	2		1	3
Number of days off during an average month		n = 89	n = 17	n = 32	n = 148
B14	Mean	6.8	6.6	5.8	6.5
	Median				7
	Std Dev	2.5	2.1	2.7	2.5
	Max	13	10	12	13
	Min	1	2	1	1
	> 3 sd	1			1
After a long workweek, how many sleep periods		n = 87	n = 17	n = 31	n = 144
B15	Mean	2.4	2.6	1.9	2.2
	Median				2
	Std Dev	0.8	1.3	0.7	0.8
	Max	5	6.5	4	5
	Min	0 (n = 1)	1	1	0 (n = 1)
	> 3 sd	2			3

	Day 91 subjects			Day w/night 17 subjects			Night 32 subjects	
	Start (n = 165)	Stop (n = 165)		Start (n = 33)	Stop (n = 33)		Start (n = 53)	Stop (n = 53)
24:00-00:59	1%	10%		0%	0%		2%	11%
01:00-01:59	1%	5%		0%	15%		0%	2%
02:00-02:59	1%	1%		0%	12%		4%	15%
03:00-03:59	2%	1%		3%	3%		0%	4%
04:00-04:59	4%	0%		12%	0%		0%	6%
05:00-05:59	12%	0%		12%	3%		9%	6%
06:00-06:59	19%	1%		9%	3%		13%	0%
07:00-07:59	19%	1%		12%	3%		4%	2%
08:00-08:59	14%	1%		15%	0%		8%	4%
09:00-09:59	5%	1%		3%	0%		4%	8%
10:00-10:59	4%	1%		12%	0%		2%	0%
11:00-11:59	4%	0%		0%	0%		2%	0%
12:00-12:59	3%	2%		0%	3%		13%	2%
13:00-13:59	1%	1%		3%	0%		0%	2%
14:00-14:59	0%	2%		3%	6%		4%	0%
15:00-15:59	2%	5%		0%	6%		4%	0%
16:00-16:59	1%	9%		6%	3%		2%	4%
17:00-17:59	2%	4%		6%	6%		6%	2%
18:00-18:59	2%	7%		0%	3%		2%	11%
19:00-19:59	1%	7%		0%	3%		2%	2%
20:00-20:59	1%	7%		0%	6%		9%	6%
21:00-21:59	1%	8%		0%	3%		4%	2%
22:00-22:59	0%	13%		0%	6%		6%	4%
23:00-23:59	0%	14%		3%	15%		2%	9%

Table A1-9. High Fatigue vs. Low Fatigue Rating

		High Fatigue (n = 45)	Low Fatigue (n = 40)	Totals (n = 150)
Gender				
A2	Male	96%	100%	97%
	Female	4%		3%
Age				
	Mean	43 years	44 years	
A3	< 30	13%	15%	14%
	30-39	24%	20%	20%
	40-49	27%	35%	31%
	50-59	33%	20%	29%
	60 +	2%	10%	6%
Employer				
A4	Company	80%	75%	73%
	Independent	20%	25%	27%
Years of Experience				
A8	Mean	18 years	21 years	19 years
	Median	16	21.5	
	Std Dev	11.7	12.6	12
	Max	42	50	50
	Min	2	2	1
Haul				
A9	Long	78%	87%	87%
	Short	22%	13%	13%
Past 3 days (combined)				
D1	Start time			n = 401
	24:00-03:59	7%	6%	5%
	04:00-07:59	50%	43%	47%
	08:00-11:59	28%	30%	27%
	12:00-15:59	10%	9%	11%
	16:00-19:59	4%	5%	6%
	20:00-23:59	2%	7%	4%
D2	Stop time			n = 386
	24:00-03:59	25%	19%	22%
	04:00-07:59	4%	0%	4%
	08:00-11:59	3%	7%	5%
	12:00-15:59	11%	9%	11%
	16:00-19:59	19%	37%	24%
	20:00-23:59	38%	28%	34%

		High Fatigue (n = 45)	Low Fatigue (n = 40)	Totals (n = 150)
D3	Hours working			n = 382
	Mean	12.7	9.6	11.4
	Median	13	10	
	Std Dev	4.1	3.4	4.1
	Max	24	19	24
	Min	2	1	0 (n = 8)
	> 3 sd			0
D4	Hours driving			n = 373
	Mean	8.6	7.4	8.3
	Median	9	7.5	
	Std Dev	3.2	3.0	3.2
	Max	15	15	20
	Min	1	2	0 (n = 2)
	> 3 sd			0
D5	Hours sleeping			n = 373
	Mean	7.2	7.7	7.3
	Median	8	8	
	Std Dev	2.1	1.8	1.9
	Max	15	12	15
	Min	2	4	0 (n = 14)
	> 3 sd			0
D6	Hours napping	n = 23	n = 19	n = 71
	Mean	2.6	1.4	2.0
	Median	2	1	
	Std Dev	2.0	0.7	1.5
	Max	7	3	7
	Min	0 (n = 93)	0 (n = 84)	0 (n = 321, 82%)
D7	Hours loading	n = 72	n = 54	n = 221
	Mean	3.4	2.1	2.6
	Median	3	1.75	
	Std Dev	2.3	1.5	1.7
	Max	10	6	8
	Min	0 (n = 44)	0 (n = 45)	0 (n = 161)
	> 3 sd	0	0	5

		High Fatigue (n = 45)	Low Fatigue (n = 40)	Totals (n = 150)
D8	Fatigue			n = 422
	Mean	5.2	1.4	3.3
	Median	5	1	
	Std Dev	1.5	0.7	2.0
	Max	7	4	7
	Min	1	1	1
How many nights since				
D25	24 hours off	39	40	n = 127
	Mean	4.2	3.2	3.6
	Median	4	3	
	Std Dev	2.2	1.8	2.0
	Max	10	7	10
	Min	0 (n = 2)	0 (n = 1)	0 (n = 5)
	> 3 sd	4	5	14
D26	36 hours off	n = 37	n = 37	n = 125
	Mean	6.7	4.8	4.8
	Median	5	4	
	Std Dev	4.8	4.6	3.2
	Max	21	21	14
	Min	0 (n = 1)	0 (n = 1)	0 (n = 3)
	> 3 sd	1	2	16
D27	48 hours off	n = 35	n = 39	n = 132
	Mean	7.8	7.8	7.4
	Median	5	4	
	Std Dev	7.9	8.3	7.6
	Max	30	30	30
	75^{th} %-ile	12	8	10
	25^{th} %-ile	4	2	3
	Min	1	0 (n = 1)	0 (n = 2)
	> 3 sd	4	0	7
D28	72 hours off	n = 34	n = 31	n = 97
	Mean	37.0	15.3	13.4
	Median	21	14	
	Std Dev	43.5	15.4	10
	Max	160	60	40
	Min	1	0 (n = 1)	0 (n = 1)
	> 3 sd	1	4	30

		High Fatigue (n = 45)	Low Fatigue (n = 40)	Totals (n = 150)
Number of days off after an average workweek				n = 144
B13	Mean	2.0	2.1	2.0
	Median	2	2	
	Std Dev	1.1	0.8	0.8
	Max	7	5	4
	Min	0.6	1	0 (n = 2)
	> 3 sd			3
Number of days off during an average month				n = 148
B14	Mean	6.0	6.6	6.5
	Median	6	7	
	Std Dev	2.3	2.4	2.5
	Max	10	12	13
	Min	1	2	1
	> 3 sd			1
After a long workweek, how many sleep periods				n = 144
B15	Mean	2.1	2.4	2.2
	Median	2	2	
	Std Dev	0.8	0.9	0.8
	Max	4	6.5	5
	Min	1	1	0 (n = 1)
	> 3 sd			3

	High Fatigue 45 Subjects			Low Fatigue 40 subjects	
	Start (n = 123)	Stop (n = 117)		Start (n = 100)	Stop (n = 98)
24:00-00:59	1%	14%		2%	8%
01:00-01:59	2%	5%		0%	6%
02:00-02:59	2%	3%		1%	4%
03:00-03:59	2%	3%		3%	1%
04:00-04:59	2%	0%		7%	0%
05:00-05:59	15%	1%		12%	0%
06:00-06:59	20%	2%		10%	0%
07:00-07:59	11%	2%		14%	0%
08:00-08:59	12%	1%		14%	3%
09:00-09:59	7%	1%		6%	2%
10:00-10:59	7%	0%		5%	0%
11:00-11:59	2%	1%		5%	2%
12:00-12:59	5%	4%		4%	4%
13:00-13:59	4%	1%		0%	0%
14:00-14:59	1%	2%		2%	3%
15:00-15:59	0%	4%		3%	2%
16:00-16:59	2%	4%		1%	15%
17:00-17:59	2%	4%		1%	8%
18:00-18:59	1%	6%		2%	9%
19:00-19:59	0%	4%		1%	4%
20:00-20:59	1%	7%		3%	5%
21:00-21:59	1%	6%		3%	8%
22:00-22:59	0%	12%		0%	6%
23:00-23:59	0%	14%		1%	8%

Table A1-10. Low Predictability vs. High Predictability

		Low Predictability (n = 45)	High Predictability (n = 49)	Totals (n = 150)
Gender				
A2	Male	96%	96%	97%
	Female	4%	4%	3%
Age				
A3	< 30	22%	8%	14%
	30-39	22%	8%	20%
	40-49	24%	39%	31%
	50-59	29%	37%	29%
	60 +	2%	8%	6%
Employer				
A4	Company	71%	73%	73%
	Independent	29%	27%	27%
Years of Experience				
A8	Mean	16 years	23 years	19 years
	Median	15 years	24 years	20 years
	Std Dev	11.1	12.2	12
	Max	42	44	50
	Min	2	2	1
Haul				
A9	Long	91%	84%	87%
	Short	9%	16%	13%
Past 3 days (combined)				
D1	Start time	n = 114	n = 127	n = 401
	24:00-03:59	7%	2%	5%
	04:00-07:59	46%	46%	47%
	08:00-11:59	26%	27%	27%
	12:00-15:59	13%	13%	11%
	16:00-19:59	5%	6%	6%
	20:00-23:59	2%	7%	4%
D2	Stop time	n = 106	n = 106	n = 386
	24:00-03:59	28%	18%	22%
	04:00-07:59	8%	2%	4%
	08:00-11:59	3%	9%	5%
	12:00-15:59	11%	8%	11%
	16:00-19:59	21%	26%	24%
	20:00-23:59	28%	37%	34%

		Low Predictability (n = 45)	High Predictability (n = 49)	Totals (n = 150)
D3	Hours working	n = 105	n = 123	n = 382
	Mean	12.2	10.7	11.4
	Median	12	11	12
	Std Dev	4.2	4.0	4.1
	Max	22	24	24
	Min	4	1	
	Count=0	2	1	8
D4	Hours driving	n = 101	n = 121	n = 373
	Mean	9.0	8.2	8.3
	Median	9	9	8
	Std Dev	3.4	3.2	3.2
	Max	20	15	20
	Min	2	1	
	Count=0	0	1	2
D5	Hours sleeping	n = 102	n = 121	n = 373
	Mean	7.0	7.6	7.3
	Median	8	8	8
	Std Dev	2.0	2.0	1.9
	Max	13	15	15
	Min	2	2	
	Count=0	4	3	14
D6	Hours napping	n = 18	n = 24	n = 71
	Mean	2.7	1.5	2.0
	Median	0	0	0
	Std Dev	1.6	0.7	1.5
	Max	6	3	7
	Min	0.25	0.5	
	Count=0	90	101	321
D7	Hours loading	n = 72	n = 63	n = 221
	Mean	2.9	2.8	2.6
	Median	2	1	1
	Std Dev	2.0	1.9	1.7
	Max	9.5	10	8
	Min	0.17	0.5	
	Count=0	34	61	161

		Low Predictability (n = 45)	High Predictability (n = 49)	Totals (n = 150)
D8	Fatigue	n = 124	n = 138	n = 422
	Mean	3.9	3.0	3.3
	Median	4	3	3
	Std Dev	2.2	1.9	2.0
	Max	7	7	7
	Min	1	1	1
How many nights since				
D25	24 hours off	n = 39	n = 39	n = 127
	Mean	4.0	3.3	3.6
	Median	4	3	4
	Std Dev	2.0	1.9	2.0
	Max	9	8	10
	Min	1	1	
	Count=0	1	3	5
	> 3 sd	3	6	14
D26	36 hours off	n = 39	n = 44	n = 125
	Mean	5.7	7.1	4.8
	Median	5	4	4
	Std Dev	3.4	8.0	3.2
	Max	16	30	14
	Min	1	1	
	Count=0	1	2	3
	> 3 sd	3	0	16
D27	48 hours off	n = 40	n = 41	n = 132
	Mean	8.3	8.0	7.4
	Median	6	4	4
	Std Dev	7.4	8.9	7.6
	Max	30	30	30
	Min	0 (n = 3)	0 (n = 3)	
	> 3 sd	0	2	7
D28	72 hours off	n = 38	n = 41	n = 97
	Mean	37.7	33.1	13.4
	Median	17	14	14
	Std Dev	46.5	44.9	10
	Max	180	160	40
	Min	2	0 (n = 1)	0 (n = 1)
	> 3 sd	0	0	30

		Low Predictability (n = 45)	High Predictability (n = 49)	Totals (n = 150)
Number of days off after an average workweek		n = 44	n = 48	n = 144
B13	Mean	2.3	2.1	2.0
	Median	2	2	2
	Std Dev	1.3	1.2	0.8
	Max	7	6	4
	Min	1	0 (n = 1)	0 (n = 2)
	> 3 sd	0	0	3
Number of days off during an average month		n = 44	n = 49	n = 148
B14	Mean	6.3	7.0	6.5
	Median	7	8	7
	Std Dev	2.5	3.1	2.5
	Max	12	16	13
	Min	1	1	1
	> 3 sd	0	0	1
After a long workweek, how many sleep periods		n = 44	n = 47	n = 144
B15	Mean	2.4	2.4	2.2
	Median	2	2	2
	Std Dev	1.2	1.1	0.8
	Max	7	7	5
	Min	1	0 (n = 1)	0 (n = 1)
	> 3 sd	0	0	3

Table A1-11. Calgary vs. Toronto vs. Montreal

		Calgary (n = 50)	Toronto (n = 50)	Montreal (n = 50)	Totals (n = 150)
Gender					
A2	Male	94%	98%	100%	97%
	Female	6%	2%	0%	3%
Age					
	Mean	45 years	46 years	42 years	
A3	< 30	10%	16%	16%	14%
	30-39	24%	12%	24%	20%
	40-49	28%	30%	36%	31%
	50-59	34%	34%	18%	29%
	60 +	4%	8%	6%	6%
Employer					
A4	Company	64%	76%	80%	73%
	Independent	36%	24%	20%	27%
Years of Experience					
A8	Mean	21 years	21 years	16 years	19 years
	Median	20 years	23 years	13 years	20 years
	Std Dev	12	13	11	12
	Max	49	50	47	50
	Min	2	2	1	1
Haul					
A9	Long	96%	90%	76%	87%
	Short	4%	10%	24%	13%
Past 3 days (combined)					
D1	Start time	n = 125	n = 143	n = 132	n = 401
	24:00-03:59	6%	1%	8%	5%
	04:00-07:59	41%	45%	54%	47%
	08:00-11:59	24%	34%	23%	27%
	12:00-15:59	15%	8%	10%	11%
	16:00-19:59	8%	6%	2%	6%
	20:00-23:59	6%	4%	2%	4%
D2	Stop time	n = 122	n = 136	n = 128	n = 386
	24:00-03:59	25%	11%	28%	22%
	04:00-07:59	6%	2%	3%	4%
	08:00-11:59	7%	4%	3%	5%
	12:00-15:59	12%	10%	9%	11%
	16:00-19:59	20%	31%	21%	24%
	20:00-23:59	28%	42%	35%	34%

		Calgary (n = 50)	Toronto (n = 50)	Montreal (n = 50)	Totals (n = 150)
D3	Hours working	n = 124	n = 136	n = 122	n = 382
	Mean	9.9	12.0	12.1	11.4
	Median	10	12	12	11
	Std Dev	4.0	4.0	4.1	4.1
	Max	20	23	24	24
	Min	1	0 (n = 2)	0 (n = 6)	0 (n = 8)
	> 3 sd	0	0	0	0
D4	Hours driving	n = 117	n = 135	n = 121	n = 371
	Mean	8.7	8.4	7.8	8.3
	Median	9	8	8	8
	Std Dev	3.5	3.0	3.2	3.2
	Max	15	19	20	16
	Min	0 (n = 2)	2	2	0 (n = 2)
	> 3 sd	0	0	0	2
D5	Hours sleeping	n = 118	n = 131	n = 124	n = 372
	Mean	7.3	7.7	6.9	7.3
	Median	8	8	7	8
	Std Dev	1.9	1.9	1.8	1.9
	Max	15	13	12	13
	Min	0 (n = 6)	3	0 (n = 8)	0 (n = 14)
	> 3 sd	0	0	0	1
D6	Hours napping	n = 16	n = 26	n = 29	n = 71
	Mean	2.3	2.5	1.4	2.0
	Median	2	2	1	2
	Std Dev	1.4	1.9	0.8	1.5
	Max	6	7	4	7
	Min	0 (n = 106, 87%)	0 (n = 109, 81%)	0 (n = 104, 78%)	0 (n = 321, 82%)
	> 3 sd				
D7	Hours loading	n = 53	n = 71	n = 97	n = 221
	Mean	2.2	2.3	2.9	2.6
	Median	2	2	2.5	2
	Std Dev	1.8	1.6	1.7	1.7
	Max	7.5	7.25	8	8
	Min	0 (n = 71)	0 (n = 61)	0 (n = 29)	0 (n = 161)
	> 3 sd	1	2	2	5

		Calgary (n = 50)	Toronto (n = 50)	Montreal (n = 50)	Totals (n = 150)
D8	Fatigue	n = 143	n = 134	n = 145	n = 422
	Mean	3.0	3.6	3.4	3.3
	Median	3	3	3	3
	Std Dev	2.0	1.9	2.0	2.0
	Max	7	7	7	7
	Min	1	1	1	1
How many nights since					
D25	24 hours off	n = 38	n = 44	n = 45	n = 127
	Mean	3.7	3.8	3.4	3.6
	Median	4	4	4	4
	Std Dev	2.3	2.4	1.2	2.0
	Max	10	10	7	10
	Min	0 (n = 1)	0 (n = 3)	0 (n = 1)	0 (n = 5)
	> 3 sd	10	3	1	14
D26	36 hours off	n = 38	n = 45	n = 40	n = 125
	Mean	5.9	4.7	3.6	4.8
	Median	6	4	4	4
	Std Dev	3.9	3.4	1.3	3.2
	Max	14	14	8	14
	Min	0 (n = 1)	0 (n = 1)	0 (n = 1)	0 (n = 3)
	> 3 sd	10	3	6	16
D27	48 hours off	n = 45	n = 42	n = 38	n = 132
	Mean	10.8	5.0	3.8	7.4
	Median	7	5	4	4
	Std Dev	9.5	3.5	1.6	7.6
	Max	30	14	9	30
	Min	1	0 (n = 1)	0 (n = 1)	0 (n = 2)
	> 3 sd	4	5	4	7
D28	72 hours off	n = 36	n = 34	n = 27	n = 97
	Mean	13.2	13.1	14.2	13.4
	Median	14	14	21	16
	Std Dev	10.4	9.5	10.7	10
	Max	40	31	30	40
	Min	1	1	0 (n = 1)	0 (n = 1)
	> 3 sd	13	11	6	30

		Calgary (n = 50)	Toronto (n = 50)	Montreal (n = 50)	Totals (n = 150)
Number of days off after an average workweek		n = 44	n = 50	n = 50	n = 144
B13	Mean	2.0	2.0	1.9	2.0
	Median	2	2	2	2
	Std Dev	0.9	0.7	0.6	0.8
	Max	4	4	4	4
	Min	0 (n = 2)	1	0,6	0 (n = 2)
	> 3 sd	3	0	0	3
Number of days off during an average month		n = 49	n = 50	n = 49	n = 148
B14	Mean	5.9	6.6	7.0	6.5
	Median	5	7	8	7
	Std Dev	3.0	2.2	2.0	2.5
	Max	13	12	12	13
	Min	1	1	2	1
	> 3 sd	0	0	1	1
After a long workweek, how many sleep periods		n = 44	n = 50	n = 50	n = 144
B15	Mean	2.1	2.4	2.2	2.2
	Median	2	2	2	2
	Std Dev	0.8	0.8	0.8	0.8
	Max	4	4	5	5
	Min	1	1	1	0 (n = 1)
	> 3 sd	3	0	0	3

	Calgary 50 subject			Toronto 50 subjects			Montreal 50 subjects	
	Start (n = 125)	Stop (n = 121)		Start (n = 143)	Stop (n = 136)		Start (n = 132)	Stop (n = 128)
24:00-00:59	2%	12%		0%	4%		3%	19%
01:00-01:59	1%	6%		0%	3%		1%	7%
02:00-02:59	2%	7%		1%	3%		1%	2%
03:00-03:59	2%	2%		0%	2%		4%	1%
04:00-04:59	5%	2%		5%	1%		5%	0%
05:00-05:59	6%	1%		10%	1%		17%	1%
06:00-06:59	14%	2%		19%	0%		20%	1%
07:00-07:59	17%	2%		12%	0%		13%	2%
08:00-08:59	10%	1%		18%	1%		14%	1%
09:00-09:59	4%	2%		8%	2%		5%	2%
10:00-10:59	6%	2%		6%	0%		2%	0%
11:00-11:59	4%	2%		2%	0%		2%	1%
12:00-12:59	10%	3%		3%	5%		3%	1%
13:00-13:59	2%	2%		2%	1%		1%	0%
14:00-14:59	3%	6%		2%	1%		2%	2%
15:00-15:59	1%	2%		1%	3%		4%	6%
16:00-16:59	0%	7%		3%	5%		1%	10%
17:00-17:59	3%	7%		2%	3%		1%	5%
18:00-18:59	3%	4%		1%	13%		1%	4%
19:00-19:59	2%	2%		1%	10%		0%	2%
20:00-20:59	2%	7%		1%	7%		2%	7%
21:00-21:59	1%	4%		2%	7%		0%	7%
22:00-22:59	2%	7%		1%	13%		0%	9%
23:00-23:59	1%	10%		0%	15%		0%	11%

Table A1-12: Long Haul vs. Short Haul

		Long Haul (n = 131)	Short Haul (n = 19)	Totals (n = 150)
Gender				
	Male	98%	95%	97%
	Female	2%	5%	3%
Age				
	< 30	15%	5%	14%
	30-39	20%	21%	20%
	40-49	31%	32%	31%
	50-59	28%	32%	29%
	60 +	5%	11%	6%
Employer				
	Company	72%	84%	73%
	Independent	28%	16%	27%
Years of Experience				
	Mean	19 years	19 years	19 years
	Std Dev	12	11	12
	Max	50	35	50
	Min	1	2	1
Haul				
	Long	0%	100%	87%
	Short	100%	0%	13%
Past 3 days (combined)				
	Start time	n = 350	n = 50	n = 401
	24:00-03:59	5%	6%	5%
	04:00-07:59	44%	66%	47%
	08:00-11:59	30%	10%	27%
	12:00-15:59	11%	14%	11%
	16:00-19:59	6%	4%	6%
	20:00-23:59	5%	0%	4%
	Stop time	n = 336	n = 50	n = 386
	24:00-03:59	24%	12%	22%
	04:00-07:59	4%	4%	4%
	08:00-11:59	5%	4%	5%
	12:00-15:59	10%	14%	11%
	16:00-19:59	21%	46%	24%
	20:00-23:59	37%	20%	34%
D3	Hours working	n = 334	n = 48	n = 382
	Mean	11.5	10.5	11.4
	Std Dev	4.2	4.3	4.1
	Max	23	21	24
	Min	0 (n = 6)	0 (n = 2)	0 (n = 8)
	> 3 sd	0	0	0

		Long Haul (n = 131)	Short Haul (n = 19)	Totals (n = 150)
D4	Hours driving	n = 324	n = 47	n = 371
	Mean	8.7	5.4	8.3
	Std Dev	3.0	2.2	3.2
	Max	16	10	16
	Min	0 (n = 2)	2	0 (n = 2)
	> 3 sd	2	0	2
D5	Hours sleeping	n = 325	n = 48	n = 372
	Mean	7.4	6.9	7.3
	Std Dev	1.9	1.6	1.9
	Max	15	10	13
	Min	0 (n = 12)	0 (n = 2)	0 (n = 14)
	> 3 sd			1
D6	Hours napping	n = 56	n = 15	n = 71
	Mean	2.2	1.4	2.0
	Std Dev	1.5	1.5	1.5
	Max	7	6,5	7
	Min	0 (n = 286)	0 (n = 35)	0 (n = 321, 82%)
	> 3 sd			0
D7	Hours loading	n = 186	n = 40	n = 221
	Mean	2.4	4.3	2.6
	Std Dev	1.8	2.3	1.7
	Max	9.5	10	8
	Min	0 (n = 151)	0 (n = 10)	0 (n = 161)
	> 3 sd			5
D8	Fatigue	n = 368	n = 54	n = 422
	Mean	3.3	3.6	3.3
	Std Dev	2.0	2.2	2.0
	Max	7	7	7
	Min	1	1	1
How many nights since				
D25	24 hours off	n = 115	n = 16	n = 127
	Mean	4.7	3.2	3.6
	Std Dev	4.2	1.3	2.0
	Max	21	5	10
	Min	0 (n = 4)	0 (n = 1)	0 (n = 5)
	> 3 sd	3	1	14

		Long Haul (n = 131)	Short Haul (n = 19)	Totals (n = 150)
D26	36 hours off	n = 118	n = 18	n = 125
	Mean	6.6	4.3	4.8
	Std Dev	6.3	3.2	3.2
	Max	30	14	14
	Min	0 (n = 3)	0	0 (n = 3)
	> 3 sd	2	0	16
D27	48 hours off	n = 115	n = 17	n = 132
	Mean	8.0	3.7	7.4
	Std Dev	8.0	2.1	7.6
	Max	30	11	30
	Min	0 (n = 2)	1	0 (n = 2)
	> 3 sd	5	1	7
D28	72 hours off	n = 110	n = 13	n = 97
	Mean	37.1	12.0	13.4
	Std Dev	47.6	10.6	10
	Max	180	30	40
	Min	0 (n = 1)	2	0 (n = 1)
	> 3 sd	0	2	30
Number of days off after an average workweek		n = 129	n = 19	n = 144
B13	Mean	2.1	2.1	2.0
	Std Dev	1.1	0.8	0.8
	Max	7	4	4
	Min	0 (n = 2)	1	0 (n = 2)
	> 3 sd			3
Number of days off during an average month		n = 130	n = 19	n = 148
B14	Mean	6.4	7.4	6.5
	Std Dev	2.6	2.0	2.5
	Max	16	12	13
	Min	1	4	1
	> 3 sd			1
After a long workweek, how many sleep periods		n = 128	n = 19	n = 144
B15	Mean	2.4	2.3	2.2
	Std Dev	1.0	0.9	0.8
	Max	7	4	5
	Min	0 (n = 1)	1	0 (n = 1)
	> 3 sd			3

	Long haul 131 subjects			Short haul 19 subjects	
	Start (n = 350)	Stop (n = 335)		Start (n = 50)	Stop (n = 50)
24:00-00:59	2%	12%		0%	8%
01:00-01:59	0%	6%		2%	2%
02:00-02:59	1%	4%		0%	2%
03:00-03:59	1%	2%		4%	0%
04:00-04:59	5%	1%		6%	0%
05:00-05:59	9%	1%		24%	2%
06:00-06:59	17%	1%		24%	0%
07:00-07:59	14%	1%		12%	2%
08:00-08:59	15%	1%		4%	2%
09:00-09:59	6%	2%		4%	0%
10:00-10:59	5%	1%		2%	0%
11:00-11:59	3%	1%		0%	2%
12:00-12:59	5%	4%		2%	0%
13:00-13:59	1%	1%		6%	0%
14:00-14:59	3%	2%		0%	8%
15:00-15:59	1%	3%		6%	6%
16:00-16:59	1%	6%		0%	20%
17:00-17:59	2%	4%		2%	12%
18:00-18:59	2%	7%		0%	8%
19:00-19:59	1%	5%		2%	6%
20:00-20:59	2%	8%		0%	0%
21:00-21:59	1%	7%		0%	2%
22:00-22:59	1%	11%		0%	0%
23:00-23:59	1%	11%		0%	18%

Table A1-13: Company vs. Contractor Drivers

		Company (n = 110)	Contractor (n = 40)	Totals n = 150)
Gender				
	Male	97%	98%	97%
	Female	3%	2%	3%
Age				
	Mean	44 years	46 years	
	< 30	15%	10%	14%
	30-39	20%	20%	20%
	40-49	29%	38%	31%
	50-59	30%	25%	29%
	60 +	5%	8%	6%
Years of Experience				
	Mean	18 years	22 years	19 years
	Std Dev	12.2	10.5	12
	Max	50	44	50
	Min	1	2	1
Haul				
	Long	85%	93%	87%
	Short	15%	8%	13%
Past 3 days (combined)				
	Start time	n = 298	n = 102	n = 401
	24:00-03:59	4%	8%	5%
	04:00-07:59	47%	47%	47%
	08:00-11:59	31%	17%	27%
	12:00-15:59	10%	15%	11%
	16:00-19:59	6%	6%	6%
	20:00-23:59	3%	10%	4%
	Stop time	n = 286	n = 99	n = 386
	24:00-03:59	21%	26%	22%
	04:00-07:59	4%	3%	4%
	08:00-11:59	3%	10%	5%
	12:00-15:59	11%	10%	11%
	16:00-19:59	27%	17%	24%
	20:00-23:59	35%	33%	34%
	Hours working	n = 285	n = 97	n = 382
	Mean	11.4	11.3	11.4
	Std Dev	4.1	4.4	4.1
	Max	24	22	24
	Min	0 (n = 4)	0 (n = 4)	0 (n = 8)
	> 3 sd			0

		Company (n = 110)	Contractor (n = 40)	Totals n = 150)
	Hours driving	n = 282	n = 90	n = 371
	Mean	8.1	8.9	8.3
	Std Dev	3.1	3.4	3.2
	Max	16	19	16
	Min	0 (n = 1)	0 (n = 1)	0 (n = 2)
	> 3 sd	1		2
	Hours sleeping	n = 278	N = 93	n = 372
	Mean	7.5	6.7	7.3
	Std Dev	1.7	2.0	1.9
	Max	12	12	13
	Min	0 (n = 9)	0 (n = 5)	0 (n = 14)
	> 3 sd	2		1
	Hours napping	n = 54	n = 17	n = 71
	Mean	1.9	2.2	2.0
	Std Dev	1.6	1.2	1.5
	Max	7	6	7
	Min	0 (n = 238)	0 (n = 83)	0 (n = 321, 82%)
	> 3 sd			0
	Hours loading	n = 167	n = 55	n = 221
	Mean	2.5	2.8	2.6
	Std Dev	1.6	2.3	1.7
	Max	7.25	10	8
	Min	0 (n = 122)	0 (n = 43)	0 (n = 161)
	> 3 sd	4		5
	Fatigue	n = 314	n = 108	n = 422
	Mean	3.4	3.2	3.3
	Std Dev	2.0	1.9	2.0
	Max	7	7	7
	Min	1	1	1
How many nights since				
	24 hours off	n = 99	n = 36	n = 127
	Mean	4.8	3.3	3.6
	Std Dev	4.1	2.1	2.0
	Max	21	9	10
	Min	0 (n = 5)	1	0 (n = 5)
	> 3 sd	2	3	14

		Company (n = 110)	Contractor (n = 40)	Totals n = 150)
	36 hours off	n = 100	n = 36	n = 125
	Mean	6.6	5.4	4.8
	Std Dev	6.3	5.2	3.2
	Max	30	23	14
	Min	0 (n = 3)	1	0 (n = 3)
	> 3 sd	0	2	16
	48 hours off	n = 96	n = 36	n = 132
	Mean	7.4	7.4	7.4
	Std Dev	7.6	7.7	7.6
	Max	30	30	30
	Min	0 (n = 2)	1	0 (n = 2)
	> 3 sd	4	2	7
	72 hours off	n = 83	n = 34	n = 97
	Mean	23.2	39.6	13.4
	Std Dev	26.2	53.2	10
	Max	100	180	40
	Min	0 (n = 1)	1	0 (n = 1)
	> 3 sd	7	1	30
Number of days off after an average workweek				
	Mean	2.1	2.2	2.0
	Std Dev	0.8	1.6	0.8
	Max	4	7	4
	Min	0 (n = 1)	0 (n = 1)	0 (n = 2)
	> 3 sd			3
Number of days off during an average month				
	Mean	6.5	6.5	6.5
	Std Dev	2.4	2.8	2.5
	Max	12	13	13
	Min	1	2	1
	> 3 sd	1		1
After a long workweek, how many sleep periods				
	Mean	2.3	2.4	2.2
	Std Dev	0.8	1.5	0.8
	Max	5	7	5
	Min	0 (n = 1)	1	0 (n = 1)
	> 3 sd			3

	Company 110 subjects			Contractor 40 subjects	
	Start (n = 298)	Stop (n = 286)		Start (n = 102)	Stop (n = 99)
24:00-00:59	1%	10%		3%	15%
01:00-01:59	0%	5%		1%	6%
02:00-02:59	1%	4%		1%	2%
03:00-03:59	1%	1%		3%	3%
04:00-04:59	6%	1%		3%	2%
05:00-05:59	9%	1%		15%	0%
06:00-06:59	18%	1%		15%	1%
07:00-07:59	13%	1%		15%	0%
08:00-08:59	16%	0%		9%	3%
09:00-09:59	6%	1%		3%	6%
10:00-10:59	6%	1%		3%	0%
11:00-11:59	3%	1%		2%	1%
12:00-12:59	4%	3%		8%	3%
13:00-13:59	1%	0%		2%	2%
14:00-14:59	2%	3%		4%	2%
15:00-15:59	3%	4%		0%	3%
16:00-16:59	1%	8%		1%	6%
17:00-17:59	2%	5%		1%	4%
18:00-18:59	1%	8%		2%	3%
19:00-19:59	1%	5%		1%	4%
20:00-20:59	1%	7%		2%	8%
21:00-21:59	0%	6%		4%	7%
22:00-22:59	0%	10%		3%	9%
23:00-23:59	2%	12%		0%	9%

Table A1-14: Tanker vs. Non-tanker Drivers

		Tanker (n = 11)	Non-tankers (n = 139)	Totals (n = 150)
Gender				
A2	Male	91%	98%	97%
	Female	9%	2%	3%
Age				
A3	< 30	9%	14%	14%
	30-39	9%	21%	20%
	40-49	36%	31%	31%
	50-59	45%	27%	29%
	60 +	0%	7%	6%
Employer				
A4	Company	73%	73%	73%
	Independent	27%	27%	27%
Years of Experience				
A8	Mean	22 years	19 years	19 years
	Std Dev	12	12	12
	Max	40	50	50
	Min	4	1	1
Haul				
A9	Long	64%	91%	87%
	Short	36%	9%	13%
Past 3 days (combined)				
D1	Start time	n = 29	n = 368	n = 401
	24:00-03:59	7%	5%	5%
	04:00-07:59	34%	47%	47%
	08:00-11:59	45%	26%	27%
	12:00-15:59	7%	7%	11%
	16:00-19:59	3%	6%	6%
	20:00-23:59	3%	4%	4%
D2	Stop time	n = 28	n = 355	n = 386
	24:00-03:59	18%	22%	22%
	04:00-07:59	0	4%	4%
	08:00-11:59	0	5%	5%
	12:00-15:59	11%	11%	11%
	16:00-19:59	36%	24%	24%
	20:00-23:59	36%	34%	34%
D3	Hours working	n = 28	n = 351	n = 382
	Mean	11.0	11.4	11.4
	Std Dev	4.0	4.2	4.1
	Max	20	24	24
	Min	5	0 (n = 8)	0 (n = 8)
	> 3 sd	0	0	0

		Tanker (n = 11)	Non-tankers (n = 139)	Totals (n = 150)
D4	Hours driving	n = 27	n = 345	n = 371
	Mean	7.5	8.3	8.3
	Std Dev	2.5	3.3	3.2
	Max	15	20	16
	Min	3	0 (n = 2)	0 (n = 2)
	> 3 sd	0	0	2
D5	Hours sleeping	n = 25	n = 345	n = 372
	Mean	7.4	7.3	7.3
	Std Dev	2.2	1.8	1.9
	Max	11	13	13
	Min	0 (n = 1)	0 (n = 13)	0 (n = 14)
	> 3 sd	0	0	1
D6	Hours napping	n = 4	n = 67	n = 71
	Mean	3.1	1.9	2.0
	Std Dev	2.2	1.5	1.5
	Max	6,5	7	7
	Min	0 (n = 24)	0 (n = 294)	0 (n = 321, 82%)
	> 3 sd	0	0	0
D7	Hours loading	n = 18	n = 200	n = 221
	Mean	2.8	2.4	2.6
	Std Dev	2.1	1.6	1.7
	Max	7	7,5	8
	Min	0 (n = 10)	0 (n = 148	0 (n = 161)
	> 3 sd	0	5	5
D8	Fatigue	n = 32	n = 387	n = 422
	Mean	3.5	3.3	3.3
	Std Dev	2.3	2.0	2.0
	Max	7	7	7
	Min	1	1	1
How many nights since				
D25	24 hours off	n = 11	n = 116	n = 127
	Mean	3.4	3.7	3.6
	Std Dev	1.6	2.0	2.0
	Max	5	10	10
	Min	0	0 (n = 5)	0 (n = 5)
	> 3 sd	0	14	14

		Tanker (n = 11)	Non-tankers (n = 139)	Totals (n = 150)
D26	36 hours off	n = 11	n = 113	n = 125
	Mean	4.3	4.7	4.8
	Std Dev	2.9	3.2	3.2
	Max	11	14	14
	Min	1	0 (n = 3)	0 (n = 3)
	> 3 sd	0	11	16
D27	48 hours off	n = 11	n = 120	n = 132
	Mean	4.3	7.6	7.4
	Std Dev	2.9	7.9	7.6
	Max	11	30	30
	Min	1	0 (n = 2)	0 (n = 2)
	> 3 sd	0	7	7
D28	72 hours off	n = 8	n = 88	n = 97
	Mean	7.6	14.0	13.4
	Std Dev	3.3	10.4	10
	Max	14	40	40
	Min	5	0 (n = 1)	0 (n = 1)
	> 3 sd	0	30	30
Number of days off after an average workweek		n = 11	n = 133	n = 144
B13	Mean	2.2	2.0	2.0
	Std Dev	0.6	0.8	0.8
	Max	4	4	4
	Min	2	0 (n = 2)	0 (n = 2)
	> 3 sd	0	3	3
Number of days off during an average month		n = 11	n = 136	n = 148
B14	Mean	8.2	6.4	6.5
	Std Dev	1.4	2.5	2.5
	Max	10	13	13
	Min	6	1	1
	> 3 sd	0	1	1
After a long workweek, how many sleep periods		n = 11	n = 132	n = 144
B15	Mean	2.5	2.2	2.2
	Std Dev	0.7	0.8	0.8
	Max	4	5	5
	Min	2	0 (n = 1)	0 (n = 1)
	> 3 sd	0	3	3

	Tanker 11 subjects			Non-tanker 139 subjects	
	Start (n = 29)	Stop (n = 28)		Start (n = 368)	Stop (n = 354)
24:00-00:59	0%	7%		2%	12%
01:00-01:59	0%	4%		1%	5%
02:00-02:59	3%	7%		1%	3%
03:00-03:59	3%	4%		2%	2%
04:00-04:59	7%	0%		5%	1%
05:00-05:59	7%	0%		11%	1%
06:00-06:59	14%	0%		17%	1%
07:00-07:59	7%	0%		14%	1%
08:00-08:59	14%	0%		14%	1%
09:00-09:59	14%	0%		5%	2%
10:00-10:59	14%	0%		4%	1%
11:00-11:59	3%	0%		3%	1%
12:00-12:59	3%	4%		5%	3%
13:00-13:59	0%	0%		2%	1%
14:00-14:59	0%	7%		3%	3%
15:00-15:59	3%	0%		2%	4%
16:00-16:59	0%	4%		1%	8%
17:00-17:59	0%	4%		2%	5%
18:00-18:59	0%	18%		2%	6%
19:00-19:59	3%	11%		1%	5%
20:00-20:59	3%	4%		1%	6%
21:00-21:59	0%	11%		1%	6%
22:00-22:59	0%	4%		1%	10%
23:00-23:59	0%	15%		0%	12%

Table A1-15. One Page vs. Full Survey

		Full Interview (n = 150)	One Page Survey (n = 153)
Gender			
A2	Male	97%	99%
	Female	3%	1%
Age			
A3	< 30	14%	5%
	30-39	20%	23%
	40-49	31%	37%
	50-59	29%	25%
	60 +	6%	10%
Employer			
A4	Company	73%	73%
	Independent	27%	27%
Years of Experience			
A8	Mean	19 years	19 years
	Std Dev	12	12
	Max	50	47
	Min	1	1
Haul			
A9	Long	87%	71%
	Short	13%	29%
Past 3 days (combined)			
D1	Start time	n = 401	n = 363
	24:00-03:59	5%	10%
	04:00-07:59	47%	51%
	08:00-11:59	27%	22%
	12:00-15:59	11%	6%
	16:00-19:59	6%	6%
	20:00-23:59	4%	4%
D2	Stop time	n = 386	n = 338
	24:00-03:59	22%	14%
	04:00-07:59	4%	7%
	08:00-11:59	5%	9%
	12:00-15:59	11%	12%
	16:00-19:59	24%	28%
	20:00-23:59	34%	30%
D3	Hours working	n = 382	n = 338
	Mean	11.4	10.0
	Std Dev	4.1	4.0
	Max	24	21
	Min	0 (n = 8)	0 (n = 3)
	> 3 sd	0	1

		Full Interview (n = 150)	One Page Survey (n = 153)
D4	Hours driving	n = 371	n = 347
	Mean	8.3	7.9
	Std Dev	3.2	3.2
	Max	16	15
	Min	0 (n = 2)	0 (n = 2)
	> 3 sd	2	0
D5	Hours sleeping	n = 372	n = 316
	Mean	7.3	7.9
	Std Dev	1.9	1.7
	Max	13	13
	Min	0 (n = 14)	0 (n = 17)
	> 3 sd	1	4
D6	Hours napping	n = 71	n = 76
	Mean	2.0	2.1
	Std Dev	1.5	1.3
	Max	7	6
	Min	0 (n = 321, 82%)	0 (n = 256)
	> 3 sd	0	5
D7	Hours loading	n = 221	n =224
	Mean	2.6	2.4
	Std Dev	1.7	1.5
	Max	8	6
	Min	0 (n = 161)	0 (n = 110)
	> 3 sd	5	11
D8	Fatigue	n = 422	n = 357
	Mean	3.3	3.2
	Std Dev	2.0	1.8
	Max	7	7
	Min	1	1
How many nights since			
D25	24 hours off	n = 127	n = 136
	Mean	3.6	3.4
	Std Dev	2.0	1.9
	Max	10	9
	Min	0 (n = 5)	0 (n = 1)
	> 3 sd	14	7

		Full Interview (n = 150)	One Page Survey (n = 153)
D26	36 hours off	n = 125	n = 135
	Mean	4.8	4.6
	Std Dev	3.2	3.2
	Max	14	14
	Min	0 (n = 3)	0 (n = 1)
	> 3 sd	16	7
D27	48 hours off	n = 132	n = 126
	Mean	7.4	5.1
	Std Dev	7.6	3.7
	Max	30	14
	Min	0 (n = 2)	1
	> 3 sd	7	17
D28	72 hours off	n = 97	n = 98
	Mean	13.4	9.8
	Std Dev	10	8.4
	Max	40	30
	Min	0 (n = 1)	1
	> 3 sd	30	44
Number of days off after an average workweek		n = 144	n = 139
B13	Mean	2.0	1.9
	Std Dev	0.8	0.6
	Max	4	4
	Min	0 (n = 2)	0 (n = 3)
	> 3 sd	3	3
Number of days off during an average month		n = 148	n = 148
B14	Mean	6.5	7.1
	Std Dev	2.5	2.1
	Max	13	12
	Min	1	0 (n = 1)
	> 3 sd	1	2
After a long workweek, how many sleep periods		n = 144	n = 141
B15	Mean	2.2	2.4
	Std Dev	0.8	0.8
	Max	5	4
	Min	0 (n = 1)	0 (n = 1)
	> 3 sd	3	3

APPENDIX B

FACTORS TO BE CONSIDERED IN EXPERIMENTAL PROTOCOLS

One of the aims of the Phase I literature review (TP 14206E) was to identify factors that should be considered in the development of experimental protocols to determine recovery periods for commercial drivers that will result in a return to “normal performance levels” at the beginning of the next work week. Table B-1 shows the factors that were identified with respect to schedules that should be examined, measures that could be used, subject selection criteria and restrictions, individual differences that might be examined, and other considerations.

With respect to the schedules that should be studied, while there have been laboratory and on-road studies of daytime driving in relation to recovery, there is minimal information on nighttime driving and recovery. Given the difficulty of obtaining good quality sleep during the day and the sleep debt associated with night driving, studies of recovery from nighttime driving are particularly critical. Based on the study of nurses on a variety of schedules, two recovery days were required based on measures of alertness (Totterdell, Spelten, Smith, Barton, & Folkard, 1995), sleep duration, mood and social satisfaction. Alertness was still improving on the third day. In another study, most shift workers reported that they needed two days with two normal sleep episodes to recover after three consecutive nights, and an additional recovery day after seven consecutive nights (Kecklund & Akerstedt, 1995). Using a small sample of drivers who completed four 13 hour nights, Wylie et al. found that, after a 36-hour recovery period, performance was worse than it had been at the start of the previous week (Wylie, Shultz, Miller, Mitler, & Mackie, 1997). Based on these studies, recovery periods examined in experimental protocols should include, at a minimum, no recovery, one night, two nights, and three nights.

With respect to measures, most studies involve subjective, physiological and performance measures. Subjective measures are relevant when doing studies on fatigue because it is essentially a subjective concept. However, subjective measures by their very nature are subject to individual interpretation and bias. Such measures can also be manipulated by respondents to reflect other environmental biases. However, careful, within-subject comparisons of valid instruments that have been assessed for reliability and internal bias can be helpful in assessing fatigue, performance and sleep, especially if they are assessed along with other more objective measures.

Physiological measures are good objective measures, but when used as psychophysiological measures (i.e., physiological measures that are intended to reflect psychological concepts such as fatigue) can be subject to difficulties in interpretation. For instance, EEG measures can serve as good measures of alertness and fatigue since there is a wide body of literature relating EEG frequencies to drowsiness potential. Eyelid closures can also be useful since it is difficult to respond to stimuli in the environment if the eyes are not sufficiently open to acquire the stimuli. On the other hand, the interpretation of measures such as heart rate are more difficult to assess since heart rate can vary because of many parameters. Without sufficient control over the environment, such measures are difficult to interpret.

Performance measures can be used as effective probes to assess performance and change in performance associated with fatigue. Such measures that have been used successfully include the PVT, a cognitive test that is very sensitive to sleep deprivation and circadian rhythm, and that was used in many of the studies we reviewed. In addition, performance measures should include driving measures, particularly lane-tracking variability, which has been shown to be sensitive to drowsiness and fatigue. Driving performance may not be as sensitive as PVT, for example, but it has strong face validity. Measures involving the identification of driving incidents are of particular interest.

With respect to subject screening criteria, age has been clearly associated with sleep quality and length, especially for shift workers. Drivers with untreated sleep disorders should be screened out. Currently, there are effective screening tools to assess, in a self-administered fashion, the most common sleep disorder of concern, i.e., sleep apnea. Instruments such as the Edentrace and the Sleep Strip can be used at home by participants. Simple instructions are given and the results are stored for later interpretation. Full polysomnographic screening is no longer necessary. In order to understand individual differences in recovery many variables should be recorded, whether or not they are used as screening criteria. These include chronotype, napping behaviour, caffeine, alcohol and drug use, family circumstances, and commuting distance.

The impact of napping on the length of recovery should be examined, as should the effect of age and other individual differences such as circadian adapters, nappers, particular chronotypes, and lifestyle issues.

Table B-1. Potential Factors to be Considered in Experimental Protocols

SCHEDULES
• Daytime, nighttime, regular, irregular • Length of recovery period • Length and timing of sleep allowed during work • Length of sleep allowed during recovery • Loading/unloading activity – length and timing • Naps allowed during work
MEASURES
• Desirable characteristics of measures: naturalistic or short learning curve • Sensitivity to circadian phase, sleepiness • Subjective measures: – Stanford sleepiness – Sleep diaries (length, quality and alertness after main sleeps and naps) – Driver assessment of whether recovery sleep was as long as was needed and, if not, what prevented them from obtaining adequate sleep – difficulty sleeping or social/family/other engagements – Job satisfaction • Physiological measures: – EEG – Polysomnographic sleep recordings – Wrist actigraph – Urine melatonin levels • Test battery measures: – PVT (lapses, fastest 10 percent) – Cognitive test battery (e.g., Walter Reed Test Battery) – Driving performance measures – simulator/on road - Lane position variability - Speed maintenance - Shifting performance - Response probes (e.g., fog) - Critical incidents assessed by video/instructors • To be recorded: – Caffeine consumption – Exposure to light – Drug use – Prior sleep-wake schedule
SUBJECT SCREENING CRITERIA
• Smoking • Caffeine use • Alcohol use • Licence type • Age • Sleep disorders • Chronotype • Toxicological screening for illicit drugs

INDIVIDUAL DIFFERENCES
• Age • Gender • Height/weight ratio as indicator of physical health • Traits predictive of vulnerability to performance impairment due to sleep loss (health status, sleep disorders, family situation, chronotype) • Habitual napper or non-napper • Psychosocial factors (young children at home, commuting distance)
RESTRICTIONS
• Rest time • Location of rest • Caffeine • Alcohol
OTHER CONSIDERATIONS
• Impact of study demands on subjects' ability to sleep • Unexpected delays (customs, traffic, etc.)

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APPENDIX C

LITERATURE REVIEW (PHASE I): DISCUSSION AND SUMMARY

TP 14206E, INVESTIGATION OF COMMERCIAL MOTOR VEHICLE DRIVER CUMULATIVE FATIGUE RECOVERY PERIODS

1. RECOVERY AND TRUCKING

A field study of recovery (Wylie, Shultz, Miller, Mitler, & Mackie, 1997), based on a very limited sample of drivers, showed that, based on sleep and lane tracking data, 60 hours off are preferable to 36 hours, for both day and night drivers, but especially for the latter . Three daytime drivers, who had two work cycles off, showed no decline in performance, while those with 36 hours off showed some decline in performance when they started their second week of driving. In general, performance of night drivers was worse than that of day drivers. The night drivers who had 36 hours off had worse performance during the second week as compared to the first week of driving. Unfortunately the impact of 60 hours off on night drivers' recovery was not investigated in this study.

Under ideal conditions, with no family or social commitments, and unrestricted time for sleep on recovery days (O'Neil, Krueger, Van Hemel, & McGowan, 1999), a time-off period that allowed two full nights and one full day off, i.e. 36 hours, allowed full recovery from daytime driving. The main limitation of this study was that it was a laboratory study, restricted to daytime driving, and there were no demands on the subjects competing for sleep time. As a result their sleep times were longer (on average 6.5 hours during work periods) than those found in other studies. For example, one study found subjects on the daytime schedule of ten hours driving starting at 09:00 slept an average of 5.4 hours (time in bed 5.8 hours) (Mitler, Miller, Lipsitz, Walsh, & Wylie, 1997). This is 1.1 hours less than the sleep obtained by the laboratory subjects.

Another laboratory study (Balkin, Thome, Sing, Thomas, Redmond, Wesensten, Williams, Hall, & Belenky, 2000), which also required subjects to carry out simulated driving during the daytime, restricted sleep to three, five, seven or nine hours. Recovery was measured over a four day, three night period. Recovery sleep was restricted to that obtainable for eight hours in bed (on average 6.5 hours). The main finding of this study was that, following significant and dose-dependent performance deterioration in the three, five, and seven hour groups, there was minimal recovery for the group restricted to three hours in bed per night, and incomplete recovery for the groups restricted to five or seven hours in bed, in that not all tasks recovered baseline performance, even after three nights of sleep. Thus, in an environment in which subjects obtained less sleep, more typical of real world driving, even with a daytime schedule and sleep taken at night, subjects did not fully recover in the 84 hour recovery period.

The three hour sleep group represents an extreme, as in this time period subjects were able to obtain 2.9 hours of sleep on average. In the Mitler et al. (1997) study, which involved real-world driving, even in the worst condition of steady night driving, and with the interference of measuring equipment and study demands on the subjects, average sleep obtained was 3.8 hours.

An additional concern with the validity of the test conditions is that the restriction of sleep in the recovery period to 6.5 hours may be somewhat low. The O'Neil et al. (1999) study, for example, allowed unrestricted sleep on recovery days, after daytime driving, and drivers slept 7.1 hours on average on recovery days.

Neither the Balkin et al. (2000) nor the O'Neil et al. (1999) studies examined schedules in which drivers drove at night. In such circumstances, drivers must perform at night, when circadian rhythms result in sub-optimal performance, and sleep during the day, when the quality of sleep is poorer. For nighttime schedules, recovery would be expected to take longer than is the case for daytime schedules.

2. RECOVERY IN OTHER CONTEXTS

A meta-analysis showed that recovery for most schedules, as measured by subjective sleepiness, was complete after one recovery day that included a full night's sleep, day or night, weekly or rapid rotation, regular or irregular. The exceptions were cabin crew flying across many time zones, who required three days for full recovery; construction workers working seven consecutive 12 hour day shifts, who required three to four days off to reach normal sleepiness values; and oil platform workers working 14 consecutive 12-hour night shifts who were still not recovered after four to five days off. There were individual differences in that, within 60 pulp and paper workers on the very rapidly rotating schedule, some recovered within the first recovery day, whereas others took three or four days to recover. The main weakness of this study is that only a subjective measure was used, and it is well known that workers can assess themselves as well rested even though there are objective signs of impairment.

A study of a variety of schedules worked by nurses suggests that a number of measures such as alertness, sleep duration, mood and social satisfaction tended to be worst on the first rest day and that at least two days of recovery is required (Totterdell, Spelten, Smith, Barton, & Folkard, 1995). Alertness is still improving on the third day of recovery, suggesting that sleep debt might persist beyond two days of recovery. While night work appeared to require additional recovery time, too much recovery time may negatively affect adaptation to a nocturnal routine. Reaction time decreased over consecutive night shifts and tended to increase on rest days following night shifts.

In a review of countermeasures against fatigue, Akerstedt stated that most shift workers reported that they needed at least two days with two normal sleep episodes to recover after three consecutive night shifts (Akerstedt, 1998). This study also demonstrated that the need for recovery increased by one day when working a succession of seven consecutive shifts. Evidence from studies involving jet lag indicates that it may take up to four days to recover after an acute shift of the sleep-wake pattern.

A study of the effect of chronic sleep restrictions showed the same amount of sleep restriction with respect to hours had a much stronger effect on performance when the sleep taken was during the day, as opposed to at night (Rogers, Van Dongen, Power IV, Carlin, Szuba, Maislin, & Dinges, 2002).This indicates that it is important to consider the timing of sleep as well as the duration of off-duty time.

In a study by Price et al., subjects underwent 88 hours of sleep deprivation, followed by either two 7-hour recovery nights followed by one 14-hour recovery night, or three 14-hour recovery nights (Price, Rogers, Fox, Szuba, Van Dongen, & Dinges, 2002). The results of this study indicate that providing a longer opportunity to spend time in bed, and to sleep, results in quicker recovery from acute sleep deprivation.

3. INDIVIDUAL DIFFERENCES

An on-road study of short-haul drivers on daytime schedules found that drivers who showed evidence of fatigue and were involved in fatigue-related incidents had less sleep and of a poorer quality than drivers who did not show signs of fatigue (Hanowski, Wierwille, Gellatly, Early, & Dingus, 2000). With respect to individual differences, 10 of the 42 drivers were involved in 86 percent of the incidents. The younger and less experienced drivers were significantly more likely to be involved in critical incidents and exhibited higher on-the-job drowsiness. Since all drivers were on the same schedule, this study suggests that individual differences in amount of sleep taken affect performance. Whether these differences are as a result of drivers deliberately cutting sleep in order to participate in family, social or other obligations, or are a result of difficulty sleeping, remains to be determined.

In a comparison of permanent day and permanent night nurses, no differences were found in total sleep time (Quera-Salva, Guilleminault, Claustrat, Defrance, Gajdos, Crowe McCann, & De Lattre, 1997). However, as compared to day nurses, night nurses tended to significantly increase their sleep on days off and to curtail their sleep on work nights. All night nurses reverted to daytime activities on their days off. Performance testing indicated that a minority of night nurses showed physiological adaptation to night work and had performance abilities similar to day nurses. Since these comparisons only involved six adapting night shift workers, this finding should be tested in future studies.

A second study of nurses found that, among 24 nurses who worked seven consecutive night shifts, 18 could be considered adapters, and 6 non-adapters, based on adaptation of cortisol levels (Hennig, Moritz, Huwe, & Netter, 1998). In contrast to the previous study, the majority were adapters.

When melatonin rhythms were studied, a gradual shift of melatonin rhythm in seven of eleven night workers showed incomplete adaptation (Weibel, Spiegel, Gronfier, Follenius, & Brandenberger, 1997). Day workers did not adapt when asked to sleep during the day.

A field study of 15 nurses working regular night shifts found that circadian rhythms can be realigned with the work schedule by a judicious schedule of light and darkness (Boivin & James, 2002). The benefit of the approach was maintained even though all night nurses reverted to daytime activities on their days off. Another study demonstrated that daytime sleep following night shifts was significantly longer in nurses in the treatment conditions (James, Chevrier, & Boivin, 2002). This observation indicates that the degree of circadian adaptation to shifted schedule can significantly affect the duration of recovery sleep.

In a review of individual differences in tolerance to shiftwork, Härmä discusses the impact of individual circadian rhythms (adaptation and phase), willingness to work nights, introversion-extroversion, chronotype, and gender issues (Härmä, 1992). Some of his findings are now considered questionable, although the negative impact of age has received continued support. For instance, many of the same factors were reviewed more recently by Nachreiner, who concluded that none of them have a consistent predictive power to assess individual ability to adapt to shiftwork (Nachreiner, 1998).

Nonetheless the author suggests that evening types adapt better and that slowly rotating systems are preferable.

In a review of various shiftwork schedules, Knauth makes recommendations on the design of shift systems (Knauth, 1997). Of particular relevance to truck drivers, who work nights and on rotating schedules, he recommends that shift workers need two days to recover from three consecutive nights and three days to recover from a series of seven consecutive night shifts. This suggests that a 36-hour recovery period would be insufficient to pay off the accumulated sleep debt. He recommends 1) that morning starts should not be too early, if feasible not before 06:30, and 2) that night shifts should start early in the night and allow the driver to sleep during the circadian nadir. This solution would substantially reduce micro-sleep episodes and fatigue.

A group of healthy individuals had three nights of normal sleep, followed by 24 hours of sleep deprivation after which they were allowed to sleep, starting in the morning (Gaudreau, Morettini, Lavoie, & Carrier, 2001). Increased age was associated with a decreased ability to recover from sleep deprivation. As expected, slow-wave sleep was increased in both the young and middle-aged groups following sleep deprivation. However, the rebound of slow-wave sleep was significantly less pronounced in the middle-aged subjects. Another study of sleep deprivation in healthy individuals found that there are significant differences between individuals in vulnerability to performance impairments from sleep loss (Van Dongen, Baynard, Nosker, & Dinges, 2002).

4. SLEEP

The Balkin et al. study involved an actigraphic assessment of the sleep of 50 long- and short-haul CMV drivers over 20 consecutive days (Balkin et al. 2000). Both groups averaged approximately 7.5 hours of sleep per night. While short-haul drivers obtained three percent of their sleep during on-duty periods, long-haul drivers obtained 44 percent of their sleep during on-duty periods. As long-haul drivers obtained almost half of their daily sleep during work-shift hours (mainly sleep-berth time), it appears that they spend a significant portion of the work shift in a state of partial sleep deprivation, until the opportunity to obtain on-duty recovery sleep presents itself. There was no off-duty duration that guaranteed adequate sleep for the long- or short-haul drivers. The authors note that as drivers likely use a substantial portion of their off-duty time to attend to personal business, off-duty time must be of sufficient duration to allow drivers to accomplish these tasks and to obtain sufficient sleep. This may be particularly important for long-haul drivers, who often did not sleep at all during off-duty periods.

There were large day-to-day variations in total sleep time for drivers in both groups. Sleep times varied for some long- and short-haul drivers by up to 11.2 hours across the 20 study days. Other drivers maintained more consistent sleep/wake schedules. Some individuals showed a pattern that suggested chronic sleep restriction with intermittent bouts of extended recovery sleep.

5. NAPPING

Napping reduces sleep debt and for this reason may reduce recovery time. No studies were found on the relationship between napping and recovery in CMV drivers.

However, a number of studies showed the efficacy of naps in improving performance and reducing sleep debt.

An examination of the napping behaviour of shift workers found that the proportion of nappers decreased with increasing length of the major sleep period (Akerstedt & Torsvall, 1985). In addition, while half of the workers normally took naps when on night shifts, almost no workers took naps on the afternoon shifts or days off. This suggests that napping is related to sleep debt. A 1989 review reports a higher frequency of napping among shift workers as compared to day workers (Akerstedt, Torsvall, & Gillberg, 1989). Naps taken during the night shift were unauthorized and involuntarily, and occurred mainly during the second half of the night shift when sleepiness was as its peak. Napping was associated with a reduction of approximately two hours in the following main sleep episode.

Napping strategy was examined in permanent day and permanent night shift workers (Tepas, Carvalhais, & Popkin, 1990). Five different napping strategies were defined in relation to whether workers napped during the workweek or only on weekends or both, and the frequency with which they napped. The authors found that permanent night workers who napped were more likely to report difficulty sleeping. No evidence was found to suggest that permanent night workers who did not nap did not do so because they were naturally short sleepers. As has been found in previous studies, permanent night workers were more likely to nap and to experience difficulty sleeping than were permanent day workers.

A study involving long-haul truck drivers found that a three hour nap opportunity in the afternoon preceding a simulated night shift had beneficial effects on driving simulator performance and on subjective and physiological measures of alertness measured up to 14 hours later (Macchi, Boulos, Ranney, Simmons, & Campbell, 2002).

A study involving air traffic controllers showed that a short workplace nap during a scheduled break on the night shift led to improvements in performance, despite its limited duration (about 18 minutes) and the fragmented nature of the sleep obtained (Signal & Gander, 2002). Similarly, the job-related performance of emergency room personnel was improved by a mid-nightshift 40-minute nap (Smith-Coggins, Howard, Kawn, Wang, Rosekind, Sowb, Balise, & Gaba, 2002). Caffeine and/or napping improved both alertness and performance during four simulated night shifts, with the greatest impact being on the first night shift, and for the combination of caffeine and napping (Schweitzer, Randazzo, Stone, & Walsh, 2002).

A 10-minute afternoon nap, following mild nocturnal sleep restriction, reduced subjective fatigue and improved performance for at least 35 minutes and improved alertness for at least one hour (Tietzel & Lack, 2002).

The effects of a one-hour maximum nap on sleep length, perceived sleepiness and quality of life were examined for night shift workers (Bonnefond, Muzet, Winter-Dill, Bailloeuil, Bitouze, & Bonneau, 2001). The nap opportunity was found to lead to a general satisfaction about the ease of work at night, and an improvement in the general quality of life.

A review of several studies found that naps were effective in maintaining performance or in improving it during periods of extended wakefulness (Rosekind, Smith, & Miller, 1995). Based on studies involving naps of durations varying from 20 minutes to eight hours, there appears to be a dose-dependent effect with a greater improvement associated with longer naps. Although sleep inertia can be a negative effect, its effects seem to disappear after 10 to 15 minutes.

A study that aimed to validate a computer model design to predict alertness levels based on the schedule of sleep and work test revealed a stronger relationship between predicted fatigue and self-rated alertness than between predicted fatigue and objectively measured performance (Fletcher & Dawson, 2001). The fatigue model predicted self-rated alertness better in the afternoon and evening hours after four consecutive shifts had been worked.

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APPENDIX D

COLLECTION OF AUXILIARY INFORMATION

1 INTRODUCTION

The purpose of this collection of auxiliary information is to inform Phase 3 contractors of the benefits and limitations of devices that might support a Phase 3 project. The benefits and limitations of various physiological, subjective rating, behavioural and driving performance measures are examined.

2 PHYSIOLOGICAL MEASURES

In this section we describe electroencephalographic (brain waves), polysomnographic (brain waves, eye movements, muscle activity, heart rate, blood oxygen and respiration) and actigraphic (movement) recording devices, as well as related analysis software.

2.1 EEG

An electroencephalographic (EEG) recording involves the interpretation of wave forms by their frequency and morphology. A recording is taken by electrodes (small metallic discs) pasted by an electricity conducting gel to the surface of the scalp. The characteristics of EEG activity, such as the frequency and amplitude of waves change in many different situations, particularly with the level of vigilance: alertness, rest, sleep and dreaming. Portable EEGs can be carried easily and can be used outside of a sleep laboratory such as in a subject's bedroom (i.e., ambulatory EEG). Sleep technicians are required to install electrodes (Sabbatini, 2003).

Benefits:

- Objective direct measure of EEG

Limitations:

- Requires a technical set-up
- Not very practical for in-vehicle use (Hartley, Horberry, & Mabbott, 2000)
- Labour intensive to analyse
- Difficult to get good quality data (Heslegrave, 2003)
- Potential differences in interpretation of EEG when active vs. lying in bed. For example, in a 1997 on the sleep of long-haul truck drivers, the EEG showed a driver in stage 1 sleep while driving for 520 seconds but video did not indicate that the subject was drowsy (Mitler, Miller, Lipsitz, Walsh, & Wylie, 1997).

2.2 Ambulatory EEG Recording Devices

Three ambulatory EEG recording devices are described below.

2.2.1 Stellate Notta

http://www.stellate.com/en/stellate_notta.html

376 Victoria Avenue Suite 200
Montreal, Quebec
Canada
H3Z 1C3

Tel. : 1 (888) 742-1306 (U.S. & Canada)
Info@Stellate.com

- Ergonomically shaped to fit on the waist
- Weighs just over 1 lb.
- Built-in pulse oximeter
- Records up to 32 channels
- Fully integrated with Stellate Harmonie workstations
- Event marker lets patients mark events on the recording file
- Approximate cost: $36,700 CAN

2.2.2 Oxford Instruments: P Series Portable

http://www.oxford-instruments.com/MDCPSN298.htm

Hawthorne, New York
Tel: (914) 593-7100

- The P Series offers full referential EEG recording capability and is capable of being used as a traditional laboratory system or used on the ward or in the patient's home.
- The P Series was the first truly portable product for full montage sleep recording.
- The P Series family is made up of the P-Series Plus and the P-Series 2 offering 26 and 18 channel recordings respectively.

2.2.3 Ortivus Biosaca

http://www.ortivus.se/

American Distributor:
Sweet Computer Services, Inc.
http://www.sweetcs.com
2324 Sweet Parkway Road
P.O. Box 276
Decorah, Iowa 52101-0276
Tel: 1 (800) 537-3927
sales@sweetcs.com

- The Biosaca enables advanced sleep and EEG investigations
- Compact and portable
- Weighs 650 g with batteries
- Digital Signal Processor with analog amplifiers and digital input for pulse oximeter.

2.3 Polysomnography

A polysomnogram consists of a simultaneous recording of multiple physiologic parameters related to sleep and wakefulness. A polysomnograph machine converts electrical signals in the body to a graphical representation which can help determine what is going on during sleep. A variety of activities are monitored during sleep such as brain waves (EEG), eye movements (EOG), muscle activity (EMG), heartbeat (EKG), blood oxygen levels and respiration. Each of these activities is represented by graphical tracings on a polysomnogram.

Benefits:

- Provides objective direct measures of various activities related to sleep

Limitations:

- Requires a technical set-up (i.e., to attach electrodes on the patient's scalp, face, chin, chest and legs.)
- Inappropriate for use on the road
- Labour intensive to analyse
- Expensive (Heslegrave)
- Physiological health measures are not always sensitive to sleep restriction. For example, in Balkin's 2000 study, heart rate, respiration, and blood pressure were not sensitive to sleep restriction (Balkin, Thome, Sing, Thomas, Redmond, Wesensten, Williams, Hall, & Belenky, 2000). These results are consistent with the view that sleep deprivation mainly impairs higher-order cognitive performance.

2.4 Polysomnography Devices

Three polysomnography devices are described below.

2.4.1 Sandman

www.sandmansleep.com

Nellcor Puritan Bennett (Melville) Ltd.
303 Terry Fox Drive, Suite 400
Kanata, Ontario K2K 3J1
Tel: 1 (800) 663-3336

Suzanne™ Recording System

- Portable system
- Used in a sleep laboratory or in subject's home
- Modular concept which allows for plug-and-play custom configurations to record from 10 to 35 channels of a patient's physiological data in both attended and unattended sleep studies
- Built-in oximetry technology
- Highly Accelerated Lifetime Testing (HALT), similar to that used by the aerospace industry to guarantee performance under a range of extreme temperature and vibration conditions

2.4.2 Oxford Instruments

http://www.oxford-instruments.com/MDCPSN298.htm

Hawthorne, New York
Tel: (914) 593-7100

Compumedics Siesta Wireless Sleep Recorder:

- Delivers diagnostics wirelessly
- Provides 32 amplified channels for data collection: any physiological signal may be recorded on any channel
- Lab PSG Small and lightweight – 300 g (9.6 oz.) with battery • Variable montage - record up to 32 channels, any data type on any channel • Radio Local Area Network - wireless waveform transmission up to 300 m (1000 ft.) - No Cables

E-Series Networked Polysomnography Amplifier:

- The Compumedics E Series has new advanced PSG recording capabilities recording 44 channels of patient inputs plus further channels for ancillary devices
- The E Series lab based system allows viewing and control of the network amplifier from any computer on the network in your lab, from an office or even from remote sites

2.5 Sleep Recording and Analysis Software

Two systems for sleep recording and analysis are described below.

2.5.1 Stellate Harmonie S

- Stand-alone, mobile or networked PC workstations
- Portable

2.5.2 All external devices such as CPAP or BiPAP are connected for accurate utilization

- Microsoft Windows interface
- A short review process with on-line event detection
- Instant preliminary reports with computer-assisted sleep staging
- Multiple hypnograms for same study comparison
- Configurable sleep graphs for unlimited graphical display of event distributions or properties. Click to go to a corresponding position in the signal file.
- Configurations from 16 to 64 channels
- Multiple DC inputs
- Software-controlled calibration and impedance measurements

Synchronized Digital Video standard on workstations:

- Video access in Look-back
- Zoom capability
- MPEG quality
- Variable-speed replay
- Real-time data and video monitoring on hospital networks or on Internet from remote locations

2.5.3 Sandman

www.sandmansleep.com

Nellcor Puritan Bennett (Melville) Ltd.
303 Terry Fox Drive, Suite 400
Kanata, Ontario
K2K 3J1
Tel.: 1 (800) 663-3336

Sandman has a few different sleep recording and analysis software programs (e.g., Sandman Spyder, Sandman Elite, Sandman Easy). The Sandman Elite program is outlined below:

- Advanced digital software filtering for any signal during recording or post recording, including 60 Hz notch filter
- Displays a list of scored event types. Statistics include the current number of events, frequency and average duration for each type
- DC device editor
- Real time RDI during collection that automatically calculates disordered breathing events on the fly
- Modular design with computer assisted PLM, respiratory, arousal, snore, heart rate, $ETCO_2$, bad data, desaturation, EKG and pH event detection
- Visual cues to highlight any amplifier filter, referencing, amplification changes, impedance check or technologist comments
- The ability to review or score studies on any computer (i.e., at home) with our unique Sandman Analysis on a CD feature

2.6 Actigraph

Actigraphs are small, wrist-worn devices that measure movement. They contain microprocessors and on board memory that can be downloaded to a computer for off-line processing. They can be used to estimate sleep quantity.

Benefits:

- Actigraphic measures are minimally intrusive (Balkin et al. 2000)
- Objective estimates of sleep quantity, as well as activity (Balkin et al. 2000)
- Combined information from actigraph records and driver logs increase reliability and specificity of the sleep data (Balkin et al. 2000)
- Long collection period (e.g., 44 days for Actiwatch Plus)
- Self contained
- A variety of models are available that can be used to monitor light levels, subjective measures of pain, mood and sleepiness, body temperature, and sound levels simultaneously with activity. Some models also include an event marker button that allows the wearer to log events of significance at the time they occur in the data record such as bed and awakening times.
- Shower-proof and rechargeable versions available

Limitations:

- Actigraphy does not allow scoring of sleep stages, which may be differentially restorative (Balkin et al. 2000)
- The reliability of actigraphy in a moving motor vehicle (e.g., when a driver is sleeping in a sleeper berth of a moving vehicle) is currently unknown (Balkin et al. 2000)

2.7 Actigraph Devices

Six actigraph devices, from two companies, are described below.

2.7.1 Ambulatory Monitoring Devices

http://www.ambulatory-monitoring.com/default.htm

E-mail: info@ambulatory-monitoring.com
Tel: 1 (800) 341-0066
Ardsley, New York

- Ambulatory Monitoring has a number of actigraph models including the Octagonal Sleep Watch, Micro Mini-Motionloggers, and the Octagonal BASIC Motionlogger as well as Basic Mini-Motionlogger Actigraphs.
- The models come with a 2-year warranty.
- According to the web site these units are lighter and smaller than MiniMitter's Actiwatch.
- Features of the Octagonal BASIC Motionlogger include:
  - Event marker
  - Audible feedback
  - 2 MB memory
  - 2-3 Hz filter
  - Sensitivity is .01G at mid band
  - Zero Crossing (ZC), Time-Above-Threshold (TAT)
  - Proportional Integrating Measure (PIM) modes of operation and Tri-mode (ZC, TAT, and PIM simultaneously)
  - Waterproof (shower safe)
  - Easy coin cell battery exchange (60-day battery life) via compartment isolated from sealed interior electronics
- Features of the MICRO Mini-Motionlogger include:
  - 1 in. diameter x 0.35 in. height - weighs under 1/2 oz. (14 g)
  - Non-volatile 32 kB memory
  - 10 Hz sample rate - 2-3 Hz bandwidth
  - Zero Crossing or Proportional Integrating Measure (low and high sensitivity) modes of operation
  - 1 minute fixed epoch length yielding up to 22 days of recording time per initialization
  - Choose from fully waterproof 6-month factory replaceable battery for complete submergibility or shower-proof model with lifetime rechargeable battery
- Features of the Octagonal Sleepwatch include:
  - 2 MB of non-volatile memory (for a data storage capacity far exceeding its 60 day battery life)
  - a Time-of-Day LCD

- two buttons for event marking, time-set, etc.
- a fuel-gauge style indicator which can be used to present a variety of information. In the standard configuration this model can collect single mode (ZC, TAT, PIM) or Tri-Mode data.
- Other optional features include additional a light sensor, sleep estimation on the wrist with presentation of estimated sleep parameters on the display, and the ability for user input of subjective information (fatigue, mood, stress, etc) or different event types via the two buttons on the face of the device
- Size 1.5 X 1.45 X 0.45 in. octagon
- Weight 1.8 oz.
- Powered by lithium coincell for over 60 days of continuous data collection
- Optional 'bulge' battery cover back plate for extended data collection

- Features of the BASIC Mini Motionlogger include:
  - Small Size - Dimensions are 4.44 X 3.30 X 0.96 cm, weight = 57 g with 32kB memory
  - Uses easily replaceable lithium batteries for run time of up to 30 days. Expandable battery compartment for extended operation
  - Event Logging – an event marker allows for a log of prearranged events
  - Water Resistant – the unit may be worn during all common daily activities
  - Note: Pre-Used Basic Mini-Motionlogger units are available (one year warranty), offering quite significant savings

2.7.2 Mini Mitter

http://www.minimitter.com/Products/Actiwatch/index.html

20300 Empire Av., Bldg, B-3
Bend, OR 97701
U.S.A.
Tel: 1 (800) 685-2999

- Mini Mitter has a number of actigraph models including the Actiwatch 16 and 64, the AW-L (Actiwatch with light) and the AW-Score with subjective scoring
- Features of the Actiwatch 16 and 64 (approximate cost: $1,075 U.S.), the standard Actiwatch models:
  - These models have an event marker button that allows for the wearer to log events of significance at the time they occur in the data record. Most often this feature is used to log Bed Times and Get up Times.
  - Weight: 17.5 g
  - Size: 28 x 27 x 10 mm
  - Non-Volatile Memory:
    - AW-16 = 16 kB
    - AW-64 = 64 kB
  - Recording Time at one minute sample interval:
    - AW-16 = 11 days
    - AW-64 = 45 days
  - Battery Life: 180 days
  - Waterproof
- The Actiwatch-L (approximate cost: $1,500 U.S.) has a small very high performance light sensor integrated into its case in place of an event marker. With

each activity record that is recorded, the light level is also recorded in Lux. Features of the AW-L includes:

- Weight: 17.5 g
- Size: 28 x 27 x 10 mm
- Non-Volatile Memory: 64 kB
- Recording Time at one minute sample interval:15 days
- Lux Range: 0.1 to 150,000
- Battery Life: 180 days
- Waterproof
- In addition to the objective activity data, the AW-Score allows for recording subjective scores for any parameter that can be classified from 0-10 (scale is programmable), providing a strong enhancement to Patient Diaries.

• The Actiwatch-Score includes a programmable alarm to prompt the patient to enter a quantifiable score (such as pain or anxiety). Alarms can be set to a schedule or to sound at random intervals. Features of the AW-Score include:
  - Weight: 21.0 g
  - Size: 31 x 28 x 10 mm
  - Scoring Scale: 0 to 10
  - Non-Volatile Memory: 32 kB
  - Recording Time at one minute sample interval: 22 days*
  - Battery Life: 90 days

*Recording time will vary depending upon the alarm schedule that has been programmed.

3 SUBJECTIVE RATINGS

In this section we describe subjective rating scales used to describe current levels of sleepiness (Stanford Sleepiness Scale), the quality and patterns of sleep (Pittsburgh Sleep Index), sleep difficulties (Karolinska Sleep Scale) and propensity to fall asleep (Epworth Sleepiness Scale).

3.1 Stanford Sleepiness Scale (SSS)

The Stanford Sleepiness Scale (Hoddes, Zarcone, Smythe, Phillips, & Dement, 1973) is a single seven-item subjective measure scale for sleepiness. It asks the participants to circle the statement that best describes how sleepy they feel at the moment they are answering the question.

Benefits (Miller, 2003):

- It may be administered many times per day
- Usually correlates with standard measures of performance
- Usually reflects the effects of sleep loss
- Used widely in research and clinical settings (Miller 2003)

Limitations:

- The weaknesses of the SSS are that the extreme values on the scale (1 and 7) are used infrequently and that the rank-ordered statements overlap several perceptual dimensions including sleepiness-wakefulness, alertness and concentration (Miller 2003)

An Introspective Measure of Sleepiness
The Stanford Sleepiness Scale (SSS)
http://www.stanford.edu/~dement/sss.html

To use the SSS, the subject selects one of seven sets of Likert-scale descriptors.

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	X

3.2 Pittsburgh Sleep Quality Index (PSQI)

The Pittsburgh Sleep Quality Index (PSQI) is an instrument used to measure the quality and patterns of sleep. It differentiates “poor” from “good” sleep by measuring seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the last month. The subject self-rates each of these seven areas. Scoring of answers is based on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert scale (Smyth, 1999).

3.3 Karolinska Sleep Scale

The Karolinska Sleep Diary (KSD) is a Likert type scale that has been validated against polysomnographic data (Kecklund & Akerstedt, 1995).

1=very alert to 9=very sleepy, fighting against sleep

- Difficulties falling asleep
- Difficulties waking-up
- Repeated awakenings with problems to fall asleep
- Not feeling well-rested upon awakening
- Premature awakening
- Disturbed **sleep**
- Too little **sleep** (less than 6h)
- Nightmares

3.4 Epworth Sleepiness Scale

The Epworth Sleepiness Scale was developed by researchers in Australia and is widely used by sleep professionals to measure sleep deprivation. Subjects are asked to rate (0= no chance of dozing, 1= slight chance of dozing, 2=moderate chance of dozing, 3=high chance of dozing) how likely they are to doze off or fall asleep in various situations (e.g., sitting and reading, watching TV, etc.) (Miller 2003).

4 BEHAVIOURAL MEASURES

In this section we describe behavioural measures that been used in previous studies to assess fatigue level in drivers. These tests comprise two performance tests: the psychomotor vigilance task, and the Walter Reed Performance Assessment Battery, and three video based measures of eyelid closures: PERCLOS, Driver Fatigue Monitor and FaceLAB.

4.1 PVT (Psychomotor Vigilance Task)

Using a handheld device with a small visual display, this test measures driver reaction time to stimuli over a 10-minute period. Measurements that are sensitive to the effects of sleep loss include median reaction time, number of performance lapses, lapse duration, and optimum response time.

Benefits:

- Limited learning effects
- Short task
- Test can be conducted on the road
- Measure has been shown to be an effective measurement of fatigue and sensitive to experimental manipulation of sleep times (Intermodal Transportation Institute, 2003)

Limitations:

- What does it tell us? How does it relate to the driver's ability? (Heslegrave 2003)

PVT-192 Psychomotor Vigilance Task Monitor
Available from Ambulatory Monitoring (New York)
http://www.ambulatory-monitoring.com/default.htm

- Hand-held, self-contained system that stores repetitive reaction time measurements
- LCD display for instructions
- Multiple subject recording capability
- Visual/audio cue
- Length of each test is programmed as is the range of the inter-stimulus intervals
- The REACT software program provides simple analysis of the PVT data in the Windows environment. The program generates two kinds of graphs: 1) Sequential displays of reaction times to successive stimuli within the trial, are plotted either as reciprocal reaction times (RRT: 1/(RT in seconds)) or as raw reaction times in milliseconds and 2) Frequency distributions of reaction times.
- One year warranty
- ~ $2,500 U.S.

4.2 Walter Reed Performance Assessment Battery

The Walter Reed Performance Assessment Battery (PAB) (Thorne, Genser, Sing, & Hegge, 1985) is a computerized psychological test battery designed for examining the effects of various state-variables on a representative sample of normal psychomotor, perceptual and cognitive tasks. The duration, number and type of tasks can be customized to different experimental needs, and then administered and analyzed automatically, at intervals as short as one hour (Sherry, 1997). Tests include two and six letter search, encoding/decoding, two column addition, serial addition subtraction, logical reasoning, digit recall, pattern recognition I and II, visual scanning, mood scales, time estimation and two and four choice serial reaction time. In addition, several tests have been added to the PAB such as the Stroop test, repeated acquisition, delayed recall and ten-choice reaction time (RT). All of these tests have been demonstrated to have some sensitivity to the effects of sleep deprivation. A variation on the PAB, adapted for the Windows operating systems is the Denve Fatigue Inventory, a computer assisted cognitive test battery. The battery consists of the choice reaction time test, the serial addition subtraction test, the manikin test, the circle target test and the light response test (Intermodal Transportation Institute, 2003).

Benefits:

- Tests have reliably shown general declines in cerebral functioning during total sleep deprivation (Heslegrave, 2003)
- More comprehensive approach to driving-related skills than PVT (Heslegrave, 2003)
- Measures subject's ability to attend and concentrate

Limitations:

- None of the tests assesses the most important driving related skills i.e. divided attention between tracking and visual search (Smiley, Boivin, Heslegrave, & Davis, 2003). Tracking deficits are related to inattention, sleepiness and run-off-road collisions.
- Greater necessity for learning than PVT, which results in a longer training period. For example, in Balkin et al.'s study on the effects of sleep schedules on commercial motor vehicle driver's performance, asymptotic performance levels were not achieved on the serial addition/subtraction task prior to initiation of the experimental phase of the study (Balkin et al. 2000). This occurred despite 3 days of training. Continued "learning effects" were evident across the entire experiment for this task as well as other measures, such as the 10-choice reaction time task.
- Learning may continue so that even subjects who are tired may continue to perform better on tasks
- More time intensive than PVT as more tests are involved (Heslegrave 2003)
- Some investigators argue that motivational variation interferes so much with S-R tests that researchers should further consider studying changes in creativity, novelty, or flexibility, often referred to as "divergent thinking skills." Such examination is vital to the study of sleep deprivation due to the importance of these skills, and the areas of the brain they entail, i.e. the frontal lobes (Smith, Hurd, Cracraft, Hyslop, Zgheib, & Hoffert, 2003)
- The administration of behaviour measures and continuums lack uniformity between the studies in which they are used. Teams of researchers devise tests, whether

they are vigilance, S-R, or placement on continuums, which they deem most appropriate for their study. While it is important to consider the purpose of the test in the design of the behavioural/performance tests, constant re-vamping of these tests prevents the development of a reliable "baseline" in the field of sleep deprivation research. This makes comparison of studies and findings extremely difficult.

4.3 PERCLOS (Percentage of Eyelid Closure)

PERCLOS is a video-based drowsiness metric. It consists of "a slow eye lid closure when 80% of the pupil is covered". PERCLOS can be measured "non invasively from dashboard mounted cameras using infra-red beams to measure retinal reflection and a light emitting diode beam to give a corneal reflection with which to measure gaze direction (by measuring the vector between the papillary and the corneal reflections)" (Hartley et al. 2000).

Benefits:

- Objective measure that is considered to be the best of the potential ocular measures for assessing fatigue (Hartley et al. 2000)
- Reported correlations between PERCLOS and lapses on the psychomotor vigilance tasks (PVT), which are considerably higher than the correlations between lapses on the PVT and self-report of drowsiness (Hartley et al. 2000)
- PERCLOS no longer has to be measured manually from videos (Hartley et al. 2000)

Limitations:

- While PERCLOS works fairly well in darkness, it does not work very well in daylight. Ambient sunlight reflects off the windows and continually bounces around the truck cab as the vehicle turns relative to the sun's rays, making it impractical to obtain retinal reflections of infrared (Grace, Byrne, Bierman, Legrand, Gricourt, Davis, Staszewski, & Carnahan, 2001)
- PERCLOS has also been shown to have difficulties for drivers with reflective dark glasses (Grace et al. 2001)
- The correlation of PERCLOS and lapses on the PVT gets substantially less the longer the hours of sleep deprivation (Hartley et al. 2000)
- PERCLOS has only been validated against PVT and against conditions of sleep deprivation. While studies demonstrate that measures of vigilance are sensitive to sleep deprivation, the relationship between measures of real time vigilance and real world crashes has not been investigated. As a result, the power of PERCLOS to predict crashes is presently unknown (Hartley et al. 2000).
- Equating fatigue with overt signs of drowsiness leads into the dangerous trap of defining an event in terms of itself. Performance decrements often occur independent of other signs of sleepiness, or the signs are too subtle to detect with any reliability. The focus should be on the various effects of operating practices on performance, not the appearance of fatigue per se (O'Neil, Kruegar, Van Hemel, & McGowan, 1999).

4.4 Driver Fatigue Monitor (DFM)

Contacts: Richard Grace (412) 481-6620, CEO and Founder
Joe Parker (412) 341-0583, Sales
Attention Technologies Inc. (www.attentiontechnology.com)
http://www.ri.cmu.edu/pub_files/pub3/grace_richard_2001_1/grace_richard_2001_1.pdf

- A system initially developed by scientists at the Robotics Institute at Carnegie Mellon University and sponsored by NHTSA.
- Second generation version of Copilot.
- A low-cost drowsy driver monitor.
- Detects and tracks human drowsiness based on eye-lid closures and provides a warning to the driver (warning sound can be turned off)
- Consists of a digital camera integrated with a low-cost digital signal processor (DSP).
- Measures slow eyelid closures as represented by PERCLOS.
- The system has been used in sleep research to measure levels of drowsiness due to its data collection abilities. Software can be run on PC.
- System can be used in a heavy cab.
- Driver Fatigue Monitor (DFM) is similar to Copilot but has an improved interface. Its display shows driver how many seconds their eyes were closed and how far they have traveled. The DFM also deals better with various light conditions. It removes reflections from eyeglasses at night. However system has difficulty in very bright sunlight.
- System has undergone a number of iterations and is ready to be used in the field. It is currently being used in a fatigue and trucking study (PI: Richard Hanowski 540-231-1513). The government is assessing its safety benefits for drivers. System will be installed in 34 trucks (long haul, overnight express) for a year. PERCLOS data will be collected along with driver performance data.
- Current purchase price is $7,500 U.S. for unit and software. Lower prices possible with purchase of higher quantities.
- Leasing and rental arrangements have not yet been designed but Joe Parker expects that yearly rental will be approximately $3,000 U.S.
- Attention Technologies are open to collaboration in the design and implementation of the study.

4.5 FaceLAB from Seeing Machines

http://www.seeingmachines.com

- FaceLAB is head, face, and gaze tracking technology that measures the position of a human head and blink events.
- FaceLAB collects real-time PERCLOS data
- A FaceLAB car kit is needed to install FaceLAB in vehicles.
- The software does not require any external devices to be worn, and tracks inside a region large enough to allow natural behaviour, without loss of data.
- FaceLAB was developed with the help of Volvo to monitor driver behaviour in real-world trials after unsuccessful trials of other eye-tracking technology (e.g., did not work under conditions of heat, sunlight, flickering light and motion).

5 DRIVING SIMULATORS

In comparison to on-road studies with instrumented vehicles, driving simulators have a number of benefits with respect to experimental control and safety. On the negative side there are issues of fidelity and simulator sickness. The benefits and limitations are outlined below. Following this there is a description of five simulator systems, Doron Precision Systems, GE Capital I-Sim, Digitran Systems, Lockheed Martin Information Systems and the National Advanced Driving Simulator in Iowa. The first four simulators are commercially available truck simulators. Mr. Jerry Rubin of the Office of Motor Carrier and Highway Safety (202-3852395) assisted us in identifying the commercially available simulators. The last simulator described is a research simulator available on a rental basis. A report on truck driving simulators will be issued shortly by the U.S. Office of Motor Carrier and Highway Safety.

5.1 Simulator Benefits and Limitations

Benefits:

- Experimental control – many extraneous variables that can affect driver behaviour can be controlled using a simulator. All drivers can be exposed to identical environmental and experimental circumstances (Nilsson, 1993)
- Allow researchers to safely investigate situations where accidents are known to be more common than usual (e.g., drivers impaired from alcohol, fatigue, or mental overload) (Nilsson, 1993)
- Allow researchers to measure many aspects of driver responses with relative ease. Measurements possible using an instrumented vehicle are not always as accessible or reliable (Godley, 1999). Monitoring equipment (e.g., eye and head tracking, video, measurement of physiological responses) is relatively easy to arrange for a simulator (Nilsson, 1993).

Limitations:

- Simulators range in fidelity in terms of their components, layout, and dynamic characteristics. The "closer a simulator is to real driving in the way it is used, in the way stimuli are presented, and the way it physically reacts to that stimuli, the greater the fidelity it is considered to have. For example, when braking, a driver may notice that the usual G-force associated with decelerating in a real vehicle is not present. This may result in the driver pressing the brake pedal harder and in stopping the simulator's motion before they intended to. Drivers will need sufficient practice performing various actions so they know how the simulator will react (Godley, 1999).
- Simulators with high fidelity tend to be expensive
- Simulators must also have predictive validity so that there is a correspondence between the simulator and the real world in the way the human operator behaves (Blaauw, 1982). Often assessments of simulators focus on physical validity (fidelity), however, for a simulator to be useful in human factors research behavioural validity must be present. As a result, a more sophisticated simulator may not have more predictive validity than a less sophisticated, and expensive one (Triggs, 1986). While absolute validity may not be possible, relative validity can be established when the differences found between experimental conditions in the

simulator and the real car are in the same direction, and have a similar or identical magnitude on both systems (Blaauw, 1982).

- An important limitation of simulator research is simulator sickness. Simulator sickness is not identical to motion sickness in that it can occur without motion (Kolasinski, Goldberg, & Hiller, 1995). It can originate from elements of the visual display and visual-vestibular interaction. The symptoms (e.g., eyestrain, dizziness, fatigue) of simulator sickness can last for more than six hours after the simulator session. Some experimental participants may retire before finishing their simulation session due to feelings of sickness. Others may continue the experiment but may adopt adaptive behaviours such as driving unnaturally slowly through corners to alleviate their discomfort (Kolasinski et al. 1995). It is important for drivers to immediately notify the experimenter of any feelings of discomfort to avoid distortion of experimental findings.
- The potential loss of subject's data due to simulator sickness means that a larger selection of participants is needed than the desired sample size

5.2 Doron Precision Systems, Inc.

http://www.doronprecision.com/dorondriver.htm

Contact: Bill Murray, VP
Tel: (607) 772-1610
P.O. Box 400, 174 Court Street
Binghamton, New York 13902-0400
U.S.A.

- Driving simulation systems
- Systems used for training and not specifically designed for research purposes
- Interactive system used for training drivers
- Consists of a virtual world, no real footage
- The system has 100 training scenarios that include highway and country settings as well as a square mile of city blocks. The scenarios are aimed at emergency vehicles which must respond to a call. In addition, they are used to train experienced bus drivers who must navigate through the traffic. Instructors can easily create their own scenarios in less than a half hour.
- Mr. Murray, the company's Vice-President, felt that the system could *not* be used for long periods of time (e.g., 20-30 minutes maximum)
- The system has been used for research purposes, however for short driving times (e.g., drugs and driving study)
- Doron generally sells their systems rather than leasing or renting them
- The Vehicle Manoeuvring Trainer (VMT) is a fully interactive system that simulates a typical transit bus or tractor-trailer, including a cab with functioning controls and instruments. Engine, transmissions and air brake sounds combined with real time high detail visuals provide realism.
- Approximate price for interactive system: $100,000 U.S.

5.3 GE Capital I-Sim

http://www.cefcorp.com/I-sim/

Contact: Dave Dolan
Tel: (801) 303-5670 or 1 (888) 259-4746
2961 West California Avenue
Salt Lake City, Utah 84104
U.S.A.

- Driver simulation technology and training systems
- Line of programs for long-haul freight carriers and private fleets (as well as others)
- Range of systems from the TrainSim VS truck transmission simulator to an immersive car/truck simulator which features a full vehicle cab (Mark II)
- Systems can be purchased or leased (Mark II purchase price: $430,000 U.S.; TrainSim VS purchase price: $85,000 U.S.)
- The two systems share the same database of scenarios database of scenarios for municipal, freeway, country, suburban and off-road settings. Scenarios are approximately 30 minutes in length. New scenarios are not programmable except for law enforcement purposes (e.g., timing of vehicle entering an intersection) but they can be linked together to allow drivers to move from city driving to freeway and rural driving (e.g., T-World).
- The Mark II Driving Simulator is a motion based system consisting of a cab and large dome which reflects the scenarios and provides a 200 degree peripheral view. The system requires a large space to house it and an intensive installation effort.
- The Mark II is modular to meet various specific training or research needs.
  - High-fidelity, realistic driving environment
  - Vehicle cab: Mid-sized, late-model manufacturers' cab; Instrument panel and controls similar to vehicle manufacturers; Fully operational dash instrumentation, indicators, wipers, horn and turn signals. The cab has an Eaton transmission which is configurable to replicate a number of other transmissions.
  - Display Enclosure: Vehicle cab installed in a light-tight enclosure; access doors for personnel; and for changing vehicle cabs; Paint-on, washable, cylindrical curved screen

– Audio and Vibration Subsystem: Digital computer generation of actual in-cab vehicle noises associated with all facets of driving (i.e., engine, tires, road noise and other vehicles)
– Operator's Console: Windows™-based, point-and-click control format used for all simulator functions; Real-time interaction with moving models through changing traffic behaviour, weather conditions, tire adhesion and day/night selections.


- A simulator, named TruckSim, at Carnegie Mellon Driving Research Centre (DRC), based on ISIM's Mark II simulator has been used for research in human factors such as countermeasures for fatigue and driver/vehicle interface issues. Additions/upgrades of the Mark II design included improved visual resolution, an enhanced four-degree of freedom motion base and the addition of an experimenter's console.
- The TrainSim VS is a computer-controlled simulator for truck driving. It is much smaller than the Mark II system, consisting of one 42 inch screen. The system can easily be moved as it is on casters.
- PatrolSim is a compact, high-performance driving simulator for the law enforcement and government marketplace.

5.4 Digitran Systems

Tel: (435) 752-9067
2176 North Main
North Logan, Utah
U.S.A.

- Develops, manufactures and markets simulator training systems for transportation and construction industries (among others).
- A variety of simulator training systems for crane operations, petroleum operations and heavy duty truck driving.

5.5 Lockheed Martin Information Systems

http://www.lockheedmartin.com/lmis/level4/truckd.html
http://www.lockheedmartin.com/lmis/driversims/index.html

Contact: John L. Sullivan - Manager, Business Development
E-mail: john.Sullivan@lmco.com
Tel: (407) 306-1656
12506 Lake Underhill Road, MP-830
Orlando, Florida 32825-5002
U.S.A.

- Provider of training systems to the U.S. Department of Defense
- Millennium Driver Trainer System™ (MDTS)
  - Thorough terrain database; a driver can experience city streets, country roads, interstate highway, and mountain passes in a single scenario
  - Weather effects ranging from light rain, through thunderstorms, to snow-packed roads
  - Realism is achieved by using Original Equipment Manufacturer cabs (e.g., Freightliner Century Class cab)
  - Similar to a real truck it has high-pressure air, full road noise, and a complete visual display. The truck moves like a real truck. It has 6 degrees of freedom, similar to an airplane simulator (e.g., surge, sway, heave).
  - Scenario generation tools allow company to build scenarios to customer's standards. Scenarios are designed with increasing levels of difficulty and complexity. Company can also price in a scenario generation tool and training to allow researchers to build their own scenarios.
  - The simulator has a large database so that it is possible to spend 8 hours on the system and not cover all of the roads. Long 8 hour scenarios can be built that include truck rest stops.
  - The built in student progression control ensures that each scenario must be completed successfully before advancing to the next one
  - Full student data tracking and management are built into the system
  - Company currently has no business model for leasing. Simulators are made on demand and cost approximately $800,000 U.S.

5.6 National Advanced Driving Simulator (NADS)

(Recommended by Mike Goodman – 202-366-5677; Office of Human-Centered Research, National Highway Traffic Safety Administration)
http://www-nrd.nhtsa.dot.gov/departments/nrd-12/nads/ResearchUses.htm
http://www-nrd.nhtsa.dot.gov/departments/nrd-12/nads/

- National Advanced Driving Simulator (NADS) is a high-fidelity, real-time driving simulator used to conduct fundamental research into the operation of the complex driver-vehicle-environment system
- As a national research facility, the simulator is accessible to the widest possible spectrum of researchers from both the public and private sectors
- The Department of Transportation has located the NADS at the University of Iowa (Iowa City), who are responsible for the daily operational research, maintenance, and long term upgrading
- NADS allows vehicle and driver data to be accurately gathered and stored

- Consists of a large dome in which entire cars and the cabs of trucks and buses can be mounted
- Driving scene and highway geometry are under the complete control of the simulator programmer
- Driver feels acceleration, braking and steering cues as if he or she were actually driving a real car, truck or bus
- The latest in visual display technology and a high-fidelity audio system
- The test subject is immersed in realistic sight, sound and movement so real that impending crash scenarios can be convincingly presented with no danger to the subject
- Mike Goodman said that the simulator is expensive to use (approximately $2,000 U.S. per hour) but there may be a reduction in price if research is part of a collaborative effort with NHTSA (and possibly the Office of Motor Carrier and Highway Safety (contact Bob Caroll)

6 VEHICLE-BASED PERFORMANCE TECHNOLOGIES

Vehicle-based performance technologies are onboard computer recording systems that automatically monitor and record vehicle operational data (e.g., truck lane deviation, steering or speed variability). There is a range of systems from commercial systems that act as sensors, focusing on safety by providing feedback to drivers related to a specific driving skill (e.g., driver steering movements), to data collection systems used for research purposes that can collect data on a number of different driving behaviours. Some groups have made their own data collection system such as Virginia Tech. Others have created systems out of existing commercial products. For example, Robert Carroll at the Federal Motor Carrier Safety Administration (FMCSA), said they had commercial vendors working together to create a system for their Fatigue Management Pilot project. This system consisted of Copilot from Attention Technologies Inc, a lanetracker from Assistware, an actigraph from Ambulatory Monitoring, and a 'black box' from Accident Prevention Plus to aggregate the data from all the systems.

Just as simulators have benefits and limitations with respect to research, so do on-road studies. These are enumerated below. Following this is a description of 3 related vehicle based performance systems: Micro DAS, In-Vehicle Data Logger (V.I. Engineering), and Virginia Tech In-Vehicle Monitoring Systems. Six Commercial Safety Feedback Systems that detect driver fatigue are then described.

6.1 Benefits and Limitations

Benefits:

- Driver's own vehicle can be used
- Objective driver behaviour data is collected on the road
- Technologies have a sound basis in research that has shown that vehicle control is impaired by fatigue
- The use of several different forms of measurement, as in the research vehicle-based performance technologies, is attractive to identify fatigue because if one measure fails to detect low arousal, another measure might be expected to pick it up (Hartley et al. 2000)

Limitations:

- Requires specialized installation by a mechanic
- Intensive data management required (e.g., must synchronize with driving logs)
- How do you decide how well subject drove and whether their difficulties related to being tired? What is the range of 'normal' variability of these measures in the driving population? How has the threshold of 'abnormal' driving behaviour been selected? Do driving difficulties relate to being tired?

6.2 Research Systems

6.3.1 Micro DAS (National Highway and Safety Administration)

Contact: Frank S. Barickman
Telephone: (937) 666-4511
Vehicle Research and Test Centre (Iowa)
National Highway Traffic Safety Administration

- Micro DAS was developed to provide a low-cost system that would allow collection of naturalistic data, that could be installed in subject's own vehicles in a relatively short period of time
- System collects real-world information on driver behaviour, driver and vehicle performance, and roadway environments in situ
- Captures greater than 22 hours of full-motion video data collection
- MicroDAS is no longer in production but may be produced commercially. Frank Barickman said that VI Engineering, Inc. was to be producing the product for Louis Tijerina
- MicroDAS is no longer in production but a system inspired by it is being produced commercially by VI Engineering, Inc. for use in human factors studies by CAMP (Crash Avoidance Metrics Partnership) (see below)
- An evolution of DASCAR (smaller form factor, easier installation, cheaper, extended capabilities)
- Can be used in a wide range of vehicles
- Relatively inexpensive portable system
- Easy installation. Can be installed directly in test participant's own vehicle in a short time period (12 h for installation; an additional 8 h for preliminary testing). Designed to be installed without permanent modifications to vehicle.
- Video recording system is capable of collecting over 22 hours of full-motion video
- Data collection can be triggered manually or based on events defined by the researcher (e.g., based on sensor data, elapsed time, time of day, and user-defined equations)
- Designed to collect antecedent data, allowing the information leading up to an event to be studied
- NHTSA does not currently manufacture these units for commercial use
- NHTSA currently has 17 units. They do not rent or lease these units.
- Transport Canada currently has one unit (contact at Transport Canada – Ian Noy)
- Similar systems can be created by adding to off the shelf systems such as Assistware which is a lateral position sensor

6.2.2 In-Vehicle Data Logger (V.I. Engineering)

http://www.viengineering.com/Solutions/Solutions.asp

Contact: Ken Kinter, Sales Engineer
Work Phone: (248) 489-1200 x240. Cell Phone: (248) 797-2470
Email: kkinter@vieng.com

- This system is in some ways an evolution of MicroDas. They looked at MicroDas as a starting point then built a system to meet the needs of CAMP (Crash Avoidance Metrics Partnership – General Motors and Toyota are members).
- System is used for human factors studies (e.g., testing new braking alert systems, driver reactions to different stimuli such as playing with the radio, etc.)
- Ken Kinter was not sure if it has ever been used in a fatigue study
- System consists of data acquisition software that they have coded. The system collects data from hardware such as eyetracker, lanetracker, GPS, 8 video cameras, as well as radar (to detect distance from objects in front and behind vehicle).
- They can reuse this code to create a personalized system for clients (cost approximately $25,000 U.S.)
- This does not include hardware such as eye tracker, titler (which puts information on video) and cameras
- System can be mounted on racks in trunk of car or on racks within a truck

6.2.3 Virginia Tech In-Vehicle Monitoring Systems

www.vtti.vt.edu

Recommended by: Mike Goodman
Contact: Tom Dingus
Tel: (540) 231-1501, ext. 11502

- Data acquisition system that collects information on lane tracking as well information from the on-board network of the vehicle (e.g., throttle position, braking)
- System can be used in a heavy cab
- The system has undergone a number of iterations in-house and is now being used in the 100-car study, a one-year study of light vehicle drivers (i.e., heavy commuters) in the Washington, D.C. area
- The system is not currently available for purchase or license but may be in the near future
- Frank Barickman of NHTSA said this system is an evolution of the Micro DAS. It includes features of both Micro DAS and DASCAR and is smaller and cheaper than its predecessors.
- According to Mike Goodman this system is reasonably priced compared to commercial products

6.3 Commercial Safety Feedback Systems

6.3.1 Steering Attention Monitor (S.A.M.)

http://www.actionimports.com.au/sam.htm

- Monitors micro-corrective movements in the steering wheel using a magnetic sensor that emits a loud warning sound when it detects "driver fatigue" by the absence of micro-corrections to steering
- System only works in very limited situations as they are too dependent on the geometric characteristics of the road and can only function reliably on motorways.

6.3.2 ZzzzAlert Driver Fatigue Warning System

www.zzzzalert.com

- Small computerized electronic device that monitors corrective movements of the steering wheel with a magnetic sensor

6.3.3 DAS 2000 Road Alert System

http://www.premiersystems.com/market

- Detects and warns drivers that they have inadvertently crossed the centre line or right shoulder lines. If either line is crossed without using the turn signals, the computer automatically sounds an audio alarm to alert the driver.

6.3.4 AssistWare Technology: SafeTRAC Drowsy Driver Warning System

http://www.assistware.com/index.html

109 Gateway Avenue, Suite 201
Wexford, PA 15090
U.S.A.
Tel: (724) 934-8965
Email: info@assistware.com

- Lane tracker system that mounts a tiny video camera on the windshield of the vehicle, facing outward toward the highway
- Watches for weaving or erratic steering
- System plugs into the cigarette lighter and can be installed in less than 10 minutes
- The basic SafeTRAC system is enhanced with diagnostic and data output capability. According to the web site this system is "ideal" for research use (Cost: $15,500 U.S.)
- Richard Hanowski said they used this system in previous studies but it was "not very reliable"

6.3.5 Accident Prevention Plus

http://www.applus.com/

- Accident Prevention Plus, Inc., designs, develops, and markets onboard computer recording systems (e.g., models: APP1000, APP2000, and APP3000) and fuel monitoring systems for commercial and fleet vehicles

- On-Board computer collects following information:
  - 50 sec. before & 10 sec. after an Accident
  - Driving Chronologies
  - Idling Chronologies
  - Maximum Speed
  - Maximum Deceleration
  - Speed Histograms
  - Engine Speed Histograms
  - Foot Brake Intensity Histograms
  - Foot Brake Occurrence/Speed Ranges
  - Gear Position Histogram
  - Driver's Identification
  - Date & Time, First & Last Use of Vehicle
  - Total Driving Time & Distance
  - Total Idling Duration
  - Dangerous Braking Occurrences
  - Hard Braking Occurrence
  - Distance/Speed Range Histogram
  - Duration/Deceleration Intensity Histogram
  - Duration/Engine Speed Range Histogram
  - Braking Occur/Speed Range Histogram

6.3.6 Traxis

http://www.traxis.ca/

Toll Free: 1 (888) 303-5222
Suite 200 - 1111 West Hastings Street
Vancouver, B.C.
V6E 2J3
Canada

- Vehicle-driver performance monitoring system
- Researchers can define violation definitions (e.g. speeding, braking, progressive shifting, idling, etc.) and status/event indicators, and then compare the driver's performance record against these standards
- The *Driver Violation Summary* report allows you to view violation information recorded by the on-board computer
- *The Driver Violation Exceptions* report evaluates the recorded violations with respect to distance, engine time and drive time

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