Final Report of Polypharmacy and Older Drivers:

Identifying Strategies to Study Drug Usage and Driving Functioning Among Older Drivers

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16. Abstract

The goal of this project was to determine if there are practical means to obtain information about drug usage by older drivers under everyday, "real world" conditions that are valid and reliable, and to measure the consequences of multiple drug use for safe driving. Further goals were to identify candidate methodologies for carrying out such studies that are both cost-effective and likely to be successful in obtaining a diverse and representative sample of older drivers. These objectives were accomplished through the following tasks: a literature review; a brainstorming session including professionals with expertise in polypharmacy and driving performance measurement; and focus groups with older drivers.

The literature review, published by NHTSA as a stand-alone document, contains three main sections. The first reviews the prevalence of medication use by community-dwelling older persons, the physiological/ metabolic effects of specific drugs and drug classes, and the known effects on driving ability. The next discusses the strengths and weaknesses of various methods that may be used to learn which prescription and over-the-counter drugs are being taken by older adults, including a consideration of which factors most strongly affect compliance with a medication regime, and which factors influence older persons' willingness to participate in studies aimed at obtaining such information. The last section examines on-road, closed course, and simulation methods that have been applied in prior studies of drug use and driving functioning.

A one-day brainstorming session was conducted to afford guidance in the development of future NHTSA research plans for measuring medication use and driving performance. Project staff and consultants prepared discussion materials that were distributed in advance to 13 panel members, who also completed rating scale exercises to measure differences of opinion with respect to the practicality, reliability, and cost-effectiveness of various research methodologies.

Four focus groups were conducted with drivers age 55 to 85 in the Tampa, FL and Philadelphia, PA vicinities to better understand the perceptions and concerns that older drivers may have about participating in future NHTSA-sponsored studies where they would be asked to disclose their usage of prescription and over-the-counter medications, and participate in an assessment of their driving abilities. Results were summarized for use in planning later NHTSA research activities.

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SI* (MODERN METRIC) CONVERSION FACTORS

APPROXIMATE CONVERSIONS TO SI UNITS

Symbol	When You Know	Multiply By	To Find	Symbol
	LENGTH			
in	inches	25.4	millimeters	mm
ft	feet	0.305	meters	m
yd	yards	0.914	meters	m
mi	miles	1.61	kilometers	km
	AREA			
in^2	square inches	645.2	square millimeters	mm^2
ft^2	square feet	0.093	square meters	m^2
yd^2	square yards	0.836	square meters	m^2
ac	acres	0.405	hectares	ha
mi^2	square miles	2.59	square kilometers	km^2
	VOLUME			
fl oz	fluid ounces	29.57	milliliters	mL
gal	gallons	3.785	liters	L
ft^3	cubic feet	0.028	cubic meters	m^3
yd^3	cubic yards	0.765	cubic meters	m^3
NOTE: Volumes greater than 1000 l shall be shown in m^3.				
	MASS			
oz	ounces	28.35	grams	g
lb	pounds	0.454	kilograms	kg
T	short tons (2000 lb)	0.907	megagrams (or "metric ton")	Mg (or "t")
	TEMPERATURE (exact)			
°F	Fahrenheit temperature	5(F-32)/9 or (F-32)/1.8	Celcius temperature	°C
	ILLUMINATION			
fc	foot-candles	10.76	lux	lx
fl	foot-Lamberts	3.426	candela/m^2	cd/m^2
	FORCE and PRESSURE or STRESS			
lbf	poundforce	4.45	newtons	N
lbf/in^2	poundforce per square inch	6.89	kilopascals	kPa

APPROXIMATE CONVERSIONS FROM SI UNITS

Symbol	When You Know	Multiply By	To Find	Symbol
	LENGTH			
mm	millimeters	0.039	inches	in
m	meters	3.28	feet	ft
m	meters	1.09	yards	yd
km	kilometers	0.621	miles	mi
	AREA			
mm^2	square millimeters	0.0016	square inches	in^2
m^2	square meters	10.764	square feet	ft^2
m^2	square meters	1.195	square yards	yd^2
ha	hectares	2.47	acres	ac
km^2	square kilometers	0.386	square miles	mi^2
	VOLUME			
mL	milliliters	0.034	fluid ounces	fl oz
L	liters	0.264	gallons	gal
m^3	cubic meters	35.71	cubic feet	ft^3
m^3	cubic meters	1.307	cubic yards	yd^3
	MASS			
g	grams	0.035	ounces	oz
kg	kilograms	2.202	pounds	lb
Mg (or "t")	megagrams (or "metric ton")	1.103	short tons (2000 lb)	T
	TEMPERATURE (exact)			
°C	Celcius temperature	1.8C + 32	Fahrenheit temperature	°F
	ILLUMINATION			
lx	lux	0.0929	foot-candles	fc
cd/m^2	candela/m^2	0.2919	foot-Lamberts	fl
	FORCE and PRESSURE or STRESS			
N	newtons	0.225	poundforce	lbf
kPa	kilopascals	0.145	poundforce per square inch	lbf/in^2

* SI is the symbol for the International System of Units. Appropriate rounding should be made to comply with Section 4 of ASTM E380.

(Revised September 1993)

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EXECUTIVE SUMMARY

This project included a literature review, brainstorming session with subject matter experts, and focus groups with older drivers. These project activities were all performed to improve NHTSA's understanding of the best methodologies to use in future research addressing the effects of multiple medications on driving functioning.

Separate chapters in this report describe and present the results of each project activity. This summary draws from all of these activities to highlight the guidelines for continuing research developed from these efforts. These guidelines are framed in response to four questions about research methodology which, together, defined the present project objectives.

The first question established the broad context for empirical investigations in this topic area by asking, *"What is our current understanding of the effects of drugs/medications, (and combinations of medications) on crash risk/crash involvement, and which should be the focus of continuing research on polypharmacy and driving functioning?"*

Building on earlier work that identified the most potentially driver impairing (PDI) drugs prescribed to older persons (LeRoy, 2004), this project narrowed the priorities for further study according to classes of drugs, not individual medications. With an emphasis on their exposure in the older population, as well as their pharmacological actions, the emerging recommendations for continuing study focus on alpha blockers and other medications used to treat high blood pressure (anti-hypertensives); sedating drugs such as the benzodiazepines, tricyclic antidepressants, and opioids; and drugs that affect blood sugar levels (anti-diabetic agents and drugs that could potentiate hypoglycemic effects).

The second question asked, more specifically, *"What are the most feasible and reliable means of measuring/monitoring drug/medication usage—including over-the-counter drugs—by older drivers?"*

To obtain complete and reliable information from older persons about their medication regimes, the researcher must simultaneously address their concerns about the privacy and confidentiality of the information revealed; the personal security of the older study participants; and the credibility of the research team and overall goals of the study. The recommended approach is a form of the "brown bag" method, where an older research participant is asked to bring all of his/her medications (including over-the-counter drugs) to an office or other neutral, non-threatening location to be inventoried by an appropriate professional. Pharmacists (active or retired) are the best choice in this regard, although nurses also may have sufficient perceived authority in this area, and offer a strong "comfort level." A member of the research team who can provide assurances of privacy and confidentiality should also be present during the brown-bag interview.

Most desirable is to employ multiple approaches for measuring/monitoring drug usage among older research participants. A recommended strategy is to complement the brown-bag review by accessing an administrative claims (pharmacy) database in which the research subject is enrolled. This will provide a historical record of the individual's (prescription) drug regime that can serve as a screen in subject recruitment, and provide a valuable point for confirming a subject's expected drugs and dosages during a specific study period.

The next question was closely related, asking *"What are the most practical and valid ways of assessing the impact of drug/medication use on actual driving performance?"*

Information about driving functioning can be obtained through direct measurements of performance behind-the-wheel, in either the subject's own vehicle or an evaluator's (dual control) vehicle, on either a closed course or in actual traffic. Simulated driving performance can be measured using a wide range of devices, from desktop units to fully interactive systems with motion platforms, high resolution, and a 360-degree field of view. Indirect measures of the effects of medications on driving performance can be made using clinical assessments of functional abilities most important for safe vehicle control. Each alternative approach has strengths and limitations.

A measurement methodology utilizing a combination of approaches is recommended to obtain the most complete understanding of the (potentially) impairing effects of multiple medications, at the highest comfort levels and the lowest perceived risk by study participants. These include clinical assessments of functional abilities, using computer-based methods, if feasible, to promote standardization in test administration and scoring, and to permit the use of specialized cognitive tests (e.g., processing speed) that require precise timing. In-vehicle assessment on a closed course with a properly qualified driving evaluation specialist is recommended, using a dual control vehicle, as a safety precaution, and a standardized protocol for observation of critical driving skills. To gain an understanding of how an older person performs in actual traffic conditions while using medications *that he or she normally takes*, instrumenting the individual's own vehicle with a data collection package that can unobtrusively record key measures of performance without an experimenter present is also recommended.

With an eye to the special characteristics of this (older) population of interest, the final question asked, *"What are the potential barriers to the participation of older persons in studies of drug/medication use and driving functioning, and how might they be overcome?"*

This project revealed a number of profound concerns among older prospective research subjects. The participation of community-dwelling older persons in studies of the effects of drugs on driving functioning will be encouraged by a strong assurance of confidentiality; individuals must remain anonymous in reports of the study's findings, and every protection possible under applicable State law to shield an individual's driving performance measures from being made available to a licensing authority must be provided. Informed consent procedures should specify to study participants all of the parties to whom the results of their driving evaluations may be made available.

In addition, the benefits of research participation, for individuals and for society, should be clearly explained; there appears a general willingness on the part of older persons queried in this project to become involved in research that can improve safety, even if it requires them to divulge information about the drugs they are taking and/or to have their driving performance evaluated. Fair compensation for the amount of time a participant must commit to the study—preferably in cash—also is important.

These guidelines provide a framework within which to develop research designs for continuing empirical investigations into the effects of drugs on driving performance. Future projects are certain to refine our understanding of key variables, while demonstrating which procedures represent the most reliable and cost-effective options that are possible within this area of inquiry.

LITERATURE REVIEW

INTRODUCTION

The purpose of the literature review was to update the Wilkinson and Moskowitz (2001) unpublished report *Polypharmacy & Older Drivers- Literature Review.* As such, it was limited to literature published since 2001 addressing polypharmacy, drugs, and older drivers. Literature was also reviewed to identify techniques used to measure/test driving skills.

Searches were conducted in Embase (which includes MedLine), PsycINFO, TRIS, and SafetyLit Weekly for recent literature (2001 to 2004) with any of the following keywords:

▪ Polypharmacy ▪ Multiple medication use ▪ Prescription drugs ▪ Over-the-counter drugs ▪ Drug use ▪ Older drivers ▪ Older adults ▪ Elderly persons ▪ Community-dwelling elderly ▪ Medication review ▪ Brown bag method ▪ Medication management ▪ Medication compliance ▪ Medication adherence ▪ Medication persistence ▪ Medication event monitoring ▪ Self medication ▪ Medication side effects ▪ Driver impairing medications ▪ Driver impairing medical conditions	▪ Inappropriate prescribing ▪ Contraindicated drugs/medications ▪ Geriatrics ▪ Gerontology ▪ Medicaid/Medicare pharmacy claims ▪ Veterans administration pharmacy benefits management database ▪ Pharmaceutical claims ▪ Prescription database ▪ Medication usage/tracking ▪ Medication dispensing technology ▪ Motor vehicle crashes ▪ Motor vehicle accidents ▪ Dose administration aids ▪ Driving skills ▪ Driving ability ▪ Driving performance ▪ Falls or falling

Approximately 1,600 abstracts were identified in the original searches. A review of titles indicated that many reports focused on medications for resistant conditions. Eliminating the terms “resistance” and “resistant” and limiting the search to human subjects age 65 and older, and abstracts to those in English, reduced the search results to 365 potentially relevant articles. In selecting articles for review, only those describing populations of likely drivers were included (i.e., “community-dwelling” populations, as opposed to residents of nursing homes or residents of group homes who suffer from developmental disabilities or conditions such as schizophrenia). Systematic differences in prescribing and in monitoring compliance in controlled settings such as nursing homes and hospitals limit the generalizability of information from these populations to community-dwelling older persons. In addition, research on multiple medication effects was primary over research on single medication effects; however, reports presenting the effects of single medications on driving performance were included to the degree that the research focused on the effects of the drug on driving performance or falling in older community-dwelling people. A set of 300 articles resulted from this first screen.

The selection of reports for review underwent further refinement with the assistance of two project consultants.[1] This screening process produced a final review set of 143 articles identifying medication use and measuring medication adherence; measuring driver performance; and polypharmacy and older persons.

The literature review has been published as a stand-alone document entitled, *Literature Review of Polypharmacy and Older Drivers: Identifying Strategies to Collect Drug Usage and Driving Functioning Among Older Drivers* (Lococo and Staplin, 2006). It is divided into three major sections to address the information needs of the current project: 1) Medication/ Polypharmacy Effects on Older Persons; 2) Methods of Measuring/Monitoring Medication Usage; and 3) Methods to Measure Driving Performance. Although prescription medications were the major focus of this review, over-the-counter medication use by older persons is included where it was reliably documented in the literature. Additional areas that received attention in the literature review on polypharmacy include: how polypharmacy among older adults impacts areas other than driving (such as falls), and older persons' use of alcohol in combination with other medications—as alcohol use was not the focus of this project. A summary of this literature follows.

MEDICATION/POLYPHARMACY EFFECTS ON OLDER PERSONS

The first section of the literature review describes medication use in the older community-dwelling population (not hospitals or nursing homes) in the United States and other countries. Within the population of community-dwelling older persons in the U.S., more than 90 percent of persons age 65 or older use at least 1 medication per week; more than 40 percent use 5 or more different medications per week; and 12 percent use 10 or more different medications per week (Gurwitz, 2004). Although the number of medications used to define "polypharmacy" ranges in research studies from 2 to 10 (Lee, 1998), the findings of Allard, Hébert, Rioux, Asselin, and Voyer (2001) that *the consumption of 3 or more drugs per day increases the risk of functional decline in elderly people by 60 percent* deserve attention. Decreases in functional ability brought on by polypharmacy have been associated with an increased risk of motor vehicle crashes (LeRoy, 2004), raising public health and safety concerns.

In a cohort study of nearly 28,000 Medicare+Choice enrollees cared for by a multispecialty practice (an ambulatory clinic setting) during a 12-month study period between 1999 and 2000, researchers found that 75 percent of the sample received prescriptions for 6 or more prescription drugs (Gurwitz, Field, Harrold, Rothchild, Debellis, Seger, Cadoret, Fish, Garber, Kelleher, and Bates, 2003). Forty-nine percent of the sample was prescribed medications in four or more categories. Combinations of medication use were not reported; however, the specific prescription medication categories and percentage of enrollees receiving prescriptions were as follows:

[1] Dr. Robert Raleigh and Dr. Marion Anders served as consultants in this project. Dr. Robert Raleigh recently retired as the Chief of the Maryland Medical Advisory Board. Dr. Anders is a world renowned expert in interactions of single and multiple drugs. He is recently retired as Chair of the Departments of Pharmacology and Physiology at the University of Rochester Medical School.

▪ Cardiovascular (53.2%) ▪ Antibiotics/anti-infectives (44.5%) ▪ Diuretics (29.5%) ▪ Opioids (21.9%) ▪ Antihyperlipidemic (21.7%) ▪ Nonopioid analgesics (19.8%) ▪ Gastrointestinal tract (19.0%) ▪ Respiratory tract (15.6%) ▪ Dermatologic (14.8%) ▪ Antidepressants (13.2%) ▪ Sedatives/hypnotics (12.9%) ▪ Nutrients/supplements (12.3%) ▪ Hypoglycemics (11.5%) ▪ Steroids (9.7%) ▪ Ophthalmics (9.6%)	▪ Thyroid (9.4%) ▪ Antihistamines (9.2%) ▪ Hormones (9.1%) ▪ Anticoagulants (7.0%) ▪ Muscle relaxants (5.4%) ▪ Osteoporosis (5.3%) ▪ Antiseizure (3.4%) ▪ Antigout (3.2%) ▪ Antineiplastics (2.8%) ▪ Antiplatelets (1.3%) ▪ Antipsychotics (1.2%) ▪ Antiparkinsonians (0.9%) ▪ Alzheimer disease (0.9%) ▪ Immunomodulators (0.04%)

The prevalence of potentially inappropriate medication use in this population has been found to range from 6 percent to 21 percent. Potentially inappropriate medications are those that: (1) *should generally be avoided* in persons 65 years or older because they are either ineffective or they pose unnecessarily high risk for older persons and a safer alternative is available, and (2) medications that should not be used in older persons known to have *specific medical conditions* (Fick, Cooper, Wade, Waller, Maclean, and Beers, 2003). Data examined by Aparasu and Mort (2004) indicate that the most prevalent of the inappropriately prescribed prescriptions to community-dwelling individuals in the U.S. include: amitriptyline and doxepin (antidepressants); chlordiazepoxide, diazepam, and flurazepam (benzodiazepines); chlorpropamide (an anti-diabetic/hypoglycemic); dipridamole (an anti-platelet agent); hydroxyzine (an antihistamine); meprobamate (an anti-anxiety drug); oxybutynin (an antispasmodic agent for the urinary tract); propoxyphene (a narcotic analgesic); non-steroidal anti-inflammatory drugs; and barbiturates. Appendix A in this Final Report provides detail about specific potentially inappropriate medications found in the literature review to be commonly prescribed for older, community-dwelling individuals, their classification, and side effects relevant to a discussion of safe driving ability.

Studies on the effects of medications, and the physiological changes that occur with age and affect how older people metabolize their medications are examined next. A range of physiological changes that may affect drug metabolism occurs with age. The liver plays a central role in the termination of drug action and has, therefore, been well studied. Liver size or volume and hepatic blood flow both decrease with age. Other physiological changes that occur with aging include reduced body mass and basal metabolic rate, reduced proportion of body water, increased proportion of body fat, decreased cardiac output, altered relative tissue perfusion, decreased plasma protein binding, reduced gastric acid production and gastric emptying time, and reduced gut motility and blood flow (Herrlinger and Klotz, 2001). Although the effect of aging on human drug metabolism has been much studied, few generalizations about how aging affects human drug metabolism have emerged. Although some measures of drug metabolism are diminished in the elderly, significant interindividual variability in drug

metabolism, drug action, and adverse reactions characterizes the elderly population (Herrlinger and Klotz, 2001; Schmucker, 2001; and Kinirons and O'Mahony, 2004).

The final section in this segment of the of the literature review provides a general overview of medication use and crash risk by examining recently conducted epidemiological and experimental studies to determine the consequences of a single class of medication on the ability to drive safely. Potentially driver impairing (PDI) medications are associated with known effects on the central nervous system, blood sugar levels, blood pressure, vision, or otherwise have the potential to interfere with driving skills. Possible PDI effects include sedation, hypoglycemia, blurred vision, hypotension, dizziness, fainting (syncope), and loss of coordination (ataxia). Single classes of medications that have been associated with an increased crash risk include the benzodiazepines, opioids, sedating antidepressants, narcotic analgesics, anti-anxiety agents, antihypertensive agents, skeletal muscle relaxants, antimanic agents (lithium), and anti-diabetic agents (LeRoy, 2004; Walsh, de Gier, Christepherson, and Verstraete, 2004; Fishbain, Cutler, Rosomoff, and Rosomoff, 2003; Leveille, Buchner, Koepsell, McCloskey, Wolf, and Gagner, 1994; Ramaekers, 2003; Szlyk, Mahler, Seiple, Vajaranant, Blair, and Shahidi, 2004).

A few studies are reported that examine multiple medication use. However, there is a dearth of research on the effects of combinations of specific medications or even combinations of drug classes on driving ability *per se*. However, in one recent and comprehensive pharmacy database analysis of multiple medicine use (LeRoy, 2004), higher percentages of crash-involved drivers were prescribed two or more prescriptions than non crash-involved drivers. The most-frequently appearing drug combinations (in descending order of frequency) in the group of crash-involved drivers age 50 and older were:

- Narcotics + Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
- Skeletal Muscle Relaxants + NSAIDs.
- Narcotics + Skeletal Muscle Relaxants.
- Narcotics + Skeletal Muscle Relaxants + NSAIDs.
- Narcotics + Antibiotics.
- Gastric Acid Secretion Reducers + Narcotics.
- Anti-Anxiety Drugs + Narcotics.
- Serotonin Reuptake Inhibitor (SSRI) Antidepressants + Narcotics.
- Narcotics + NSAIDs + Antibiotics.

MEASURING/MONITORING MEDICATION USAGE

Researchers across several decades have described patient compliance as "the best documented, but least understood health behavior" (Coons, 2001; Becker and Maiman, 1975). Although a variety of methods to measure compliance exist, problems with validity and reliability are inherent with every one of them (Marinker, Blenkinsopp, Bond, et al., 1997). Vik, Maxwell, and Hogan (2004) state that presently there is no generally accepted gold standard for measuring adherence. This section of the literature review begins with a discussion of methods used to measure compliance, including the pros and cons of each method. These methods include: clinical judgment, patient's self report, clinical response, biochemical measures, pill

counts, pharmacy records, and electronic medication monitoring devices. A brief summary of the pros and cons of each method follows.

Physician's Clinical Judgment. Studies have shown that physicians' *clinical judgments* of compliance are no more accurate than predicting compliance by chance (American Pharmacists Association/APhA, 2003; Bikowski, Ripsin, and Lorraine, 2001).

Patient's Clinical Response. The APhA (2003) reports that for many medications, a patient's *clinical response* to a medication is only weakly related to compliance. In addition, while some studies suggest that the absence of predictable adverse side effects is correlated to noncompliance, the link between compliance and adverse effects has not been consistent in the literature.

Patient Self Report. In many studies, information obtained using the *patient self-report* method has correlated positively to information obtained from random pill counts, pharmacy records, biochemical measures, and electronic medication monitors. In several studies reviewed by APhA (2003), querying patients about their compliance resulted in the detection of over 50 percent of patients with poor compliance, with a specificity of 87 percent. Congruence of pharmacy records and self-reported medication use is of importance because self-reports of medications are often used as a surrogate for health status or the presence of chronic diseases, and are important when studying medication compliance, polypharmacy, and drug interactions. Self reports of medication are frequently used in population-based studies where pharmacy records are lacking or are expensive to obtain. A particular self-report method—the brown bag method of medication review—has been found to provide a reasonable substitute for pharmacy records as a measure of current medications (Caskie and Willis, 2004).

Biomechanical Measures. *Biochemical measures* of patient compliance (blood and urine sampling) to measure drug presence and concentrations are objective, but not practical, convenient, or appropriate for most circumstances, and not always reliable (APhA, 2003).

Pill Counts. *Pill counts* measure compliance by comparing the number of doses remaining in a container with the number of doses that should remain, if the patient's compliance were perfect. This method can provide an overestimation of compliance if the patient is aware that a pill count is going to be conducted—patients may remove excess doses and discard them. Another drawback to this method is that it cannot verify that a dose removed from a container was actually consumed, or whether it was consumed at the correct time. Pill counts are not suitable for medications taken on an as-needed basis (APhA, 2003).

Pharmacy Records/Administrative Databases. The use of *pharmacy records* to estimate compliance based on pharmacy refills, correlates favorably with electronic measurement, but shares some of the same problems that are intrinsic to pill counts (APhA, 2003). A refill record will provide information about how much medication was dispensed in a given interval, but it can not validate that the medication was actually consumed or consumed at the correct time. In addition, refill records cannot guarantee that a patient is not obtaining medications from pharmacies other than the one being monitored, and cannot guarantee that the patient is not stockpiling medications or sharing them with others. Also, samples given to patients by their

physicians would not show up in the pharmacy database, resulting in an overestimate of noncompliance. Pharmacy records were used in some of the studies that employed the brown-bag method, as a means of identifying members at risk for polypharmacy for inclusion in those medication-review studies. Other researchers have used pharmacy databases to determine the relative frequency of various combinations of medications, and to conduct case-control studies of the use of medications and adverse outcomes such as motor vehicle crashes (LeRoy, 2004). As noted by LeRoy, an advantage to the use of claims data is that it is not dependent on patient recall of medication and disease information. However, in interpreting results derived from analyzing administrative claims data, the following sources of error or influence must be considered: reporting error (including under-reporting); ascertainment error (correctly billed but incorrectly diagnosed); and detection bias (frequent visits yield increased opportunity to detect).

Electronic Medication Monitoring Devices. *Electronic medication monitoring devices* use microchip technology to record and download data to a computer for review and analysis describing the actual data and time that a dose is removed from a container. Although they are recognized as the "gold standard" of compliance assessment, the method has drawbacks similar to the pill count method and the pharmacy refill method—electronic medication monitoring devices cannot assure that a dose that was removed was actually consumed or administered correctly. In addition to errors introduced when a bottle is opened and no medication is taken, errors may be introduced when a patient removes two doses during one opening (one for the morning and one for the afternoon) and only one event gets recorded for two doses taken (APhA, 2003).. Despite these limitations, electronically measured adherence has been more highly associated with clinical outcomes than self report (Liu, Golin, Miller, Hays, Beck, Sanandaji et al., 2001) and pill counts (Namkoong, Farren, O'Connor, and O'Mally, 1999).

This section of the literature review also examines the factors affecting compliance with medication regimes. Medication-related factors associated with low compliance include: increases in the complexity, cost, and duration of medication regime; increases in the number of prescribed medications; and increases in the severity of side effects. Patient-related factors that correlate with low compliance include: limited access to health care; financial problems; communication barriers; and lack of social support. The prescriber-related factors that correlate with low compliance include: a poor prescriber-patient relationship; poor prescriber communication skills; a mismatch between the prescriber and patient regarding health beliefs; and a lack of positive reinforcement from the health-care provider.

This section of the literature review also examines several factors that affect older persons' willingness to participate in research and offers some lessons learned to help in recruitment of elderly patients into studies. Cooperation of the candidate subjects' pharmacy and physicians increases subjects' willingness to participate in studies (Ory, Lipman, Karlen, Gerety, Stevens, Singh, Buchner, Schechtman, and the FICIT Group, 2002). Patients are more likely to undergo medication review if it is recommended by their physicians (Nathan, Goodyer, Lovejoy, and Rashid, 1999; Ory et al., 2002). In addition, explaining the benefits of participating a medication review in recruitment letters to subjects has been shown to increase participation (e.g., "a medication review will ensure that you are taking only the necessary medications to control your medical conditions, the doses are correct, and the medications are safe to be taken

together") (MacRae, Lowrie, MacLaren, Kinn, and Fish, 2003; Farris, Ganther-Urmie, Fang, Doucette, Brooks, Klepser, and Kuhle, 2004).

METHODS TO MEASURE DRIVING PERFORMANCE

The literature review concludes with a section that synthesizes methods used in studies to measure driving performance, highlighting methods that appear to hold the greatest promise for evaluating the effects of drugs on driving performance while also acknowledging shortcomings and limitations that have been reported in the literature.

Road tests have long been considered the gold standard for measuring driving ability. They have widely-recognized limitations, however. In addition to inconsistencies in the administration and scoring of the results, which presents a major challenge to standardized and objective assessments, as a rule examinees are not exposed to the most risky and demanding situations where driving errors that lead to crashes are most likely. Nevertheless, Ramaekers (2003) asserts that actual driving tests are *essential* to conclusively define the potential impact of drugs on driving. The literature review presents the advantages and disadvantages of naturalistic studies (driving in traffic) and controlled driving studies (driving on a closed course).

The literature review also includes a discussion of the pros and cons of driving simulation to measure driving performance. Driving simulators have been touted as offering experimental control for driving performance evaluation; they have also been criticized for a lack of fidelity for many aspects of actual driving (and therefore poor generalizability to conditions outside the laboratory), as well as simulator sickness (particularly for older adults). Another difficulty in evaluating the utility of this method is the ambiguity attached to the term "driving simulation." Testing systems bearing this label range from actual vehicles on motion platforms with fully-interactive control over high-resolution virtual environments, to "driving bucks"—a single seat with basic wheel and pedal controls for user inputs—that offer a more limited display of the driving environment and little or no motion, to desktop computer graphic/video presentations of selected driving scenarios for 'part-task' measurement (e.g., visual search, hazard detection). This review considers three categories, or levels, of simulation that range from non-interactive, computer graphic and/or digital video visuals with no motion, to interactive, computer graphic visuals with full motion.

As one additional perspective, a combination of approaches to investigate the effects of medications on the ability to drive has been advocated by Álvarez and del Río (2002). These authors note that relevant psychological and functional capabilities can be analyzed using vigilance and performance tests, psychomotor test batteries, reaction tests, etc., but should be complemented by simulator and on-road studies. Similarly, Keller, Kesselring, and Hiltbrunner (2003) offered the opinion that psychological tests in combination with an on-road test allow for a balanced judgment of a patient's fitness to drive. Their psychological assessment (including cognitive tests, a tracking task with divided attention, psychomotor tests, and assessments of impulse control and spatial orientation), when compared to the results of an on-road test, yielded consistent results in 88 percent of the cases studied (38 of 43 patients with neurological disabilities). Keller et al. (2003) also cite other researchers (Sundet, Goffeng, and Holt, 1995) in concluding that, while a psychological assessment sheds light on a subject's perceptual

efficiency, goal-oriented behavior, distractibility, psychomotor efficiency, and impulse control, a road test is key to demonstrate the subject's capacity to retrieve from procedural memory the technical skills of handling a car, the capacity to allocate and shift attention, and to keep a general overview of concurrent events, all of which are required for safe and successful driving.

BRAINSTORMING SESSION

INTRODUCTION

The purpose of the brainstorming session was to update NHTSA's understanding of the following four topics:

1. The effects of drug and medicine combinations on functional abilities key to safe driving.
2. The most feasible and reliable means of monitoring/measuring drug and medication usage—including over-the-counter drugs, and/or alcohol—by (older) drivers.
3. The most practical and valid ways of assessing the impact of drug/medication usage on actual driving performance.
4. Potential barriers—legal, ethical, and practical—to the participation of older persons in studies of drug/medication use and driving.

The 1-day brainstorming session was conducted in June, 2005 in Washington, D.C. Project staff and consultants were assisted in this task by 13 panel members representing the following areas of expertise:

- Motor Vehicle Administration, Medical Advisory Board Physicians.
- Clinical Pharmacologists.
- Doctors of Pharmacy.
- Administrative Pharmacy Database Research Specialists.
- Certified Driving Rehabilitation Specialists (CDRS)/Occupational Therapists (OT).
- Research Psychologists.
- Gerontologists.

A list of meeting attendees, including project staff and consultants, expert panelists, and NHTSA staff is provided in Appendix B. All attendees were provided with the literature review (conducted earlier in the project) one week prior to the meeting, and were advised that the material would serve as the starting point for discussion of the four topic areas during the meeting.

Each of the four broad areas of discussion noted above was introduced by project staff, who provided a 15-minute summary of the current state of the knowledge as reflected in the literature review, and then identified a small number of specific topics to focus the ensuing group discussion. In some areas, there was additional guidance from NHTSA staff attending the meeting, to explain Agency priorities or to signal when a topic under discussion was outside the Agency's normal scope of activities.

Discussion proceeded for 1 to 2 hours per topic area; this was recorded and transcribed to assist project staff in summarizing the content of the discussions. Experts also completed rating scales for selected topics to highlight similarities and differences of opinion among the group with respect to *practicality*, *reliability*, and *cost-effectiveness*, plus an *overall* rating, of various research methodologies.

RESULTS

The following pages summarize the discussion among experts, NHTSA, and project staff who participated in the brainstorming session. These discussions were organized around an explicit agenda or set of questions presented to the group as a whole. Descriptive statistics are included where rating scales were completed for a given topic. Raw data describing the results of the rating scale exercises are presented in tables in Appendices C through G.

Topic Area 1: What are the Effects of Combinations of Medicines on Functional Abilities Key to Safe Driving?

GROUP DISCUSSION AGENDA:

- How should polypharmacy be defined for future NHTSA research? (number of medications, prescription only or include over-the-counter medications, herbal remedies, and alcohol).
- What classes of medications and combinations should be the focus in future NHTSA studies, based on their effects on functional abilities key to safe driving?
- How should the test sample be defined (e.g., % male to female; age groupings; and at what age to start: 55+, 65+, 75+, 85+)?

The following points were provided as additional guidance from NHTSA attendees in the meeting:

- It is important to separate the effects of the medications from the effects of the illness for which the medications are being taken. In some cases, the medications will improve driving performance and in other cases they will cause driving performance to deteriorate.
- The timing of medication administration in relation to the timing of driving needs to be taken into account. Since older drivers do most of their driving during the day, it may be of no consequence that certain medications are taken at night, if those medications have no residual effects on driving performance during the day.
- NHTSA has an infrastructure to support the prosecution and adjudication of alcohol-impaired driving, but not for drug-impaired driving. So if someone is using both medications and alcohol, and is pulled over by law enforcement, he or she will be pursued based on the presence of alcohol. There are also practical limitations in detecting the presence of drugs by labs used by law enforcement, whereas the presence of alcohol is much more easily detected. Since older people are not typically in the

population apprehended for drunken driving, alcohol and medication interactions are not a focus in the current discussion.

Defining Polypharmacy and Identifying Drug Classes for Future Research

- Although the literature review highlighted the fact that the definition of polypharmacy varies from the concomitant use of 3 to 10 medications, the brainstorming experts agreed that assigning a number is a meaningless starting point. A person could have congestive heart failure and diabetes and be taking 10 medications appropriately. Contrast that person with someone taking an over-the-counter sleep aid and a long-acting benzodiazepine who would be much more impaired taking these 2 medications than the aforementioned person taking 10. And, taking two drugs could be less-impairing than taking one drug, depending on the class of the drugs; thus, the number of drugs is almost meaningless. The focus on polypharmacy should be on multiple classes of drugs—not on the number of drugs *per se*.

- Also, rather than a focus on *numbers* of medications, the focus should be on the *effects* of medications (the symptom), as the causal element of the driving impairment. Focus on level of alertness (a mental effect), and categorize drugs into a hierarchy for risk of impairing one's level of alertness. This approach could make it possible to say when combining a low-risk medication will increase the impairing effects of the high-risk medications. Also, drugs with motor (physical) effects such as dizziness, and those with visual effects should be considered.

- Level of alertness is a global parameter for cognitive function, as level of alertness affects all of the higher critical functions—if there is a decrement in alertness, there will be a decrement in the "executive" functions. However, level of alertness may be fine at the same time there is a decrement in executive functioning (e.g., as in strokes, dementia). The downside to limiting the definition of cognition to "level of alertness" is that the spectrum where alertness is impaired is relatively small, and there is a larger segment where more subtle deficits would show up and would be missed. But the effects of the medications (the impairments) must be related to increased crash risk in order for the research to have relevance for NHTSA.

- Experts recommended that classes of medications to be considered in any research on the topic of polypharmacy and driving should include—but not necessarily be limited to—the following: alpha blockers (potential for severe hypotension; common in the older male population); anti-diabetic agents (potential for hypoglycemia); sedating types of drugs such as the benzodiazepines, tricyclic antidepressants, and possibly the opioids; drugs that could potentiate hypoglycemic effects; and anti-hypertensive agents (because of their hypotensive effects).

- Extraneous factors such as fatigue/sleep deprivation will also affect a person's driving performance, and need to be accounted for in a study of the effects of polypharmacy on driving. Also, length of time on medication (defining stable dosing) may have an effect on driving, so that needs to be documented. However, research should not be limited to

those on stable doses, because it is the group that is *not* on stable dosing who is at highest risk. Also, those presumed to be on stable doses, but who are not compliant (and therefore not stable at all) are more likely to be at high risk.

- Although the potential effects of over-the-counter herbal remedies are increasingly being studied in other countries, and some of the mechanisms are beginning to be understood, the evidence on outcomes (adverse events and drug-drug interactions) isn't strong enough to justify including these substances in research on polypharmacy and driving.

- Over-the-counter (OTC) medications *other* than herbal remedies should be included in future research, because increasingly, the Food and Drug Administration (FDA) has been moving medications from prescription to OTC, particularly the nonsteroidal anti-inflammatory drugs (NSAIDs) and antihistamines, and there is ample science on which to recommend inclusion of these medications.

- Setting aside the aforementioned NHTSA comments on this subject, there was not any clear-cut agreement among the panelists regarding whether alcohol should be included as an agent that causes interactions with medications. In the practices of the CDRSs and physicians, older people are in the drinking-and-driving population and are using medications; they just are not picked up by law enforcement teams that generally operate at night (when older people are less likely to be on the road); and when they are picked up, it is often not reported. Alcohol-use screening of all admissions in an acute-care hospital in one physician's practice showed that 20 percent used alcohol regularly, and the majority of the users were over age 60. Alcohol used at night may still be present and interact with medications used during the day.

- To enhance the cost-effectiveness of research on polypharmacy and driving, studies should be limited to drugs/classes of medications that have high exposure in the population of interest, in contrast to those that may be more impairing but have a much lower frequency of use.

- To identify target drugs/drug classes of interest and their effects on driving, or to gain information that could alter practices for prescribing, it makes more sense to do a cross-sectional study than a longitudinal or an epidemiological study. In the latter case, the magnitude of a study needed to ensure enough people who were on a given medication or class of medications, and who had an outcome of interest, would be excessive.

- Concern was voiced among panelists that there are an overwhelming number of variables impinging upon the topic of polypharmacy and driving. Between the medical conditions, and the physical conditions, studies may demonstrate significant associations but are unlikely to demonstrate a causal effect between medication use and crashes. NHTSA participants acknowledged this, and reiterated that the hope was to do research to inform programmatic efforts—to inform drivers, physicians who prescribe, pharmacists who advise their customers, licensing agencies and Medical Advisory Boards, and possibly law enforcement, to be able to recognize signs of impairment. The purpose of future

research in this area is not to come up with a basis for restricting driving for individuals who take particular medications.

Defining "Older Drivers" For Future Research

- Most of the potential for problems with respect to polypharmacy and traffic safety is found among drivers age 70 and up; it is primarily in this group where multiple medications are being used, for multiple conditions. In addition, since crashes are the outcomes of interest in database analyses, and crashes are less frequent in the "young-old" age group (e.g., 55 to 70), it makes more sense to focus research upon the older age groups.

- At the same time, educational efforts should begin by age 55; people often start taking more than one medication around that age, and should be aware of potential interactions as well as effects on driving. Thus, separate groups of people, e.g., age 65+ and those under age 65 should be included in future studies evaluating the impact of education and awareness campaigns.

- It would be a significant omission to exclude drivers with cognitive impairment from studies of polypharmacy and driving, despite the fact that it may be difficult to determine whether they perform poorly because of their cognitive impairment or because of the medications they are taking. There a large percentage of the older population with cognitive impairments, and many of the medications that put people at risk for crashes are cognitively impairing.

Topic Area 2: What are the Most Feasible and Reliable Means of Monitoring/Measuring Medication Use?

GROUP DISCUSSION AGENDA:

- What are the most feasible and reliable means of identifying medication use by older drivers (including OTC medications and alcohol?)

- What are the most feasible and reliable ways of ensuring, as best as possible, that potential test subjects are compliant with their medication regimes?

Methods to Identify Medication Use

Discussion Summary

- When asking people to self-report medications, the manner of questioning is important to get the most complete picture of what people are taking. For example, it may be necessary to go through a review of medical conditions/symptoms/body systems with the patient, particularly to learn about the use of non-prescription medications. For example,

a person may be asked, "What do you use when you have a headache?" or "What do you take when you have cold symptoms, and how often do you take it?"

- Pharmacists and physicians in the group stated that the gold standard for determining what drugs people are taking is an in-home medicine review, i.e., going into a person's home to look at and list their medications. The in-home review is a luxury, however, that researchers can seldom afford. Next best is asking people to bring their medicines to be inventoried during an in-office review ("brown-bag" review). These two methods provide information that could be omitted when looking at a physician report of medications, because often, more than one physician prescribes for a patient. Multiple physicians prescribing is also a drawback to the use of some pharmacy databases—for example a Veteran's Administration pharmacy database would provide an incomplete picture of medication use when patients obtain medications from physicians in the community, in addition to going to the VA to get prescriptions filled.

- When conducting the brown-bag method, a gerontologist indicated that it is important to do so in a private, confidential setting (as opposed to a public or social setting), where people are more likely to be forthcoming about medications they use. It's also important to remind people to bring in all medications, specifying both prescription and over-the-counter medications. It may also be useful to provide a checklist of medications used for certain purposes to help them collect everything (headaches, pain, cold, etc.).

- It may be necessary to ask people what they are taking on two separate occasions: one time as a general overview of what medications they take; and the second time to find out what they took (or didn't take) on the particular day that driving performance is going to be measured. People may alter their medication regime when they want to perform well (as in a driving evaluation).

- Self-reports of medication use were considered to be an adequate method by brainstorming session participants, providing that the research subject brings a "significant other" to help collaborate/confirm what is being taken, and how much or how often. This is particularly important for people with cognitive impairment.

- It is advisable to first ask the subject's physician to complete a form indicating what medications have been prescribed, and then ask the patient, "Are you still taking this? Are you taking anything else? Is there one physician who knows everything you take and helps you monitor any interactions?"

- If a research study is going to include alcohol, ask subjects if they have ever had problems with alcohol, or been to an AA meeting. Also, ask them to describe their typical alcohol consumption for the week.

- If physicians are asked to report what medicines a patient is taking, the researcher must get the names of all the prescribing physicians, and then mail a form to each physician (with the patient's authorization to release the information) for the physician to complete. Motor Vehicle Administration Medical Advisory Boards often follow this practice.

- It is good to use multiple approaches to obtain data about medication use—for example, asking people and then checking an administrative claims database.

- There are databases (pharmacy claims data—both Medicaid and Insurance claims) that may allow researchers to generate and test hypotheses related to drugs and driving impairment.

- The Centers for Medicare and Medicaid Services (CMS) data on the National Medicaid population (a subset of all older adults who are poorer, sicker, and more have disabilities) contains all drugs provided under a fee-for-service setting—both prescription and over-the-counter. A cross-sectional examination of such data could determine the volume of polypharmacy in questionable areas, and suggest which drugs/combinations are associated with the most serious driving impairment. Such a data-driven approach could establish a rationale for further empirical studies of the effects of drugs on driving.

- A drawback to the use of administrative claims data is that crashes are not coded as "at fault" vs. "not-at-fault." The only thing that can be determined with the crash "e-code[2]" is if the person was the driver. Another caution is that in "e-code" analyses, crashes are underreported in both Medicaid and Medicare claims data.

Rating Scale Responses

Following discussion of this topic, expert panelists and project consultants completed rating scales to rate the practicality, reliability, and cost effectiveness, and to give an "overall" rating, for each of seven methods of identifying medication use:

A. Physician's Reports (mailed requests for what is in the patient's record).
B. Patient Self Reports (face-to-face).
C. Brown Bag Review.
D. Pharmacy Records (administrative claims databases).
E. In-Home Medicine Review.
F. Mailed Survey to Patient.
G. Proxy Report (concurrence of self-report by a significant other).

Participants placed a letter corresponding to a particular method on a scale that ranged from 1 (the worst rating) to 100 (the best rating), and were advised that more than one method could be designated the same rating, if methods were considered equal. Participants also completed an "overall" rating that was intended to incorporate *all* the facets (practicality, reliability, and cost-effectiveness). Several participants provided ratings for a combination of methods.

[2] External cause of injury code (E Code) in the range 810.0-816.9 and 819.0-819.9, motor vehicle traffic collision injury. E Codes are a coding system with-in the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), which are routinely entered into the Trauma Registry for each trauma patient.

Summary statistics were calculated across all 14 respondents, and were also calculated within 4 areas of specialty: for the 5 physicians and pharmacists (MDs and PharmDs), 3 driving evaluators (OTs/CDRSs), 3 behavioral researchers, and 3 database experts. These statistics are presented in tables in Appendix C. The results are briefly described below.

Without combining methods, the methods that received the three highest ratings across *all experts* in terms of practicality were: pharmacy records (mean rating = 78), patient face-to-face self report (mean =76), and mailed survey to patient (mean = 70). The method rated as least practical across all experts was the in-home medicine review (mean rating = 36). Practicality ratings provided by the *physicians and pharmacists*, the *behavioral researchers*, and the *database experts* showed the same three methods with the highest practicality ratings. *Driving evaluators* rated mail-in physician reports (mean rating = 77), pharmacy records (mean rating = 77), and mailed surveys to patients (mean rating = 72) as the most practical methods.

In terms of reliability of methods for identifying medication use, the in-home medicine review was rated the highest by all panelists (mean ratings ranged from 85 to 93 across expert area) followed by the brown-bag method (mean ratings ranged from 75 to 84 across expert area). The poorest method varied across expert group, with *physicians* and *behavioral researchers* indicating proxy reports as the worst, *driving evaluators* indicating mailed surveys to patients as the worst, and *database experts* rating mailed requests for physicians' reports as the worst.

In terms of cost-effectiveness, the administrative database method (pharmacy claims) was rated the best by the *physicians/pharmacists* and the *database experts*, and was in the top three highest rated methods for all other expert areas. *Driving evaluators* rated mailed requests for physician reports as the most cost effective, and behavioral researchers rated mailed surveys to patients as the most cost-effective method. All expert groups rated the in-home medicine review as the least cost-effective method.

Across all experts groups, overall ratings indicated a preference for the brown-bag review (mean rating = 75), pharmacy records (mean rating = 73), and the in-home medicine review (mean rating = 66) methods, while the proxy report was rated the worst (mean = 51). There were some interesting differences in how experts from the various disciplines weighted practicality, reliability, and cost-effectiveness in producing their "overall" ratings, however. For example, the ratings by the driving evaluator group indicated that the best method would be to *combine* physician reports with pharmacy records and in-home medicine reviews for the best result; or, to combine patient self-reports with pharmacy records, and proxy reports.

Measuring Compliance

Discussion Summary

- One panelist indicated that when using administrative claims databases and comparing cases (drivers with crashes) and controls (drivers without crashes), one doesn't really need to be concerned about compliance, because there would be both compliant and non-compliant medication takers in both groups (adjusting for severity of illness).

- Other experts on the panel agreed that compliance is a tricky area, and also one in which researchers concerned with the effects of (poly)pharmacy on driving need not regard as their primary concern. To study what and how medications affect driving, it may only be necessary to determine what people were taking at the time they had their driving evaluation and what they took earlier that may still be in their systems.

- Two reasons for measuring compliance were noted. First, people who are prescribed medications for medical conditions but are not taking it may perform worse because their medical condition is not controlled. Also, if a person is compliant sometimes but not others, he or she may not be in a population that is considered to be "stable" dosing, so medication effects are exaggerated.

- If compliance is going to be measured, it is useful to employ two methods: for a prospective study, patient self-report and pharmacy refill records should suffice. A second self report should be obtained the day of testing to determine what subjects took in the morning and the day before the driving evaluation.

- Panelists generally agreed that, if you are going to infer the role of a drug in an outcome, it is useful to have at least a general understanding of the level at which a research participant is compliant. A rudimentary measure, such as low, medium or high compliance, which could be obtained from an administrative pharmacy database, may be all that's required. Compliance could also be adequately assessed with a questionnaire, separating medications into classes ("medicines for sleep," for example).

Rating Scale Responses

Two sets of rating scale responses were solicited to capture the discussion group's opinions in this topic area, one relating to practicality/reliability/cost-effectiveness of alternative methods and the other relating to older persons' willingness to participate in research.

In the first case, eight methods of measuring compliance to the medication regime were considered by the brainstorming experts:

A. Physicians' Clinical Judgment.
B. Self-Report (Questionnaire).
C. Patients' Clinical Response.
D. Biomechanical Measures.
E. Pill Counts.
F. Pharmacy records (Administrative Claims Databases).
G. Electronic Medication Monitoring.
H. Proxy Report.

The first set of ratings addressed practicality, reliability, and cost-effectiveness, as well as an overall rating. Summary statistics are presented in the tables located in Appendix D for all experts together, and broken out by discipline. These rating scale results are briefly described below.

Across experts, the most practical methods of measuring compliance were patient self-report questionnaires (mean rating = 74), pharmacy records (mean rating = 71) and proxy reports (mean rating = 65). Not surprising, the least practical method was biomechanical measures (mean rating = 27). The *physician/pharmacist group* responded with this pattern of ratings. The *driving evaluators* combined self-report questionnaires with either pharmacy records (1 respondent's rating = 80) or proxy reports (1 respondent's rating = 90) for the two best methods, followed by combining physicians' clinical judgment with patients' clinical response (1 respondent's rating = 80). However, this group rated physicians' clinical judgment alone as the poorest (mean rating = 8), followed by patient's clinical response (mean rating = 18). The *behavioral researchers* determined that patient self-report questionnaires (mean rating = 78) and pharmacy records (mean rating = 72) were the best method, with biomechanical measures the worst (mean rating = 19). The *database experts* indicated that the best method was pharmacy records (mean rating = 87), followed by patient self-report questionnaires (mean rating = 76) and pill counts (mean rating = 68). They rated the biomechanical measures as the least practical (mean rating = 32).

Across all experts, the most reliable methods were biomechanical measures (mean rating = 77), electronic medication monitoring (mean rating = 72), and pill counts (mean rating = 69). The least reliable across expert types was physician's clinical judgment (mean rating = 35). The same pattern of results was shown by ratings provided by physicians/pharmacists. Without combining methods, *driving evaluators* designated proxy reports (mean rating = 78) and biomechanical methods (mean rating = 73) as the most reliable, and physicians' clinical judgment as the least reliable. One driving evaluator combined self report questionnaire with pharmacy records and rated this as the best method (mean rating = 85) and one driving evaluator combined three methods and rated the combination as 85: self report questionnaire, electronic medication monitoring, and proxy report. *Behavioral researchers* rated electronic medication monitoring the most reliable (mean rating = 87), followed by pill counts (mean rating = 78), and patient's clinical response (mean rating = 72). Physicians' clinical judgment was rated the least reliable by this group. *Database experts* rated clinical response as the most reliable (mean rating = 85), followed by biomechanical measures (mean rating = 80), and pharmacy records (mean rating = 75), while physicians' clinical judgment was rated as the least reliable by this group of experts.

Across all experts, the most cost-effective methods were self-report questionnaire (mean rating = 79), pharmacy records (mean rating = 76), and proxy report (mean rating = 76). The least cost-effective method was the biomechanical measures (mean rating = 26). This pattern of results characterized the *physician/pharmacist* ratings. Without combining methods, the driving evaluators rated the pharmacy records and proxy reports as the most cost-effective methods (mean rating for each method = 75), and when self-report questionnaires were combined with pharmacy records, one respondent rated the combination as a 95. The *behavioral researchers* assigned the highest cost-effectiveness ratings to self-report questionnaires (mean rating = 81) and electronic medication monitoring (mean rating = 80), and the lowest ratings to biomechanical measures (mean rating = 20), physicians' clinical judgment (mean rating = 21) and pharmacy records (mean rating = 21). *Database experts* assigned the highest cost-effectiveness ratings to pharmacy records (mean rating = 90) and self-report questionnaires (mean rating = 78), and the lowest ratings to biomechanical measures (mean rating = 27).

Across all evaluation criteria and all experts (without combining methods), the highest overall ratings were given to self-report questionnaires (mean rating = 68), pharmacy records (mean rating = 66), and pill counts (mean rating = 64), and the lowest ratings were given to biomechanical measures (mean rating = 38). The *physicians and pharmacists* demonstrated precisely this pattern of ratings. The *behavioral researchers* also assigned the lowest ratings to biomechanical measures, but gave the highest overall rating to patients' clinical response (mean rating = 76), followed by pill counts (mean rating = 72), and pharmacy records (mean rating = 60). *Database experts* provided the highest ratings to pharmacy records (mean rating = 80), followed by self-report questionnaires (mean rating = 74), and electronic medication monitoring (mean rating = 72), while rating physicians' clinical judgment as the poorest method (mean rating = 40). Among the *driving evaluators*, one combined self report with proxy report and electronic medication monitoring for a rating of 100; another combined self report with pharmacy records for a rating of 90; and another combined clinical response and proxy report for a rating of 90.

The other rating scale asked group members for their opinions regarding older persons' willingness to participate in research, as a function of the method used to measure medication usage. Fourteen methods were listed, as follows, including selected sub-methods deserving attention in their own right based on information presented in the Literature Review:

A. Physician's Clinical Judgment.
B. Self-Report – Questionnaire.
C. Patient's Clinical Response.
D. Brown Bag – Physician led.
E. Brown Bag – Pharmacist led.
F. Brown Bag – Pharmacy-student led.
G. Brown Bag – Nurse led.
H. Biomechanical: Saliva.
I. Biomechanical: Urine.
J. Biomechanical: Blood.
K. Pill Counts.
L. Pharmacy Records (administrative claims databases).
M. Electronic Medication Monitoring.
N. In-Home Medical Review.

Summary statistics for these ratings are presented in the Appendix E, for all experts together and broken out by area of expertise. Results are briefly described below.

Across all experts, the methods that were rated most likely to be acceptable to prospective research participants included the physician-led brown-bag method (mean rating = 74), the pharmacist-led brown-bag review (mean rating = 71), and pharmacy records (mean rating = 71). Clustered only slightly below these were the pharmacy-student-led brown-bag method (mean rating = 67), the patient self-report questionnaire method (mean rating = 66), and the nurse-led brown-bag method (mean rating = 64). The methods least likely to be acceptable to research participants, not surprisingly, were the three biomechanical measures, with mean ratings ranging from 28 to 37. Except for the *database experts*, all subgroups of experts rated the

physician-led brown bag method the highest, followed by the pharmacist-led brown-bag method. *Pharmacy database* experts rated the pharmacy records method the highest (mean rating = 85), followed by the patient self-report method (mean rating = 73), and electronic medication monitoring (mean rating = 70). The patient self-report method was also rated high by *the physicians/pharmacist group* (mean rating = 74).

Topic Area 3: What are the Most Practical and Valid Ways of Assessing the Impact of Medication Usage on Actual Driving Performance?

GROUP DISCUSSION AGENDA:

- What are the most practical and valid ways of assessing the impact of drug/medication usage on actual driving performance?

Discussion Summary

- Guided by the Literature Review, this discussion specifically emphasized driving performance as an outcome, as crashes are rare events. The focus was on identifying the best ways to test driving competence, using measurable behaviors, as opposed to epidemiological studies where crashes are the outcome.

- A panelist questioned the practicality of using OT/CDRSs to conduct on-road evaluations, due to the limited number and availability of these specialists in the U.S.

- Another panelist suggested making use of trained driving instructors for conducting in-car evaluations, to overcome the problem of limited numbers of OT/CDRSs.

- OT/CDRS panelists commented that, in any study designed to measure the effect of a medication on driving performance (either an improvement or a decrement), it would be desirable to conduct a driving evaluation *prior* to the administration of medications; this would require contact with prescribing physicians, which reduces the practicality of this method.

- A physician noted that judging the best method of determining drug effects on driving performance depends on the question being asked. To investigate whether an underlying condition believed to be responsible for driving difficulties can be successfully treated with medications (i.e., to improve driving performance) may require a different approach than testing an hypothesized negative effect of drugs on driving.

- Instrumenting peoples' vehicles could be a way of collecting more data, more quickly and efficiently. However, because there is no driving evaluator to intervene if the driver makes a critical or hazardous error, this is ethical only if people are being asked to drive as they usually do under their current medication regime. It would not be acceptable as an experimental approach where new medicines are being introduced.

- An OT offered that it could also be useful to instrument an evaluator's car to pick up subtle effects related to medication; for example, a medication may have a particular physical effect, or otherwise impact the person's capacity to drive in a manner that is difficult to observe directly.

- Participants suggested that it might be practical to use GPS to determine how people who are driving their own vehicles find their way from point to point, while acknowledging that many unsafe behaviors (like stopping in the middle of an intersection to read signs) would not be picked up with a GPS. An outboard camera or an evaluator would be required to determine this.

- Adding cameras to instrument a person's own car could also be used to record what was happening outside of the vehicle, to establish a context for the driver's behavior. There remains a caution with any research protocol that requires someone to drive in an unfamiliar area without a driving evaluator, however, as this introduces risk that would not otherwise be part of the driver's daily routine.

- If a person has adapted to medication, it may take a long time for any adverse driving events to show up, if at all. Exposure to a wide array of unexpected events and situations would be required to determine <u>all</u> safety consequences of medication use; this suggests testing on a closed course utilizing a driving evaluator or OT with a properly equipped car (to intervene if necessary), or testing in a simulator.

- The executive component of driving is the most important thing to test when researching the effects of polypharmacy, according to the driving evaluators. A clinical assessment of cognitive function should be done before going on-the-road; without this information, it will be more difficult to attribute any effects on driving performance to medication use.

- Ideally, a pre-test of driving functioning should be conducted prior to people taking their medications. Or, a study could require people to stop taking their medications, to obtain a baseline measure of performance.

- Because it is highly unlikely that peoples' medication regimes could be changed, research designs for future work in this area could benefit from multivariate analysis techniques to help explain the contributions of medications, medical conditions, age, cognitive function score, etc. on driving performance.

- It may be more fruitful to do "data mining" in administrative databases than to conduct an instrumented vehicle study to examine "global issues." However, to answer small, specific questions, and/or to test hypotheses generated through prior database analyses, an instrumented vehicle study could be appropriate. A continuing research program on polypharmacy and driving could be designed to first perform "database studies" to determine key medications or conditions. Then, the combinations of interest can be evaluated experimentally, using the methods favored by participants in this brainstorming session in studies with smaller test samples.

- A database expert underscored the benefit of using large population databases to identify potential associations or potential risks. This is a relatively low-cost approach. Other database experts indicated that it is possible to link databases, yielding a great richness of information, although there may be special authorizations required in the Federal sector to do this.

- A panelist suggested analyzing driving performance data that may already reside in State DMVs, in relation to prescription drug information from a database like Medicare or Medicaid. It was also noted that, currently, only Illinois and New Hampshire require renewing drivers (over age 75) to take an on-road test.

- An OT/CDRS perspective is that these professionals (OTs) routinely perform rigorous on-road evaluations. While such road tests may vary slightly, and it is important to have the inter-rater reliability between OTs, these road tests should be strong candidates for use in NHTSA studies on drugs and driving.

Rating Scale Responses

Two sets of rating scale responses were solicited to capture the discussion group's opinions in this topic area, one relating to practicality/reliability/cost-effectiveness of alternative methods and the other relating to older persons' willingness to participate in research.

In the first case, seven methods of measuring driving performance were considered by the experts participating in the brainstorming session:

A. Closed Course (Controlled Exposure).
B. On-Road, In Traffic (with a Trained Observer).
C. Simulation Level III: Interactive, Computer Graphic Visuals, Full Motion.
D. Simulation Level II: Interactive, Computer Graphic Visuals, Restricted Motion or No Motion.
E. Simulation Level I: Non-Interactive, Computer Graphic and/or Digital Video Visuals, No Motion.
F. Instrumented Vehicle (with Driver's Own Car).
G. Functional Measures Validated as Crash Predictors.

Summary statistics are presented in Appendix F, for all experts together, and broken out by area of expertise. Results are briefly described below.

With regard to the practicality of one method vs. another and across all experts, the top three measures were: functional measures validated as crash predictors (mean rating = 75), closed course (mean rating = 65), and on-road, in traffic (mean rating = 63). Level III simulation received the lowest rating (mean rating = 39). Ranked similarly and falling midway between the best and worst methods were the remaining two simulation levels and the instrumented vehicle method (ratings ranged between 54 and 58). *Physicians and pharmacologists* rated functional measures as the most practical method (mean rating = 75), followed by simulation level I (mean rating = 69), and on-road/in traffic measures (mean rating = 63). *Driving evaluators* tied on-road

testing and functional measures as the highest (mean rating = 72), followed by closed course evaluations (mean rating = 70). They rated the three simulation measures as the lowest (ranging from 28 to 38), with the higher-fidelity methods rated poorer than the lower-fidelity methods. The *behavioral researchers* rated the functional measures best (mean rating = 78), followed by simulation level II (mean rating = 73), and the closed-course method (mean rating = 68). Interestingly, for the instrumented vehicle method, the behavioral researchers provided the lowest rating of all the expert types (mean rating = 25) as well as the simulation level III method (mean rating = 20). The *database experts* rated the functional measures highest (mean rating = 75), followed by the instrumented vehicle method (mean rating = 68), and the closed course method (mean rating = 65).

With regard to reliability, the highest-rated method across expert types was the instrumented vehicle (mean rating = 72), followed closely by the on-road method (mean rating = 71) and the functional measures (mean rating = 70). Simulation level I was given the lowest average rating (51). The same pattern was seen in the ratings of the *physician/pharmacist* group, with the functional measures and the instrumented vehicle method tied as the highest (mean rating = 76), followed by the on-road method (mean rating = 74). The *driving evaluators* grouped the on-road test and the functional measures as the best method (mean rating = 90), followed by the combination of the closed course method and functional measures (mean rating = 75). Without grouping methods, driving evaluators rated the functional measures as the best method (mean rating = 70), followed by the instrumented vehicle and on-road tests (tied at 63), and simulation level III (mean rating = 62). The *behavioral researchers* rated the closed-course method highest (mean rating = 80), followed by the instrumented vehicle method (mean rating = 67), and functional measures (mean rating = 65). They rated simulation level I as the poorest (mean rating = 28). The *database experts* rated the on-road method as the most reliable (mean rating = 85), followed by the instrumented vehicle method (mean rating = 82), and the closed course method (mean rating = 80).

In terms of cost-effectiveness, the best-rated method across all expert groups was the functional measures method (mean rating = 77), followed by the instrumented vehicle (mean rating = 63), and the closed-course method (mean rating = 61). The simulation methods were the poorest-rated measures (ratings ranged from 30 to 51), with the high-fidelity methods receiving lower ratings. The *physician/pharmacist* group followed this pattern. *Driving evaluators* rated the functional measures as most cost effective (mean rating = 73), followed by the instrumented vehicle (mean rating = 65), and then the on-road method (mean rating = 63). The *behavioral researchers* rated the functional measures and the closed course test as the best methods (mean ratings were 79 and 60, respectively); the next highest measure, the instrumented vehicle, received a much lower rating from this group (44). The *database experts* rated the functional measures as the most cost-effective method (mean rating = 73), followed by simulation level I (mean rating = 72) and the instrumented vehicle method (mean rating = 68).

For overall ratings, across all experts, the instrumented vehicle and on-road methods were rated highest (68), followed by the functional measures (64) and the closed course method (59). Simulation level I was rated lowest (mean rating = 40), followed by simulation level III (mean rating = 43) and simulation level II (mean rating = 45). The *physician/pharmacist* group rated the functional measures highest overall (mean rating = 72), followed by the instrumented vehicle

(mean rating = 70), and the on-road method (mean rating = 68). One member of this group gave the highest rating of 95 to the combination of three methods: on-road, instrumented vehicle, and functional measures. The *driving evaluators* rated the on-road test as the best overall measure at 85, followed by the instrumented vehicle at 72, and the closed course at 48. One member of this group gave the pairing of closed course, on-the-road, and functional measures the highest possible rating of 100. The *behavioral researchers* rated the closed course as the best overall method at 65, followed by functional measures at 62, and the instrumented vehicle method at 56. The *database experts* rated the instrumented vehicle as the best overall method at 74, followed by the on-road method at 70, the closed course method at 68, and the functional measures at 67. The simulation measures ranged from 56 to 62, with the lower-fidelity methods receiving higher scores.

In the second set of ratings during this part of the brainstorming session, panelists were asked to rate the likelihood that older people would be willing to participate in research on medication and driving, as a function of the method used to measure driving performance. The same seven measures (A-G) above were rated. Summary statistics are presented in Appendix G, for all experts together and broken out by area of expertise. Results are briefly described below.

Across all expert groups, the functional measures placed the highest in these ratings, at 69, followed by the instrumented vehicle method at 61, the closed course method at 59, and the on-road method at 58. The simulation methods received mean ratings ranging from 48 to 54, with the lower-fidelity methods receiving higher ratings. The *physician/pharmacist* group rated the functional measures the highest at 63, followed by simulation level I at 62, and the on-road tests at 60. The remaining measures were not rated as radically different from one another, with simulation level II receiving a rating of 58, instrumented vehicle and on-road evaluations effectively tied at 57, and simulation level III at 54. The *driving evaluators* rated the functional measures as the highest (mean rating = 78), followed by closed course and on-road measures tied at 65, instrumented vehicle at 56, and the simulation measures ranging from 40 to 42. The *behavioral researchers* rated the functional measures as the highest, at 78; followed by the instrumented vehicle at 60, the on-road method as 57, and the closed course at 56. The simulator methods ranged from 40 to 50, with the lower-fidelity methods again receiving higher ratings. The *database experts* rated the instrumented vehicle method highest at 70; followed by the functional measures at 65, simulation level I at 57, simulation level II at 54, the closed course and on-road evaluations tied at 53, and simulation level III at 52.

Topic Area 4: What are the Potential Barriers—Legal, Ethical, and Practical—to the Participation of Older Persons in Studies of Medication Use and Driving?

GROUP DISCUSSION AGENDA:

What are potential legal, ethical, and practical barriers to studying older persons' use of medication and its effects on driving performance, and encouraging older persons' participation in such studies, taking the following factors, at a minimum, into account?

- Health Insurance Portability and Accountability Act (HIPAA)?
- Public safety?
- Fear of loss of license for poor performance?
- Fear of having drug regime changed?

- Several OT/CDRSs voiced that participating in a research protocol where subjects with severe impairments do not get reported to the driver licensing agency would violate their ethical standards. One CDRS stated that she absolutely could not send a research participant back out on the road who she had observed to be severely impaired; it is a requirement that people coming in for (clinical and driving) evaluations come with another licensed driver, who can drive them home if the evaluation outcome is poor. In contrast, a panelist who has conducted research for the National Institute on Aging (NIA) stated that it is standard agency protocol to let a person with a poor evaluation continue to drive. Another approach to this potential ethical dilemma was described by a panelist who is a Medical Advisory Board physician as well as a university researcher: as per informed consent procedures, researchers may report impairment in driving ability to the driver's family and primary physician—but not to the DMV—if there is not a mandatory reporting requirement in the State in which the research is being conducted. More generally, researchers may be guided by the reporting requirement for those in clinical practice in a given State. For example, if reporting is mandatory, then the research team would be required to report negative results to the licensing agency. If reporting is voluntary, then the research team would do whatever clinicians in that environment would do if a research subject's driving performance is impaired.

- Several panelists thought that the Health Insurance Portability and Accountability Act (HIPAA) regulations for the privacy of health information would <u>not</u> be an issue if informed consent was obtained from the participants, for specified research activities. These would include sending letters to participants' physicians to obtain reports of prescribed medications; and, linking databases with identifiers to determine the relationship between medication use and (retrospective) crashes. However, it was pointed out that there are different interpretations of HIPAA as a function of what type of site is conducting the research, e.g., a university versus a Veteran's Administration site. It was further stated that different Institutional Review Boards (IRBs) may view the same study, performed under the same circumstances, quite differently; and these subjective bodies impose their own restrictions.

- The informed consent process should be consistent with HIPAA's rules for privacy of health information. For example, if the research team finds signs of severe cognitive, visual, or physical impairment or uncovers an ultra-high-risk medication that a person is taking, there should be some method for notifying the primary physician. This may discourage potential research participants, however; and in a mandatory-reporting jurisdiction, it is likely that few would voluntarily participate. In this way, HIPAA provisions could reduce the likelihood of participation in research where driving privileges may be affected.

- It was agreed that as long as a researcher is not manipulating a person's drug regime *and* a subject regularly drives while taking the medications being studied, that individual does not pose any more risk to public safety or to him/herself by participating in a research study on driving and drugs than he or she would if not a participant in the study.

- A physician and researcher underscored the inadvisability of performing future research that introduces medications or combinations of medications to individuals, or withdraws existing medications.

- An OT perspective is that anytime a study requires people to drive in an unfamiliar area, they may be a public safety risk. This risk would increase if they were driving their own car, because there is no dual control; this would be a particular concern for people with cognitive impairments.

- Discussants raised the concern that somehow a research participant's auto insurance company could learn about a poor driving performance evaluation, and raise that person's premiums. This will be another potential barrier to research participation, unless research protocols can offer a protection of confidentiality/anonymity in this regard. Experts agreed that in this kind of research, the perceived risk (of loss of license) significantly outweighs the benefit (gadgets, payments, insurance reductions for good performance).

- A potential barrier to research participation may be raised, if poor performance on a driving evaluation is to be reported to the subject's family. An older driver may be reluctant to participate in a study if he or she thinks the results could lead to efforts by others to try to restrict driving.

- Some populations of interest (e.g., ethnic or cultural or socioeconomic) may be unwilling to participate in research on drugs and driving, because they try hard to always be "below the Government's radar screen." They don't want to be noticed or singled out, because they don't trust the system. This may be true particularly for non-native English speakers or Medicaid recipients.

- An incentive to encourage research participation could include giving away some type of gadget to help people keep track of what medications to take and when to take them (e.g., pill organizer, counter, etc.). Also, a "driving report card" may be looked upon positively by some older drivers, to show their adult children that their driving capabilities are intact in the various areas assessed.

- Recruiting research participants through physicians' contacts was suggested. If a physician encourages a patient to do something that involves health care, the patient often complies because of the physician's support for the activity—it makes it worthwhile in the patient's eyes.

- Another possibility for recruiting drivers is through "safe driving courses" (e.g., AAA, AARP) that explicitly address the effects of aging and medications on driving performance. This may be less threatening than recruiting through—for example—physicians; but it is likely that this recruitment strategy would yield a more fit population than the general population of licensed (older) drivers.

- Another recruiting tool could be a "pharmacy review" of prescription and OTC medicines a person is taking. This could identify medications that do not need to be continued. Many people view the need to take multiple medicines as a negative thing, and they may be encouraged to participate in a study if they thought it might somehow reduce the number of drugs they are taking.

FOCUS GROUPS

INTRODUCTION

Four focus groups were conducted with older drivers to better understand the perceptions and concerns that they may have about participating in future NHTSA-sponsored studies where they would be asked to: (1) disclose their usage of prescription and over-the-counter medications; and (2) participate in an assessment of their driving abilities. These focus groups were intended to explore a variety of methods by which each of the above two phases of future research might be accomplished. Although focus groups are not statistically representative of the demographic groups from which the panelists are drawn, they provide other analytical advantages that are worthwhile, including creation, validation, or dismissal of working hypotheses concerning the objectives being studied.

Focus group panelists were queried to determine:

1. Their general willingness to participate in such research studies.
2. Their preferences for how data on their use of medications would be collected.
3. Their preferences for how the effects of medications on their driving abilities would be observed or measured.
4. Concerns that could prevent older drivers from willingly participating in such research.
5. Incentives which might improve the willingness of older persons to participate in these studies.

Location

During the month of December 2005, four 2-hour focus groups were conducted by a project consultant[3], who is a professional focus group moderator. Two focus groups each were conducted in the vicinity of Tampa, FL and Philadelphia, PA, at professional facilities with their own staff and equipment dedicated to focus group support (one-way mirror observation rooms, recording equipment, etc.).

Participants

Roughly equal numbers of male and female drivers were recruited by focus group facility staff, with at least 25 percent minority participation. At the Pennsylvania site, recruitment of African-American participants was emphasized, without excluding other minorities, and in Florida, recruitment of Hispanic-Latino participants was emphasized. All participants were compensated according to local market conditions.

On average, each focus group consisted of ten panelists. The groups were divided according to age; at each site there was one group of panelists age 55 to 69 and one group of panelists age 70 to 85. All panelists held a valid driver's license, stated that they drive on a regular basis (at least 5 trips per week), and use a variety of prescription and over-the-counter

[3] Mr. Warren W. Ashburn, Research and Marketing Counsel, Bridgeville, PA.

medications on a regular basis. Appendix H presents the "screener" developed by project staff that was used for subject recruitment.

Focus Group Protocol

The focus group discussion guide is presented in Appendix I. The protocol for the groups is summarized below. The moderator spent the first 10 minutes introducing himself and the research topic, and provided assurance to the panelists that he was an independent moderator, that they would not be asked to disclose anything that makes them uncomfortable, and that their driving privilege would not be affected in any way as a result of their participation in the discussion. He then asked participants to briefly introduce themselves, and then engaged them in a warm-up topic for approximately 15 minutes about how driving may have changed for them over the past few decades, before delving into discussions about their preferred methodologies for identifying medication use and measuring driving performance.

Methods of Identifying Medication Use

For the first topic of interest—methods of determining what medications older people take—the moderator spent 30 minutes generating discussion and feedback from participants about their willingness to participate in research, based on which of 14 different potential methods of collecting medication data are used. These are listed below.

METHOD 1: Bringing all your medications in a bag to your family doctor or a nurse at the practice so a complete list can be made, and a discussion can take place about when and how you take the medications.

METHOD 2: Bringing all your medications in a bag to your pharmacist, so a complete list can be made, and a discussion can take place about when and how you take the medications.

METHOD 3: Bringing all of your medications in a bag to someone at the company who is conducting the research (research assistant), so a complete list can be made, and a discussion can take place about when and how you take the medications.

METHOD 4: A nurse comes to your home to make a list of prescription and over-the-counter medications, and has a discussion with you about when and how you take your medications.

METHOD 5: A pharmacist comes to your home to make a list of prescription and over-the-counter medications, and has a discussion with you about when and how you take your medications.

METHOD 6: A researcher comes to your home to make a list of prescription and over-the-counter medications, and has a discussion with you about when and how you take your medications.

METHOD 7: An occupational therapist comes to your home to make a list of prescription and over-the-counter medications, and has a discussion with you about when and how you take your medications.

METHOD 8: Filling out a survey that the researchers mailed to you, asking you to list all the medications you take, the dosages, and how often you take them.

METHOD 9: Coming to the researcher's office by yourself to talk about what medications you take (without bringing them in).

METHOD 10: Coming to the researcher's office to talk about what medications you take (without bringing them in), and bringing a significant other with you (spouse or companion who lives with you) to help you remember what medicines you take.

METHOD 11: Giving your consent to a researcher to send a letter to all of your doctors, asking them to list all the medications they prescribed for you. The doctors would send that list back to the researcher.

METHOD 12: If the researchers had obtained a list of medications that had been prescribed to you, would you then feel comfortable bringing your over-the-counter medications to the research group so those could be added to your list of medications, and then talking to the researcher about whether you still take all the prescription medications the doctors listed?

METHOD 13: Having special caps placed on the medications you take that record the date and time of day each time you open the container.

METHOD 14: Researchers would obtain information about the prescription drugs you take by accessing pharmacy databases (which are created when you fill and refill a prescription).

Following the discussion of the pros and cons of the various methods of collecting data about medication use, participants spent 20 minutes completing a card-sorting task. For this task, participants were given a stack of 14 cards, each describing one of the 14 methods. Participants were asked to sort the cards into two piles: a "bad pile" containing cards with the methods they find unacceptable, and a "good pile" containing cards describing methods with which they would be comfortable as research participants. They were then asked to draw an "X" through each of the cards in the "bad pile," and to rank-order the methods in the "good pile" from most preferred (rank of 1) to least preferred.

Methods of Measuring Driving Performance

For the second topic of interest—methods of measuring driving performance—the moderator spent 20 minutes generating discussion and feedback from participants about their willingness to participate in research using 6 potential methods assessing driving performance. The 6 methods are listed below:

METHOD 1: Studies where you drive a vehicle with dual controls (like a driver education car) on a *closed course* and either a driving instructor or an occupational therapist sits in the passenger seat while you drive the car.

METHOD 2: Studies where you drive a vehicle with dual controls (like a driver education car) on the road *in traffic*, and either a driving instructor or an occupational therapist sits in the passenger seat while you drive the car.

METHOD 3: Studies conducted where you drive *your own car*, on a closed course, and either a driving instructor or an occupational therapist sits in the passenger seat while you drive the car.

METHOD 4: Studies conducted where you drive *your own car*, in traffic, and either a driving instructor or an occupational therapist sits in the passenger seat while you drive the car.

METHOD 5: Studies conducted where you drive *your own car*, *in traffic*, and miniature audio or video recording instruments are mounted in the vehicle to record the driving scene and how you respond to it (braking, steering, speed control).

METHOD 6: Studies that measure your vision, your memory, and physical abilities such as your strength and flexibility in your arms and legs, that are known to be important for safe driving and which may be affected by medications. These would be brief tests, using paper and a pencil, or might be presented on a computer.

Following the discussion of the pros and cons of the various methods of assessing driving performance, participants spent 10 minutes completing the same type of card-sorting task described above, for the 6 methods.

Concerns about Participating in Future Research and Research Incentives

The focus groups closed with a 10-minute discussion to highlight the biggest concerns older drivers may feel about participating in future research studies, where they would be asked to disclose their medication use and have their driving skills assessed. Other points of discussion included the kinds of assurances of confidentiality that would be needed and the kinds of incentives/compensation that could increase the likelihood of participation in future studies of this nature.

RESULTS

Panelists in both cities and both age groups largely described themselves as competent, seasoned and careful drivers. They saw the experience of driving as being more difficult today than in the past, but assigned blame for that to the growing carelessness (e.g., cell phone users) and the aggressiveness (e.g. speeders, tailgaters) of other drivers, rather than to their own diminished skills.

Only after considerable probing were the panelists willing to admit any loss of skill, except for problems with night vision. Only panelists over age 75 were willing to admit any real limitations; however, even they were more likely to describe themselves as more patient and cautious than in the past, rather than more fearful or concerned about their own response time.

Among the more interesting and useful products of focus group discussions are the actual words of the panelists. Included in this summary are sample comments from the eight hours of taped discussion that best represent the attitudes that emerged from the groups. The quotes are coded so they can be referenced to a specific group location and age cohort. The first letter of the code, either a “T” or a “P,” indicates Tampa or Philadelphia. The second letter of the code, either a "Y" or an “O,” indicates the younger group (55-69) or the older group (70+).

Methods of Identifying Medication Use

The moderator explained the purpose of the proposed studies and the general methodological parameters to be explored. By direct and indirect questioning and by careful listening, an assessment was made regarding the willingness of the panelists to reveal to a stranger their personal array of medications.

Panelists indicated <u>almost total willingness</u> to share information about their medications. Although never queried about it directly, individuals volunteered a large amount of information about the drugs they were taking in the course of the discussions. This was true in both cities and both age groups. However, throughout the process of sorting methods into two groups (acceptable/would participate vs. unacceptable/would not participate) fewer older drivers perceived as many of the methods as acceptable as the younger drivers. This means that it will likely be much harder to recruit participants age 70 or older in future research on medications and driving than those in the 55-to-69 age group.

I don't mind telling what I'm using because it is helping me. TY

I don't care if somebody knows that I take blood pressure medicine. I'll tell anybody that. TY

If it were for a reputable purpose and organization like the National Highway Transportation Safety Board (sic), I would be willing to tell them anything they wanted to know. TY

We all take many kinds of medicine. So what? I would be willing to talk about it. PO

With some probing, two overall concerns emerged about the prospective research—one that might be a real barrier to participation, the other a factor that might reduce interest in it.

1. Fear of loss of driving privileges. This is a serious concern, and one that if not addressed would almost certainly prevent the success of the study. Note that the issue is not confidentiality *per se*. Panelists weren't worried about that. It is the potential consequences that might accrue from being perceived by some authority figure as a flawed driver. As might be expected, this reaction was strongest among the more vulnerable, older population.

   A lot of times people are not going to tell you the truth because they feel nervous that they will lose their driving privilege. TY

2. Study purpose and validity. This is not likely to cause people to refuse to participate in the study, but it would probably reduce their likelihood of volunteering. Throughout each of these focus groups, panelists had to be repeatedly assured that the study was worth doing. Their skepticism was aroused because they feel that they already self-police their use of medications and driving and that, therefore, this issue may not be a real problem. And some felt that the problem was too complex and individually driven to make a broad study viable. Younger panelists were somewhat more likely to raise this issue and be less trusting than older panelists.

Willingness to Participate

This discussion section began with a review of the goals and objectives of prospective future studies, and by reiterating assurances of confidentiality and no impact on driving privileges. Then, each of the key methodological variables was introduced and discussed, one by one. Finally, a paper study was conducted in which panelists could select and rank-order their preferences among the methodologies they found acceptable.

Methods 1 through 3. Bringing all medications in a bag to (family doctor, pharmacist or researcher) to (an office, pharmacy or research facility) so that a complete list can be made and a discussion can take place about when and how medications are taken.

The medications-in-a-bag approach was generally well received by all groups and should be considered a strong candidate for conducting future research. This was one of the two highest-scoring methods. However, it appears that the person conducting the medication reviews is likely to have a major impact on the degree of participation.

Many panelists expressed a slight preference for simply preparing/bringing in a list of their medications, dosages, etc. The reason for this is that at least half the panelists already carry a list of their prescription medications on them at all times. In the older groups, as many as 70 percent had such a list on their persons. These people preferred to use the list. Some suggested

that those being surveyed be given an option (i.e., bring their medications in a bag or bring a list of medications).

> *I always carry in my wallet a list of all the medications I take. If something happened to me, they would know what I'm taking. PO*

> *I carry a list because, if I'm out of town and run out of my medicine, I can go to another doctor and he can prescribe it. PO*

Regarding the type of person who should conduct the interview, all three choices were acceptable to most panelists. However, there were some strong, clear preferences. The most acceptable choice, by a wide margin, was a pharmacist, followed in order by a doctor and a professional research person. Several reasons were cited.

- A pharmacist is most likely to know about all classes of medicine, including the newest ones, and to understand potential interactions and reactions. A doctor will know medicines in his or her own field of expertise, but not others.

- A bonus benefit of participating in the study would be to learn from the pharmacist all about the effects of their medications.

- A pharmacist will be knowledgeable but less judgmental than a doctor.

> *There is a positive aspect (to this research) in that you're not riding along with a physical condition. PO*

> *Some people would be interested in learning what effects their medications have on their bodies. TY*

> *The pharmacist knows more about the medications than the doctor. TY*

> *The pharmacist. The doctor knows only the medications in his field. The pharmacist knows all about the medications. TO*

> *Pharmacists really do know more about these drugs than the doctor. The doctors just get a bill of goods from the drug companies. PO*

> *I would rather have a pharmacist because some doctors don't know the reaction of some medications with other medications. PY*

Again, panelists did not rule out the other choices, they were only less comfortable. Doctors have some obvious advantages from a qualifications and empathy standpoint. Researchers, though, were seen as more neutral, less likely to judge or threaten in some way.

Likely-to-participate percentages also varied by age group. Pharmacists were deemed acceptable for this role by the highest percentage of participants overall at 63 percent (70%

among younger; 55% among older). Doctors were deemed acceptable by the next highest percentage of participants—by 55 percent across age groups (62% among younger; 47% among older). Professional researchers were the least acceptable personnel among the three types, with 46 percent of participants overall indicating that they would be willing to participate (55% among younger; 42% among older.)

Methods 4 through 7. The technical options are exactly as described in Methods 1 through 3 except that the interview would not be conducted in an office, pharmacy, etc., but in the person's home. Also, the option was added to have the interview conducted by a nurse or an occupational therapist (OT).

Reactions to this series of options were strong, spontaneous and highly negative. Two-thirds were strongly opposed to it. It appears that every concern and suspicion that panelists might have about the study was instantly brought forth in response to holding an interview in their homes—confidentiality, breach of privacy, personal security, etc.

I don't like anybody coming to my home. I would not invite them in! That's today's world. TY

No! That's invasion! I don't think so! TO

I would be suspicious. PO

While it appears unlikely that doing the research in subjects' homes would draw much participation, the question of who the panelists trusted more to come into their homes was still discussed. Generally, the most trusted (or least threatening) figure was the nurse. Overall, 46 percent approved of a nurse conducting research in the subject's home (35% among younger panelists and 57% among older panelists). Next highest in approval was the pharmacist, by 38 percent overall (27% among younger panelists and 41% among older panelists). Third in acceptability was the professional researcher, with 24 percent approving this method overall (12% among younger panelists and 35% among the older panelists). Last was the occupational therapist, with 12 percent overall approval—identical for both younger and older groups.

Method 8. Fill out a survey that the researchers mailed to you, asking you to list all the medications you take, the dosages and how often you take them.

Even though this method was perceived as the easiest, only about half the panelists said they would cooperate with this approach. The major drawback seems to be a fear that survey results would fall into the wrong hands, because the method is too anonymous to be trusted.

No. It's not personal. I prefer the face-to-face approach. Then, I'd know it would be going to the right people. TO

I would be suspicious of that. I would worry that it was going to some nebulous person. That would make me uncomfortable. PO

I would say "no." We are inundated with questionnaires. PO

The moderator then suggested that participants be given a code number for the questionnaire, instead of signing the questionnaire (to preserve confidentiality). This improved the rate of promised response. But, some panelists still doubted.

If I didn't have to put my name on it, I'd do it. PO

Nay! There may be a code on that, even if I didn't have to sign my name. I'd be interviewed in person, but not in writing. PO

Younger drivers are more likely to participate in a written survey (57% said "yes") than older ones (35% said "yes").

<u>Methods 9 and 10</u>. Come to the researcher's office (alone or with a companion) without bringing the medications with you. The interviewer would ask you to remember your medications and dosages.

Method 9 was very popular, receiving a positive vote by 65 percent overall, the highest of any listed method. Second highest was bringing in the bag of medicines to a pharmacist (acceptable for 63% overall). In general, panelists liked the ease of it. Younger panelists were more likely to support this method (75%) than older panelists (55%). Older panelists were more worried that they would not be able to recall all their medications. Allowing the older panelists to bring in a list resolves their problem.

Bringing a companion (Method 10) introduces issues of privacy and drops the rate of acceptance. Fifty-two percent of younger panelists say they might do this while only 37 percent of older panelists would.

<u>Method 11</u>. Give your consent to a researcher to send a letter to all of your doctors, asking them to list all the medications they prescribed for you. The doctors would send that list back to the researcher.

Based on these focus groups, there isn't the slightest chance of getting significant cooperation from drivers if this method were employed in the research. It received, by far, the lowest willing-to-participate score (19%) and was equally disliked in both cities and age groups.

No way! Confidentiality! And, doctors are not going to get that stuff back on time. TY

No! I got no control! I wouldn't do it. TY

There is a margin of error. They can get the names wrong. TY

No! That's none of the government's business. TO

I would object. I wouldn't participate in anything like that. PO

<u>Method 12</u>. The researcher obtains a list of medications that have been prescribed to you. You then bring in your over-the-counter medications to add to the list. The researcher then talks to you about all the medications.

The response to this method is likely an aberration, or misunderstanding of the intent of the method. After vehemently objecting to the idea of obtaining the list of medications from a third party, panelists here say that they would participate (51% overall, 57% older panelists and 45% younger panelists). This response should probably be interpreted to mean simply that they are willing to bring in their over-the-counter medications.

<u>Method 13</u>. Having special caps placed on the medications you take that record the date and time each time you open the container.

Panelists genuinely disliked this idea. They found it inconvenient, impractical and annoying. Seventy-one percent said that they would not participate in a study in which this were the central methodology.

Why would I go to all that trouble? Just write it down on a piece of paper. PY

<u>Method 14</u>. Researchers would obtain information about the prescription drugs you take by accessing pharmacy databases.

Only 34 percent of all panelists would agree to participate in a study using Method 14, with more older panelists likely to participate (40% say "yes") than the younger ones (27% say "yes"). The existence of the pharmacy databases had not occurred to most of them before, and they found the fact disturbing.

Rank-Ordering Exercise

Each panelist was provided with a stack of cards, each containing one of the fourteen methods discussed above. They were instructed to divide all the cards into two piles: one representing "I would participate in the study," and the other representing "I would not participate in the study." Then, they were to draw an "X" across all cards in the negative pile. The positive cards were then to be put in preferential order and numbered starting with a "1" to indicate first choice. Table 1 presents the percentage of drivers willing to participate in research to identify medication use, for each of the 14 methods, as a function of focus group location and participant age group. The mean rank is provided for each method. Figure 1 provides the willingness-to-participate percentages by age group and overall, for each method, and Figure 2 provides the mean rankings of preferences, among the methods deemed acceptable.

Methods of Measuring Driving Performance

Once again, the moderator provided the panelists with a broad-brush idea of the prospective research, focusing attention on the need to observe and measure driving performance after taking their usual (combination of) medications. All groups indicated a general willingness to participate in the study as outlined.

This time, though, the level of enthusiasm was less and the level of concern greater than in the previous phase. Generally, panelists perceived a greater opportunity to "look bad" and perhaps even to be penalized for poor performance. Some worried about safety during the study. Many questioned the ability to control all the variables in the study and to produce a reliable finding.

Based on these groups, it appears that people would participate, but with a greater degree of pre-sell needed and, possibly, greater incentives. The key factors emerging from the discussions that would encourage participation are:

- Absolute assurance of confidentiality.
- Absolute assurance of no consequences.
- Absolute assurance of safety.
- The absence of critique or judgment.

> *Older people are afraid of losing their driving privileges. TY*
>
> *I would be OK if the person didn't make any comment/criticisms of my driving. TY*
>
> *Senior citizens are worried about losing their license. I don't think they would agree to somebody watching them. TY*
>
> *If you were taking a drug that made you dizzy, would you go and do this study? I wouldn't want them seeing that. TO*

Table 1. Results of the Card-Sorting Task for Methods of Identifying Medication Use.

	Method	Percentage Willing to Participate					Mean Ranking when Deemed Acceptable
		City		Age Group		Total (%)	
		Tampa (%)	Phila. (%)	Young-Old (%)	Old-Old (%)		
1	Bring bag of medicines to family doctor or nurse	62	47	62	47	55	2.2
2	Bring bag of medicines to pharmacist	55	70	70	55	63	2.5
3	Bring bag of medications to a researcher	47	50	55	42	46	4.7
4	A nurse comes to your home to list your medications	40	52	35	57	46	3.6
5	A pharmacist comes to your home to list your medications	30	45	27	47	38	3.8
6	A researcher comes to your home to list your medications	17	30	12	35	24	5.7
7	An OT comes to your home to list your medications	0	25	12	12	12	5.0
8	Fill out a mailed survey	50	47	57	35	46	3.3
9	Go to a researcher's office alone to talk about your medications	60	70	75	55	65	2.9
10	Go to a researcher's office with a companion to talk about your medications	52	42	52	37	45	3.4
11	Researcher sends a request to your doctor to list your medications	15	22	20	17	19	6.4
12	You bring OTC meds to researcher to complete list of prescription meds completed by doctor (in Method 11)	40	57	40	57	51	4.6
13	Special caps are placed on your medicine bottles to document doses	17	40	27	30	29	3.6
14	Researchers access pharmacy databases	37	30	27	40	34	3.5

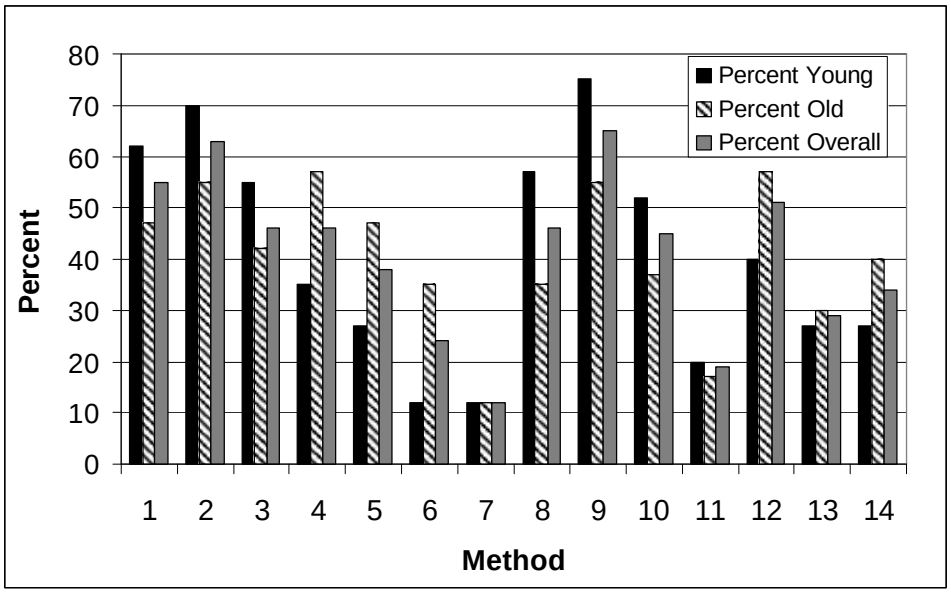

Figure 1. Percent of Discussants Willing to Participate as a Function of Method Used to Collect Medication Use and Participant Age Group.

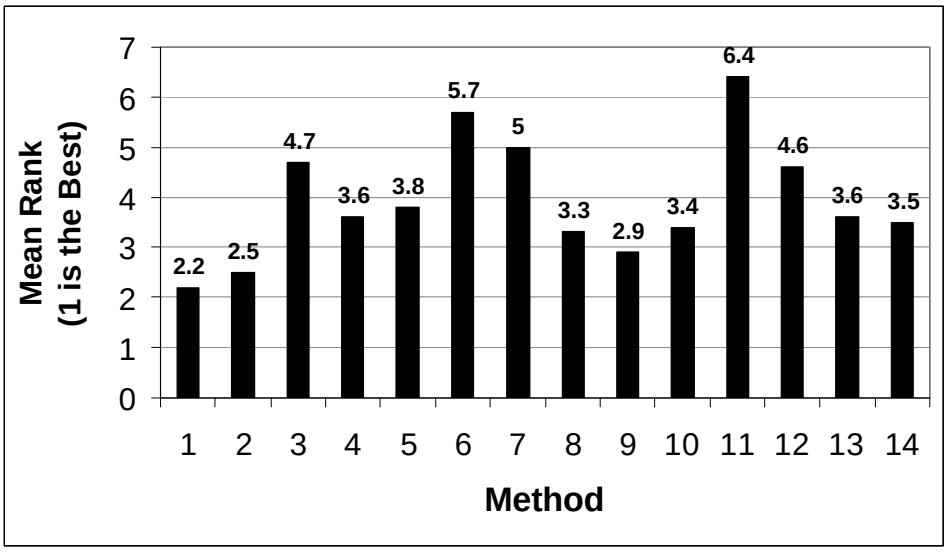

Figure 2. Mean Rating for Methods of Identifying Medication Use, when Methods were Deemed Acceptable.

(Note: Since this methodology involved rank-ordering with "1" meaning "best," the lower the average rating, the more preferable the method).

METHODS

1. Bring bag of medicines to family doctor or nurse
2. Bring bag of medicines to pharmacist.
3. Bring bag of medications to a researcher.
4. A nurse comes to your home to list your medications.
5. A pharmacist comes to your home to list your medications.
6. A researcher comes to your home to list your medications.
7. An OT comes to your home to list your medications.
8. Fill out a mailed survey.
9. Go to a researcher's office alone to talk about your medications.
10. Go to a researcher's office with a companion to talk about your medications.
11. Researcher sends a request to your doctor to list your medications.
12. You bring OTC meds to researcher to complete list of prescription meds completed by doctor (in Method 11).
13. Special caps are placed on your medicine bottles to document doses.
14. Researchers access pharmacy databases.

Willingness to Participate

This discussion section began with a review of the goals and objectives of the research, and reiteration of assurances of confidentiality and no impact on driving privileges. Then, each of the key methodological variables was introduced and discussed, one by one. Finally, a paper study was conducted in which panelists selected and rank-ordered their preferences for methods that they found acceptable.

> **Methods 1 and 2. Method 1: You drive a vehicle with dual controls on a closed course and either a driving instructor or an occupational therapist sits in the passenger seat while you drive the car. Method 2: Same technique, but test is conducted in traffic, not on a course.**

Panelists were comfortable with the idea of testing in the dual-control car, depending on where the test was conducted. Testing on a driving course generated willingness to participate by 59 percent of the participants. Testing in traffic dropped the percentage of discussants who would be willing to participant to 31 percent—the lowest of any method tested.

The striking thing about the willingness-to-participate percentages is that the older group was more comfortable driving a test car with dual controls in "live" traffic (50% positive) than the younger group (12% positive).

I would feel much safer on the course. PY

There is no way I would take a chance on the highway. PY

> **Methods 3 and 4. Method 3: Drive your own car on a closed course with a driving instructor or occupational therapist in the passenger seat. Method 4: Same technique, but test is conducted in traffic, not on a course.**

The concept of driving their own car (as opposed to a dual-control car) was viewed more positively overall, primarily reflecting the Tampa group's pattern of response. There was little difference by age. Sixty-three percent of the panelists indicated that they would participate if Method 3 were employed in the research (57% of the Tampa respondents and 67% of the Philadelphia respondents). Looking at the acceptability of Method 1 by location, only 22 percent of the Tampa respondents would participate if a dual-control car were used, compared to 95 percent of the Philadelphia respondents.

Even in Method 4, involving actual traffic, 54 percent across locations and age said "yes" to participation, although still more Tampa respondents than Philadelphia respondents were comfortable with driving their own cars than a dual-control test vehicle. Clearly, the comfort level of driving their own car is important to many.

<u>Method 5</u>. You drive your own car in traffic and miniature audio and video recording instruments are mounted in the vehicle to record the driving scene and how you respond to it.

The response to this idea was controversial. Responses ran from out-right opposition to genuine enthusiasm. Many "Big Brother" comments were made. On the other hand, some found the idea even less intrusive than the other observation methods, because another person is not in the car and because one is likely to forget the presence of the recording devices over time.

The Tampa groups were much more enthusiastic than the Philadelphia groups—65 percent of the Tampa group and 35 percent of the Philadelphia group would be willing to participate. Overall, though, panelists were split 50%-50% with regard to the acceptability of Method 5.

I think that's great. That's the best one of all. TO

Most people would forget about it after a while. PO

After a day or two, I'd become accustomed to it. PY

My car is my private space. I don't want anybody taping my private moments. PY

<u>Method 6</u>. A study method to briefly measure your vision, memory, and physical abilities needed to drive safely, using either paper-and-pencil tests, or tests that might be presented on a computer.

This was the most popular method tested, but still only one of several that might be appropriate to implement in future studies. Overall, 69 percent of panelists indicated that they would be willing to participate in research using this method. Seventy-five percent of the younger group was positive about this method, compared to 60 percent of the older group. These are high percentages for both, but the higher percentage of younger drivers indicating willingness may be explained by greater comfort with computers among this age group.

Rank-Ordering Exercise

Each panelist was provided with a stack of cards, each containing one of the six methods discussed above. They were instructed to divide all the cards into two piles: one representing "I would participate in the study," and the other representing "I would <u>not</u> participate in the study." Then, they were to draw an "X" across all cards in the negative pile. The positive cards were then to be put in preferential order and numbered, starting with a "1" to indicate first choice.

Table 2 presents the percentage of drivers willing to participate in research to determine the effects of their medications on driving performance, for each of the 6 methods, as a function of focus group location and participant age group. The mean rank is provided for each method. Figure 3 provides the willingness-to-participate percentages by age group and overall, for each

method, and Figure 4 provides the mean rankings of panelists' preferences among the methods that were deemed acceptable.

Barriers to Participation

The biggest concerns were loss of driving privileges as a consequence of poor performance on the driving assessment, and a fear that confidential information could fall into the wrong hands. A few participants commented that they know their medications can make them dizzy, and if they felt dizzy (or otherwise impaired), they probably would not participate in the driving evaluation phase. This raises a question about a bias that could result if those people whose driving is most affected by (multiple) medication use select themselves out of the study.

Incentives to Increase Participation

Participants would expect to be compensated. Nearly all panelists expressed a preference for cash, although a willingness to accept other kinds of remuneration, especially free meal coupons, was indicated.

Participants commented that the demands on their time in the medication identification phase would be significantly less than in the driving phase, and that study compensation would need to reflect that.

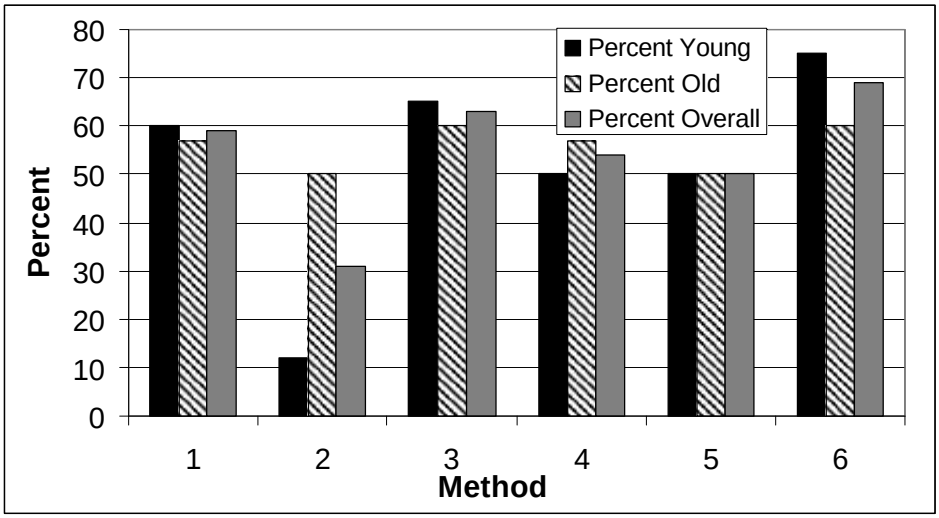

Figure 3. Percent of Discussants Willing to Participate as a Function of Method Used to Measure Driving Performance and Participant Age Group.

METHODS

1. Drive a dual-control vehicle on closed course with driving instructor or OT.

2. Drive a dual-control vehicle in traffic with driving instructor or OT.

3. Drive your own car on closed course with driving instructor or OT.

4. Drive your own car in traffic with driving instructor or OT.

5. Drive your own car in traffic with video recording equipment but no observer.

6. Studies to measure vision, memory, & physical abilities (paper/pencil or PC).

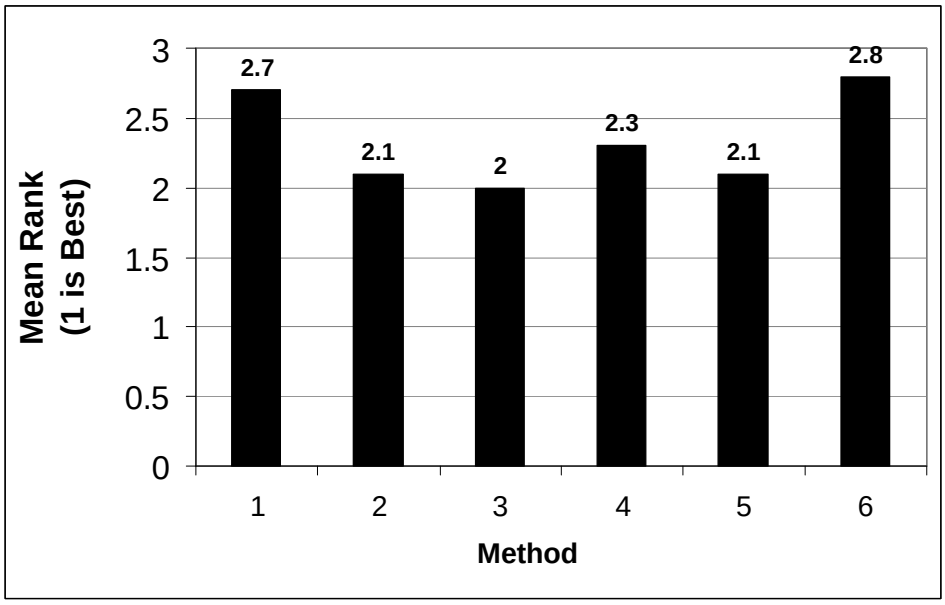

Figure 4. Mean Rating for Methods of Measuring Driving Performance, when Methods were Deemed Acceptable.

(Note: Since this methodology involved rank-ordering with "1" meaning "best," the lower the average rating, the more preferable the method).

Table 2. Results of the Card-Sorting Task for Methods of Measuring Driving Performance.

Method		Percentage Willing to Participate					Mean Ranking when Deemed Acceptable
		City		Age Group		Total (%)	
		Tampa (%)	Phila. (%)	Young-Old (%)	Old-Old (%)		
1	Drive a dual-control vehicle on closed course with driving instructor or OT	22	95	60	57	59	2.7
2	Drive a dual-control vehicle in traffic with driving instructor or OT	22	40	12	50	31	2.1
3	Drive your own car on closed course with driving instructor or OT	57	67	65	60	63	2.0
4	Drive your own car in traffic with driving instructor or OT	65	42	50	57	54	2.3
5	Drive your own car in traffic with video recording equipment but no observer	65	35	50	50	50	2.1
6	Studies to measure vision, memory, & physical abilities (paper/pencil or PC)	70	67	75	60	69	2.8

CONCLUSIONS AND RECOMMENDATIONS

Through performance of three, complementary efforts in this project—a literature review, brainstorming session with subject matter experts, and focus groups with older drivers—a base of information and opinion has emerged that will guide future research in the area of medication use and driving functioning. The conclusions and recommendations that follow are keyed to specific topics and research design issues highlighted in the objectives and statement of work for this project. Specifically,

- What is our current understanding of the effects of drugs/medications, and combinations of medications, on crash risk/crash involvement, and which should be the focus of continuing research on polypharmacy and driving functioning?
- What are the most feasible and reliable means of measuring/monitoring drug/medication usage—including over-the-counter drugs—by older drivers?
- What are the most practical and valid ways of assessing the impact of drug/medication use on actual driving performance?
- What are the potential barriers to the participation of older persons in studies of drug/medication use and driving functioning, and how might they be overcome?

CURRENT UNDERSTANDING OF DRUG/MEDICATION EFFECTS AND FUTURE RESEARCH FOCUS

Our conclusions in this area rest upon the preceding review by Wilkinson and Moskowitz (2001) and the update for recent (2001 through 2004) reports conducted in the present literature review. An exploratory analysis of an administrative claims database by LeRoy (2004), which linked patient-level pharmacy information with codes denoting injuries resulting from motor vehicle crashes, also was instrumental in shaping our current understanding of potentially driver impairing (PDI) medications. For crash-involved drivers age 50 and older, the combinations that now appear to be of greatest concern are:

- Narcotics/narcotic analgesics *plus*
    - Non-steroidal anti-inflammatory drugs (NSAIDs)
    - Skeletal muscle relaxants
    - Anti-anxiety drugs
    - Selective serotonin reuptake inhibitor (SSRI) antidepressants
    - Antibiotics
    - Gastric acid secretion reducers
- Narcotics/narcotic analgesics *plus* NSAIDs *plus*
    - Skeletal muscle relaxants
    - Antibiotics

A number of single (classes of) medications that have been linked to increased crash risk, including *antihypertensive* agents and *anti-diabetic* agents, have not shown significant associations with motor vehicle crashes/injuries in combinations with other (prescription) drugs in the limited cases that have been examined to date. From our review of the literature, we would

not conclude that sufficient evidence exists to exclude these classes from future polypharmacy and driving studies, however.

This perspective was ratified by the comments of experts participating in the brainstorming session. They were also in agreement that the proper focus for continuing work in this area should be on classes of medications—rather than the total number of drugs—that a person is taking.

The brainstorming session participants, having been provided in advance with the literature review findings, further prioritized drugs/medications for future research based on their exposure in the (community dwelling) population of older persons. Our recommendations in this area accordingly are to concentrate on combinations including:

- Alpha blockers and other drugs that affect blood pressure (anti-hypertensive medications).
- Sedating drugs such as the benzodiazepines, tricyclic antidepressants, and opioids.
- Drugs that affect blood sugar levels (anti-diabetic agents and drugs that could potentiate hypoglycemic effects).

A research strategy of utilizing epidemiological studies and/or analyses of large (e.g., administrative claims) databases to select and prioritize drugs and combinations of drugs for future empirical studies was broadly recommended by the brainstorming session participants; we endorse this approach, too, in principle, although its feasibility remains to be demonstrated. We also recommend that over-the-counter (OTC) drugs be included in future study designs to the extent that an OTC drug has been shown to impair functional ability(ies) needed for safe driving, or has been associated with significantly elevated crash involvement through database analyses or epidemiological research.

Finally, there was support in the literature and among the experts in the brain-storming session that the interaction of medications and alcohol can be properly *excluded* as a primary focus of continuing polypharmacy research. It is recommended that potential subjects in such studies be screened to identify and restrict the participation of those who drink alcohol in addition to their medication regime.

MEASURING/MONITORING DRUG/MEDICATION USE BY OLDER PERSONS

The literature review indicated a variety of ways in which researchers might learn which medications an (older) person is using, each with its own strengths and limitations. Taking practicality and feasibility into account, in addition to the accuracy of results likely to be obtained using competing methods considerably narrows the list of approaches that can be recommended to measure/monitor drug use by research study participants.

The overriding conclusion in this area is that, to obtain complete and reliable information from older persons about their medication regimes, the researcher must simultaneously address a number of specific and essential concerns:

- *Privacy* – Older persons will divulge information about the drugs they take only to someone who they believe will keep it in confidence, who will not communicate about it to anyone (including a family member, or their own physician) without their consent. It is

therefore important to rely on face-to-face interactions, which can provide such assurances, whereas mailed surveys or telephone contacts cannot.

- *Security* – Older persons do not want a stranger coming to their residence if it can be avoided.
- *Credibility* – Older persons prefer to discuss the medications they are taking with a recognized authority in this area, one who can provide advice and answer questions as well as receive information.

With this in mind, it is recommended that researchers do not attempt to learn about an older person's medications by initiating direct contacts with a son/daughter or spouse, or with the individual's doctor. The best approach emerging from the focus group discussions is a form of the "brown bag" method—which was also rated highly by the brainstorming session experts—where an older research participant is asked to bring all of his/her medications (including over-the-counter drugs) to an office or other neutral, non-threatening location to be inventoried by an appropriate professional. Pharmacists (active or retired) are the best choice in this regard, although nurses also may have sufficient perceived authority in this area, and offer a strong "comfort level." A member of the research team who can provide the required assurances of privacy and confidentiality should also be present during the brown-bag interview.

If possible, multiple methods should be employed to identify what medications an older person is taking. Specifically, the combination of accessing an administrative claims (pharmacy) database and using a brown-bag interview may be recommended. The information obtained from the pharmacy database will provide a historical record of the individual's (prescription) drug regime. It can serve as a screen in subject recruitment, and provides a valuable point of reference for confirming a subject's expected drugs and dosages during a specific study period.

A self-report of all drugs taken within twelve hours preceding a driving evaluation by a consenting older research participant should be obtained. Corroboration of his/her drug usage preceding the driving evaluation by a spouse or family member is also desirable—which, it may be noted, is markedly different than *beginning* the inquiry into an older person's drug regime through such contacts.

ASSESSING THE IMPACT OF DRUG/MEDICATION USE ON DRIVING PERFORMANCE

The literature review generated descriptions of various measurement approaches to investigate the relationship between (multiple) drug usage and driving functioning, which were discussed and rated by experts in the brainstorming session. The top candidates emerging from these project activities included in-vehicle evaluations, on both a closed course and (with certain safeguards) in actual traffic; instrumented vehicle studies to observe driver behavior under more "naturalistic" conditions; and clinical measures of the effect of medications on specific functional abilities needed for safe driving.

The focus group discussions with older drivers refined our understanding of what are likely to be acceptable methodologies with this cohort. One conclusion from these discussions is that older persons have a strong preference for using their own vehicles, and especially if an

evaluation is to be conducted in actual traffic. A closed driving course was also clearly preferable to an on-road evaluation among the focus group participants, because of safety concerns; and this concern was magnified by the prospect of using an unfamiliar vehicle (e.g., a dual-control car) and/or having a stranger (an occupational therapist or other driving evaluation specialist) riding with them. The responses of the older discussants to an instrumented vehicle methodology were split, with some objecting to the "big brother" aspect of unobtrusive monitoring, while others very much appreciated the prospect of driving their own cars without an evaluator physically present.

Our resulting recommendations for measuring driving performance with older persons taking (multiple) medications include the use of:

- *Off-road (clinical) assessments of functional abilities* – These may be performed using paper-and-pencil methods but computer-based methods are recommended if feasible, to promote standardization in test administration and scoring and to permit the use of specialized cognitive tests (e.g., processing speed) that require precise timing. The functional measures derived from prior NHTSA research in this area[4] are recommended.
- *In-vehicle assessments on a closed course with a driving evaluator* – These behind-the-wheel measures should be performed in a dual-control vehicle, as a safety precaution; because they are not exposed to actual traffic conditions it is likely that this will be acceptable to a majority of older research participants. The driving evaluator should be an OT or other driving evaluation specialist, using an evaluation protocol that is accepted by an applicable certifying body, institution, or organization.
- *Assessments under actual traffic conditions in an instrumented vehicle* – The older person's own car should be instrumented for this purpose. To heighten acceptance of this method, it should be emphasized that individuals need only drive as they would "normally" (i.e., apart from any involvement with the study) and that it is not necessary for another person to accompany them.

An across-the-board recommendation, regardless of the methodology employed, is that researchers evaluate the effects of medications on driving performance among older persons *only for those drugs that individuals are already taking* prior to their enrollment as test subjects.

IDENTIFYING AND ADDRESSING BARRIERS TO RESEARCH PARTICIPATION BY OLDER PERSONS

The conclusions to be drawn in this area rest primarily on the comments of older persons participating in the focus group discussions held in Pennsylvania and Florida. On the positive side, there was a general willingness on the part of discussants to become involved in research that can improve safety for older drivers, including studies that require them to divulge information about the drugs they are taking and/or to have their driving performance evaluated. Their participation remains contingent upon a number of explicit requirements, however, as referenced in the following recommendations.

[4] cf. *Model Driver Screening and Evaluation Program (vol. 3)*, DOT HS 809 581. May be accessed at *http://www.nhtsa.dot.gov/people/injury/olddrive/modeldriver/3_3_desiging.htm#Screening%20and%20Assessment%20Techniques*

To encourage the participation of community-dwelling older persons in future investigations of the effect of drugs on driving functioning, researchers should:

- Provide absolute assurances that information and data obtained in the study will remain confidential, with all individual participants remaining anonymous in reports of the study's results.
- Provide absolute assurances that participation in the study will have no impact on the license status or driving privilege of any individual, subject to the laws of the State in which the study is conducted.
- Strictly observe informed consent procedures that specify to study participants all of the parties to whom the results of their driving evaluations may be made available.
- Provide incentives, preferably cash but possibly coupons for services at local stores or restaurants, that represent fair compensation for the amount of time a participant must commit to the study.
- Clearly explain the benefits, to society and to themselves, that are expected to result from the older driver's participation in the planned study.

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APPENDIX A:
Potentially Inappropriate Medications Commonly Prescribed for Older, Community-Dwelling Individuals

Drug Class	Particular Inappropriate Drugs Prescribed	Description & Side Effects Negatively Impacting Driving Ability
Antidepressants	Amitriptyline (“Elavil”; “Endep”; “Limbitrol” - combination with chlordiazepoxide)	Amitriptyline is a tricyclic antidepressant used to treat symptoms of depression. Amitriptyline may cause side effects including: drowsiness, weakness or tiredness; excitement or anxiety; difficulty falling asleep or staying asleep; restlessness; blurred vision; pain, burning, or tingling in the hands or feet; confusion; and unsteadiness.
	Doxepin (“Adapin;” “Sinequan”)	Doxepin is used to treat depression and anxiety. Side effects from doxepin are common: drowsiness weakness or tiredness; excitement or anxiety; and insomnia.
Benzodiazepines	Chlordiazepoxide (“Librium”)	Chlordiazepoxide is a long-acting benzodiazepine used to relieve anxiety and to control agitation caused by alcohol withdrawal. Side effects from chlordiazepoxide are common and include: drowsiness, dizziness, tiredness, and weakness.
	Diazepam (“Valium”)	Diazepam is a long-acting benzodiazepine used to relieve anxiety, muscle spasms, and seizures and to control agitation caused by alcohol withdrawal. Side effects include: drowsiness, dizziness, tiredness, and weakness
	Flurazepam (“Dalmane”)	Flurazepam is a short-acting benzodiazepine used on a short-term basis to help people fall asleep and stay asleep through the night. Side effects from flurazepam are common and include: headache, hangover effect (grogginess), drowsiness, dizziness or lightheadedness, and weakness.
Anti-Diabetic (Hypoglycemics)	Chlorpropamide (“Diabinese”)	Chlorpropamide is used to treat type II (noninsulin-dependent) diabetes (formerly 'adult-onset'), particularly in people whose diabetes cannot be controlled by diet alone. Chlorpropamide lowers blood sugar by stimulating the pancreas to secrete insulin and helping the body to use insulin efficiently.
Anti-Platelet Agents	Dipridamole (“Persantine”)	Dipyridamole is used with other drugs to reduce the risk of blood clots after heart valve replacement. It works by preventing excessive blood clotting. It is used in combination with blood thinners such as Coumadin. Dipyridamole is also used with aspirin to reduce the risk of death after a heart attack and to prevent another heart attack.. Although side effects from dipyridamole are not common, they can occur, and include: dizziness, headache, flushing (feeling of warmth), and itching.
Antihistamine	Hydroxyzine (”Atarax”; “Vistaril”)	Hydroxyzine is an antihistamine with anticholinergic (drying) and sedative properties that is used to treat allergic reactions (used to relieve the itching caused by allergies) It is also used to control the nausea and vomiting caused by various conditions, including motion sickness. It is also used for anxiety and to treat the symptoms of alcohol withdrawal. Although side effects from hydroxyzine are not common, they include: drowsiness; dizziness; chest congestion; headache.

Drug Class	Particular Inappropriate Drugs Prescribed	Description & Side Effects Negatively Impacting Driving Ability
Anti-Anxiety	Meprobamate (“Equanil;” “Meprospan;” “Miltown;” “Miltown 600;” “Neuramate”)	Meprobamate is used to treat anxiety disorders or for short-term relief of the symptoms of anxiety. It is also used for muscle relaxation. Although side effects from meprobamate are not common, they can occur, and include: drowsiness; headache; difficulty coordinating movements (clumsiness and unsteadiness); excitement; and weakness.
Antispasmodic (urinary tract)	Oxybutynin (“Ditropan”)	Oxybutynin is used to relieve urinary and bladder difficulties, including frequent urination and inability to control urination. It also helps to decrease muscle spasms of the bladder. Although side effects from oxybutynin are not common, they can occur, and include: blurred vision, dry eyes, and drowsiness
Narcotic Analgesic	Propoxyphene (“Darvon Puvules;” “Darvon-N”)	Propoxyphene is used to relieve mild to moderate pain. Although side effects from propoxyphene are not common, they can occur, and include: dizziness, lightheadedness, drowsiness, mood changes, and headache.
Non-steroidal anti-inflammatory drugs (NSAIDs)	Specific drugs not mentioned in literature, but Beers list includes: Indomethacin, phenylbutazone, ketorolac, mefenamic acid, and piroxicam	Nonsteroidal anti-inflammatory drugs (also called NSAIDs) are used to relieve some symptoms caused by arthritis (rheumatism), such as inflammation, swelling, stiffness, and joint pain. Certain side effects, such as confusion, swelling of the face, feet, or lower legs, or sudden decrease in the amount of urine, may be especially likely to occur in elderly patients, who are usually more sensitive than younger adults to the effects of nonsteroidal anti-inflammatory drugs. Also, elderly people are more likely than younger adults to get very sick if these medicines cause stomach problems. With phenylbutazone, blood problems may also be more likely to occur in the elderly.
Barbiturates	Specific drugs not listed in literature, but Beers list includes: butalbital, pentobarbital, and secobarbital.	Barbiturates belong to the group of medicines called central nervous system (CNS) depressants (medicines that cause drowsiness). Some of the barbiturates may be used before surgery to relieve anxiety or tension. In addition, some of the barbiturates are used as anticonvulsants to help control seizures in certain disorders or diseases, such as epilepsy. The barbiturates have been used to treat insomnia (trouble in sleeping); but if they are used regularly (for example, every day) for insomnia, they are usually not effective for longer than 2 weeks. The barbiturates have also been used to relieve nervousness or restlessness during the daytime. However, the barbiturates have generally been replaced by safer medicines for the treatment of insomnia and daytime nervousness or tension. Confusion, mental depression, and unusual excitement may be more likely to occur in the elderly, who are usually more sensitive than younger adults to the effects of barbiturates

APPENDIX B: Brainstorming Session Attendees

NHTSA Project "Polypharmacy and Older Drivers: Identifying Strategies to Collect Drug Usage and Driving Functioning Among Older Drivers"

June 21, 2005

Radisson Hotel
Washington, D.C.

Project Staff:

Kathy H. Lococo
TransAnalytics, LLC
Kulpsville, PA 19443

Loren Staplin, Ph.D.
TransAnalytics, LLC
Kulpsville, PA 19443

Jane Stutts, Ph.D.
University of North Carolina
Highway Safety Research Center
Chapel Hill, NC 27599-3430

Project Consultants:

Robert R. Raleigh, M.D.
Chief, Maryland MVA Medical Advisory Board
Glen Burnie, MD 21062

Marion W. Anders, D.V.M., Ph.D.
Professor and Chair Emeritus
Department of Pharmacology and Physiology
University of Rochester Medical Center
Rochester, NY 14642

NHTSA Contracting Officer's Technical Representative:

Suzanne Feldman, Ph.D.
U.S. Department of Transportation
National Highway Traffic Safety Administration
Office of Research and Technology, NTI-132
Washington, D.C. 20590

NHTSA Observers

Dr. Linda Cosgrove
Ms. Esther Wagner
Dr. Jessie Blatt
Ms. Christine Sicinski
Ms. Joan Harris
Dr. Rhonda Moore

Expert Panelists
David Baugh Senior Technical Advisor Office of Research Development and Information Centers for Medicare and Medicaid Services Baltimore MD 21244-1850
Raman Gill Chahal, M.D., MPH. Psychiatrist, Johns Hopkins Medical School Faculty Consultant to Maryland MVA Medical Advisory Board Director Intensive Psychiatric Treatment Services, Johns Hopkins Bayview Medical Center Assistant Professor of Psychiatry, Johns Hopkins University. Baltimore, MD 21224
Gregory A. Compton, M.D. Internal Medicine/Geriatrician Consultant to Maryland MVA Medical Advisory Board Open Delta Consulting, Inc Highland, MD 20777
Francesca Cunningham, Pharm.D. Program Manager, Outcomes Research Pharmacy Benefits Management/Strategic Healthcare Group Department of Veteran's Affairs Hines, IL 60141
Jeffrey Elias, Ph.D Chief Cognitive Aging Behavioral and Social Sciences National Institute on Aging Bethesda, MD, 20892
Karen Farris, B.S. Pharm., Ph.D. Associate Professor, College of Pharmacy, University of Iowa Division of Clinical and Administrative Pharmacy Iowa City, IA 52241
Kimberly Harwood White, MS, OTR/L, CDRS Certified Driver Rehabilitation Specialist Johns Hopkins Driving Program Baltimore, MD

Expert Panelists
Aida A. LeRoy, PharmD Health Care Outcomes Research and Drug-Use Analysis Executive Vice President Iatrogen, LLC Great Falls, VA 22066
Richard Marottoli, M.D., M.P.H. Internal Medicine/Geriatrician Faculty, Yale University Yale University School of Medicine New Haven, CT 06504
Daniel Roenker, Ph.D. Professor of Psychology Department of Psychology Western Kentucky University Bowling Green, Kentucky 42101
Nina Silverstein, Ph.D. Associate Professor of Gerontology Gerontology Institute University of Massachusetts, Boston Boston, MA 02125-3393
Renee Tyree, PharmD, CDRS Certified Driver Rehabilitation Specialist D & R Innovative Mobility Tempe, AZ 85284
Carol J. Wheatley, OTR/L, CDRS Certified Driver Rehabilitation Specialist Workforce and Technology Center Maryland Division of Rehabilitation Servcies Baltimore, MD 21218

APPENDIX C: Brainstorming Rating Scale Results
Methods for Identifying Medication Use

A. Physician's Reports (mail requests)
B. Patient Self-Report (face-to-face)
C. Brown Bag Review
D. Pharmacy Records (administrative database)
E. In-Home Medicine Review
F. Mailed Survey to Patient
G. Proxy Report

Practicality

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	Sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	51.5	28.2	10-95	4	51.3	32.8	10-90	3	76.7	17.6	60-95	3	23.33	12.6	10-35	3	55.0	22.9	35-80
B	12	75.8	14.8	50-95	4	76.3	13.8	60-90	2	65.0	21.2	50-80	3	90.0	5	85-95	3	68.3	12.6	55-80
C	12	64.8	18.0	35-90	3	66.7	23.6	40-85	3	66.7	15.3	50-80	3	68.3	29.3	35-90	3	57.3	4.6	52-60
D	13	77.7	18.6	30-95	4	67.5	26.3	30-90	3	76.7	16.1	65-95	3	81.7	15.3	65-95	3	88.3	11.6	75-95
E	13	35.7	22.8	5-79	4	33.8	29.6	5-70	3	31.7	17.6	15-50	3	26.7	16.1	15-45	3	51.3	27.0	25-79
F	13	70.4	21.2	20-95	4	76.3	14.4	55-85	3	71.7	20.8	55-95	3	63.3	37.9	20-90	3	68.3	18.9	55-90
G	10	59.1	18.4	35-90	3	58.3	28.4	35-90	2	67.5	17.7	55-80	2	47.5	10.6	40-55	3	62.0	16.6	50-81
B + G	1	80	--	--	0	--	--	--	1	80	--	--		--	--	--	--	--	--	--
B + C + G	1	70	--	--	1	70	--	--	0	--	--	--		--	--	--	--	--	--	--

Reliability

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	Sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	61.7	18.3	30-85	4	73.8	9.5	60-80	3	65.0	18.0	50-85	3	65.7	16.8	55-85	3	38.3	10.4	30-50
B	13	63.9	17.0	30-95	4	65.0	12.3	50-75	3	60.0	17.3	50-80	3	56.7	23.6	30-75	3	73.3	20.2	55-95
C	13	81.5	6.9	70-90	4	83.8	9.5	70-90	3	75.0	5.0	70-80	3	83.3	2.9	80-85	3	83.3	5.8	80-90
D	13	69.2	12.6	50-90	4	71.3	15.5	50-85	3	65.0	5	60-70	3	66.3	16.0	50-82	3	73.3	15.3	60-90
E	12	90.0	5.6	75-95	4	92.5	2.9	90-95	2	90.0	0	90-90	3	91.7	2.89	90-95	3	85.0	10.0	75-95
F	12	55.1	15.3	20-75	3	65.0	13.2	50-75	3	51.3	15.2	35-65	3	47.3	23.7	20-62	3	56.7	7.6	50-65
G	11	61.3	26.9	15-95	4	60.0	30.8	15-80	2	74.5	29.0	54-95	2	35.0	14.1	25-45	3	71.7	25.2	45-95
B + G	1	80	--	--	--	--	--	--	1	80	--	--	--	--	--	--	--	--	--	--
A +E	1	95	--	--	--	--	--	--	1	95	--	--	--	--	--	--	--	--	--	--
E + G	1	90	--	--	--	--	--	--	1	90	--	--	--	--	--	--	--	--	--	--
A + B + D	1	100	--	--	--	--	--	--	1	100	--	--	--	--	--	--	--	--	--	--

APPENDIX C: Brainstorming Rating Scale Results
Methods for Identifying Medication Use (Continued)

A. Physician's Reports (mail requests)
B. Patient Self-Report (face-to-face)
C. Brown Bag Review
D. Pharmacy Records (administrative database)
E. In-Home Medicine Review
F. Mailed Survey to Patient
G. Proxy Report

Cost-Effectiveness

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	64.5	26.8	5-95	4	53.7	33.5	5-80	3	91.0	5.3	85-95	3	56.7	10.4	45-65	3	60.0	32.8	30-95
B	12	66.3	24.1	25-90	3	68.3	37.5	25-90	3	48.3	22.6	25-70	3	85.0	5.0	80-90	3	63.3	15.3	50-80
C	12	59.6	18.9	35-90	3	70.0	18.0	50-85	3	51.7	7.64	45-60	3	60.0	21.8	35-75	3	56.7	28.9	40-90
D	13	78.7	18.4	35-95	4	81.3	4.8	75-85	3	74.3	34.1	35-95	3	68.3	20.2	50-90	3	90.0	5.0	85-95
E	13	40.0	22.4	10-90	4	38.8	19.3	10-50	3	46.7	20.2	35-70	3	25.0	13.2	15-40	3	50.0	36.1	20-90
F	13	78.5	19.7	30-95	4	73.8	30.7	30-95	3	76.7	23.6	50-95	3	81.7	12.6	70-95	3	83.3	10.4	75-95
G	12	62.5	17.5	40-90	4	68.8	21.0	40-90	3	60.0	17.3	50-80	2	57.5	24.8	40-75	3	60.0	17.3	50-80

Overall

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	54.5	19.0	10-75	4	53.8	29.3	10-70	3	56.7	16.1	45-75	3	56.7	23.6	30-75	3	51.3	6.4	44-55
B	12	65.3	17.1	35-80	4	65.0	20.4	35-80	2	67.5	17.7	55-80	3	63.3	24.7	35-80	3	66.3	14.0	52-80
C	13	75.3	13.3	45-85	4	81.3	7.5	70-85	3	82.3	4.6	77-85	3	70.0	21.8	45-85	3	65.7	12.5	57-80
D	11	73.1	12.8	45-85	4	72.5	8.7	60-80	1	45.0	--	--	3	74.7	12.9	60-84	3	81.7	5.8	75-85
E	13	66.4	23.2	30-97	4	57.5	22.2	30-80	3	80.7	16.0	65-97	3	78.3	24.7	50-95	3	52.0	25.0	32-80
F	13	55.9	15.3	25-81	4	60.0	7.1	50-65	3	51.7	12.6	40-65	3	41.7	20.1	25-65	3	68.7	11.0	60-81
G	10	51.2	20.7	20-80	4	53.8	26.9	20-80	1	35.0	--	--	2	37.5	10.6	30-45	3	62.3	16.6	47-80
B + G	1	75	--	--	--	--	--	--	1	75	--	--	--	--	--	--	--	--	--	--
C + D	1	95	--	--	1	95	--	--	--	--	--	--	--	--	--	--	--	--	--	--
A + B + D	1	95	--	--	--	--	--	--	1	95	--	--	--	--	--	--	--	--	--	--
A+ D + E	1	100	--	--	--	--	--	--	1	100	--	--	--	--	--	--	--	--	--	--
B + D + G	1	100	--	--	--	--	--	--	1	100	--	--	--	--	--	--	--	--	--	--
A + B + D + G	1	80	--	--	--	--	--	--	1	80	--	--	--	--	--	--	--	--	--	--
A + B + E + G	1	90	--	--	--	--	--	--	1	90	--	--	--	--	--	--	--	--	--	--

APPENDIX D: Brainstorming Rating Scale Results
Methods of Measuring Compliance to the Medication Regime

A. Physicians' Clinical Judgment
B. Self-Report (Questionnaire)
C. Patient's Clinical Response
D. Biomechanical Measures
E. Pill Counts
F. Pharmacy Records (admin. databases)
G. Electronic Medication Monitoring
H. Proxy Report

Practicality

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	Range	n	mean	sd	range	n	mean	sd	range
A	13	46.4	30.2	1-85	5	63.2	36.6	1-90	2	8.0	9.9	1-15	3	38.7	19.5	25-61	3	51.7	7.6	45-60
B	13	73.5	15.0	50-97	5	75.0	13.2	55-90	2	60.0	14.1	50-70	3	78.0	17.5	60-95	3	75.7	19.1	60-97
C	13	44.2	27.1	5-97	5	44.6	30.2	5-70	2	17.5	3.5	15-20	3	41.7	20.2	30-65	3	64.0	29.6	40-97
D	14	27.4	21.1	5-75	5	25.6	20.8	5-58	3	35.0	35.0	10-75	3	18.7	7.6	12-27	3	31.7	22.6	10-55
E	14	49.7	21.0	20-90	5	51.0	25.8	30-90	3	45.0	20.0	25-65	3	33.7	11.9	20-41	3	68.3	5.8	65-75
F	14	71.0	18.4	25-100	5	74.0	8.9	65-85	3	49.0	25.1	25-75	3	72.3	11.7	62-85	3	86.7	12.6	75-100
G	14	45.0	23.4	15-97	5	50.4	18.8	25-70	3	40.0	18.0	20-55	3	20.3	5.0	15-25	3	65.7	28.9	40-97
H	9	64.9	17.9	22-80	3	72.3	6.8	67-80	1	75.0	--	--	3	52.3	29.1	22-80	2	67.5	3.5	65-70
A + C	1	80	--	--	--	--	--	--	1	80.0	--	--		--	--	--	--	--	--	--
B + F	1	80	--	--	--	--	--	--	1	80.0	--	--		--	--	--	--	--	--	--
B + H	1	90	--	--	--	--	--	--	1	90.0	--	--		--	--	--	--	--	--	--

Reliability

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	34.8	29.4	1-85	4	31.5	33.5	1-75	3	35.0	43.6	5-85	3	38.7	36.7	10-80	3	35.0	15.0	20-50
B	13	61.0	18.2	21-95	4	63.8	9.5	50-70	3	65.0	13.2	50-75	3	46.0	25.5	21-72	3	68.3	23.6	50-95
C	13	60.2	30.4	5-95	4	32.5	32.0	5-65	3	60.0	30.0	30-90	3	72.3	15.8	55-86	3	85.0	13.2	70-95
D	13	76.5	12.3	55-95	4	82.5	8.7	75-95	3	73.3	18.9	60-95	3	68.3	12.6	55-80	3	80.0	8.7	70-85
E	13	69.2	17.1	25-90	4	71.3	11.1	55-80	3	53.3	25.7	25-75	3	78.3	7.6	70-85	3	73.3	17.6	55-90
F	13	63.1	16.4	25-90	4	57.5	23.3	25-80	3	56.7	7.64	50-65	3	65.0	8.7	60-75	3	75.0	18.0	55-90
G	13	71.6	19.9	25-90	4	76.3	18.0	50-90	3	50.0	25.0	25-75	3	87.0	3.0	84-90	3	71.7	12.6	60-85
H	8	63.6	20.7	27-80	2	72.5	3.5	70-75	2	77.5	3.5	75-80	2	38.5	16.3	27-50	2	66.0	20.7	45-87
B + F	1	85.0	--	--	--	--	--	--	1	85.0	--	--	--	--	--	--	--	--	--	--
B + G + H	1	85.0	--	--	--	--	--	--	1	85.0	--	--		--	--	--	--	--	--	--

APPENDIX D: Brainstorming Rating Scale Results
Methods of Measuring Compliance to the Medication Regime (Continued)

A. Physicians' Clinical Judgment
B. Self-Report (Questionnaire)
C. Patient's Clinical Response
D. Biomechanical Measures
E. Pill Counts
F. Pharmacy Records (admin. databases)
G. Electronic Medication Monitoring
H. Proxy Report

Cost-Effectiveness

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	44.5	29.9	1-80	4	57.8	38.1	1-80	3	43.3	34.0	5-70	3	20.7	9.8	15-32	3	51.7	25.7	30-80
B	12	79.0	12.8	50-90	4	86.3	4.8	80-90	2	62.5	17.7	50-75	3	81.0	8.5	73-90	3	78.3	16.1	60-90
C	13	40.9	24.1	1-90	4	36.5	30.5	1-75	3	30	20	10-50	3	43.3	15.3	30-60	3	55.0	30.4	35-90
D	13	26.2	13.9	5-45	4	28.8	19.3	10-55	3	28.3	17.6	10-45	3	20.0	13.2	5-30	3	26.7	5.8	20-30
E	13	59.6	16.9	20-80	4	63.8	13.2	45-75	3	53.3	11.6	40-60	3	51.7	27.5	20-70	3	68.3	16.1	50-80
F	13	76.2	16.0	50-95	4	76.3	19.3	50-95	3	75.0	0	75-75	3	20.7	9.3	10-27	3	90.0	8.7	80-95
G	13	47.1	21.5	10-95	4	46.3	14.9	25-60	3	53.3	2.9	50-55	2	80.0	7.1	75-85	3	68.3	23.6	50-95
H	6	75.8	8.6	60-85	1	80	--	--	1	75	--	--	--	--	--	--	2	70.0	14.1	60-80
B + F	1	95	--	--	--	--	--	--	1	95	--	--	--	--	--	--	--	--	--	--
B + H	1	85	--	--	--	--	--	--	1	85	--	--	--	--	--	--	--	--	--	--

Overall

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	39.5	28.5	5-85	4	38.8	37.1	5-80	3	43.3	36.9	15-85	3	36.7	37.5	15-80	3	39.7	4.5	35-44
B	12	68.2	17.4	25-92	4	73.8	7.5	70-85	2	62.5	17.7	50-75	3	59.0	29.7	25-80	3	73.7	16.5	60-92
C	12	52.4	28.5	5-92	4	31.3	32.0	5-75	2	37.5	10.6	30-45	3	75.7	11.0	65-79	3	67.3	21.9	50-92
D	13	38.2	18.2	10-75	4	28.8	17.5	10-50	3	50.0	22.9	30-75	3	31.7	18.9	10-45	3	45.3	10.5	25-56
E	13	64.2	17.1	30-92	4	65.0	12.3	50-75	3	46.7	20.8	30-70	3	71.7	12.6	60-85	3	73.0	16.5	62-92
F	12	65.9	19.2	30-92	4	68.8	14.4	50-80	2	47.5	17.7	35-60	3	60.0	26.0	30-75	3	80.3	12.6	67-92
G	13	57.8	21.1	25-92	4	57.5	16.6	40-80	3	50.0	17.3	30-60	3	51.7	34.0	25-90	3	72.0	18.7	55-92
H	6	60.8	16.7	33-75	1	75	--	--	1	65	--	--	2	41.5	12.0	33-50	2	71.0	8.5	65-77
B + F	2	92.5	3.5	90-95	1	95	--	--	1	90	--	--	--	--	--	--	--	--	--	--
C + H	1	90	--	--	--	--	--	--	1	90	--	--	--	--	--	--	--	--	--	--
B + G + H	1	100	--	--	--	--	--	--	1	100	--	--	--	--	--	--	--	--	--	--

APPENDIX E: Brainstorming Rating Scale Results
Older People's Willingness to Participate as a Function of Method of Measuring Medication Use

A. Physician's Clinical Judgment
B. Self Report – Questionnaire
C. Patient's Clinical Response
D. Brown Bag — Physician Led
E. Brown Bag —Pharmacist Led
F. Brown Bag—Pharmacy Student Led
G. Brown Bag—Nurse Led
H. Biomechanical: Saliva
I. Biomechanical: Urine
J. Biomechanical: Blood
K. Pill Counts
L. Pharmacy Records (Admin. Databases)
M. Electronic Medication Monitoring
N. In-Home Medical Review

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	Range	n	mean	sd	range
A	14	56.9	28.2	5-99	5	49.0	27.3	5-70	3	60.0	17.3	50-80	3	60.7	43.9	10-87	3	63.0	34.6	30-99
B	14	65.5	24.7	1-95	5	74.0	14.8	50-90	3	52.0	45.9	1-90	3	57.0	15.7	40-71	3	73.3	22.6	50-95
C	13	49.4	31.0	1-99	4	43.8	27.2	5-65	3	43.7	39.9	1-80	3	55.7	37.9	12-80	3	56.3	37.3	30-99
D	13	73.5	11.6	50-90	5	80.0	6.1	70-85	3	73.3	2.9	70-75	3	63.7	12.7	50-75	2	72.5	24.8	55-90
E	14	71.2	10.3	50-90	5	76.4	4.2	70-80	3	73.3	2.9	70-75	3	61.7	10.4	50-70	3	70.0	18.0	55-90
F	14	67.3	12.6	50-90	5	71.4	9.9	55-80	3	70.0	8.7	60-75	3	61.7	10.4	50-70	3	63.3	23.1	50-90
G	14	64.4	15.8	30-90	5	73.2	5.0	69-80	3	56.7	23.6	30-75	3	60.3	9.0	50-66	3	61.7	24.7	45-90
H	13	36.6	19.4	1-83	5	42.6	25.1	20-83	3	30.33	25.9	1-50	2	32.5	10.6	25-40	3	35.7	10.1	25-45
I	14	29.0	16.4	1-60	5	41.0	19.5	10-60	3	17.0	13.9	1-25	3	25.0	8.7	20-35	3	25.0	10.0	15-35
J	14	28.4	22.0	1-75	5	40.0	28.3	10-75	3	13.7	12.1	1-25	3	31.7	17.6	15-50	3	20.3	17.5	1-35
K	14	59.4	17.0	35-100	5	62.2	7.6	50-69	3	61.7	16.1	50-80	3	40.0	5.0	35-45	3	71.7	25.7	50-100
L	14	71.1	16.1	42-100	5	69.2	10.0	55-80	3	68.3	15.3	55-85	3	63.0	22.7	42-87	3	85.0	18.0	65-100
M	14	55.6	17.6	30-100	5	58.8	11.2	45-70	3	53.3	7.6	45-60	3	38.3	14.4	30-55	3	70.0	26.5	50-100
N	12	54.3	17.2	25-80	4	58.5	19.0	40-79	2	30.0	7.1	25-35	3	55.7	9.0	47-65	3	63.3	15.3	50-80

APPENDIX F: Brainstorming Rating Scale Results
Methods of Measuring Driving Performance

A. Closed Course
B. On-the Road (in Traffic)
C. Simulation: Level 3
D. Simulation: Level 2
E. Simulation: Level 1
F. Instrumented Vehicle (Driver's own car)
G. Functional Measures Validated as Crash Predictors

Practicality

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	64.6	16.6	35-90	5	60.0	17.7	35-80	3	70.0	26.5	40-90	2	67.5	10.6	60-75	3	65.0	13.2	55-80
B	13	62.7	19.5	25-100	5	63.0	22.0	25-80	3	71.7	30.1	40-100	2	47.5	3.5	45-50	3	63.3	7.6	55-70
C	13	39.0	26.6	5-77	5	49.4	34.2	5-77	3	28.3	17.6	10-45	2	20.0	21.2	5-35	3	45.0	22.9	20-65
D	13	54.3	23.1	15-75	5	60.2	26.3	15-80	3	33.3	16.1	15-45	2	72.5	10.6	65-80	3	53.3	20.8	30-70
E	13	58.0	23.0	25-80	5	68.8	19.7	35-85	3	38.3	15.3	25-55	2	55.0	42.4	25-85	3	61.7	18.9	40-75
F	12	55.8	23.5	10-85	4	55.0	23.8	30-80	3	65.0	15.0	50-80	2	25.0	21.2	10-40	3	68.3	20.8	45-85
G	13	74.8	15.4	45-95	5	75.4	17.5	45-90	3	71.7	2.9	70-75	2	77.5	24.8	60-95	3	75.0	21.8	50-90

Reliability

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	14	67.9	20.8	15-95	5	66.0	18.2	40-90	3	46.7	28.4	15-70	3	80.0	0	80-80	3	80.0	15.0	65-95
B	14	71.4	20.5	25-95	5	74.0	14.3	55-95	3	63.3	25.7	35-85	3	61.7	32.2	25-85	3	85.0	10.0	75-95
C	14	67.4	13.9	45-90	5	69.8	9.5	60-85	3	61.7	17.6	45-80	3	61.7	15.3	45-75	3	75.0	18.0	55-90
D	14	57.9	17.6	15-85	5	66.0	8.2	60-80	3	55.0	15.0	40-70	3	40.0	22.9	15-60	3	65.0	20.0	45-85
E	14	51.1	19.3	10-75	5	63.0	7.0	57-75	3	48.3	12.6	35-60	3	28.3	23.6	10-55	3	56.7	20.2	35-75
F	13	72.3	13.8	45-87	4	75.8	3.0	73-80	3	63.3	17.6	45-80	3	67.3	21.1	45-87	3	81.7	7.6	75-90
G	14	70.1	10.9	45-85	5	76.4	7.7	65-85	3	70.0	8.7	60-75	3	65.0	8.7	55-70	3	65.0	18.0	45-80
A + G	1	75	--	--	--	--	--	--	1	75	--	--	--	--	--	--	--	--	--	--
B + G	1	90	--	--	--	--	--	--	1	90	--	--	--	--	--	--	--	--	--	--

APPENDIX F: Brainstorming Rating Scale Results
Methods of Measuring Driving Performance (Continued)

A. Closed Course
B. On-the Road (in Traffic)
C. Simulation: Level 3
D. Simulation: Level 2
E. . Simulation: Level 1
F. Instrumented Vehicle (Driver's own car)
G. Functional Measures Validated as Crash Predictors

Cost-Effectiveness

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	60.8	15.1	30-80	5	64.0	20.7	30-80	3	58.3	18.9	45-80	2	60.0	14.1	50-70	3	58.3	2.9	55-60
B	13	58.6	14.4	25-85	5	60.4	6.4	52-65	3	63.3	22.6	40-85	2	42.5	24.8	25-60	3	61.7	5.8	55-65
C	14	30.1	23.7	1-60	5	33.0	29.3	5-75	3	17.0	20.4	1-40	3	25.3	22.4	1-45	3	43.3	20.8	20-60
D	14	40.7	23.9	15-85	5	49.0	30.9	20-85	3	25.0	17.3	15-45	3	33.3	20.2	15-55	3	50.0	18.0	30-65
E	14	51.1	27.6	10-95	5	58.2	27.7	31-90	3	31.7	16.1	20-50	3	38.3	27.5	10-65	3	71.7	28.4	40-95
F	13	63.0	19.2	35-95	4	71.8	14.2	55-85	3	65.0	17.3	45-75	3	44.0	10.2	35-55	3	68.3	27.5	40-95
G	13	76.5	11.0	55-95	4	79.3	10.6	72-95	3	73.3	10.4	65-85	3	79.3	9.3	73-90	3	73.3	17.6	55-90

Overall

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range
A	13	58.7	17.5	20-75	5	54.0	17.5	30-75	2	47.5	38.9	20-75	3	65.0	10.0	55-75	3	67.7	2.1	66-70
B	13	67.5	18.8	17-85	5	68.0	14.4	45-80	2	85.0	0	85-85	3	52.3	32.2	17-80	3	70.3	0.6	70-71
C	14	43.1	17.2	10-75	5	38.0	17.5	10-55	3	41.7	20.2	30-65	3	40.7	10.1	30-50	3	55.7	21.8	32-75
D	14	44.6	18.3	15-77	5	44.4	9.5	35-60	3	36.7	20.2	25-60	3	40.0	27.8	15-70	3	57.3	21.1	35-77
E	14	40.1	21.2	10-80	5	44.0	16.7	25-70	3	23.3	5.8	20-30	3	28.3	20.2	10-50	3	62.3	22.5	37-80
F	13	68.0	16.9	25-90	4	70.0	10.8	55-80	3	71.7	12.6	60-85	3	56.0	27.6	25-78	3	73.7	18.2	54-90
G	12	64.0	18.8	30-85	5	72.0	12.2	58-85	2	45.0	7.1	40-50	3	61.7	28.4	30-85	2	66.5	23.3	50-83
A + B + G	1	100	--	--	--	--	--	--	1	100	--	--	--	--	--	--	--	--	--	--
B + F + G	1	95	--	--	1	95	--	--	--	--	--	--	--	--	--	--	--	--	--	--

APPENDIX G: Brainstorming Rating Scale Results
Older People's Willingness to Participate as a Function of Method Used to Measure Driving Performance

A. Closed Course
B. On-the Road (in Traffic)
C. Simulation: Level 3
D. Simulation: Level 2
E. . Simulation: Level 1
F. Instrumented Vehicle (Driver's own car)
G. Functional Measures Validated as Crash Predictors

Method	All Experts				Physicians & Pharmacologists				Driving Evaluators				Behavioral Researchers				Database Experts			
	n	mean	sd	range	n	mean	sd	range	n	mean	sd	range	n	mean	sd	Range	n	mean	sd	range
A	14	58.8	18.2	25-85	5	60.2	24.2	25-85	3	65.0	13.2	50-75	3	55.7	16.8	45-75	3	53.3	20.2	35-75
B	14	57.8	15.3	25-80	5	56.8	23.5	25-80	3	65.0	8.7	60-75	3	56.7	10.4	45-65	3	53.3	10.4	45-65
C	14	47.9	19.3	10-70	5	54.0	25.4	10-70	3	41.7	7.6	35-50	3	40.3	27.4	16-70	3	51.7	7.6	45-60
D	14	50.7	18.2	25-70	5	58.4	20.6	25-75	3	40.0	13.2	30-55	3	45.0	26.5	25-75	3	54.3	5.1	50-60
E	14	53.6	19.1	25-75	5	62.0	18.9	35-80	3	40.0	21.8	25-65	3	50.0	26.0	35-80	3	56.7	2.9	55-60
F	10	61.3	16.5	35-85	3	57.3	21.1	35-77	2	55.5	7.8	50-61	2	60.0	28.3	40-80	3	70.0	13.2	60-85
G	11	68.8	18.4	30-90	4	62.5	25.0	30-90	2	77.5	3.5	75-80	2	78.0	17.0	66-90	3	65.3	18.5	45-81

APPENDIX H: FOCUS GROUP SCREENER

Recruit for 10 panelists
Moderator and contact: Warren Ashburn

Good day/evening, my name is _____. We are conducting a brief market study on the subject of driving practices among senior citizens. I would like to ask you just a few short questions. First, a couple of background questions:

Do you or anyone in your family work for an advertising agency, marketing research firm, newspaper, broadcast station, or department of transportation?
Yes ( ) *No ( )*

(If yes, terminate. If no, continue.)

Have you attended a market research discussion in the past six months?
Yes ( ) *No ( )*

(If yes, terminate. If no, continue.)

In which of the following age categories are you?

Under 55 (terminate)
55 to 69 (continue)
70 to 79 (continue)
80 or older (continue)

(Note: The FIRST focus group should include only qualified panelists age 70 or older. If possible, we would like to see three or more panelists in this group age 80 or older.

(The SECOND group should include only qualified panelists between 55 and 69).

We are anxious to have a good ethnic diversity in these discussion groups. Which of the following description best describes your ethnicity?

Caucasian _____

Hispanic _____

African-American _____

NOTE: The goal is to have 3 or 4 Hispanics in each focus group in FL and 3 or 4 African Americans in each focus group in PA.

Do you have a valid driving license?

Yes ( ) No ( ) (terminate)

How many separate driving trips (of any length) do you take in the average week?

0 to 4 _____ (terminate)

5 or more _____ (continue)

My last question has to do with prescription medications which you use on a regular basis. How many such medications do you take? We do not need to know what medications they are.

0 to 1 (terminate)

2 or more (continue)

(NOTE: PLEASE AIM FOR A 50-50% MIX OF MALE AND FEMALE PANELISTS).

Invite eligible respondents to the session:

We are conducting a discussion among small groups of people like you on the subject of driving on (date and time). The session will last roughly 90 minutes. No special preparation is necessary on you part. Most people find these discussions interesting and fun. Refreshments will be served.

For Florida participants: *In addition, you will receive) a $50 stipend.*
For Pennsylvania participants: *In addition, you will receive a $75 stipend.*

Would you like to attend?

APPENDIX I: FOCUS GROUP DISCUSSION GUIDE

I. *Introduction (10 minutes)*

(Because we anticipate some sensitivity and concern on the part of panelists, this introduction and the first discussion topics were designed, even more than usual, to comfort the participants.)

A. As you learned when they called you, this discussion group has to do with the topic of driving. As you can see from looking around the room, I am especially interested in learning more about the driving practices of mature drivers.

B. Before we learn more about what we are studying, it is important that I tell you a bit more about who I am and who I am not.

1. *I am an independent research moderator. Role. Objectivity.*
2. *I am not connected in any way with the police, the bureau of traffic safety or other government agency nor with any part of the medical community.*

C. Therefore…

1. *You will not be asked any embarrassing questions nor for any confidential information you would not willingly volunteer.*
2. *Nothing you say will be associated with you personally. Results will be reported only for the entire group, not individually.*
3. *Your driving status will not be affected in any way as a result of this discussion.*
4. *You will not be approached again in the future by me or other members of the study team.*

D. Focus group protocol (stick to the topic, share the floor)

E. Panelist introductions (generic personal introductions)

II. *Topic warm-up (15 minutes)*

A. Just about everyone here has been driving for a very long time. I know that you have seen the conditions of driving, driver attitudes, etc. change significantly. But what about YOU? How have you changed… physically or emotionally… changes that have effected how you drive?

B. What are your greatest difficulties or concerns as a driver today? What do you do about them?

(After everyone seems comfortable with the focus group environment…)

C. Who is the sponsor? This discussion is sponsored by the National Highway Traffic Safety Administration. This agency is devoted to promoting driver and highway safety.

What is the problem? A recent national survey among adults 65+ (not in nursing homes or hospitals) showed that 40% use 5 or more different medications per week and that 12% use 10 or more. The Agency is interested to learn what the effects on driving performance are when people take multiple medications (including over the counter). The Agency will then use that information to create educational campaigns for the public and for physicians and pharmacists to make them aware of possible risks. If people know when they are at risk, they will be better able to make decisions about if they should drive, and where and when they may be able to drive safely.

How will they research the topic? There will be two phases to the research. Tonight we start Phase I. Phase II will come much later. In Phase II, we will need to learn what specific medications people are taking and then actually measure their driving skills to see if there are any resulting impairments. Again, your participation in the group is for Phase I only; we are not asking you to be involved in Phase II. What is Phase I? Well, we think that some people may feel reluctant to discuss their medications and driving. So, our purpose tonight is to discuss what would influence mature drivers to get involved in such research and what forms the research should take.

III. *Learning what medications mature drivers take. (30 minutes)*

A. When we conduct Phase II of the research, we will need to ask people about what specific medications (prescription and over-the-counter) people take. I am not going to ask anyone tonight about your medications. If you wish to discuss your medications, know that any thing you say is anonymous and confidential.

B. So, the question to you is… under what conditions you would share information about your prescriptions and over-the-counter medication use. I am going to suggest some ways to get at this, but first, do you have any thoughts or suggestions?

C. *Here are some specific ideas for collecting this information. I am interested in knowing whether you would feel comfortable or uncomfortable being asked to do this and, if you would not participate, why not. <u>Remember: the results of any of these tests would be confidential and would not have any effect on your driving status.</u>*

1. *You bring all your medications in a bag to a private office away from other people. A list would be made of them and you would be asked about when and how often you take each. This interview would be conducted by one of the following:*

   - ✓ *A family doctor or nurse.*
   - ✓ *A pharmacist.*
   - ✓ *A neutral research person.*

   (Solicit comments both about collection method and collection personnel.)

2. *Someone would come to your home to conduct the same interview about your medications. This interview would be conducted by one of the following:*

   - ✓ *A family doctor or nurse.*
   - ✓ *A pharmacist.*
   - ✓ *A neutral research person.*

   (Solicit comments both about collection method and collection personnel.)

3. *You would fill out a survey that researchers mailed to you asking about your medications and use.*

4. *You would come to a researcher's office to talk about your medications but you would not be required to bring them. If you like, a relative or friend could come with you.*

5. *With your advance permission, a researcher would send a letter to all your doctors, asking them to list all the medications they prescribed for you. The lists would be sent back to the researcher.*

   If this is OK, would you be willing to bring your over-the-counter medications into the researcher so that they could be added to your list?

6. *Special caps would be placed on the medications you take on a regular basis. These caps would record the date and time on each occasion that you opened the bottle.*

7. *Information about your prescription drug use would be obtained from pharmacy databases.*

III B. *Card Sort Exercise (20 minutes)*

A. Here is a set of 14 cards. Each card describes one of the ways we have just been discussing to collect information about the medications people use.

B. Read the cards and sort them into TWO piles… One pile for those in which you WOULD participate and one pile for those in which you WOULD NOT participate.

C. Now take the "bad pile", ones that you would not participate in. Draw an "X" through each card in this stack.

D. Now take the "good pile". Put them in order according to the method you prefer first, second best, third best and so on. Number each card accordingly.

IV. *Learning how the medications you take may affect your driving. (20 minutes)*

A. The point is similar to the topic we just discussed. We would like to learn under what conditions it would be OK to have your driving skills observed and evaluated… after taking the medications you normally take.

B. Here are some specific ideas for making these observations. I am interested in knowing whether you would feel comfortable or uncomfortable being asked to do this and, if you would not participate, why not. <u>Remember: the results of any of these tests would be confidential and would not have any effect on your driving status.</u>

1. You would drive a vehicle with dual controls, like a driver education car. A driving instructor or occupational therapist would ride in the passenger seat as you drove. This test might be done on:

- ✓ *A closed course, or.*
- ✓ *On the road in traffic.*

(Discuss both methodology and test venue.)

2. You would drive your own car, again observed by a driving instructor or occupational therapist. This test might be done on:

- ✓ *A closed course, or.*
- ✓ *On the road in traffic.*

(Discuss both methodology and test venue.)

3. You would drive your own car in traffic, with miniature audio or video recording instruments mounted in the vehicle to record you response to various driving situations.

4. *You would take a brief (20 minutes) test on computer or with paper and pencil either in your home or at an office. This test would measure your vision, memory and physical abilities after taking your usual medication.*

IV B. *Learning how the medications you take may affect your driving. (10 minutes)*

A. Here is a set of 6 cards. Each card describes one of the ways we have just been discussing to collect information about the effects of medications on driving performance.

E. Read the cards and sort them into TWO piles… One pile for those in which you WOULD participate and one pile for those in which you WOULD NOT participate.

F. Now take the "bad pile", ones that you would not participate in. Draw an "X" through each card in this stack.

G. Now take the "good pile". Put them in order according to the method you prefer first, second best, third best and so on. Number each card accordingly.

V. *Conclusion (10 minutes)*

A. Based on what you know about the situation of older people driving and using multiple medications, do you feel that further study is worthwhile?

B. Based on everything you have heard here today, what would you say was the biggest concern you might have about participating in a study like the ones discussed here today?

C. What kinds of assurances of confidentiality would be needed for you to participate?

D. It is very likely that the researcher would offer some form of incentive to the people participating in the study. What would you suggest as an appropriate incentive? Cash? How much? Gift certificates? Meals at a local restaurant? Movie or theatre passes?

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