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DRUG RESEARCH METHODOLOGY. VOLUME I: THE ALCOHOL-HIGHWAY SAFETY EXPERIENCE AND ITS APPLICABILITY TO OTHER DRUGS

Alan C. Donelson
Mary E. Marks
Ralph K. Jones
Kent B. Joscelyn

The University of Michigan
Highway Safety Research Institute
Ann Arbor, Michigan 48109

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16. Abstract

This report presents the findings of a workshop concerning the alcohol and highway safety experience, which includes research efforts to define the drinking-driving problem and societal responses to reduce the increased highway safety risk attributable to alcohol. A cross-disciplinary panel of experts examined its history, methodologies employed in research, and approaches to the development and implementation of preventive measures (countermeasures). From these discussions a conceptual framework for use in comparing alcohol and other drugs was developed. Categories include (1) the process of risk identification; (2) measures of risk to indicate impaired driving ability; and (3) approaches to preventive measures that reduce the increased highway safety risk attributable to alcohol and other drugs. This report summarizes comparisons between alcohol and other drugs, based on the substance, its delivery system, and the user population. Conclusions and recommendations concerning the applicability of the alcohol and highway safety experience to efforts related to other drugs are presented.

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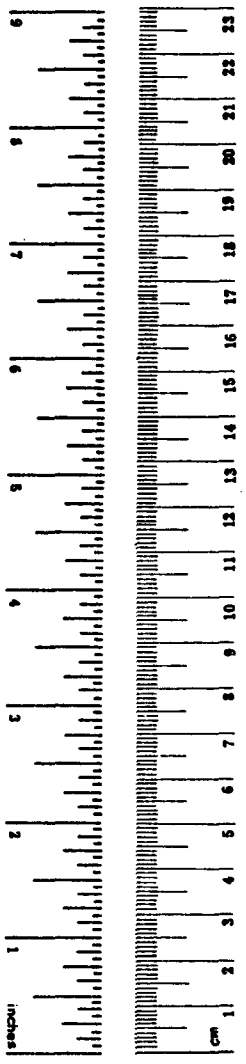
METRIC CONVERSION FACTORS

Approximate Conversions to Metric Measures

Symbol	When You Know	Multiply by	To Find	Symbol
	LENGTH			
in	inches	*2.5	centimeters	cm
ft	feet	30	centimeters	cm
yd	yards	0.9	meters	m
mi	miles	1.6	kilometers	km
	AREA			
in^2	square inches	6.5	square centimeters	cm^2
ft^2	square feet	0.09	square meters	m^2
yd^2	square yards	0.8	square meters	m^2
mi^2	square miles	2.6	square kilometers	km^2
	acres	0.4	hectares	ha
	MASS (weight)			
oz	ounces	28	grams	g
lb	pounds	0.45	kilograms	kg
	short tons (2000 lb)	0.9	tonnes	t
	VOLUME			
tsp	teaspoons	5	milliliters	ml
Tbsp	tablespoons	15	milliliters	ml
fl oz	fluid ounces	30	milliliters	ml
c	cups	0.24	liters	l
pt	pints	0.47	liters	l
qt	quarts	0.95	liters	l
gal	gallons	3.8	liters	l
ft^3	cubic feet	0.03	cubic meters	m^3
yd^3	cubic yards	0.76	cubic meters	m^3
	TEMPERATURE (exact)			
°F	Fahrenheit temperature	5/9 (after subtracting 32)	Celsius temperature	°C

*1 in = 2.54 (exactly). For other exact conversions and more detailed tables, see NBS Misc. Publ. 286, Units of Weights and Measures, Price $2.25, SD Catalog No. C13.10:286.



Approximate Conversions from Metric Measures

Symbol	When You Know	Multiply by	To Find	Symbol
	LENGTH			
mm	millimeters	0.04	inches	in
cm	centimeters	0.4	inches	in
m	meters	3.3	feet	ft
m	meters	1.1	yards	yd
km	kilometers	0.6	miles	mi
	AREA			
cm^2	square centimeters	0.16	square inches	in^2
m^2	square meters	1.2	square yards	yd^2
km^2	square kilometers	0.4	square miles	mi^2
ha	hectares (10,000 m^2)	2.5	acres	
	MASS (weight)			
g	grams	0.035	ounces	oz
kg	kilograms	2.2	pounds	lb
t	tonnes (1000 kg)	1.1	short tons	
	VOLUME			
ml	milliliters	0.03	fluid ounces	fl oz
l	liters	2.1	pints	pt
l	liters	1.06	quarts	qt
l	liters	0.26	gallons	gal
m^3	cubic meters	35	cubic feet	ft^3
m^3	cubic meters	1.3	cubic yards	yd^3
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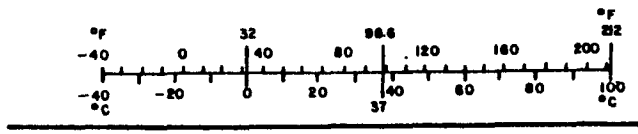

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Special recognition is due to those who participated in the workshop and whose expert contributions formed the basis for the report:

- Stephen D. Benson
- Robert F. Borkenstein
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- Markku Linnoila
- Robert E. Willette
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- Richard Marcus
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- Alex Richman
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We gratefullv acknowledge the staff of the Belmont Conference Center, whose gracious service contributed to a setting and atmosphere most conducive to productivity. We especially thank Mrs. Mary Force, director of the center, and Ann Higgins, our conference coordinator, both of whom greatly facilitated planning and arranging of this workshop.

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A working draft was circulated among participants, who reviewed it for accuracy and comprehensiveness. The final text was then prepared, based on their comments. We acknowledge with special thanks the detailed and thoughtful comments provided by Professor Robert F. Borkenstein, whose critique of the working draft guided the preparation of the final product.

Other HSRI personnel also made important contributions. This report was edited by James E. Haney. Anne L. VanDerworp served as production editor. Deborah M. Dunne, lead word processing operator, produced the report. Draft versions of the report were produced by clerical staff of the Policy Analysis Division under the supervision of Jacqueline B. Roval.

We thank all who contributed.

Kent B. Joscelyn
Principal Investigator

Alan C. Donelson
Principal Investigator

PREFACE

This report presents the results of one of a series of workshops on methodological issues in research on drugs and highway safety. The workshops addressed discrete--but interrelated--topics. The workshops were conducted by the University of Michigan Highway Safety Research Institute (HSRI) for the National Highway Traffic Safety Administration as part of a larger research program on drugs and driving.

A reader interested in the subject area will find the other workshop reports and technical reports produced under the research program of value. The workshop reports are:

- Drug Research Methodology. Volume One. The Alcohol And Highway Safety Experience And Its Applicability To Other Drugs.
- Drug Research Methodology. Volume Two. The Identification Of Drugs Of Interest In Highway Safety.
- Drug Research Methodology. Volume Three. The Detection And Quantitation Of Drugs Of Interest In Body Fluids From Drivers.
- Drug Research Methodology. Volume Four. Epidemiology In Drugs And Highway Safety: The Study Of Drug Use Among Drivers And Its Role In Traffic Crashes.
- Drug Research Methodology. Volume Five. Experimentation In Drugs And Highway Safety: The Study Of Drug Effects On Skills Related To Driving.

Other reports prepared under the HSRI project include an annotated bibliography of literature on drugs and driving and related topics:

- Joscelyn, K.B., and Donelson, A.C. 1979. Drugs And Driving: A Selected Bibliography. Supplement One. National Highway Traffic Safety Administration technical report DOT-HS-803-879;

as well as a comprehensive review of past, ongoing, and planned efforts

related to the study of and the response to the drug and driving problem:

- Joscelyn, K.B.; Donelson, A.C.; Jones, R.K.; McNair, J.W.; and Ruschmann, P.A. 1980. Drugs and Highway Safety 1980. National Highway Traffic Safety Administration contract no. DOT-HS-7-01530.

The latter report supported the preparation of a report to Congress by the Secretary of Transportation as requested in Section 212 of the Highway Safety Act of 1978. Both reports cited above developed from and extended similar work done under earlier contracts from NHTSA:

- Joscelyn, K.B., and Maickel, R.P. 1977. Drugs And Driving: A Research Review. National Highway Traffic Safety Administration technical report DOT-HS-802-189.

- Joscelyn, K.B., and Maickel, R.P. 1977. Drugs And Driving: A Selected Bibliography. National Highway Traffic Safety Administration technical report DOT-HS-802-188.

- Joscelyn, K.B., and Maickel, R.P., eds. 1977. Report On An International Symposium On Drugs And Driving. National Highway Traffic Safety Administration technical report DOT-HS-802-187.

- Joscelyn, K.B.; Jones, R.K.; Maickel, R.P.; and Donelson, A.C. 1979. Drugs And Driving: Information Needs And Research Requirements. National Highway Traffic Safety Administration technical report DOT-HS-804-774.

- Jones, R.K., and Joscelyn, K.B. 1979. Alcohol And Highway Safety 1978: A Review Of The State Of Knowledge. National Highway Traffic Safety Administration technical report DOT-HS-803-714.

- Jones, R.K., and Joscelyn, K.B. 1979. Alcohol And Highway Safety 1978: A Review Of The State Of Knowledge. Summary Volume. National Highway Traffic Safety Administration technical report DOT-HS-803-764.

- Jones, R.K.; Joscelyn, K.B.; and McNair, J.W. 1979. Designing A Health/Legal System: A Manual. The University of Michigan Highway Safety Research Institute report no. UM-HSRI-79-55.

These reports provide entry points to the literature on alcohol, other

drugs, and highway safety for readers desiring general reviews as well as information on specific topic areas. In addition, the reports can serve as sources for identifying both U.S. and foreign literature pertinent to each reader's needs.

CONTENTS

1.0 INTRODUCTION

This report presents the findings of a workshop that examined the alcohol and highway safety experience and its applicability to other drugs. The workshop was held on 28-31 January 1979 at the Smithsonian Institution's Belmont Conference Center, Elkridge, Maryland. The workshop was one of a series conducted by the Policy Analysis Division of The University of Michigan Highway Safety Research Institute, under the sponsorship of the U.S. Department of Transportation, National Highway Traffic Safety Administration contract DOT-HS-7-01530.

1.1 Background

The extent to which the use of drugs by drivers contributes to highway safety problems is unknown (Joscelyn and Maickel 1977a; Willette 1977; Joscelyn, Jones, Maickel, and Donelson 1979). Research has not established that any drug besides alcohol increases the probability of a traffic crash and associated losses. (The term "alcohol" is used here and throughout this report to mean ethyl alcohol, or ethanol.) Although present knowledge about drugs and driving is limited, available evidence indicates that drugs alone or in combination with alcohol or other drugs **can** impair driving skills and **may** increase the likelihood of traffic crashes. Further inquiry in this area is warranted. Among the factors that limit the state of knowledge are problems and issues in major areas of drug and driving research.

In November 1976, The University of Michigan Highway Safety Research Institute (HSRI) received a contract entitled "Drug Research Methodology" from the National Highway Traffic Safety Administration (NHTSA). Its general objectives are:

- to develop a greater understanding of the nature of the drug and driving problem on the basis of existing literature; and

- to define directions for future research with greater precision than has been done in the past NHTSA-sponsored efforts.

The project emphasizes the generation of possible solutions to research issues in drugs and highway safety. The overall task is to identify and develop methodologies for research in drugs and driving. Specific objectives of this study are:

- to identify problem areas that should be addressed in drug methodology;
- to identify alternative approaches to research that could be implemented with current technology; and
- to provide a listing of priority items of research that NHTSA could address in the foreseeable future.

To accomplish these objectives, an approach based on workshops was used to examine issues in four distinct but interrelated areas:

- The Identification of Drugs of Interest in Highway Safety;
- The Detection and Quantitation of Drugs of Interest in Body Fluids from Drivers;
- Epidemiology in Drugs and Highway Safety: The Study of Drug Use Among Drivers and Its Role in Traffic Crashes; and
- Experimentation in Drugs and Highway Safety: The Study of Drug Effects on Skills Related to Driving.

The division of topics had advantages as well as a possible disadvantage. For example, on one hand, a tighter focus on specific issues could be achieved. On the other hand, for some topics the wisdom and expertise of participants in other workshops might be lost. To offset this disadvantage, summaries of earlier workshops were mailed to invitees, and participants were later asked to comment on findings as well as issues in those areas.

These workshops, conducted in the spring and summer of 1978, were highly productive and brought to focus other issues in related areas of

drugs and driving. In 1978, a contract modification called for additional workshops within the scope of the statement of work. In January 1978, a fifth workshop, the subject of this report, dealt with the alcohol and highway safety experience and its relation to the study and control of the drug and driving problem. The remaining workshops will address other topics of priority interest to NHTSA.

These workshops constitute a series in which each is an integral part. Although the workshops were self-contained and are reported in separate volumes, in general the progression of topics has been systematic. An apparent exception is Workshop V, reported here as Volume One. This deserves some explanation. References and comparisons to the study of and the response to the alcohol-crash program occurred frequently during the first four workshops. In fact, public sensitivity to the alcohol-crash problem has itself led to an awareness that other drugs also have the potential to increase traffic crash risk. As described below, Workshop V was therefore planned to examine the alcohol and highway safety experience in detail. As Volume One, the report on Workshop V serves as an introduction to the others, provides a historical perspective, and describes the relation of the alcohol and highway safety experience to other drugs. The workshop reports are designed to be read sequentially. A reader desiring information on a specific topic area, however, can refer to the particular volume of interest.

Another task under this contract is to update the literature review performed for NHTSA under contract DOT-HS-4-00994 (Joscelyn and Maickel 1977b). A report produced under this contract (Joscelyn and Donelson 1979) presents an annotated bibliography of recent literature on drugs and driving to supplement the parent volume. Another in this series of bibliographic reports is planned for publication in the summer of 1980.

1.2 Scope and Objectives of Preceding Workshops

The first workshop, The Identification of Drugs of Interest in Highway Safety, addressed the question of which drugs should be considered in the study of methodological and other issues. Its purpose was to identify

drugs (1) that should be the focus of near-term, NHTSA-sponsored research on drugs and driving, and (2) that should be the focus for discussing research issues in the other workshop. Two objectives of that workshop were:

- to develop a way to estimate the risk potential of drugs, based on an approach that formulates subjective judgments of experts and that synthesizes present knowledge in distinct fields related to drugs and driving; and
- to produce an initial rank ordering of identified drugs of interest, based on subjective estimates of their risk potential.

One output of Workshop I, the list of drugs of interest, became a basis for discussion in the second workshop. It served to identify drugs with greater perceived risk to highway safety, thus guiding the emphasis of discussion in this and the other workshops.

Workshop II dealt with methods of analysis for drugs in human body fluids. In the context of epidemiologic and experimental research to define the drugs and driving problem, the purposes of Workshop II were these:

- to identify problem areas and research issues related to the analysis of body fluids for drugs;
- to provide detailed and workable approaches to resolving analytical problems; and
- to suggest research to resolve methodological issues.

Its specific objectives were as follows:

- to outline analytical requirements for research in drugs and highway safety;
- to identify techniques and methods to detect and quantitate the drugs of interest;
- to provide alternative solutions for other problems pertaining to analysis for drugs (e.g., collection, handling, and storage of specimens; testing of laboratories for proficiency).

Output of Workshop II, for example (approaches to screening body fluids for drugs) fed into the third workshop, described below.

Workshop III focused on epidemiology in drugs and highway safety. One of two major approaches to research in this field, surveys of drug use in driving populations present great difficulty. Problems with existing data arise in part from methods of drug analysis employed in past studies. But other issues and constraints in this research area also hamper progress. The purpose of the third workshop, therefore, was to resolve these issues to the extent possible. Its objectives were the following:

- to identify methodological and other issues in research to indicate the highway safety risk of drugs;
- to suggest approaches to resolving problems in the design and conduct of epidemiologic studies; and
- to recommend research needed in this area.

The main emphasis was on epidemiologic approaches and their constraints.

Workshop IV examined experimental research in drugs and highway safety. Complementing epidemiologic research, experimentation refers to studies performed under controlled conditions, usually in a laboratory setting, to measure the effects of drugs on skills related to driving. In general, research in this area has been unsystematic. Although studies of drug effects are numerous, they are rarely comparable. Major problem areas include analysis of the driving task; development and validation of tests measuring driving performance; and theoretical, practical, and ethical issues involved in the study of drug effects in human subject populations. The purpose of Workshop IV was to identify major problem areas and issues of concern and to suggest ways to advance research in this area. Its objectives were:

- to identify research issues in the determination of drug effects on driving performance;
- to propose approaches to resolving specific problems in measuring the effects of drugs on driving performance; and
- to suggest further research in this area.

One expected output of this workshop was an identification of valid surrogate measures of driving performance for testing drugs that may increase highway safety risk. The design and conduct of future experiments were also of special concern.

Workshop V, the subject of this report, developed from the first four. As might be expected, prior workshop discussions often turned for reference to the alcohol and highway safety experience. A separate workshop to examine the alcohol-safety experience was therefore planned.

1.3 Purpose of Workshop V

The first-recognized (and still unsolved) drug and driving problem involves alcohol. Traffic crashes are a major cause of death in the United States, and research indicates that a significant drinking-driving problem exists nationwide. Both experimental and epidemiologic approaches have defined the problem. These approaches rely greatly on the ease of alcohol detection and measurement. The patterns of research that have evolved for alcohol may form an analogy, or model, for studying the relationship between other drugs and highway safety.

The influence of the alcohol-safety experience on the design and conduct of research on other drugs is pervasive, as discussions in previous workshops indicated. Participants often referred to research and preventive measures pertaining to alcohol and highway safety. They frequently mentioned the "alcohol model" in discussing methodological issues in drug and driving research. Alcohol is, of course, a drug. As a drug, alcohol may be discussed generally along with other substances in pharmacological or sociological contexts. But, as the previous workshops indicated, reliance in highway safety on general parallels between alcohol and other drugs may be unfounded.

Alcohol and other drugs differ--often profoundly—according to their use, effects, and the characteristics of user populations. How these differences affect the design and conduct of highway safety research on drugs other than alcohol has not been widely discussed in the literature. Although reference has been made to an "alcohol model," this conceptual framework has not been precisely defined. The purpose of Workshop V,

therefore, was to examine in its entirety the alcohol issue in highway safety, including its history, research methodology, and efforts to reduce the magnitude of the drinking-driving problem.

The specific objectives of Workshop V were as follows:

- to determine the extent to which highway safety research and programs for alcohol form a model for other drugs;
- to define, as appropriate, a conceptual framework for the alcohol model;
- to develop a general framework for comparing alcohol and other drugs in the context of highway safety research;
- to evaluate differences between alcohol and other drugs in terms of the general framework; and
- to assess the applicability of the alcohol and highway safety experience to other drugs.

It was hoped that Workshop V would describe more precisely the alcohol and highway safety experience and express more clearly the differences between alcohol and other drugs and their import for drug and driving research.

To accomplish these aims, recognized experts both in the field of alcohol and highway safety and in research on other drugs and driving were brought together. Some of the participants have studied the alcohol-safety problem for a considerable number of years and thus could contribute a historical perspective to the ensuing discussion. Others have actively pursued research that has contributed substantially to knowledge of the similarities and differences between alcohol and other drugs. Both epidemiologic and experimental approaches were represented by the research experience of participants.

In addition, an effort was made to assemble a cross-disciplinary group. The researchers invited to the workshop each represented one or more disciplines directly or indirectly related to drugs and driving. Areas of expertise included psychology (experimental, clinical, and social); physiology; psychiatry; pharmacology (basic, clinical, and behavioral); pharmacy; medicine; law; analytical chemistry; toxicology; epidemiology;

and public policy analysis.

Participants were active in many areas of research, including the following:

- alcohol and highway safety, including basic and applied research and the development and evaluation of preventive measures;
- epidemiology of drug use;
- methodology to detect and quantitate alcohol and other drugs in blood and other body fluids, including breath;
- drugs and behavior, both basic and clinical research; and
- drugs (including alcohol) and driving.

The participants, from both inside and outside the government, functioned as an interdisciplinary group in an informal workshop setting. A moderator with an extensive background in the area of alcohol, drugs, and highway safety functioned as "lowest common denominator." The moderator served (1) to link panel members from different areas of research, (2) to provide a ground for basic understanding in a many-disciplined group, and (3) to ensure that the workshop's product could be used by a lay audience.

1.4 Scope of Report

This report has five sections. The four that follow are briefly described below.

Section 2.0, The Alcohol and Highway Safety Experience, briefly summarizes the history of the alcohol and driving problem, research approaches used to define the problem, and approaches to reduce the highway safety risk of alcohol.

Section 3.0, A General Framework for Alcohol, Other Drugs, and Highway Safety, describes three basic elements in a conceptual structure developed from discussions of the alcohol-safety experience.

Section 4.0, A Comparison of Alcohol with Other Drugs, discusses differences between alcohol and other drugs in terms of the general framework.

Section 5.0 presents the conclusions and recommendations of the panel.
A bibliography lists references cited in the text of the report.
Appendix A provides a list of participants of Workshop V.

2.0 THE ALCOHOL AND HIGHWAY SAFETY EXPERIENCE

The discovery of alcohol, its use, and (probably) its misuse are firmly rooted beneath the surface of recorded history. The effects of alcohol have long been known, both praised and reviled. Although the history of alcohol use is beyond the scope of this report, the reader should remember that social problems related to alcohol consumption predate modern transportation. As one participant noted, patterns of drinking behavior were not superimposed on driving, but vice versa. Basic attitudes toward alcohol still influence societal responses to the drinking-driving problem. The problem of driving after drinking has, therefore, a social psychological dimension that extends beyond the scope and practice of highway safety per se (Cisin 1963).

The alcohol and highway safety experience comprises both research to define the drinking-driving problem and societal responses to the problem. In order to address questions about its relevance and applicability to other drugs, participants of Workshop V reviewed the history of alcohol and highway safety. They identified specific elements of this experience, including approaches to the measurement and control of the drinking-driving problem.

This section summarizes discussions of the alcohol and highway safety experience, which were based primarily on the personal knowledge and experience of participants. To establish as much common ground as possible, review articles as well as a list of references to the literature were sent to each invitee prior to the workshop. Subsequent discussions, therefore, touched on many topics well known to each participant. Many of these topics were not discussed fully, and some important points were mentioned briefly or were simply assumed. To supplement workshop discussions and to provide the reader with additional background information, Section 2.0 includes material summarized from literature available to and used by participants of this workshop. Even so, because

limitations of space do not allow full treatment of all relevant topics, the reader is referred to references cited in this report for more detailed information on alcohol and highway safety.

Four subsections organize topics under the following headings:

- Epidemiologic Research: Studying Alcohol Use Among Drivers;
- Experimental Research: Studying the Effects of Alcohol on Skills Related to Driving;
- Approaches to Reduce the Magnitude of the Drinking-Driving Problem (Countermeasures);
- Measuring the Drinking-Driving Problem: The Central Role of Blood Alcohol Concentration (BAC) and Technology for Alcohol Analysis.

The division of topics is suggested by fundamental differences in research approaches and by the distinction between studying a problem and managing its consequences.

For example, research to define the nature and extent of the drinking-driving problem has used two basic approaches: **epidemiology** and **experimentation.** Epidemiology is the science concerned with the distribution and etiology of disease in human populations. The scope of epidemiologic research has broadened over the years, and the methods of epidemiology have been applied to social problems other than disease, for example, drug-related problems. In general, epidemiologic studies attempt to describe how certain phenomena are related. ". . . The investigation of a relationship can be seen to progress from demonstration of statistical association to demonstration that the association is causal, and ultimately to ascertainment of its directness" (MacMahon, Pugh, and Ipsen 1960, p.12).

According to Wigle (1975), however, the traditional notion of **causality** in disease ("one disease, one cause") has been a hindrance in the study of nonacute disease and noninfectious conditions in general. This general point relates directly to alcohol, drugs, and traffic crashes. For example, "the finding that a drug is present in a crash victim or driver does not, by itself, establish a causal relationship between the drug's presence,

driver impairment, and crash causation" (Joscelyn and Maickel 1977a, p.84). The analyses of many factors is necessary to determine what factors contribute significantly to crashes involving alcohol or other drugs. As Stewart (1970) has pointed out, epidemiology is particularly appropriate for the study of conditions with multiple manifestations and complex interrelations, where correlation means interaction rather than cause-and-effect.

As exemplified by research on alcohol and traffic crashes, constraints inherent in the nature of events under study and in the limited amount of resources available to conduct definitive studies often prevent demonstration of direct associations between variables. Because the methods of epidemiology are primarily observational, **experimentation** complements epidemiology. An experimental approach can provide tests for observed relationships by isolating for study important independent and dependent variables. These variables can be measured under controlled conditions, usually in a laboratory, to examine and explain the associations observed through epidemiologic study. Both approaches--epidemiology and experimentation--have served to describe the relationship between alcohol and traffic crashes.

Preventive measures, or countermeasures, develop from the definition of a problem. Designed to intervene between two (or more) events, such measures attempt to reduce the magnitude of consequences that result from the established relationship of the events. To the degree an association between events is direct, the effect of countermeasures will be proportional to their successful implementation. Their effectiveness, of course, must be determined through methods of evaluation, which are similar to those of epidemiology.

2.1 Epidemiologic Research: Studying Alcohol Use Among Drivers

The history of the drinking-driving problem, one participant observed, is a history of demonstrating associations. Before the advent of personal motor vehicles, alcohol's effects in man were common knowledge--and the source of social concern. State laws prohibited public drunkenness, and by 1900 the Temperance Movement had gained substantial momentum.

The introduction of the private automobile and its widespread acceptance extended to driving performance alcohol's potential to impair human behavior.

Given the social climate, it is not surprising that alcohol became suspect as a factor in traffic crashes. Observations of alcohol's role in highway mishaps were forthcoming as early as 1904 (The Quarterly Journal of Inebriety 1904). By the 1930s, amid increasing concern over the magnitude of the drinking-driving problem, the scientific study of the problem was defined and advocated. Heise (1934) outlined four basic approaches; one approach, **measurement of the amount of alcohol in the body,** supported both experimental and epidemiologic approaches. This was consistent with the fact that the presence of a substance in the body is necessary but not sufficient evidence of its effect. "As it turned out, the most critical variable for this purpose was **blood alcohol concentration,** or BAC, which describes alcohol presence in terms of the weight of alcohol found in a given volume of blood" (Jones and Joscelyn 1979a, p.2).

Technical advances in analytical chemistry supplied numerous qualitative and quantitative tests for alcohol. In its report to the 27th National Safety Congress in 1938, the National Safety Council Committee on Alcohol and Drugs (then known as the Committee on Tests for Intoxication) described chemical tests for alcohol in "blood, urine, saliva, breath, and spinal fluid. Test methods included the Heise Test, Widmark Micro-Method, Friedmann's Method, Harger Micro-method, Harger Breath Test and the Muehlberger Test" (National Safety Council 1978, p.3-4).

Holcomb (1938) conducted the first study to compare the BACs of a sample of drivers injured in traffic crashes with those of a sample of drivers not involved in crashes but using the same roads. He found that twenty-five percent of the crash-involved drivers were intoxicated by legal standards, but that only two percent of the drivers not involved in crashes were so intoxicated. Since then, a number of epidemiologic studies, both descriptive and analytic, have described the extent to which alcohol is involved in crashes of various levels of severity.

Descriptive epidemiologic studies are primarily concerned with the

distribution of traffic crashes and associated factors. Such studies indicate the frequency of involvement of drinking drivers in fatal crashes, serious injury crashes, and crashes involving only property damage. As recently reviewed by Jones and Joscelyn (1979a,b) findings show that approximately 40 to 55% of drivers fatally injured in traffic crashes have blood alcohol concentrations in excess of 0.10% w/v--the legal limit for alcohol-impaired driving in most states. Comparable figures for personal injury and property damage crashes are 9 to 13% and 5%, respectively. In the past, such data have been generalized (inaccurately) to statements that alcohol "causes" fifty percent of all traffic crashes. Such statements are not true, though alcohol use by drivers is clearly a substantial highway safety problem

Descriptive epidemiologic studies have also collected data pertaining to times and places of traffic crashes, as well as demographic and drinking variables for crash-involved drivers. "Driver and driving characteristics associated with a higher than average involvement--that is, those occurring with greater relative frequency--in alcohol-related serious crashes are:

- male sex,
- age of 20 to 60 years,
- heavy drinking,
- preference for beer over other alcoholic beverages,
- nighttime driving habits,
- weekend driving habits, and
- history of prior arrests for drunk driving" (Jones and Joscelyn 1979b, pp.89-90).

In the absence of comparisons with the larger driving population, however, the magnitude, or extent, of the drinking-driving problem remains unknown. This is the purpose of **analytic** epidemiologic studies, which interpret observed distributions of traffic crashes in terms of possible aggravating factors.

Analytic epidemiologic studies determine the prevalence of drinking both among crash-involved drivers and among noncrash-involved drivers. Depending on the depth of investigation, these studies may also examine

the distribution of other variables, such as drinking and driver characteristics, between the populations compared. These comparisons are crucial; for example, the frequency of drinking among crash-involved drivers could be the same as, or even less than, the frequency of drinking among all drivers. Without this comparison no statement of alcohol's influence on the likelihood of crash-involvement can be made.

Controlled studies of alcohol-crash risk (defined as the relative probability of a traffic crash involving drinking and its attendant losses) have compared the BACs of drivers involved in the various types of crashes and of drivers using the roads at approximately the same times and places of the crashes. Among the more rigorous of these studies were those by Borkenstein et al. (1964); Perrine, Waller, and Harris (1971); McCarroll and Haddon (1962); Holcomb (1938); and Farris, Malone, and Lilliefors (1976). These studies have consistently indicated the risk of being involved in a serious crash is much greater at BACs over 0.10% w/v than it is with no alcohol (Jones and Joscelyn 1979a,b). In addition, "characteristics of drivers with a higher than average risk of crashing after drinking a given amount are:

- female sex,
- youth (under 20 years old)
- old age (over 60 years old), and
- light drinking habits. (Jones and Joscelyn 1979b, p.90)

Epidemiologic research has thus demonstrated a strong relationship between alcohol and traffic crashes. Through experimentation, how alcohol impairs driving performance as well as possible interactions of alcohol and other factors associated with traffic crashes can be examined more directly.

2.2 Experimental Research: Studying the Effects of Alcohol on Skills Related to Driving Performance

Over the years, experimental research on the action of alcohol has characterized its pharmacological and behavioral effects both in man and animal. Of greatest interest, of course, are studies concerned with the effects of alcohol on human behavior, especially behavior related to

driving. The volume of relevant experimental research exceeds that of epidemiologic research, but the literature exhibits problems that prevent its becoming a unified body of information (Levine, Greenbaum, and Notkin 1973; Perrine 1974). For example, past research evidences a value-loading, or bias, in the design and conduct of studies where demonstration of **impairment** by alcohol was (apparently) the purpose of "experimentation." **Who** did the research becomes as important as the methods or findings themselves.

Another difficulty presented by the experimental literature on alcohol is the great variety of behavioral and other effects reported. As reviewed by Wallgren and Barry (1970), for example, the following are classes or types of alcohol's effects:

- electrophysiological (e.g., electroencephalogram [EEG], galvanic skin response [GSR], electrocardiogram [ECG, EKG]);
- sensory (e.g., visual sensation and perception);
- sensory-motor (ocular-motor, reaction time [simple and complex], tracking);
- motor (nystagmus, muscular steadiness and strength);
- verbal performance;
- problem solving;
- learning and memory; and
- emotions (motivation, mood).

Alcohol's effects on behavior involve a range of functions, from simple to complex. Some behavioral measures are deceptively "simple." For example, tests of reaction time can bring into play such factors as information processing and the ability to concentrate or to divide attention, depending on the method employed. The term **reaction time** itself may be one of the most misused in research on driver behavior. For instance, **timing** can be more important than quickness of response—a shortened time of response can be very dangerous in some driving

situations.

The literature describing alcohol's effects on behavior is often inconsistent, with occasional reports of improved performance conflicting with reports of behavioral impairment. Biphasic effects of alcohol, excitatory and inhibitory, have been described for certain behaviors, depending on time of testing and the dose of alcohol employed. In general, however, the depressant actions of alcohol result in decreased or impaired performance, especially at blood concentrations of alcohol at or above 0.08% w/v.

The time of testing and amount of alcohol taken are not the only variables that determine the kind and magnitude of alcohol's effects on behavior. "The response to the same alcohol dose may vary greatly in different situations and in different individuals" (Wallgren and Barry 1970, p.353). Thus, age, gender, skill, and personality differences among subjects can influence the effects of alcohol in experimental studies, especially at lower BACs (e.g., below 0.05% w/v). Even experimental settings and conditions can affect findings (e.g., Wallgren and Barry 1970, pp.353-358).

Experimental research designed specifically to examine the effects of alcohol on driving performance has relied on the following methodological approaches:

- one or more discrete behavioral tests to measure skills believed related to driving;
- driving simulators, simple or complex, to reproduce at least part of the actual driving task in the laboratory; and
- closed-course driving tests, including basic maneuvers that tap certain abilities used during actual driving.

As discussed in Workshop IV of this series, each approach has its advantages and drawbacks.

For example, a test-battery approach can measure a number of skills within a relatively short period of time without costly equipment (e.g., a driving simulator or an instrumented car) or extensive facilities. Discrete tests of behavior can measure performance variables related to specific

driving skills, for example, eye movements in a search and recognition task. This approach to measuring drug effects on driving performance may appear far removed from real-world driving, a task that integrates many skills and in which a driver can compensate for an impaired skill. Thus, results from these tests cannot easily be used to predict driver impairment at given BACs, though mechanisms by which alcohol impairs driving may be described more precisely.

Experimental research based on driving simulators and closed course driving has, perhaps, more "face-validity." Attempts to increase "realism" in tests of alcohol effects on driving performance, however, have not produced a totally consistent picture of alcohol's effects. The lack in consistency may be due to intersubject variability as well as differences in study design, experimental methods, task demands, dose and form of alcohol employed, and time of testing. Nevertheless, numerous studies have shown that alcohol impairs human performance in these "driving-like" experimental settings. For example, noting inconsistencies among results of driving simulator studies, Heimstra and Struckman (1974) still concluded that the studies indicate the impairment of higher mental functions as a major contributing factor to alcohol-induced decrements in driving performance. "Closed course driving experiments indicate that the ability of many drivers to perform parking maneuvers becomes impaired at low BACs (i.e., .04% to .06% w/v). Closed course driving performance at low speeds appears to be degraded for average drinkers at BACs of .08% to .10% w/v, but less so for heavy drinkers. Closed course driving performance at moderate speeds has been shown to be impaired at BACs as low as .05% to .07% w/v" (Jones and Joscelyn 1979a, p.49).

Experimental research has thus confirmed epidemiologic studies that point to alcohol as an important factor in traffic crashes. Many basic behaviors related to driving are impaired in most people at BACs equal to or greater than 0.08% w/v, and some people are impaired at 0.04% w/v. The accumulation of evidence indicates that alcohol can be a significant aggravating factor and suggests **how** the effects of alcohol can contribute to traffic crash-involvement.

2.3 Approaches To Reduce The Magnitude Of The Drinking-Driving Problem (Countermeasures)

Well before scientific studies indicated the nature and extent of the drinking-driving problem, preventive measures directed at the problem were developed and implemented.

In the decade following Prohibition, the public's awareness of highway safety problems, including alcohol, increased. In 1936, the National Safety Council established the Committee on Tests for Intoxication (name changed later to the Committee on Alcohol and Drugs). In succeeding years, the Committee proved a potent force in the area of alcohol and highway safety, even though "its role has been limited to developing recommendations for its control, including legislation, enforcement, education, chemical testing equipment, training of testing personnel, and other aspects of alcohol countermeasure programs (National Safety Council 1978, p.1). Table 2-1 presents a partial listing of the Committee's activity.

One participant emphasized that the National Safety Council was not alone in its efforts. The American Bar Association, the American Medical Association, the Traffic Institute, the National Committee on Uniform Traffic Laws and Ordinances, the New York University Center for Safety Education, along with a "host of local safety councils," contributed to what has been a **movement.**

The initial President's Highway Safety Conference in 1946 provided another impetus for action on the drinking-driving problem. This conference recognized alcohol as the greatest single human factor in traffic crashes and recommended that immediate action be taken. The following ten years witnessed a growth in activity against the drinking driver and increased use of chemical testing for alcohol (see Table 2-1). Federal awareness and interest continued to grow between 1955 and 1965, during which time an appointed committee in Congress studied problems in highway safety. As a result, the U.S. Congress passed the Highway Safety Act of 1966, bringing the U.S. Government into the alcohol and highway safety field.

In its 1968 report to Congress on alcohol and highway safety the U.S. Department of Transportation (1968) observed that a wide variety of

TABLE 2-1

A PARTIAL LISTING OF ACTIVITY BY THE NSC COMMITTEE ON ALCOHOL AND DRUGS, 1936-1977, AS WELL AS RELATED EVENTS*

YEAR	ACTION, RECOMMENDATIONS, OR RELATED EVENT
1937	"Motor Vehicle Intoxication Report" form developed for use by investigating officers and examining physicians (subsequently revised in 1939 and 1961).
1938	In collaboration with a special committee of the AMA (Committee to Study Problems of Motor Vehicle Accidents), Committee established chemical standards for the legal interpretation of "under the influence of alcohol" in terms of BAC or its equivalent: • less than 0.05% w/v, no influence of alcohol within the meaning of the law; • between 0.05% and 0.15% w/v, alcoholic influence usually present, but courts of law should consider driver behavior and circumstances leading to arrest; and • 0.15% w/v: definite evidence of "under the influence."
1939	Committee assisted officials in Indiana and Maine in developing legislation dealing with evidence obtained through chemical tests for alcoholic intoxication. (Indiana law passed in March 1939; Maine law passed in April 1939.)
1943	Final draft of "Model Legislation on Driving Under Influence" completed and submitted to the National Committee on Uniform Traffic Laws and Ordinances (model law adopted in 1944 for inclusion in the Uniform Vehicle Code; as of 1948, ten states enacted legislation in substantial accord with chemical test provisions).
1950	Completion of sponsored research at Michigan State University that confirmed comparability and reliability of chemical tests for alcohol in blood, breath, and urine.
1952	Resolution on "implied consent" provision for state laws forwarded to National Committee on Uniform Traffic Laws and Ordinances; resolution dealt with chemical testing as a condition precedent to the issuance of a driver license.
1953	State of New York passes first Implied Consent Law.

1954 45 states, 464 jurisdictions of 10,000 population or more using chemical tests to measure BAC; 18 states had passed chemical test statutes.

1957 U.S. Supreme Court upholds chemical analysis of blood for determining intoxication by alcohol (Breithoupt vs. Abram, 352 U.S. 432, 1957).

1962 The Uniform Vehicle Code amended to lower the BAC prescribed in state statutes for "under the influence," from 0.15% to 0.10% w/v, following recommendation developed by Committee in 1960.

1967 Committee finalized its "Model Program for the Control of Alcohol for Traffic Safety," requested by the U.S. Department of Transportation National Highway Safety Bureau.

1969 45 states had enacted some type of Implied Consent Law; only one state, Mississippi, had not enacted some kind of chemical test law. (Illinois became the 50th state to enact an Implied Consent Law in 1972.)

1971 Committee adopted position that a BAC of 0.08% w/v indicates impairment of driving performance.

1973 Committee provided a special review for the National Bureau of Standards on a proposed "Performance Standard for Quantitative Breath Alcohol Measuring Instruments".

1974 Under a contract from the National Highway Traffic Safety Administration (NHTSA), Committee members support federal alcohol-safety efforts, including a workshop on roadside survey methodology and reviews of the literature and proposed standards.

1975 Under the NHTSA contract, the Highway Safety Program Manual, Volume 8, "Alcohol in Relation to Highway Safety," is revised, among other tasks.

Committee approved a new definition of alcohol concentration for possible revision of the UVC:

"Alcohol concentration shall mean
(1) grams of alcohol per 100 milliliters of blood
(2) grams of alcohol per 210 liters of breath."

1977 During the 7th International Conference on Alcohol, Drugs, and Traffic Safety in Melbourne, Australia, an Award of Merit from the International Committee was presented to the NSC for its sustained support of activities in the field.

* Summarized from NSC report entitled "Recommendations of the Committee on Alcohol and Drugs 1936-1977" (NSC 1978).

preventive measures had been tried, but that scientific techniques had not been applied to development of control efforts or to measurement of their effectiveness. From 1968 to the present, federal intervention and support for highway safety programs grew. The Alcohol Safety Action Project (ASAP) represented a large-scale, ambitious program resulting from federal sponsorship; projects in thirty-five jurisdictions attempted to apply and evaluate countermeasures systematically.

Jones and Joscelyn (1979a) described five categories of programs that specifically address drinking drivers:

- Legal,
- Health,
- Public Information and Education,
- Technological, and
- Systems.

Based on legal concepts of **general** and **special deterrence,**the **legal** approach has been the primary approach to the drinking-driver problem. Legal approaches rely on the Traffic Law System (TLS) and its four functions (law generation, enforcement, adjudication, and sanctioning) (Joscelyn and Jones 1972).

In recent years, problem drinking (including alcoholism) has been increasingly recognized as a disease and a public health problem rather than a crime. As defined by Filkins (1969), the **health** approach had the following major functions: case-finding, diagnosis, prescription, treatment, follow-up, and evaluation. He recommended that the health and legal systems better coordinate their efforts to reduce the drinking-driving problem in a combined **health-legal** approach. In the combined approach, the legal system acts as the primary casefinder. Joscelyn and Jones (1971) further developed this concept, describing a Drinking-Driver Control System consisting of agencies of the TLS and an even more informal Alcoholism Control System that attempts to treat and rehabilitate drunken drivers. In practice, the health-legal system is complex, revealing a general lack of coordination among the various agencies involved. A recent report reviews the health-legal systems in terms of working and functional objectives (Jones, Joscelyn, and McNair 1979).

Termed "campaigns" in the literature, **public information and education** approaches have operated as countermeasures separately and in conjunction with other approaches. **Technological** approaches to the control of the drinking driver have been used almost entirely to support legal and health approaches. Devices that measure alcohol in breath or blood are examples of specific applications of technology to this problem.

The **systems approach**, distinguished by its emphasis on the problem as a whole rather than on its component parts, was applied in the area of alcohol and highway safety in the Joscelyn and Jones analysis of the so-called Drinking Driver Control System (Joscelyn and Jones 1971). The nationwide Alcohol Safety Action Project also attempted the systems approach (McKnight, Adams, and Personeus 1971), in an effort to tie together the four existing approaches described above.

Unfortunately, the lack of adequate evaluation allows only the most guarded conclusions about the effectiveness of any of the above approaches. For example, in their recent review of alcohol and highway safety, Jones and Joscelyn (1979a) concluded the following:

> - The targets of programs that have followed these approaches have usually been defined only in general terms, for example, all drunk drivers, social drinker-drivers, problem drinker-drivers.
>
> - To date only one large-scale alcohol-safety program, the British Road Safety Act of 1967, has clearly been shown to have reduced crash losses involving drinking drivers and the effects of that program were transitory.
>
> - The state of knowledge about fundamental hypotheses upon which most past alcohol-safety programs have been based is totally inadequate for designing and operating effective programs. . . .

This lack of knowledge is not unique to the field of alcohol-safety. Efforts to apply the legal and health approaches to controlling other forms of individual and societal risks (e.g., crime, drug dependence) are also hampered by similar informational deficiencies (p. 189).

2.4 Measuring The Drinking-Driving Problem: The Central Role Of Blood Alcohol Concentration (BAC) and Technology For Alcohol Analysis

One element of the overall alcohol and highway safety experience cannot be overemphasized: **blood alcohol concentration** (BAC), in its role as an objective measure of alcohol presence and effect.

Efforts both to determine the nature and extent of the drinking-driving problem and to reduce its magnitude depended on measures that described the problem. The basic issue addressed has been **impairment**--the point at which an operator of a motor vehicle drives in a condition that increases the risk of a traffic crash beyond an acceptable level.

The development of measures of impairment proceeded along two lines: (1) behavioral tests and (2) chemical tests of alcohol concentration in body fluids. Early work focused on driver behavior and the driving task. Impaired drivers were detected and described by their physiological condition and observed behavior. In addition to impaired driving itself (e.g., weaving, slowing and speeding, etc.), behavioral measures were based on the performance of certain tasks, such as walking a straight line or standing steady with the eyes closed. For a period of time, efforts to develop standardized behavioral techniques for measuring impairment progressed. One recent result in this area has been the technique of photographic recording of impaired driver behavior (e.g., movie, video-tape, etc.).

Difficulties with a purely behavioral approach arose. Researchers had not precisely defined the driving task and characteristics of its impairment. In particular, as participants stressed, such qualitative measures of driving and driver impairment were not readily accepted into enforcement and judicial systems. Behavioral methodology simply lacked the credibility necessary for use as sole evidence in court. The reliability of behavioral tests was in doubt. "Studies have shown that physicians' use of conventional psychomotor tests for intoxication may result in inaccurate diagnoses perhaps as much as 50% of the time" (McCarroll and Haddon 1962). Use of such behavioral tests by police officers to identify intoxicated drivers is further complicated by the drivers' high motivation to avoid arrest. The result is often an increased ability to mask the

influence of alcohol on body sway, walking a straight line, and other tests of coordination" (Jones and Joscelyn 1979a, p.9).

Blood alcohol concentration (BAC) became accepted as the most objective measure of driver impairment by alcohol. The NSC Committee on Alcohol and Drugs was instrumental in gaining widespread support for enactment of laws giving legal meaning to BACs (e.g., 0.10% w/v). This body also sponsored research on the development and testing of technology to measure BAC through breath analysis. In fact, "breath-alcohol analysis technology has had an enormous impact on the entire field of alcohol safety, providing a relatively convenient means for quantifying what is certainly the most important single variable describing alcohol-impairment: blood alcohol concentration. Without the technique, it is doubtful that either of the legal or the health/legal approaches, as known today, would be possible" (Jones and Joscelyn 1979a, p.170).

The intent underlying the legal BAC limit was simply to make convictions for driving-while-intoxicated easier to obtain and to get the drunken driver off the road. Behavioral measures and testimony about impaired driving (often referred to as "the reasonable and prudent man philosophy") did not prove effective and thwarted efforts to use the legal approach. The definition of a BAC limit encouraged the collection of additional, more objective evidence of impairment by enforcement officers and aided the obtaining of convictions. (Participants noted that individuals can be impaired well below statutory BAC limits, e.g., 0.10% w/v, but pointed out that the average BAC found upon arrest is generally much higher, about 0.15%-0.20% w/v, since higher BACs make convictions easier to obtain.)

Participants emphasized that the development, use, and public acceptance of BAC as a measure of driver impairment is a key element in the alcohol and highway safety experience. "Impairment" became operationally defined by the amount of alcohol present. In fact, as of December 1978, twelve states have passed so-called "per se" laws, which make driving with a BAC exceeding a given value illegal in itself; impairment is not even considered in terms of behavioral evidence of driving disability. Historically, emphasis on the BAC interrupted the

development of behavioral measures based on the driving task or human performance. The BAC concept, in assuming legal meaning and significance for enforcement, adjudication, and sanctioning, greatly influenced the direction of the alcohol and highway safety experience, both in research and in preventive measures.

2.5 Summary

Participants outlined the alcohol and highway safety experience to provide a basis for discussing its applicability to drugs other than alcohol. The purpose of these discussions was to identify major elements of the alcohol-safety experience.

Epidemiologic and experimental approaches were used in research to define the drinking-driving problem. Before scientific studies described the nature and extent of the problem, however, efforts were underway in response to a perceived problem. The National Safety Council Committee on Alcohol and Drugs contributed much to the public's awareness and desire for action. By the time Borkenstein et al. had completed their landmark case-control study in Grand Rapids, most states had already passed implied consent laws.

The U.S. Government entered the alcohol-safety field with the passage of the Highway Safety Act of 1966. The Alcohol Safety Action Project was launched soon afterward. Despite its scope and level of funding, ASAP's effect on the drinking-driving problem remains unclear. But few other programs--large- or small-scale--have proven any of the countermeasure approaches effective.

The central element in the alcohol and highway safety experience was the objective measure of driver impairment by alcohol: **blood alcohol concentration** (BAC). Techniques to measure BAC advanced both research to define the drinking-driving problem and societal responses to the problem.

3.0 A GENERAL FRAMEWORK FOR ALCOHOL, OTHER DRUGS, AND HIGHWAY SAFETY

Research defining the relationship between alcohol and highway safety and societal responses to the drinking-driving problem have at times been termed the "alcohol model." In policy formulation, the **alcohol model** has been used as a paradigm for planning future efforts not only for alcohol but for other drugs as well. Participants of Workshop V found the word "model" inappropriate, since it has many uses and different connotations. They pointed out that the alcohol and highway safety **experience** includes methodology, measures, and relationships between alcohol and traffic crashes. In their view, these items constituted a set of discrete categories and elements rather than a model per se.

The following major categories were drawn from prior discussion of the alcohol and highway experience:

- risk identification;
- risk measures; and
- preventive measures, including their evaluation.

Participants considered these categories broad enough to form a general framework in which to discuss both alcohol and other drugs in the context of highway safety. Section 3.0 further defines and discusses these categories.

3.1 Risk Identification

In the context of highway safety, **risk** has been defined as the probability of a traffic crash and attendant losses. **Risk identification** is the process by which factors associated with traffic crashes are identified. As discussed in Section 2.0, research on the relationship between alcohol and highway safety has used two complementary approaches, epidemiology and experimentation. Both approaches have served to determine the nature and extent of the drinking-driving problem

and to indicate the increased likelihood of traffic crashes attributable to alcohol. For other drugs, these basic approaches have also been applied to estimate (1) their potential to increase risk to highway safety and (2) their prevalence in different driving populations, both accident- and nonaccident-involved.

Experimental research similar to that done on alcohol has measured the effects of other drugs on behavior believed related to driving performance. Findings of strong drug effects indicate **potential** risk to highway safety; findings of statistically significant drug effects may not indicate a substantial risk potential, especially if the magnitude of measured effects is not great. Experimental studies also serve to describe **how** a drug may affect driving performance, for example, by indicating specific skills or mechanisms by which a drug influences behavior.

In the process of risk identification, epidemiologic studies complement experimentation and vice versa. In the case of drugs and driving, the objective is to determine whether drug-impairment of drivers is causing significant traffic crash loss and, if so, how much loss and under what circumstances. The first step in the process involves an examination of the prevalence of a performance-impairing drug among crashed drivers. If the prevalence is very low, then the drug may not represent a serious traffic crash risk, and further study to determine the number of the crashes that were caused by drugs usually is not warranted.

A relatively high prevalence of the drug among crashed drivers is indicative that further study is needed to determine how many of the crashes that **involved** the drug were actually **caused** by the drug. This often involves a second step in which drug use among drivers who have crashed and drug use among drivers who have not crashed are compared. If the percentage of drug use among the crashed drivers is higher than the percentage of drug use among the noncrashed drivers, **and** these two groups of drivers are alike in every respect except their drug use, then there is reason to believe that drugs are actually causing at least some of the crashes in which they are involved.

Estimation of the actual number of crashes (or crash losses) that may

be expected to be caused by the drug in a given time period follows. Causation is said to occur when the fraction of crashes involving drug use by drivers and a given set of other factors is greater than the fraction of crashes not involving drug users and the same set of other factors. These two fractions also may be expressed as conditional probabilities. Algebraically, this condition for causation may be written as:

$$P(C|D) > P(C|\bar{D}), \text{ or} \tag{3-1}$$

$$\frac{P(C|D)}{P(C|\bar{D})} > 1, \text{ or} \tag{3-2}$$

$$P(C|D) - (P(C|\bar{D}) > 0 \tag{3-3}$$

where

$P(C|D)$ = the conditional probability of a crash given the drug and a set of other factors, Fo

$P(C|\bar{D})$ = the conditional probability of a crash given no drug and the set of other factors, Fo

The left-hand side of the inequality 3-2 is called the **relative risk** by epidemiologists, and the left-hand side of 3-3 is called the **attributable risk.** Clearly, then, the expected number of crashes caused by the drug each year is the product of the number of crashes that occur each year and the attributable risk.

Unfortunately, the data needed to estimate the values of these two conditional probabilities are difficult to obtain. Strictly speaking, the data would require a controlled experiment in which two groups of drivers who were alike in every respect except their use of the drug would be allowed to drive for a given period of time in identical driving environments. Conceptually, an ideal survey in which such groups could be identified could be conducted, thus keeping the study within the realm of epidemiologic rather than experimental research. The number of crashes experienced by each group would be counted and divided by the number of drivers in the respective group, and estimates of the two probabilities would be obtained.

Obviously, such an ideal experiment could not be conducted in the real world because of practical as well as moral and ethical considerations.

The practical limitations arise because of the impossibility of designing an experiment in which all "other factors" are identified and controlled. Thus, the role of drug use in causing a crash will always be subject to uncertainty, and one will never be able to say exactly how many crashes are actually caused by a drug. The ideal survey is impractical, but could be approximated through the use of cohort groups as is discussed later in this chapter.

Attempts are sometimes made to estimate the attributable risk associated with a given factor directly from so-called clinical analyses of accident data. In this approach, individual traffic crashes are examined by trained analysts who make informed judgments about causation (Treat et al. 1977). If the crashes form a representative sample of crashes nationwide, then attributable risk is simply the fraction of the crashes examined that were judged to have been caused by the factor (for example, a given amount of a given drug).

A major shortcoming of the clinical approach is its reliance on the judgment and intuition of the analysts who may not recognize some of the subtle mechanisms in the chain of causes that lead to the crashes. Also, because only crashes are examined, a factor that may often prevent a crash may be considered only as a cause of a crash. The beneficial effect of the factor is thus not accounted for, a particularly strong shortcoming in the case of some therapeutic drugs.

These difficulties in determining **attributable** risk have led epidemiologists to back up one step and compute **relative** risk as an indicator of the degree to which crashes that **involve** a factor are actually **caused** by that factor. While relative risk involves the same two conditional probabilities as attributable risk, it turns out that the ratio of the two probabilities is much easier to come by than their **difference.** Instead of counting crashes among drug users and nondrug users, one counts drug users and nondrug users among crashed drivers and noncrashed drivers. Relative risk is then approximated by the expression:

$$R_R(D) = \frac{P(C|D)}{P(C|\bar{D})} \approx \frac{P(D|C)/P(D|\bar{C})}{P(\bar{D}|C)/P(\bar{D}|\bar{C})} \quad (3\text{-}4)$$

where

$R_R(D)$ = relative risk of the drug

$P(D|C)$ = the conditional probability of the drug and Fo given a crash

$P(D|\bar{C})$ = the conditional probability of the drug and Fo given no crash

$P(\bar{D}|C)$ = the conditional probability of no drug and Fo given a crash

$P(\bar{D}|\bar{C})$ = the conditional probability of no drug and Fo given no crash

The operational requirements for computing these four factors also present difficulties to the epidemiologist, but the problems appear to be much less severe than those encountered in estimating $P(C|D)$ and $P(C|\bar{D})$ directly. Nevertheless, no epidemiologic study has yet provided reliable estimates of relative risk for drugs other than alcohol. Attributable risk has not been reliably determined even for alcohol.

In discussing the process of risk identification for drugs, the panel stressed the necessity of studying populations of crash-involved drivers other than those fatally injured. One participant noted that drugs other than alcohol do not appear overrepresented in fatal accidents in foreign studies. No large-scale surveys have been attempted, however. In addition, some drugs such as marijuana were not detectable. Given these qualifications, caution seems indicated in basing conclusions about the highway saftey risk of drugs only on studies of fatally injured drivers.

Participants cautioned, that substances that can impair driving performance are numerous, while time and funding available for their study is limited. Accordingly, the panel pointed out the necessity of specifying a range of drugs for further investigation. (This was one objective of Workshop I, The Identification of Drugs of Interest in Highway Safety. Workshop I participants (1) developed a procedure to

estimate the potential of drugs to increase the likelihood of traffic crashes and attendant losses, that is, their **risk potential**; and (2) produced a rank ordering of identified drugs of interest based on subjective estimates of risk potential.)

Participants then outlined several approaches to indicate the increased likelihood of traffic crashes due to drugs. Detailed discussion of these approaches was avoided because this topic was the focus of prior workshops in this series devoted to epidemiology and experimentation in drugs and highway safety. The purpose of their discussion was to illustrate the process of risk identification with the following general methodologies:

- laboratory tests of drug effects on skills related to driving (experimental research);
- descriptive epidemiologic studies;
- case-control studies (also termed "case history studies" [MacMahon, Pugh, and Ipsen 1960]); and
- cohort studies.

Laboratory testing of drug effects on skills related to driving constitute the area of experimental research. One participant pointed out that a number of paradigms have been identified as limiting factors in safe driving performance. For example, the information-processing and the divided-attention paradigms are applicable to city driving; the drowsiness paradigm is relevant to long-distance or highway driving. The panel expressed the viewpoint that much useful information could be gained from laboratory studies of human performance that indicate the highway safety risk potential of various drugs.

Descriptive epidemiologic research involves efforts to profile drug-involved traffic crashes and responsible drivers. Essential is the disaggregation of accident data. Important variables include:

- type of crash (fatal, degree of personal injury, property damage only);
- driving environment (urban, rural, traffic density);

- high-, low-speed impact;
- time of day;
- day of week;
- weather condition;
- age;
- gender;
- socioeconomic status;
- marital status; and
- driving history.

Profiling the crash-involved, drug-using driver provides a way of defining the driving population of interest. The disaggregation of data into victim profiles also sets directions for future preventive measures if justified by research that establishes one or more drugs as priority targets for countermeasure action.

Another descriptive method of risk identification was the more extensive use of secondary sources of exposure data. For example, researchers could examine the annual prescription and refill volume for drugs. Participants suggested that a small positive correlation between number of prescriptions and prevalence in the driving population could be expected. Data pertaining to the use of drugs among fatally injured and impaired drivers from offices of medical examiners and coroners and police agencies might also be assembled and analyzed.

The following analytic epidemiologic approaches were mentioned:

- the case-control study (also termed case-history study [MacMahon, Pugh, and Ipsen 1960]); and
- the cohort study.

The case-control study provides the data needed for calculating relative risk, while the cohort study provides the data needed for calculating attributable risk in addition to relative risk.

One example of the case-control approach often referred to by participants was the landmark survey conducted by Borkenstein et al. (1964, 1974). The Grand Rapids study (as it is called) featured roadside stop procedures as a means to obtain a sample of nonaccident drivers present at the time and location of fatal and nonfatal personal injury crashes. Breath specimens were obtained to compare the presence and amount of alcohol in both accident and nonaccident populations. Crash and driver characteristics were also identified and analyzed.

In discussing this approach, some participants expressed their preference for the descriptor **case-contrast** over "case-control." They emphasized that this term did not simply represent a shift in semantic fashion. Rather, it served to indicate the inherent limitations of this type of study. A case history study--as termed in the epidemiologic literature—is **retrospective** "and involves 'looking backward' from effects to preceding causes . . ." (MacMahon, Pugh, and Ipsen 1960, p.45).

Practical constraints in epidemiologic research using this approach usually--if not always—prevent the rigorous control over critical variables that is associated with experimentation. For example, groups of nonaccident drivers selected for comparison with a sample of crash-involved drivers defined as "cases" rarely, if ever, approximate the degree of subject matching possible in experimental research. The word "control" implies closer comparisons than actually possible. Thus, the word **contrast** (1) emphasizes the absence of control over many potentially relevant factors that may contribute to crash-involvement and perhaps (2) lessens the tendency to expect simplistic cause-and-effect relationships to emerge from this kind of research.

The other general approach in analytic epidemiology is the **cohort study,** referring to an investigation over time of a group of individuals defined according to the presence or absence of exposure to risk factors—here, the use of drugs—hypothesized to increase the likelihood at traffic crashes. A cohort study is **prospective** in that it "involves 'looking forward' from supposed causes to subsequent effects" (MacMahon, Pugh, and Ipsen 1960, p. 45). An example of a cohort study might be a longitudinal study of crash-involvement in a group of drivers chronically

using a drug compared to a suitable sample of drivers who do not use drugs.

In outlining these approaches to risk identification, participants acknowledged constraints on drug and driving research. For example,

- In epidemiologic research:
  - -- limited funding
  - -- lack of cooperation by driver-subjects
- In experimental research:
  - -- absence of validated measures of driving performance in laboratory testing
  - -- restrictions on use of human subjects that preclude testing of drug effects on representative groups of drivers who use certain drugs of interest (e.g., females of childbearing age)

3.2 Risk Measures

The process of risk identification defines the nature and extent of a drug and driving problem and indicates the highway safety risk attributable to alcohol and other drugs. Required are criteria by which to determine when an operator of a motor vehicle drives in a condition that increases the risk of a traffic crash beyond an acceptable level. This is the function of risk measures, the second category of the conceptual framework.

Measures of risk operationally define that reduction in the ability to drive safely which increases the likelihood of a traffic crash. Two methodologies for measuring driver impairment were identified by the workshop panel: chemical tests for detecting and quantitating substance presence and behavioral tests of driver impairment.

For the purposes of highway safety, chemical measures of substance presence require that drug concentrations in blood and other body substances be correlated with impairment of driving performance. The concept of a presumptive limit, for example, 10% w/v, has been

established for alcohol. Experimental studies of drug effects on driving performance are needed to correlate body fluid concentrations of drugs (and active metabolites) with results of behavioral testing. ("Active metabolites" are chemical compounds that are produced from the parent drug by metabolism in the body and that have pharmacological activity in their own right.)

Some panel members were pessimistic about defining presumptive limits for all drugs of interest in biofluids; one participant expressed the belief that for 90 percent of these drugs, possibly more, it may be impossible to develop a BAC-equivalent in the foreseeable future. Difficulties in establishing presumptive limits for drugs other than alcohol stem from (1) their physicochemical properties and (2) lack of correlation between their concentrations in body fluids and their behavioral effects.

Prohibitive analytical requirements for detecting and quantitating drugs in body fluids and the costs associated with routine analyses may indicate that alternative approaches to developing measures of driver impairment are more feasible. The panel discussed behavioral measures of performance as another approach to the measurement of driver impairment. This approach involves ways of measuring impairment and correlating it with driving safely; there is no absolute requirement to relate impairment to specific drugs and specific drug concentrations.

Participants stressed that behavioral tests of human skills must be appropriate to the variable of concern, that is, driving performance. In this approach, as used in dealing with the drinking-driving problem, critical components of driving performance must be specified and impaired driving must be carefully defined. A battery of tests might be developed and validated to measure impairment of behavioral functions critical to actual driving. Among the types of tests that might be included are the following: tests for vigilance and attention, for associative capacity, for verbal memory, and for rate of information processing; standing steadiness (motor control); decreased hazard recognition (risk-taking); and speed of response. (Workshop IV, Experimentation in Drugs and Highway Safety: The Study of Drug Effects on Skills Related to Driving, focused on this and other related issues.)

The panel noted that for behavioral tests of driver impairment to be successful and acceptable for the purposes of highway safety, such measures should not test learning or intelligence. In addition, these tests should measure gross rather than subtle impairments; their interpretation should be unequivocal. The examples cited above fit such requirements. Moreover, measuring gross impairment as a strategy for detecting and apprehending impaired drivers does not focus upon the etiology of specific causative agents and is thus general.

The panel recognized difficulties associated with an approach based on behavioral measures of risk. One problem pertains to the use of behavioral measures in law enforcement. A complicated test battery would not be suitable for law enforcement purposes; only if tests were simple and easy to administer (and, of course, valid) would they be practical for use in the field by an enforcement officer.

Another legal problem involves the adjudication process. Participants expressed concern about the difficulty of obtaining convictions for driving under the influence based solely on behavioral evidence, that is, the subjective reports of enforcement officers. One participant suggested an approach used in California as one way to deal with this issue. In that state, a driver may be stopped for probable cause and arrested for an alcohol-impaired driving violation. If, after arrest, it is determined by chemical tests of body fluids that a substance other than alcohol that can impair driving is involved, a more serious charge, such as driving under the influence of drugs, can be placed.

An approach to developing behavioral tests more acceptable for use as evidence of driver impairment was suggested. With BAC as an index of impairment, norms of performance decrements accompanying a BAC of, for example, 0.10% w/v, could be established for a number of simple tests related to driving ability, such as standing steadiness and reaction time. Using these tests at roadside for evaluating a suspected drug-impaired driver, an officer could detect impairment exceeding that associated with the legally established BAC limit. Because performance on these tests would be linked to BAC, behavioral evidence based on results of their use may be more persuasive. This approach requires the development of a

set of behavioral measures related to critical aspects of the driving task and validated with respect to actual driving. The tests of driving-related skills should be general because many drugs (and other conditions, such as disease) that can impair driving ability have profiles of behavioral effects different than that for alcohol. In other words, the set of behavioral measures should be general with respect to driving performance and not aimed at detecting only those effects produced by alcohol.

In summary, the panel noted that whatever risk measures are chosen--chemical or behavioral--selected measures must be reliable and valid; they must be relatively easy to apply. Moreover, risk measures must serve one's purpose well (i.e., detection of driving skill impairment); they must yield a minimum of false positives and of false negatives. This is important both for the risk identification process and for possible preventive measures.

3.3 Preventive Measures and Their Evaluation

The third element of the general framework for alcohol, other drugs, and highway safety, **preventive measures**, represents the societal response to an identified problem. This category represents an unfinished chapter in the alcohol and highway safety experience. Attempts to deal with increased risk due to alcohol and other drugs may be grouped in three subcategories:

- the substance itself;
- the delivery system; and
- the population of users.

Responses directed at the problem substance are usually designed to decrease its availability within a population. For example, alcohol may only be sold during designated hours in most communities; likewise, legal age limits have been set for the sale of alcoholic beverages within each state. The most extreme form of preventive measures focused on the substance is prohibition of the substance. This tactic applied to alcohol had little effect on the drinking-driving problem (U.S. Department of Transportation 1968, p. 77-78).

Some parallels for restricting the availability of other drugs already

exist. Again, the most extreme form of restriction is the prohibition of drugs (e.g., cocaine, heroin, marijuana); possession of these illicit drugs alone is sufficient to constitute a criminal offense. The manufacture, marketing, and distribution of many licit drugs is also restricted through federal regulations and the scheduling of drugs with abuse potential (e.g., codeine, diazepam).

Responses directed toward the delivery system of the substance make use of an elaborate regulatory system concerned with both **availability** and **liability.** Retail outlets and drinking establishments must be licensed for the delivery of alcohol; control over conditions of sale is also exercised; for example, location, hours, and price are all subject to local restrictions. Moreover, civil liability exists for persons who provide alcohol to those already inebriated or those under the legal age limits.

Formal delivery systems that exist for dispensing drugs other than alcohol may prove to be a good target for preventive measures. The prescribing of drugs is one area to which civil liability applies; the physician, dentist, and (in some states) the pharmacist are responsible for adequately warning patients about the known effects of a substance on driving ability. Other responses aimed at the delivery system could be directed at the manufacturing system; if a new drug impaired driving-related skills, it might be feasible to prevent a drug's entry to the market or to restrict its availability through others controls, such as scheduling.

The **user** is the third identified target of responses to reduce the highway safety risk attributable to alcohol and other drugs. This group of societal responses makes use of the legal system to deal with alcohol- or other drug-impaired drivers as well as PI&E campaigns directed toward the general population.

The processes of detection and apprehension, adjudication, and sanctioning have been commonly employed with the impaired driver. This legal approach applied to alcohol has relied greatly on BAC from detection through sanctioning. More recently, the BAC has been used in case-finding for referral to and treatment in the health system.

Public information and education campaigns, such as those used in

some ASAPS, have used mass media, school settings, etc., to educate the public about the hazards of driving while intoxicated. Similar informational approaches could be used for other drugs via physician's offices, pharmacies, etc.

Evaluation of preventive efforts is a necessary step in this general framework discussed by the workshop panel. One participant remarked that impression and assumption, rather than scientific evaluation, have been used too often in the public sector. A plethora of highway safety measures could be introduced, and traffic crashes might decline; law enforcement officials would then be hesitant to change any one measure since that might be the effective one. It was further noted that methodology now exists for evaluating the components and interactions among components of prevention programs. The ASAPs, for example, did attempt to introduce some modern quantitative evaluation techniques into the arena of highway safety. Further use of this methodology might allow for the phasing out of ineffective measures and the augmenting of effective ones. Because these techniques have not been extensively employed, their degree of applicability in highway safety has not been established.

3.4 Summary

The alcohol and highway safety experience suggests a general framework for alcohol, other drugs, and highway safety. Three main categories were identified by the panel: risk identification; risk measures, and preventive measures.

The process of risk identification involves:

- estimating the potential of drugs to increase the likelihood of traffic crashes and attendant losses;
- studying the characteristics of drivers who use drugs and of crashes involving them;
- determining the prevalence of drugs among different driving populations, including drivers involved in fatal, personal injury, and property damage crashes; and
- measuring both the relative risk and attributable risk

associated with the use of drugs by drivers.

The methodologies of experimentation and epidemiology are basic tools used in risk identification.

Measures of risk comprise the second category of the general framework discussed by the panel. The purpose of risk measures is to define the point at which the operator of a motor vehicle drives in a condition that increases risk beyond an acceptable level. Two approaches to the development of risk measures for alcohol and other drugs were identified: chemical tests for drugs and behavioral tests of impairment. For alcohol, the emphasis has been on BAC, determined by blood or breath analyses.

Societal responses to reduce highway safety risk attributable to alcohol and other drugs make up the third category of the general framework. Preventive measures have been directed at the substance, its delivery system, and the user. Participants noted that evaluation of preventive measures has been infrequent at best. Nevertheless, without evaluation, a rational approach to dealing with an identified problem is impossible; lack of evaluation mitigates any systematic program to deal effectively with the problem.

Based on the alcohol and highway safety experience, this section has outlined a general framework for discussing alcohol, other drugs, and highway safety. Alcohol and other drugs, however, differ in their use, effects, and user populations. Differences between alcohol and other drugs, discussed at length in the next section, include the relative ease of breath analysis for alcohol and the use of most other drugs as therapeutic agents in the treatment of disease. It is important to assess these and other differences in evaluating the applicability of the alcohol and highway safety experience to other drugs. This is the intent of the next section.

4.0 A COMPARISON OF ALCOHOL WITH OTHER DRUGS

Alcohol is one of many drugs. As a drug, alcohol may be discussed generally along with other substances in terms of pharmacology or sociology. But, as the panel indicated, total or blind reliance on the alcohol experience in highway safety is unwarranted for other drugs.

Alcohol is a unique drug both in a chemical sense and in its use. Alcohol is a small, simple molecule; its chemical properties and its presence in large amounts permit its detection and measurement by (relatively) noninvasive techniques, for example, breath testing. The chemical properties of other drugs not only differ from alcohol, but also vary considerably among and within their many diverse classes. The analysis for other drugs in body fluids is more complex and requires methods based on blood testing.

In general, alcohol is socially accepted, widely available, and widely used, irrespective of most economic and social variables. The patterns of use for other drugs are more complex and less well-defined. Licit and illicit drugs are not widely used relative to alcohol consumption. Society sanctions the medical use of licit drugs but not the nonmedical use of drugs other than alcohol, caffeine, and nicotine. Consequently, the use of most drugs other than alcohol is a sensitive personal, even legal, issue for many people.

Alcohol and other drugs differ--often profoundly--in their use, effects, and the characteristics of user populations. How these differences affect the design and conduct of research on drugs other than alcohol and highway safety has not been widely discussed in the literature. Participants in Workshop V identified differences between alcohol and other drugs and evaluated these differences in terms of the general framework presented in Section 3.0. This section presents the comparison of alcohol with other drugs. Table 4-1 provides a capsule summary of this discussion.

TABLE 4-1

COMPARISONS BETWEEN ALCOHOL AND OTHER DRUGS

Alcohol	Characteristic	Other Drugs
Single chemical entity	CHEMISTRY	Numerous, diverse chemical entities, some substances (e.g., marijuana, opium) are complex natural products. There are many different classes of drugs.
Small, simple molecule		The chemical structure of most other drugs is complex.
A general depressant that may have both excitatory and inhibitory effects (biphasic action). The effects are dose and time dependent.	PHARMACODYNAMICS (effect of a substance on the body)	Most drugs have more selective action than do general depressants. There are a wide range of effects: depression, stimulation, analgesia, hallucination, antianxiety action, etc. Also dose and time dependent.
Tolerance and dependence		Tolerance and dependence are seen for some drugs or classes of drugs. Some drugs show enhanced potency with chronic use.
It is absorbed rapidly, distributed like total body water (at equilibrium), enters metabolism of the body (energy source), and is excreted in the urine and breath.	PHARMACOKINETICS (effect of the body on a substance)	Pharmacokinetics of other drugs is much more complex. Great variations from drug to drug in the rates of absorption, distribution, metabolism, and excretion. Most drugs are present in the body in both active and nonactive forms. Other drugs are metabolized primarily in the liver. Compounds with pharmacologic activity can be produced from the parent drug (active metabolites). Most drugs (or their metabolites) are excreted in the urine or bile. Due to low volatility, almost all other drugs are not found in the breath in significant amounts.
The most common use is recreational (e.g., social drinking), but other patterns exist, including alcoholism.	USE OR EXPOSURE in the general or driving population	Patterns of use for drugs include: recreational (e.g., marijuana, cocaine), therapeutic, illicit use or misuse of therapeutic drugs, and self-medication.

TABLE 4-1

COMPARISONS BETWEEN ALCOHOL AND OTHER DRUGS (Continued)

ALCOHOL	CHARACTERISTIC	OTHER DRUGS
Its use is widespread with general acceptance of alcohol use but not of abuse. The frequency and quantity of use varies from heavy drinking to infrequent consumption. Only about 30% of the general population abstains from alcohol use.	AVAILABILITY	Almost all drugs are much less-widely used than alcohol. The therapeutic use of drugs, but not their nonmedical use, is sanctioned by law. Patterns of drug use are not well defined for most drugs.
Available through relatively loosely controlled retail outlets (like an "over-the-counter" drug) with age limits for purchase.		Federal and state governments regulate production, marketing, and availability of controlled substances, as well as most other drugs. Licit drug distribution is through the health-care system (primarily through physicians and pharmacists) while illicit drug sales are through "street marketing" (e.g., marijuana).
Alcohol users reflect the total population (in terms of age, socio-economic level, etc.).	USER POPULATION	The characteristics of the drug user population varies according to the drug and its legal status.
There are relatively simple tests available to detect and quantitate the amount of alcohol in breath, blood, urine, and other body substances. Alcohol, which is present in relatively large amounts, can be analyzed using portable breath-testing instruments.	CHEMICAL TESTS on body fluids or breath	Analysis is relatively complex for almost all controlled substances. Instrumentation is expensive and nonportable. Presently, blood specimens are required to determine amount of drug present in the body. Only minute quantities of these psychoactive drugs are required to produce measurable effects.

4.1 Comparisons Based on Substance

Although alcohol is a drug, it is a drug with special properties. The dissimilarities between alcohol and other drugs have implications for the kinds of risk measures that are developed and the preventive measures that are applied within the general framework for studying alcohol, other drugs, and highway safety.

The effects of alcohol--pharmacological and behavioral—differ from most other drugs. Its pharmacological effects may be discussed in terms of its pharmacodynamics (the effects of a substance on the body) and its pharmacokinetics (the effects of the body on the substance). Pharmacodynamically, alcohol is a general depressant, but depending on the dose and time of testing, may have excitatory and inhibitory effects (biphasic action). Drugs with other than purely depressant effects have different profiles of effects. With respect to pharmacokinetics, rates of absorption, distribution, metabolism, and excretion vary among drugs. Pharmacokinetic variables influence the time course and intensity of drug effects. These basic differences in kind and duration of action express in effects on behavior.

Differences in behavioral effects occur, and may be pronounced when acute and chronic administration are compared. Research indicates that tolerance to some drugs may exceed that observed with alcohol. Although intersubject and intrasubject variability is observed experimentally with all drugs, much greater variability seems to exist for drugs other than alcohol.

The physicochemical properties of alcohol contribute directly to the ease of its detection and quantitation. At equilibrium, it is distributed like body water, and one can analyze a person's breath or blood and estimate the alcohol concentration in other body tissues. This has led to a reliance upon BAC as a fundamental risk measure in highway safety. With no known exceptions, this is not the case with other drugs. One participant remarked that, given the state of the art today, a specimen of blood is required if meaningful quantitative results for drugs other than alcohol are desired. No noninvasive method designed for the detection of

drugs other than alcohol and usable by nontechnologists (e.g., the Breathalyzer®) currently exists—nor are such methods likely to exist for the forseeable future.

Even if drug concentration data were obtained in a case of impaired driving, it would not be definitive in most cases. Nevertheless, this kind of information is essential in the risk identification process. As one participant commented, the ability to detect and quantitate drugs now exceeds the ability to understand what that measured amount means. The concept of the BAC has been easy to understand; the effects of drunken behavior are readily apparent and observable to most everyone. That is not the case with other drugs. The influence of many drugs upon performance, and especially upon driving performance, is relatively subtle or not yet defined. In many instances, even the minimum blood concentrations for behavioral effects are not known. Certainly no operational definition of impairment equivalent to a BAC of 0.10% w/v is—or can be—established at this time for most drugs of interest.

The correlation of drug concentrations and driving impairment is further complicated by the large variety of drugs already on the market and the steady introduction of new drugs to the market. The panel expressed doubt about the feasibility of producing a single index like the BAC for each other drug. Instead, many different indices for the variety of drugs or clases of drugs may be required. Moreover, the use of multiple drugs by drivers renders this approach impracticable.

The workshop panel agreed that when one begins to look at drugs other than alcohol in highway safety, the problem becomes a polydrug problem rather than that of a single substance. Practitioners and researchers have to be concerned with the driver who uses diazepam and alcohol, or marijuana and alcohol, or any other combination of substances. Little is known about the combined effects of drugs on human performance. Even a driver with a BAC well below a legal limit of 0.10% w/v could face an increased risk of a traffic crash when using another drug at the same time. The recognition of a polydrug problem in highway safety points out the need for additional research on the combined effects of drugs on driving performance. In addition, given that

the problem extends beyond that of a single substance, the use of a single chemical measure (a BAC of 0.10% w/v) may no longer apply; reassessment of the current legal definition of driver impairment may be warranted.

The workshop panel also pointed out that an awareness of the possible enhancement effects of drugs must be maintained. This viewpoint is rarely found in the alcohol literature. The picture of alcohol effects, as one participant noted, has been developed on the basis of a "one-tailed model," dealing only with the issue of impairment. The therapeutic value of many drugs, however, may outweigh their adverse side effects on driving performance. For example, a driver taking medication to control epilepsy may present a far lesser risk to highway safety than his driving without that medication. The panel suggested that the responsibility for demonstrating impairment to driving skills by drugs, particularly prescription drugs, is that of the highway safety researcher.

4.2 Comparisons Based on the Exposure to Alcohol and Other Drugs

The characteristics of exposure to drugs in the general driving population are important factors in estimating the highway safety risk of alcohol and other drugs. These factors may also provide directions for the development of preventive measures to control increased risk to highway safety due to these substances. Included in the workshop discussions of exposure factors for alcohol and other drugs were usage patterns, delivery systems, and substance availability.

How a drug is used is important information for risk identification and subsequent preventive measures. In the broadest sense, these uses can be legal (use of licit drugs) or illegal (use of illicit drugs). The use of licit drugs may be further subdivided into recreational use and therapeutic use. Alcohol is the most commonly used recreational drug. Therapeutic agents are those drugs used medically; they may be bought over the counter or obtained by prescription from physicians.

The delivery of alcohol has been controlled by the licensing of retail stores and drinking establishments. Moreover, the owners of these outlets have been made legally liable for the sale of alcohol under circumstances

established by law. Similar to licensed outlets for the delivery of alcohol are the pharmacies, which exist for the delivery of prescription or therapeutic drugs. The marketing of over-the-counter (OTC) drugs is federally regulated; their sale is much less controlled than prescription drugs.

The panel suggested, however, that the more formal delivery systems for use of legal drugs may provide opportunities for intervention that do not exist for alcohol. For example, a driving-specific test battery could be added to the already extensive premarket testing of drugs done by the pharmaceutical industry. Several steps could be taken if a drug were found to impair driving ability: it could be prohibited; its availability could be restricted; or it could be marketed with more explicit warning labeling. Another tactic is to make the information available and put the onus on the physician, or dentist, who must adequately warn the patient about driving under the drug's influence. The civil litigation process could then take over.

The panel cautioned that restricting the availability of drugs already on the market depends on careful development of risk information. Alcohol has been shown to increase highway safety risk. There is little evidence to indicate that other drugs increase the likelihood of traffic crashes. Several panel members suggested that drugs are probably less a problem for highway safety than is alcohol. Nevertheless, definitive studies have not been conducted.

The illicit drug category presents a different picture. Detection of presence alone is sufficient for litigation purposes. Possession of an illegal drug is an offense in itself. Enforcement of laws concerning drug-impaired driving requires that impairment of driving ability be established and that the presence of a corresponding amount of positively identified substance be proved. Prohibition of a substance may reduce its availability, but its use and influence on highway safety may continue.

4.3 Comparisons Based on Population Exposed to Alcohol and Other Drugs

The **exposed population** refers to users of alcohol and other drugs. Both "who uses the drug?" and "why is the drug used?" are central

questions. "Who" refers to such variables as age, gender, socioeconomic status, health status, and experience with the drug. These characteristics may greatly influence the risk potential of a drug. For example, the driving skills of naive drinkers may be more impaired than those of experienced drinkers. "Why" pertains to the reasons or motivation for use of a drug. Drugs commonly used for "recreation" (i.e., intoxication) would have higher risk potentials than similar drugs used only as therapeutics agents.

The panel noted that a broad and detailed data base exists for the epidemiology of alcohol users. This data base identifies the kinds of problems that occur with alcohol use, their sequence, and their frequency. No comparable information exists for the wide range of therapeutic and illicit drugs in use today. Moreover, one participant pointed out, all clinical and case identification activities within the alcohol area emphasize driving experience; that is, it is a routine procedure for every clinician and therapist to inquire about the client's driving history. Such is not the case for other drugs; it was noted that questions regarding motor vehicle operation and responsibility are rarely raised when dealing with substance abuse.

It would not be surprising to find differences in accident type and frequency for different groups of users. One participant cited evidence of such from studies in Helsinki, Finland, conducted among various groups. Drugs were detected in less than 5% of a sample of 100 randomly selected drivers arrested for drinking and driving (Alha et al. 1977). Evidence of drugs was greatest, however, in a sample of 100 pedestrian injury cases (10-20%). The results of these studies also indicated that use of drugs and alcohol within cities increased accident involvement and that the effect of the alcohol and the psychoactive drugs was additive.

To date similar epidemiological studies of drug use are rare in the United States. Development of this information is important to identify the highway population at risk and to design and implement more effective countermeasures.

4.4 Summary

Alcohol differs from other drugs in its physicochemical properties, its pharmacological and behavioral effects, and the user population. These differences have implications for research on the relationship between other drugs and highway safety and societal responses to identified drug and driving problems.

The ease of alcohol detection and measurement in breath is a fundamental consideration in developing risk measures based on chemical tests of drug concentration in body substances. The physicochemical properties of other drugs will probably preclude similar approaches to risk identification and to preventive measures. Important differences between the effects of alcohol and other drugs also exist. Behavioral measures of risk must take these into account. Multiple drug use by drivers complicates the traditional focus on single substances and their influence on driving behaviors associated with traffic crash risk.

The therapeutic use of licit drugs and their possible enhancement of driving ability in persons with disease conditions must also be assessed. Alcohol is primarily used as a recreational drug; a vast proportion of other drug use is through the health care system. The combined use of alcohol and other drugs, especially psychoactive prescription drugs, may present a substantially increased highway safety risk.

Differences in the delivery system for alcohol and most other drugs indicate that countermeasure actions aimed at controlled substances can be applied at intervention points that do not presently exist for alcohol.

Whereas the drinking driver has been the focus of extensive, if not completed research efforts, the user populations of other drugs have not been well defined. This kind of information for crash-involved and general driving populations must be developed to identify the highway population at risk.

5.0 CONCLUSIONS AND RECOMMENDATIONS

The alcohol and highway safety experience has greatly influenced approaches to the study of other drugs and their role in traffic crashes. The purpose of this workshop was to describe more precisely the alcohol-safety experience and to evaluate its applicability to other drugs.

Participants in Workshop V described the history of alcohol and highway safety. Key elements were drawn from this set of activities to form a general framework for alcohol, other drugs, and highway safety. The main elements of the general framework are:

- The process of risk identification, including epidemiology and experimentation;
- the development of risk measures, which, for alcohol, has been **blood alcohol concentration**; and
- the responses to reduce highway safety risk directed at the substance, its delivery system, and the user.

Participants discussed the extent to which research on other drugs and highway safety should attempt to replicate the approach taken for alcohol.

The panel agreed that the risk identification process used for alcohol should be emulated. The first step of this process is to see if there is a problem; the prevalence of drug use occurrence (alone and in combination with alcohol, and other drugs) among different driving populations is yet to be determined. The next step is to assess the likelihood of future accidents due to particular substances. Methods to detect and quantitate drugs in body fluids and to define the user populations are essential to the risk identification task.

The identification of a drug problem in highway safety is somewhat limited by the technology of drug analysis. Few noninvasive techniques exist for detecting drugs, at least techniques that can be used by persons with limited technical training. Blood is the preferred body fluid for

detection and quantitation of most substances. The panel suggested that further research should be directed to developing noninvasive methods (e.g., breath, saliva analyses) for measuring high priority drugs.

Risk identification can be aided by analyzing accident data to learn who is getting injured. Disaggregation of data will lead to more definitive information about substances associated with different types of traffic crashes and various characteristics of the user population. As one participant remarked, if a drug is only taken at bedtime, it may not present much risk to highway safety. Another participant expressed doubt that the highway safety risk generated by drugs would be large enough to warrant a major social concern. These concerns point to the necessity of measuring the nature and extent of the problem and its contribution to highway safety.

The panel, therefore, recognized the great value of epidemiological research in highway safety. Descriptive and analytic surveys along with experimental research must be done to define highway safety problems resulting from the use of drugs other than alcohol before development of programs for prevention can be focused. Workshop participants recommended that laboratory studies of human performance be continued in the process of risk identification. Relationships between impaired performance in the laboratory and BAC have been demonstrated repeatedly. This information is lacking for most other drugs. Demonstrations of decrements in performance provide a means for determining the potential risk of other drugs to highway safety. Development of objective measures of drug-induced impairment--both chemical and behavioral--would allow a better assessment of any problem that does exist.

Although the panel members agreed that the risk identification process used for alcohol should be emulated, they stressed that it should be accomplished in less time for other drugs. Identification of a drug and driving problem, development of drug analytical methodology, and measures of behavioral impairment are requirements for risk identification. Participants suggested that research to meet these requirements be done in parallel so that the entire process can be

accomplished in a shorter period of time.

Most critical at the present stage of risk identification for drugs other than alcohol are epidemiologic studies that compare the prevalence of drug use among crash- and noncrash-involved populations stopped at roadside. Unless this kind of survey is done, no statements about relative risk for drugs will be possible and fragmentary data from police and other agencies will remain indicative but not definitive of a drug and driving problem.

Risk measures indicate the degree of driver impairment that increases highway sfety risk beyond socially acceptable levels. For alcohol, this has been defined in terms of BAC, for example, 0.10% w/v. The panel cautioned that the BAC concept may not be applicable to all drugs and, probably, not even to most drugs. Certainly no comparable definitions of impairment now exist for other drugs.

The development of chemical tests of impairment by drugs is a task complicated by several factors. One difficulty stems from the difficulty of routine analysis for the wide range of drugs that must be considered in highway safety. Participants thought that the task was technically feasible, given proper prioritization. To accomplish it, however, would likely absorb a significant amount of resources. Moreoever, even if drug concentrations in driver body fluids were determined in cases of impaired driving, the data would have little meaning except in instances of clear substance misuse or abuse. Drug concentrations in body fluids must still be related to decrements in skills related to driving.

The drinking-driving problem is one of a single substance. That may not be the case for other drugs; the drug and driving problem may be a **polydrug** problem, that is, one better characterized by multiple substance use by drivers. The panel doubts that a single relative index based on the BAC could be developed for most other drugs. A variety of measures for the various drugs or drug classes will more likely be necessary.

Alternatives to chemical measures of drug-impaired driving are behavioral measures of impairment. By focusing on behavior per se, there is no need to relate impairment to specific drugs or drug concentrations. What must be carefully specified, however, are critical components of the

driving task. Once those components are specified, a set of tests might be developed to measure impairment of important functions of the driving task. The development of behavioral measures, however, depends on the funding of human performance researchers to define the driving task in terms of behavioral functions.

The panel also recognized current constraints on using behavioral measures of risk within the legal system. Convictions have relied greatly upon the presence and amount of a substance (e.g., BAC). Without such evidence, participants expressed reservations about the frequency of obtaining convictions for impaired driving.

The third element of the general framework is the societal response for reducing highway safety risk. The panel suggested that other drugs may be controlled in ways different from the traditional means to reduce the highway safety risk of alcohol. The vast majority of drugs are distributed through the health care system; thus, the ability to intervene within the delivery system indicates dimensions of countermeasure action that simply do not exist for alcohol. For example, medical personnel (physicians, physicians' attendants, dentists, etc.) could administer tests of impairment (if valid tests were to be developed) to measure the effect of a prescribed drug; the patient could then be advised of potential risks accordingly. Another tactic suggested by the panel is to require premarket testing for impairment to measure the potential of new drugs to impair driving-related skills. This approach also depends on developing a set of behavioral measures that encompass a broad spectrum of different drug effects. Drugs that substantially affect performance might be prohibited or marketed with restrictive labeling. In the latter instance, information about a drug's side-effects would be made available to medical personnel; the onus for adequately warning patients about driving under the influence of the drug might be placed on those who prescribe them. The civil litigation process could then be used in cases of malpractice. The panel cautioned, however, that the ability to restrict drug availability depends upon careful development of risk information, and this responsibility falls upon the highway safety research community.

The workshop panel also suggested that highway safety researchers and

practitioners not concern themselves with demonstrating the relationship between driving impairment and illicit drugs at this time. Participants noted that if a drug is illegal, detection of mere presence is usually sufficient for prosecution under laws pertaining to illegal possession of controlled substances. It is not necessary to establish levels of impairment in order to sanction the individual. In this approach, the violation would be nonvehicular.

The panel observed that the development of behavioral methodology to test drugs for their potential to impair driving performance is one alternative approach to preventive measures based soley on the legal approach. Reliance on the traffic law system has dominated the alcohol and highway safety experience. A simple test battery might be used at the point of delivery of drugs, particularly for therapeutic agents. Two examples are premarketing evaluation of new drugs and the testing of drug effects on patients by physicians. Intervention **before** drugs become a problem in highway safety could result in fewer cases for handling by the criminal justice system.

Data on cases arising in the criminal justice system may provide information for the identification and development of preventive measures and could support program planning. In various jurisdictions throughout the United States, drivers are arrested for driving under the influence of drugs under existing laws. These data, if collected and analyzed, could be disaggregated for inquiry into factors associated with drug-impaired driving, such as driver characteristics, types of drugs, combinations of drugs, including alcohol. Participants noted that this kind of information, obtainable at less cost than large-scale field studies, might lead to the identification of specific high-risk groups within the larger driving population. The panel also pointed out that the identification of driver-user characteristics is a necessary step in defining the nature and extent of the drug and driving problem, a step not fully completed for alcohol.

The requirement for evaluation of highway safety research and preventive measures was reemphasized by the panel. Participants recognized the contribution of the Alcohol Safety Action Project in the

development of evaluation methodology, but stressed that these efforts must continue. One participant stated that the technology of evaluation has reached a level where the components of prevention programs and their interactions can be assessed. Effective measures can be identified and augmented while ineffective ones can be phased out. Greater use of evaluation methodology could lead to more efficient application of limited resources. Unfortunately, because techniques developed through evaluation research have not been extensively employed, their usefulness in the area of alcohol, other drugs, and highway safety has not yet been established.

In summary, the panel of Workshop V described a general framework for alcohol, other drugs, and traffic safety. This framework was developed from discussions of the alcohol and highway safety experience. The main elements of this conceptual structure include the process of **risk identification**; the identification, development, and application of **risk measures**; and societal responses to reduce the likelihood of traffic crashes and associated losses due to drugs other than alcohol alone (**preventive measures**). Participants indicated the extent to which highway safety research on other drugs should attempt to replicate approaches taken for alcohol. The panel agreed that the risk identification process (i.e., the step-by-step demonstration of relationships between drugs and traffic crashes) should be emulated--but must be accomplished in less time. The BAC concept, however, was not applicable to all drugs and, probably, not even to many drugs; more effort needs to be directed toward the development of behavioral measures of impairment. Many drugs might be controlled in ways different from the traditional means to reduce the highway safety risk of alcohol since the vast majority are distributed through the health care system. Costly national preventive programs for drugs other than alcohol, however, are not warranted until the drug and driving problem is defined.

APPENDIX A

LIST OF WORKSHOP PARTICIPANTS

DRUG RESEARCH METHODOLOGY
THE ALCOHOL AND HIGHWAY SAFETY EXPERIENCE
AND ITS APPLICABILITY TO OTHER DRUGS

LIST OF WORKSHOP PARTICIPANTS

This workshop was held on 28-31 January 1979. The following persons participated, their titles, positions, and addresses being those at the time of the workshop.

Stephen D. Benson, Ph.D. NRD-42
Contract Technical Manager
U.S. Department of Transportation
National Highway Traffic Safety Administration
Trans Point Building
2100 Second Street, S.W.
Washington, D.C. 20390

Professor Robert F. Borkenstein
Center for Studies of Law in Action
Indiana University
327 Sycamore Hall
Bloomington, Indiana 47901

Ira H. Cisin, Ph.D.
Director
Social Research Group
George Washington University
2401 Virginia Ave. N.W.
Washington, D.C. 20037

Alan C. Donelson, Ph.D.
Assistant Research Scientist
Policy Analysis Division
Highway Safety Research Institute
The University of Michigan
Huron Parkway at Baxter
Ann Arbor, Michigan 48109

Kurt H. Dubowski, Ph.D.
University of Oklahoma
Medical Center
P.O. Box 26901
Oklahoma City, Oklahoma 73190

Kent B. Joscelyn, J.D.
Head, Policy Analysis Division
Highway Safety Research Division
The University of Michigan
Huron Parkway at Baxter
Ann Arbor, Michigan 48109

Markku Linnoila, M.D., Ph.D.
Head, Clinical Psychopharmacology Laboratory
Box 2921
Duke University Medical Center
Durham, North Carolina 27710

Roger P. Maickel, Ph.D.
Professor of Pharmacology and Toxicology
Head, Department of Pharmacology and Toxicology
Purdue University
West Lafayette, Indiana 47907

Mary Elizabeth Marks, Ph.D.
Research Investigator
Policy Analysis Division
Highway Safety Research Institute
The University of Michigan
Ann Arbor, Michigan 48109

Arthur J. McBay, Ph.D.
Chief Toxicologist
State of North Carolina
Office of the Chief Medical Examiner
P.O. Box 2488
Chapel Hill, North Carolina 27514

Alex Richman, M.D.
5909 Jubilee Road
Halifax, Nova Scotia B3H 2E2 Canada

Monroe B. Snyder, Ph.D. NRD-42
Acting Chief
Problem-Behavior Research Division
Office of Driver and Pedestrian Research
Research and Development
National Highway Traffic Safety Administration
2100 Second Street, S.W.
Washington, D.C. 20590

Robert E. Willette, Ph.D.
Chief, Research Technology Branch
National Institute on Drug Abuse
Parklawn Building, Rm. 942
5600 Fishers Lane
Rockville, Maryland 20857

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