

DRUG RESEARCH METHODOLOGY. VOLUME FOUR.
EPIDEMIOLOGY IN DRUGS AND HIGHWAY SAFETY:
THE STUDY OF DRUG USE AMONG DRIVERS
AND ITS ROLE IN TRAFFIC CRASHES

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June 1980

Prepared for
U.S. Department of Transportation
National Highway Traffic Safety Administration
Washington, D.C. 20590

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16. Abstract This report presents the findings of a workshop on epidemiology in drugs and highway safety. A cross-disciplinary panel of experts (1) identified methodological issues and constraints present in research to define the nature and magnitude of the drug and driving problem; and (2) outlined approaches to the design and conduct of surveys to estimate the highway safety risk attributable to the use of drugs other than alcohol alone. Participants addressed specific topic areas in the context of two general issues: (1) the sequence of research needed to establish drugs other than alcohol as a priority concern in highway safety; and (2) the relationship of data provided by different types of surveys and information required for policy decisions. Conclusions and recommendations related to the future direction of epidemiologic research and to the type of studies now required to advance the state of knowledge about drugs and driving are summarized.					
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Other HSRI personnel also made important contributions. This report was edited by James E. Haney. Anne L. VanDerworp served as production editor. Douglas J. VanDenBerg, 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. Royal.

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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-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.

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1.0 INTRODUCTION

This report presents the findings of a workshop on epidemiology in drugs and highway safety. The workshop was held on 21-23 May 1978 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 no. 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; Organisation for Economic Co-Operation and Development 1978; Seppala, Linnoila, and Mattila 1979; Joscelyn, Jones, Maickel, and Donelson 1979). (The word "drug" is used here and throughout this report in its most generic sense; that is, substances not usually considered drugs are included within its meaning, for example, carbon monoxide and organic toxicants. "Drugs of interest" are substances that have the potential to increase the likelihood of traffic crashes and concomitant losses.) Research has not established whether any drug besides alcohol increases the probability of a traffic crash and associated losses. 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 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 specify workable and detailed approaches 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 1979, a fifth workshop dealt with the alcohol and highway safety experience and its relevance to the study and control of the drug and driving problem.

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, entitled "The Alcohol-Highway Safety Experience and Its Applicability to Other Drugs" and reported as Volume One. This deserves some explanation. References and comparisons to the study of and the response to the alcohol-crash problem 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. Workshop V was therefore planned to examine the alcohol-highway safety experience in detail. As Volume One, the report on Workshop V serves as an introduction to the others, provides an 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.

The first workshop in this series, 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 workshops. 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. The ranking identified 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 body fluids from drivers. In the context of epidemiologic and experimental research to define the drug and driving problem, the purposes of Workshop II were:

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

Its specific objectives were:

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

The findings of Workshop II supported the examination of issues in epidemiologic research in Workshop III, the subject of this report.

1.2 The Purpose of Workshop III, Epidemiology in Drugs and Highway Safety: The Study of Drug Use Among Drivers and Its Role in Traffic Crashes

Epidemiology is the science concerned with the incidence, distribution, and control of disease in populations. Beyond the study of disease, the methods of epidemiology have been broadly applied to the study of social phenomena, including drug-related problems (Elinson and Nurco 1975; Rootman and Billard 1975; Richards and Blevens 1977). The epidemiologic approach in drugs and highway safety involves determining:

- the characteristics of drivers and traffic crashes that are associated with the use of drugs;
- the prevalence of drug use in different driving populations and the degree of association between drug use and traffic crashes as well as other problem driving behavior; and
- the increased risk of traffic crashes attributable to drug effects on driving performance.

Epidemiologic research on drugs and driving complements experimentation in defining the nature and extent of this problem.

Surveys of drug use in driving populations present great difficulty. To date, no large-scale, carefully controlled survey has compared the prevalence of drugs other than alcohol in accident- and nonaccident-involved drivers. Past studies have been limited in scope and marked by methodological problems (Joscelyn and Maickel 1977a; Willette 1977; Joscelyn et al. 1979). Problems with existing data stem in part from methods of drug analysis employed in past research. But other issues and constraints in this research area also hamper progress. For example, limited funding has precluded systematic study; low rates of cooperation in samples of at-risk drivers cast doubt on the reliability of findings. Above all, the absence of suitable control groups from the on-the-road driving population has prevented reliable estimates of the relative highway safety

risk of drugs other than alcohol.

The purpose of Workshop III, therefore, was to examine these issues in detail. 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 research; and
- to recommend research needed in this area.

Because Workshop II considered issues related to drug analysis, the main emphasis in Workshop III was on approaches to epidemiologic research.

To accomplish these aims, experts were invited from fields of research requiring knowledge and application of epidemiologic principles as well as familiarity with issues in this kind of research. Among the disciplines represented were sociology, social psychology and psychiatry; epidemiology; biostatistics; pharmacology, toxicology, and physiology; and law. Participants were active in research that included the design and implementation, on a national scale, of surveys of drug use; the conduct and the evaluation of research in several areas of highway safety, including drugs and driving; and the development of potential countermeasures in highway safety. The group as a whole was well versed in the technical and logistical features of epidemiologic research.

The participants, both from inside and outside the government, functioned as an interdisciplinary group in an informal workshop setting. A moderator with an extensive background in research on 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 general audience.

1.3 Scope of Report

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

Section 2.0, Epidemiology in Drugs and Highway Safety, provides background information on epidemiologic research and the process of risk identification.

Section 3.0, Epidemiologic Research to Indicate the Highway Safety Risk of Drugs Other Than Alcohol, outlines means by which the relationship between drugs and highway safety may be defined.

Section 4.0, Constraints on Epidemiologic Research on Drugs and Highway Safety, describes issues and problems that impede and limit research in this area.

Section 5.0 presents the conclusions and recommendations of the panel.

Appendix A summarizes the review of findings in Workshops I and II by participants in Workshop III.

Appendix B is a list of participants of Workshop III.

A bibliography of references cited in the text is provided at the end of this report.

2.0 EPIDEMIOLOGY IN DRUGS AND HIGHWAY SAFETY: BACKGROUND INFORMATION

Workshop discussions about epidemiologic research on drugs and highway safety assumed a basic understanding of epidemiology and its methods. For the reader unfamiliar with these subjects, this section provides background information that covers the following topics:

- epidemiology and the application of its methods;
- the process of risk identification; and
- determining the significance of drugs as highway safety risk factors.

To present in detail the theoretical basis and practice of epidemiology is beyond the scope of this report. Nevertheless, an understanding of the principles of epidemiology and their application in highway safety research would appear valuable, especially in the area of drugs and driving. The reader desiring more information of this kind is referred to MacMahon, Pugh, and Ipsen (1960); Haddon, Suchman, and Klein (1964); Susser (1975); and Sudman (1976).

2.1 Epidemiology and the Application of its Methods

Traditionally, "epidemiology is the study of the distribution and determinants of disease prevalence in man" (MacMahon, Pugh, and Ipsen 1960, p.3). The methods of epidemiology are primarily **observational**. Unlike experimentation, which is characterized by **intervention** and in which efforts are made to control all but the one or two variables of interest, epidemiologic research attempts to observe as many factors as feasible in order to develop hypotheses about their relationship to the event and about their interaction with each other.

The discipline and methods of epidemiology have long been associated

with medical science, especially applied in the study of sudden, marked increases in the prevalence of acute, infectious diseases (epidemics). But as MacMahon, Pugh, and Ipsen note, the concept of "epidemic" has broadened over the years to include gradual upsurges of chronic, noninfectious diseases, such as coronary heart disease and lung cancer. "A second trend has been growing realization of the value of knowledge of disease frequency and distribution during both epidemic and nonepidemic times, even when the predominant concern may be with the explanation of epidemics" (MacMahon, Pugh, and Ipsen, p.4). In highway safety, an analogy might be an increased emphasis on individuals or driving populations who do not exhibit problem driving behavior, to aid the development of hypotheses about traffic crash causation.

Traffic crashes and their consequences--injuries, deaths, and other losses--can be likened to disease in society. (Interestingly, so can inappropriate drug use.) Gordon (1949) described the "epidemiology of accidents":

It is not so generally appreciated that injuries, as distinguished from disease, are equally susceptible to this approach, that accidents as a health problem of populations conform to the same biologic laws as do disease processes and regularly evidence comparable behavior. (p.18)

Like many diseases, traffic crashes have multiple causes. To determine what causes accidents, factors associated with the driver, vehicle, and driving environment may be studied.

According to Wigle (1975), 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 observation has also been made in the field of accident research.

Ideally, the approach must be intentionally multifactorial and must avoid **unsupported** presuppositions as to the primary causes either of accidents in general or of those in the specific group under study. Unsupported presuppositions . . . have proved a stumbling block to many who, in discerning the unique contributions of their own disciplines, have attempted to explain essentially all accident

phenomena in terms of the concepts and groups of variables with which they are customarily concerned. (Haddon, Suchman, and Klein 1964, p.15)

MacMahon, Pugh, and Ipsen (1960) refer to the involvement of multiple factors in the causation of events as "the web of causation," preferring this descriptor over the common phrase "chains of causation," which tends to oversimplify.

The methods of epidemiology evolved in the 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). With respect to the explanation and prevention of traffic crashes, the numerous factors operating **before** the crash are of interest. As Stewart (1970) has pointed out, epidemiology is particularly appropriate for the study of conditions with multiple manifestations, where correlation means interaction rather than cause-and-effect.

In fact, the classical notion of **cause**, which was deterministic, has been replaced by the theory of probability. Probability statements indicate the likelihood or degree of certainty about events, and do not assume absolute certainty about their occurrence. Epidemiologic research findings are inherently probabilistic, measuring the **degree** and **directness** of association among various factors and the phenomenon under investigation.

The central issue here--how important are drugs as factors in crash causation--is addressed by the process of **risk identification**. In the following discussion, the terms "cause" and "causation" are used in the probabilistic sense described above.

2.2 The Process of 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 and their relative importance measured. With respect to drugs and

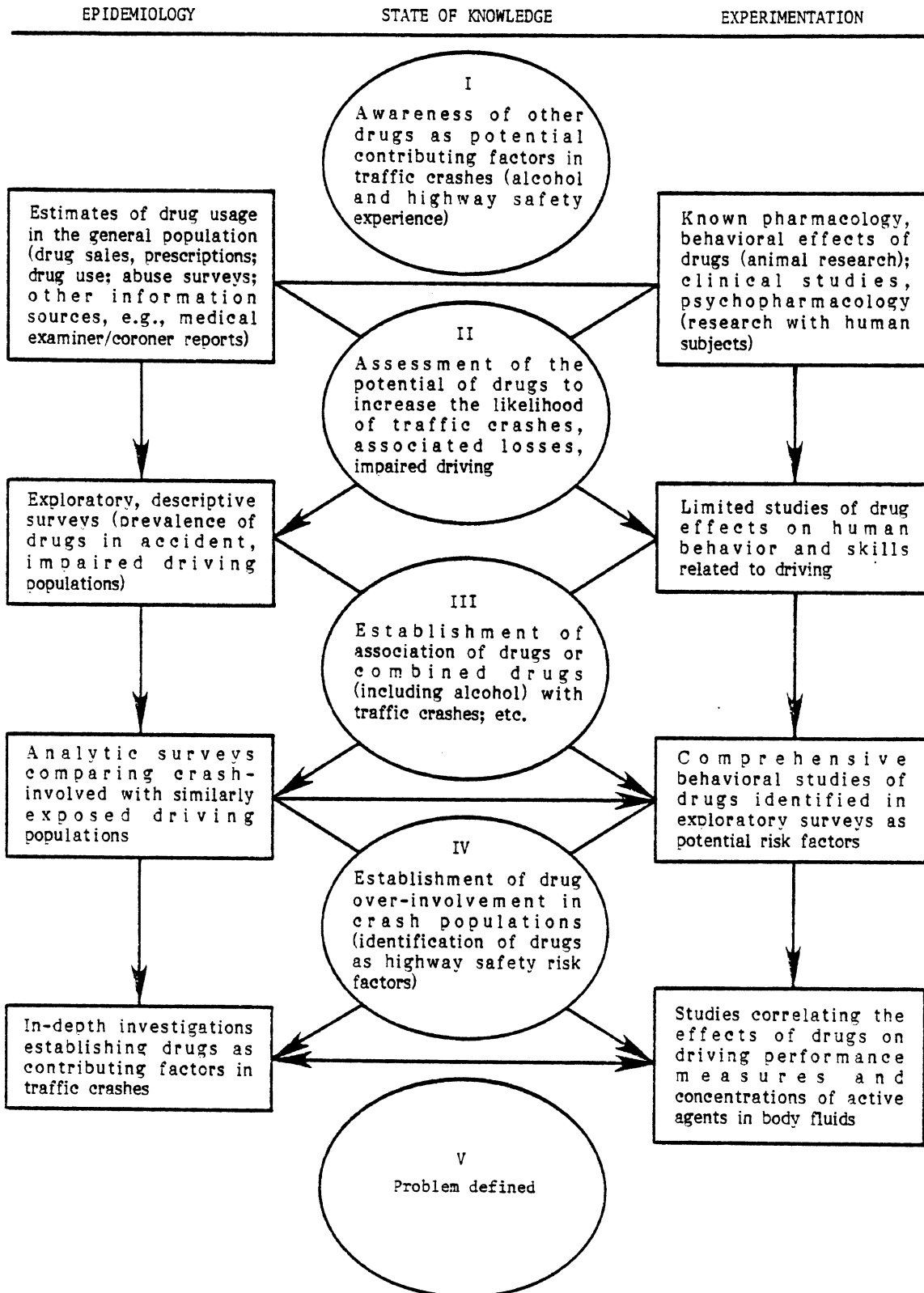
highway safety, the process of risk identification involves research to define the problem (problem definition). Research on the relationship between alcohol and highway safety has used two complementary approaches, epidemiology and experimentation. Both approaches have served to determine the nature and extent of the drinking-driving problem and to indicate the increased likelihood of traffic crashes associated with alcohol use by drivers. 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.

In defining the role of epidemiologic research in drugs and highway safety, it is important to stress the complementarity of epidemiology and experimentation. Figure 2-1 illustrates this point, depicting research on drugs and driving as a process that advances the state of knowledge toward a definition of the problem. Progressively more rigorous studies using both epidemiologic and experimental approaches are required. Arrows represent the output of research efforts; findings from epidemiologic research can be used for more in-depth experimental studies, and vice versa. Initial, exploratory research narrows the focus of later efforts, for example, by identifying a limited set of drugs of interest. This coordination of research becomes essential as the overrepresentation of particular drugs in crash populations is estimated. Certain drugs may be associated with other risk factors that contribute significantly to traffic crashes; mere presence does not indicate that a drug "caused" an accident, simply that a driver had used the drug sometime prior to the traffic crash. Some drugs can be detected in body fluids long after their effects on driving skills have ceased. Data on concentrations of active agents associated with impairment of driving-related skills, therefore, can confirm and extend the findings of field surveys.

Experimental research similar to that done on alcohol has measured the effects of other drugs on skills 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

FIGURE 2-1

PROBLEM DEFINITION IN DRUGS AND HIGHWAY SAFETY AS A PROCESS:
COMPLEMENTARITY OF EPIDEMIOLOGIC AND EXPERIMENTAL RESEARCH



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 mechanisms by which a drug influences behavior.

In the case of drugs and driving, the role of epidemiologic research is to determine whether drug-impairment of drivers is causing significant traffic crash loss and, if so, how much loss and under what circumstances. Exploratory, descriptive research examines the prevalence of drugs known to have the potential to impair performance in different driving populations and within different segments of the same driving populations. Risk factors other than drug use—for example, driver and crash characteristics—are examined also, to develop alternative hypotheses that may serve to explain the observed distributions. If a drug's prevalence is very **low**, then its use by drivers may not represent a serious traffic crash problem, and further study to determine the number of the crashes actually caused by the drug usually is not warranted.

In contrast, 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 additional studies 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.

2.3 Determining the Significance of Drugs as Highway Safety Risk Factors

Estimation of the actual number of crashes (or crash losses) attributable to the use of a drug in a given time period follows. The purpose of the discussion below is to present the formal basis for identifying drugs (or any other risk factor) as a significant highway safety problem.

A causative association is said to exist when the fraction of crashes

involving drug use by drivers—and a given set of other factors (F_0)—is greater than the fraction of crashes not involving drug users and the **same** set of other factors (F_0). These two fractions also may be expressed as conditional probabilities. Algebraically, this condition for causation may be written as:

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

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

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

where

$P(C|D)$ = the conditional probability of a crash given the drug and a set of other factors, F_0

$P(C|\bar{D})$ = the conditional probability of a crash given no drug and the set of other factors, F_0

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. Studies required to obtain these data blur the distinction between experimentation and epidemiology, and epidemiologic research to establish etiology (the study of causation) has been termed "experimental epidemiology" (MacMahon, Pugh, and Ipsen 1960, pp.268-279). Strictly speaking, the data would require a controlled study in which two groups of drivers who were alike in every respect except their use of the drug would drive for a given period of time in identical driving environments. 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 study 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 a study 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 study is impractical, but might be approximated through other approaches.

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).

One 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 estimate **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 an approximation of 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:

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

where

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

$P(D|C)$ = the conditional probability of the drug and F_0 given a crash

$P(D|\bar{C})$ = the conditional probability of the drug and F_0 given no crash

$P(\bar{D}|C)$ = the conditional probability of no drug and F_0 given a crash

$P(\bar{D}|\bar{C})$ = the conditional probability of no drug and F_0 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.

2.4 Summary

Epidemiology and experimentation are two complementary approaches used to define the nature and extent of the drug and driving problem. The objective of epidemiologic research is to determine the actual highway safety risk due to drug use among drivers. In the process of risk identification, progressively more rigorous studies are required to establish the role of drugs in traffic crash causation. The significance of drugs as highway safety risk factors is indicated by studies that provide data on the relative risk, attributable risk, or both, of traffic crashes associated with the use of drugs by drivers.

3.0 EPIDEMIOLOGIC RESEARCH TO INDICATE THE HIGHWAY SAFETY RISK OF DRUGS OTHER THAN ALCOHOL

This section describes epidemiologic approaches to indicating the actual highway safety risk of drugs other than alcohol. The presentation of topics, however, does not reflect the order of their treatment in the workshop. In order to report the sometimes complex discussions, we attempt instead to capture their substance in a series of stages.

First, questions put to the panel are listed. Next, technical terms used in the workshop are defined and general characteristics of designs and methods are described. Specific approaches to the study of drugs and highway safety are then outlined. Finally, issues related to the design and conduct of epidemiologic research on drugs and highway safety are summarized.

3.1 Research Questions in the Epidemiology of Drugs and Highway Safety

The sequence in responding to an issue in highway safety--define the problem; develop, test, and evaluate potential countermeasures; then demonstrate and implement those proved effective--has barely reached the first phase for drugs other than alcohol. Although we are not in total ignorance, the present state of knowledge still offers no definite statement of the problem. Likewise, although all states proscribe (to some extent) driving under the influence of drugs other than alcohol, enforcement of these laws is difficult and sporadic, and subject to many constraints. Prospects for nearterm research in the United States and elsewhere do include a few rigorous studies of the prevalence of drug use among fatally injured and other drivers. Some much needed information will be available to better describe the nature and extent of the problem within the next five years.

Instead of discussing ongoing or planned research, participants were asked to consider the next step in defining the problem--indicating the actual highway safety risk of drugs. This meant assuming two things:

1. that research to define the problem will be done at least in fatally injured and in seriously injured populations of drivers, and with more rigor than in past studies; and
2. that some drugs or drug groups will be found with a frequency warranting further study.

The panel recognized that no drugs may appear often enough to require more involved study. But since positive findings might result from ongoing or planned projects, efforts by NHTSA to plan now were deemed prudent. The main focus, then, was on research to extend the line of inquiry beyond gathering evidence to show that a problem exists.

A series of related questions was put to the group of experts:

- How can we find out whether drugs other than alcohol occur more often in the population of drivers involved in accidents than in the population at risk?
- What is the population of drivers at risk? What do we know about the at-risk population?
- Given a defined population of drivers involved in accidents, how can we obtain a control sample from the at-risk population?
- Which methods for assessing the highway safety risk of drugs best suit the conditions of present-day research in highway safety?
- Is the approach typified by the Grand Rapids study by Borkenstein et al. (1964, 1974) the appropriate epidemiologic model for studying drugs other than alcohol?
- What other means can we use to measure the use of drugs in control populations? What are their limitations, their strengths and weaknesses?
- What variables should we control in studying the prevalence of drugs among drivers in the at-risk population?

These questions reveal not only the topics discussed, but also the level of

inquiry of Workshop III. What was sought was not so much specific methods as alternative approaches to epidemiologic research. Participants were asked to point out not only the most **desirable** approaches, but the most **feasible** as well. This entailed consideration of constraints in epidemiologic research linking drug use and highway safety (see Section 4.0).

3.2 Epidemiology in Drugs and Highway Safety: Strategy, Survey Sampling, and Data Collection Techniques

As defined in Sections 2.2 and 2.3, highway safety risk is the probability of a traffic crash and concomitant losses. Two different measures of risk--**relative risk** and **attributable risk**--are used to describe the nature and magnitude of the association between risk factors and the event under study. Relative risk is more indicative of the degree and directness of causal association; attributable risk indicates what proportion of cases in a given population is due to effective exposure to the risk factor.

The strategy of epidemiology represents a series of investigations of increasing precision to establish the significance of risk factors in the etiology of traffic crashes. As emphasized in Table 3-1, the **formulation** and **testing** of alternative hypotheses is central to the process of risk identification. The examples given in Table 3-1 are strictly hypothetical, for illustrative purposes only.

As outlined by Kish (1965, pp.17-22), various sampling approaches have been used to make inferences about populations. A **population** is the group of units, or **elements**, for which information is obtained. "**Survey sampling**, or population sampling, deals with methods for selecting and observing a part (sample) of the population in order to make inferences about the whole population" (Kish 1965, p.18).

Alternative sampling approaches include:

- **haphazard** or **fortuitous** sampling, where elements are selected on the basis of convenience or availability;
- **judgment sampling**, based on the judgment of experts who

TABLE 3-1

THE STRATEGY OF EPIDEMIOLOGY
(With Examples Pertinent to the Study of Drugs and Highway Safety)

(from MacMahon, Pugh, and Ipsen 1960, p. 32 [examples added])

STEPS IN PROCESS	DEFINITION	EXAMPLES
(1) Descriptive Epidemiology:	description of the distribution of disease, with comparisons of its frequency in different populations and in different segments of the same population	<ul style="list-style-type: none"> ● traffic crash and violation rates among drug and nondrug users ● driver and crash characteristics in drug- and nondrug-involved crashes ● prevalence of drug use in different driving populations
(2) Formulation of Hypotheses:	tentative theories designed to explain the observed distribution of the disease in terms of causal associations of the most direct nature possible	<ul style="list-style-type: none"> ● drug-impaired driving skills increase the probability of a traffic crash in young (less driving experience) and older (lessened driving ability) driving populations ● drug use by drivers increase the probability of traffic crashes more in urban than rural areas; alternative hypothesis--drug use simply more prevalent in urban areas ● drug x increases traffic crash risk more than drug y; alternative hypothesis--drug x is simply used more often by drivers

TABLE 3-1 (Continued)

THE STRATEGY OF EPIDEMIOLOGY
 (With Examples Pertinent to the Study of Drugs and Highway Safety)

(from MacMahon, Pugh, and Ipsen 1960, p. 32 [examples added])

STEPS IN PROCESS	DEFINITION	EXAMPLES
(3) Analytic Epidemiology:	observational studies designed specifically to examine the hypotheses developed as a result of descriptive studies	<ul style="list-style-type: none"> ● a cohort study to examine the traffic crash risk of patients receiving chronic drug treatments compared to patients not receiving drug treatments ● a case-history study to estimate the relative risk of drug use among drivers of different ages
(4) Experimental Epidemiology:	experimental studies on human populations to test in a stringent manner those hypotheses that stand the test of observational analytic studies	<ul style="list-style-type: none"> ● (hypothetical only) the combined use of alcohol with other drugs is responsible for the increased traffic crash risk associated with other drug use: a study to estimate the traffic crash risk of drivers who use alcohol together with drugs compared with the traffic crash risk of drivers who use similar drugs but abstain from alcohol; and who have similar characteristics and driving exposure

select a sample believed representative of the population of interest;

- **quota sampling**, a form of "purposive" sampling, in which a sample is built to match the population of interest on key demographic or other variables; and
- **probability sampling**, using random selection methods in which every element has a known, nonzero probability of being selected, and which results in samples designed to allow **statistical inference** about the population based on measures of variability computed from collected data. (Kish 1960, pp.19-20)

Each of these approaches is useful, depending on research objectives, and each has advantages and disadvantages. The first three sampling approaches "have in common a heavy dependence on the validity of broad assumptions about the distributions of the survey variables [here, in particular, drug use] in the population" (Kish 1965, p.19). In probability sampling, selection procedures based on simple random sampling or its modifications are employed to enable statistical inference about the population from which the sample is drawn. Table 3-2 summarizes information about these approaches.

As outlined in Table 3-3, the actual highway safety risk associated with drug use among drivers can be estimated by comparing crash and noncrash driving populations. Over-involvement of drugs in traffic crashes can be indicated by calculating the percentage of drivers using drugs in both populations. Which of the two different ratios in Table 3-3 is calculated depends on how the groups were selected, for example, on the basis of known drug use or on the basis of crash involvement. The better matched the groups are the greater the confidence that the difference observed is due to use of the drug. But still not ruled out is the possibility that some other factor gives rise to the difference between groups.

As participants in Workshop III discussed **general approaches** to define the relationship between drugs and highway safety, they characterized epidemiologic research studies in a number of ways:

- the purpose of an epidemiologic study;

TABLE 3-2

SAMPLING APPROACHES

Haphazard or Fortuitous Sampling

- Useful in the initial stages of discovery, such as exploratory research to identify potential problems.
- Helpful in focusing research questions requiring more rigorous studies.
- Claims that data collected by this approach are representative of more general populations cannot be supported; researcher not justified in generalizing from this kind of data.
- The accuracy of statistics generated by this approach cannot be assessed.

Examples of haphazard samples:

- a group of body fluid specimens from drivers in cases of particular interest to a medical examiner or coroner;
- a group of data collection sites selected from those that express an interest in participating in a study.

Judgmental Sampling

- Differs from haphazard or "self-selected" samples in that researcher controls the selection of elements.
- Expert judgment, based on existing knowledge, is used to select areas that are believed representative of the population of interest.
- Inference based on data from judgment samples is generally restricted to areas or groups of elements included in the study.
- An alternative to probability sampling where the latter is not feasible.
- Statistical estimates for more general population values not possible.

Example of Judgment Sample:

- a group of counties selected from different regions of the country to indicate something about a national population, for

example, the population of drivers injured in traffic crashes.

Purposive Sampling (see Neyman 1934)

- Requires that there exists a known quantity (or set of known quantities) highly correlated with (linearly related to) the quantity or variable of interest; for example, the total **number** of traffic crashes in a county (quantity of interest) is roughly proportional to the county's average population (known quantity, linearly related). Areas are grouped according to the known quantity and chosen randomly within each group to avoid intentional bias.
- Certain statistical methods can be used to produce estimates representative of the population under study; however, the accuracy of estimates cannot be determined.
- The sequential and (relatively) infrequent nature of traffic crashes complicates the design of practical data collection efforts, especially in drug and driving research.

Example of Purposive Sampling:

- selection of a set of traffic fatalities to represent the national population based on key variables that characterize that population (time of day, day of week of crash; age, gender of driver; type of vehicle and roadway; etc.).

Probability Sampling

- Designs of probability samples are developed so that statistics of importance can be estimated accurately enough to permit meaningful statements about the population. For all probability samples, estimates of the accuracy of sample statistics are possible.
- Sample design incorporates knowledge about the sampled population, using **randomization** to guard against intentional bias.
- There are a great variety of probability sampling designs to meet practical, cost, and informational requirements.

Example of Probability Sample:

- A group of hospitals in a state, selected at random from all hospitals in the state, for a study of drug use among drivers injured in traffic crashes.

TABLE 3-3
 COMPARING DRIVING POPULATIONS TO INDICATE
 THE SIGNIFICANCE OF DRUGS AS RISK
 FACTORS IN HIGHWAY SAFETY

A. Four Groups of Drivers Distinguished

		Dependent Variable(s) (Type of crash, injury, etc.)	
		+	-
Independent Variable(s) (Drug, Class of Drug, etc.)	+	Crash Drug Present (group a)	No Crash Drug Present (group c)
	-	Crash Drug Absent (group b)	No Crash Drug Absent (group d)

B. Over-Involvement of Drugs in Traffic Crashes: An Indication of Risk

Two ratios showing over-involvement (after Susser [1975])

Approach 1, the case-control study:

$$\frac{\left[\begin{array}{c} \text{percentage of accident-involved drivers} \\ \text{using a drug or class of drugs} \end{array} \right]}{\left[\begin{array}{c} \text{percentage of non-accident-involved} \\ \text{drivers using a drug or class of drugs} \end{array} \right]}$$

$$\frac{\frac{a}{a+b} \times 100}{\frac{c}{c+d} \times 100}$$

Approach 2, the cohort study:

$$\frac{\left[\begin{array}{c} \text{percentage of drug users involved in accidents} \end{array} \right]}{\left[\begin{array}{c} \text{percentage of nondrug users involved in accidents} \end{array} \right]}$$

$$\frac{\frac{a}{a+c} \times 100}{\frac{b}{b+d} \times 100}$$

- how comparison populations are selected;
- how many times a sample is studied (or how many samples are studied over time); and
- sources of data and methods for collecting data.

The type of study selected depends on the purpose of the research and the nature of the questions asked. Exploratory (or descriptive) surveys might show, for example, the degree of association between drugs and crashes ("prevalence" studies), and identify driver and crash characteristics associated with drug involvement. Explanatory (or analytical) surveys go further to show the **significance** of drugs as risk factors, for instance, by over-involvement in crashes. But the fact of over-involvement may not be enough. Other factors may be responsible for, or may explain away, the observed differences.

To better account for findings of over-involvement and to address possible alternative hypotheses, factors other than drugs should also be investigated. Even though variables are not directly controlled, **which** and **how many** variables are observed and matched is a matter of sampling design and methods of collecting data. Depending on the nature of the variables selected for study, one of several designs may be more appropriate. How these variables are measured may also affect the choice of method.

The two general approaches to investigation outlined in Table 3-3 are commonly termed **retrospective** and **prospective**. The "case-control" study is an example of a retrospective survey, in which the selection of comparison groups is based on the dependent variable (accident involvement). Other terms used to describe this approach are "case-contrast" and "case-history" studies. The former term is used to emphasize the difficulty involved in matching comparison groups with the sample of cases; the latter term indicates that this method "involves 'looking backward' from effects to preceding causes . . ." (MacMahon, Pugh, and Ipsen 1960, p.45).

Prospective studies are those which compare populations selected on the

basis of the independent variable (drug use). These are also termed "cohort studies," since exposure to the risk factor leads to the formation of cohorts in the population. Cohort studies require only that the criteria or condition of selection, that is, use of drugs, **precede** the event under study. But such studies need not commence **before** the events, for example, traffic fatalities, occur. Cohort studies may also be based on historical records, and populations may be assembled for comparison after the fact.

As shown in Table 3-3, the case-control approach compares the percentage of accident-involved drivers using a drug with the percentage of nonaccident-involved using the drug. A cohort study compares the percentage of accidents in the population of drug users with the percentage of accidents in the population of nonusers. The difference lies in how the groups were selected for comparison. Both approaches yield data indicating the highway safety risk of drugs.

Additional terminology describes how a population is studied over time. A **cross-sectional** study selects samples for comparison during a restricted period of time. **Longitudinal** studies may involve (1) repeated sampling of a defined population—for example, injured drivers—in which the elements (drivers) differ; or (2) repeated study of the same sample over a number of years.

Surveys may rely on **primary** or **secondary** sources of data. For research in drugs and driving, primary data are those collected for the express purpose of relating variables of drug use and driving experience. Primary sources include the chemical analysis of the body fluids of drivers for drugs and interviews with drivers. Data for secondary analyses may include measures both of the use of drugs and of accident experience, or may describe such variables in isolation. Medical histories, driving records, data from investigations by coroners, and surveys of drug use are examples of secondary sources. Although not intended for such use originally, these data may be obtained and compared to estimate the relationship between drugs and highway safety. The reliability, completeness, comparability, and availability of records and data are factors that must be considered in

compiling information from secondary sources.

How variables of drug use and accident experience are measured characterizes the nature of data obtained by survey. Data may be **objective** or **subjective**; the measures may **directly** or **indirectly** relate to variables under study. For example, analyses for drugs in the body fluids of drivers are objective. The self-reported use of drugs by drivers is subjective. Both measures, however, are direct. An indirect measure of drug use would be a record of prescriptions for a drug. **When, where, and how** the drug was used remain unknown. As a direct inquiry of accident experience, an investigation of a traffic crash may describe a driver's culpability, his role in causing a crash. Data on the average frequency of accidents in a population are much less direct.

Participants pointed out that such questions as which design(s) to choose and which method(s) to apply boil down to (1) control over variables of interest and other significant factors; (2) reliability; and (3) feasibility. Unfortunately, these crucial aspects of epidemiologic research are not in themselves simple. For example, which factors other than drugs should we examine in surveys relating drug use and accidents? The relationship between drug use by drivers and traffic crashes may be influenced by factors associated with driver, vehicle, and environment. As stated by the panel, incorporating all—or even most—important factors in one design or one study is plainly not possible (see below). The **reliability** of data is a function not only of a design's technical rigor, but its source, as well. Which kinds of data are acceptable may depend on their intended use, for example, for exploratory research or to support countermeasure development. Finally, as one might suspect (or fear), the **desirability** of designs or methods does not parallel their **feasibility**. Rather, feasibility is a function of constraints on research. The choice of design and method is complex, and requires that legal, practical, and cost factors be considered.

Likewise, as noted above, attempts by participants to answer questions listed at the start of this section produced a complex treatment of these topics. We try in the next subsection to report their discussions in a

simplified manner. First, several forms of the general hypothesis that drugs increase highway safety risk are listed. Second, because some research designs and survey methods are basic to several kinds of studies, different approaches outlined by participants are presented on two levels. On one level, general characteristics of designs and methods are described. On the next level, approaches to epidemiologic research in drugs and driving are detailed.

3.3 Survey Designs and Methods for Epidemiologic Research in Drugs and Driving

The choice of designs and methods flows in part from hypotheses underlying research. In the area of drugs and driving a general hypothesis states that the use of drugs (alone or in combination with other drugs, including alcohol) by drivers increases the likelihood of traffic crashes and associated losses; that is, drug use by drivers increases highway safety risk. One participant described three forms of this hypothesis:

1. Given individual differences, persons using a drug (i.e., under its influence) will have an accident experience different from when they are not using the drug (self-control study).
2. Persons using a drug will have an accident experience different from **other** persons not using the drug (case-control study).
3. Users of a drug as a **group** will have an accident experience different from nonusers (group-control study).

All forms of the general hypothesis assume that, on the average, differences in accident experience will be in the direction of increased highway safety risk. The first hypothesis is unequivocal. In testing it, surveys termed **self-control studies** produce evidence about as conclusive as is possible to get. The second hypothesis is slightly weaker. Even if confirmed by **case-control studies**, other factors may intervene and explain differences between samples. The third hypothesis is looser still. In **group-control studies**, a longer chain of relationships links independent

and dependent variables, leaving more room for other factors to affect the findings.

Epidemiologic studies differ according to which form of the general hypothesis they test. The designs and methods applied in research differ in how directly they measure variables under study and in their control over other factors. The following subsections deal with general characteristics of designs and methods and with specific approaches to epidemiologic research in drugs and driving.

3.3.1 Limitations, Strengths, and Weaknesses of Survey Designs and Methods. The paragraphs below summarize points made by participants about designs and methods held in common by the specific research approaches mentioned. The information presented reflects the expertise of participants from fields that require this knowledge. Although the topics below were not discussed comprehensively, we believe their brief treatment here supports the discussion of specific approaches to surveys of drugs and driving.

The main focus of discussion was on surveys to indicate the highway safety risk of drugs. In addition, the role and uses of descriptive surveys, or exploratory studies, were also pointed out. Such research efforts usually cover only two of the four cells described in Table 3-3. Because no control group is obtained for comparison, their findings are inconclusive with respect to the relationship between drug use and traffic crashes. For example, results showing some degree of association between drug use and traffic crashes may not be significant. A drug that appears in ten percent of the crash population may appear just as frequently in the at-risk population (no overinvolvement). But these kinds of surveys do have value. For example, a list of drugs of interest may be refined to reflect the prevalence of drugs in populations of accident-involved drivers. If enough cases are found, other variables associated with drug-involved accidents might be identified. Descriptive surveys, along with experimental studies, help formulate hypotheses for further epidemiologic research.

By way of contrast, explanatory (analytic) studies can determine

whether a drug or class of drugs occurs more often in a sample from a crash population compared to a control sample. Overinvolvement, or overrepresentation, shows that a factor may warrant measures designed to lessen its impact on highway safety. This really depends on the frequency or probability of the factor's presence in the at-risk population and/or the ability to apply countermeasures cost-effectively. Estimates of **attributable risk** form the basis of action once an overrepresented factor is identified. Because they can assess other variables, case-control studies may also be invoked to study whether drugs are overinvolved in traffic crashes and to find out if the presence of other factors can explain away the relationship between drug use and traffic crashes.

The types of study mentioned above--self-control, case-control, and group-control--may have sampling designs in common. Participants referred most to probability sampling, either simple random or stratified. If it were desired to match different samples for a number of factors other than drugs (numerous in themselves), then a random design would require very large sample sizes, a drawback in terms of cost. Stratified probability sampling reduces sample size while ensuring adequate representation of factors deemed important for control. If drugs were the only variable of interest, then a study using simple random design might be done with samples of manageable size. But such a design frees from control other factors, such as driver and environmental characteristics. A control sample might then differ significantly from the accident sample in some significant way. Studies of multiple factors would be more definitive of the relationship between drugs and highway safety, especially if the factors placed under control **already** show some association with traffic crashes (e.g., age, sex).

As noted above, surveys can be designed to sample a population longitudinally--either taking repeated measures of the same sample of elements or sampling the population repeatedly with one measure taken per sample. A longitudinal design with a single large sample gives a study the ability to work statistically with many variables. In a prospective study, factors antecedent to an event--for example, a traffic crash--can be

distinguished (drug use, no drug use). Other factors that may also explain the events may be "planted in time," and whether they were antecedent or consequential to drug use may be determined. A cross-sectional design based on a single sampling of a population, in contrast, correlates the presence of factors and the event with less ability to state which factor precedes another in a causal chain. These designs are in part complementary, for they tend to narrow the choice of methods for collecting data. For example, a longitudinal design lends itself to methods that emphasize subject characteristics over environmental factors. Studying a large sample over time suggests surveys based on questionnaire rather than a series of periodic studies using the roadside-stop approach, which would necessitate the "banding" of research subjects as is done in wildlife conservation studies. The latter data collection method (roadside surveys) would make the cross-sectional design a less costly approach. A combined approach--repeated sampling of a population using the cross-sectional design--could be used to monitor the prevalence of drug use in different driving populations, but would still be limited for the purpose of determining the nature of association between drug use and traffic crashes.

Methods of collecting data in surveys may be objective or subjective. Objective data are highly prized. In research on drugs and driving, analyses of body fluids for the presence and amount of drugs and their metabolites most objectively describe the use of drugs by drivers. Self-reports of drug use are subjective. Accident reports and official driving records describe the event under study more objectively than self-reported data and third person accounts. Related to the degree of objectivity or subjectivity are questions of reliability--the room for error or false reporting in data obtained by survey.

Analyses of existing data, usually obtained for other reasons, may be compared to data obtained from primary sources (e.g., surveys of drug use among drivers). The secondary analysis of survey data, existing records, and medical information is less costly but usually less suitable for the purpose at hand. There is no first-hand control over the collection and handling of data, much less over the definition of case. Sources of data

linking both independent variables must first be found and their reliability assessed. Despite their drawbacks, secondary data may afford "high-payoff" analyses, their main advantage.

3.3.2 Specific Approaches to Epidemiologic Research in Drugs and Driving. Responding to such questions as "Which method?" and "Which design?", participants described specific approaches to epidemiologic research in drugs and driving. Knowledge of existing constraints, the topic of Section 4.0, perhaps limited thought given to "ideal" studies. The approaches as outlined do show the range of possible studies. Their limitations, strengths, and weaknesses are noted as well.

Uppermost in the mind of the panel was the type of case-control study done for alcohol by Borkenstein et al. (1964, 1974). The Grand Rapids study, as it is called, featured the roadside stop as a means to obtain a control sample matched on environmental factors such as the time and location of the accident case. Breath specimens were obtained to measure objectively the presence and amount of alcohol in drivers. In this case-control approach, defining "cases" comes first. The population of accident-involved drivers must be chosen for study. Two well-defined groups are drivers fatally injured and drivers seriously injured (requiring emergency room care). In one approach, specimens from the fatally injured population may be obtained from coroners and medical examiners. Specimens from the population of injured drivers could be obtained from hospital sources, from local officials such as police, or, conceivably, from the accident victim directly. Interviews with injured drivers are also possible, and could be done along with specimen analysis. The culpability of drivers, often not easily determined, may be an important factor that reflects drug use, and should be considered in stratifying cases.

Several variants of this case-control approach are possible, based on different methods of data collection. For example, instead of obtaining specimens of body fluids, the roadside-stop survey may use a questionnaire to elicit information from the control sample. Alternatively, drivers in the at-risk population may be identified at roadside and interviewed later in

their homes. According to participants, rates of refusal to cooperate may be a function of the setting. Less threatening settings may produce a higher rate of response from subjects.

The case-control roadside survey uniquely places under control, as much as possible, time, location, and other environmental factors related to crashes. In the Grand Rapids study, the characteristics of subjects were not matched in the randomized roadside stop. Refinements to bring subject factors under control could be made in future such studies. Sometimes overlooked, the roadside-stop approach with analysis of body fluids objectively links drug use and driving. It also precisely measures a crucial variable, the **quantity** of drug present. Interviews, however detailed, can hardly approach the strengths of roadside surveys that employ specimen collection and analysis.

One participant suggested a survey of two-car crashes, a specific case-control study in which the case and the control are selected simultaneously. This approach was termed "inferred exposure." (The concept of "exposure" is general to studies of highway safety risk. Exposure to accidents may be measured in various ways. When accident experience itself forms the basis for measuring exposure, the result is more usually termed "induced exposure." The concept of exposure and induced exposure in highway safety have been reviewed by Chapman [1973] and Haight [1973], respectively.)

In the two-car crash survey suggested, variables of time and location are controlled absolutely. Both drivers may be fatally injured or not. Different combinations (e.g., fatally injured and seriously injured) are possible, and the extent of injury may be a covariant. The hypothesis under study would be that "at-fault" drivers will show greater drug use than not-at-fault drivers. This type of survey represents a strong case-control approach. It is limited in that this type of crash occurs infrequently. Also, the criterion "at fault" may be equivocal. For instance, fault may be partial in both drivers' cases. This approach also narrows the universe of cases, for example, by excluding single car crashes, thus limiting the extent to which findings may be generalized.

Related to this kind of study are surveys that include all persons involved in a traffic crash, including pedestrians and passengers. At least, the argument goes, they were present at the time and site of the crash, and they form possible contrast groups for comparison to accident-involved drivers. As such, these studies become lines of evidence in a field of research where no single study can supply all the needed information.

Case-control studies such as the roadside survey deal with drug use and subject factors as characteristics of momentary, not long-term, significance. Poles apart are surveys based on face-to-face interviews with questionnaires of drug use and driving experience. The latter surveys can obtain self-attributed, historical information on drug use, driving, and the influence of drug use on driving experience. Such studies can match subject variables as closely as possible, treat drug use as a more or less stable factor, and assume that momentary environmental factors are essentially unimportant. Just as interviews at roadside might include questions about subject characteristics, however, surveys based on self-report could include questions to infer environmental factors involved in accidents.

Studies based on questionnaires—including face-to-face interviews and surveys by mail—may be surveys of households or special populations. **Group-control studies** would compare user and nonuser groups for accident experience. **Self-control studies** would compare the accident experience of users while using and not using drugs, as reported by the subjects themselves. Questionnaire-based studies could be run separately on a large (national) or small (statewide) scale, or "piggy-backed" on existing studies, for example, national surveys of nonmedical drug use (Abelson, Fishburne, and Cisin 1978; Johnston, Bachman, and O'Malley 1977). Questions relating drug use and driving are included now in one such survey and may be included in future surveys funded through the National Institute on Drug Abuse. Difficult to dissociate in such studies are other factors associated with drug use, such as risk-taking, the measuring of which is not the purpose of these studies.

Record-based approaches were also mentioned. Basically, records

pertaining both to drug use and accident experience are necessary. A survey might start with either variable. Surveys of drug use could identify users and nonusers; subjects could then be interviewed and their driving records obtained. An example of a group-control study was mentioned. A recent survey compared the driving records of patients (ex-heroin users) maintained on methadone and a control group identified by the patients as being similar but as not using narcotics. A survey might start with driving records and interview subjects about their use of drugs. One advantage of this approach is its lower cost; but its price is a looser association of accidents and drug use, a characteristic of the group-control study.

One record-based approach is intended to reduce some of the biases of case-contrast groups and to reduce some of the time requirements and costs of a prospective study. A **trohoc** study ("trohoc" is **cohort** spelled backwards) differs from a prospective study in that cohorts are identified **after** cases arise in a population. But they are similar in that cohorts are assembled on the basis of historical records made **before** the critical events. Possible studies were described as examples. Servicemen involved in driving accidents might form a set of cases. Enlistment records or records of periodic medical examinations could be used to select contrast groups, e.g., men interviewed or examined before and after each person later involved in a crash. Another set of cases might be obtained through records of treatment centers for drug abuse. The more closely matched the groups, of course, the better.

Finally, detailed descriptive studies of drug-involved accidents were suggested as another strand of evidence linking drug use and highway safety. Based on in-depth investigation of accidents, such studies could point out differences in the culpability of drivers, as well as other variables involved in these accidents. They could help focus the study of the drug and driving problem by accurately describing the kind of accidents and driver errors associated with drugs. If the set of accidents under study is a probability sample and representative of crashes in a population, then estimates of attributable risk are possible. The method of in-depth

accident investigation combined with specimen analysis can also emphasize **mechanism**—how drugs contribute to highway safety risk, how drug use may lead to crash-causing driving behavior, and how drug-involved crashes can be identified with greater certainty. The "clinical assessment" of accidents can show how risk may be generated. But this approach has at least one important limitation. The variable of greatest interest, the **concentration of drug** found in driver body fluids, rarely supplies a definitive statement of driver impairment. Only high concentrations known to cause gross impairment clearly indicate that a drug's role in an accident was causal. Conclusive cases for analysis may be few in number as a result.

3.4 Issues in the Selection of Designs and Methods for Epidemiologic Research in Drugs and Driving

A number of issues surfaced as participants discussed surveys to link drug use and highway safety. Among them were the following:

- the sequence of research needed to establish drugs other than alcohol as a priority concern in highway safety; and
- the relationship between the kind of data that different surveys provide and the kind of data needed for policy decisions.

When pressed for alternatives to the kind of survey typified by the Grand Rapids study--roadside-stop approach with control for environmental variables and with analyses of body fluids for drugs--participants countered with their own questions. How important is that kind of information? How rigorous must data linking drug use and highway safety be?

The response they received was basically this: the importance of case-control data was a matter for policymakers to decide. At the same time, policymakers cannot deal with questions about technical rigor. Specialists in an area of research must state the degree of rigor required, then outline the methods to achieve it. Alternatively, they might describe each possible approach and the kind of information that will result from its use. Then policymakers can decide on that basis which methods best suit their

needs.

The panel, in turn, pointed out several dimensions along which types of surveys might be ranked. Most apparent were the levels of refinement in research to define the relationship between drugs and highway safety:

1. **Exploratory research:** including studies of the prevalence of drugs in crash populations and experimental studies of drugs and their effects on behaviors believed related to driving.
2. **Risk studies:** where the crash population and contrast groups are compared for the prevalence of drugs.
3. **Absolute risk studies:** where the actual risk attributable to drugs is determined by obtaining data on their relative risk and the frequency of drug use in the total driving population.
4. **Causal studies:** given that the highway safety risk of one or more drugs has been established, in-depth investigations to determine the mechanisms by which the drugs(s) increase(s) risk.

Exploratory research can justify the cost in time and dollars to carry out studies that indicate risk. Unless surveys of the latter kind show overinvolvement of drugs in the crash population, further research to describe relative or absolute risk is unlikely. Data on relative risk alone do not specify how resources for countermeasures should be allocated. Studies that show absolute or attributable risk more strongly indicate the magnitude of the problem. Participants stressed that such studies "should be done especially if countermeasures are contemplated." But questions of "causality" entail a very long research enterprise. Such questions, in the opinion of the panel, are not going to be answered by a single strategy. Rather, a number of converging approaches--including experimental research--must combine to yield definitive information on the role of drugs in traffic crashes.

The sequence of research in drugs and driving was viewed as a series of refinements in the state of knowledge. Within each step, levels of refinement were also possible. For example, a case-control study might go

beyond a simple comparison of the prevalence of drugs. Collateral data obtained **post hoc** could describe accident and driver characteristics. A roadside survey could be designed to match subject as well as environmental variables. The culpability of drivers in the accident sample might be determined. In surveys of drug use, questions could be developed to extend the level of inquiry, obtaining more detailed information on the relation of drug use and accident experience.

Participants pointed out that questions of which design or method to apply return to the idea of **control**—control over other variables that may also contribute to traffic crashes. The many factors that pertain to the environment, to the subject, even to driving behavior (e.g., time of day, exposure) force the conclusion that no single study can possibly achieve control over all the variables of interest. Because different designs control different variables, more than one kind of study and even more than one type of survey is needed. For example, in the case-control approach, adequate control groups are difficult to obtain, perfect control impossible. Several contrast groups will be advantageous. The more such groups to compare to sets of cases, the more confidence one has in research findings. Also suggested were a series of case-control studies, overlapping with respect to certain critical variables. In these approaches, the accumulation of evidence is the aim, rather than one definitive survey.

Participants observed that studying only drivers fatally injured in traffic crashes may be misleading. The primary effect of drugs may not be an increase in fatalities. Compensatory behavior by drivers may actually decrease fatalities but increase injuries stemming from less serious crashes. The emphasis, therefore, should rest on obtaining a general statement of "crash risk," including other populations of accident-involved drivers besides those fatally injured.

It was also pointed out that, in determining overinvolvement or relative risk, an emphasis solely on single agents may also be misleading. Classes of drugs (based on use of pharmacologic effects) may as a **whole** be overinvolved in accidents, whereas a given member of a class may not. Another possibility was raised. One member of a class of drugs may be

found predominantly in the crash population, but another member found so in the nonaccident group. Thus, studies must be sensitive both to the aggregation and disaggregation of drugs in classes.

The desirability of a national study to establish the relative risk of drugs was expressed. Citing the high cost of such an effort, one participant suggested that a series of local replications might suffice in its stead. If the relative risk statistic were sufficiently large and confirmed by other studies conducted under varied conditions, perhaps this approach would make a national study unnecessary.

Participants related the "hierarchy of conclusivity" in designs and methods to the possible uses of the data produced. They stated that the confidence in any decision made depends entirely on the quality of comparison groups and the nature of the contemplated action. Exploratory research and surveys based on self-reports are best used as indicators for a relationship between drugs and highway safety. They can provide a basis for higher quality research. Confirmation of their findings, if positive, should be done by a roadside approach, certainly **before** legislation is enacted. If the countermeasure being considered is in the category of public information/education programs, less conclusive evidence and less rigorous studies are required. Again, only studies that determine **attributable risk** can show how resources for countermeasures should be allocated. A drug with a very high relative risk may occur very rarely; a drug with a lower relative risk but with a much greater frequency of use might have higher priority. The efficacy of a countermeasure, however, does play a role in such decisions. A drug with a high relative risk and a rare but applicable population may receive a higher priority for action than otherwise expected.

3.5 Summary

A series of questions about the application of epidemiologic research methodology in drugs and highway safety was put to the panel. Subsequent discussions described the strategy of epidemiology, the process of identifying drugs as risk factors and establishing the nature and extent of

their role in traffic crash causation. The appropriateness of alternative sampling approaches depends on the research questions asked. To indicate the actual highway safety risk of drug use among drivers, prospective or retrospective surveys that compare the prevalence of drug use among crash and noncrash populations are required.

Participants described different study designs and data collection methods and indicated that the choice among them depends on which variables must be controlled, the reliability of the data collected, and the legal, practical, and cost feasibility of implementing each type of study.

The hypothesis that drug use among drivers increases highway safety risk can be tested by self-control, case-control, and group-control studies. As more specific hypotheses are formulated on the basis of findings from descriptive surveys, analytic surveys (cohort and case-control studies) with more focus can be carried out.

The panel also identified specific approaches to epidemiologic research on drugs and highway safety. Ideas for the design and conduct of research studies were shared. Finally, issues related to the selection of designs and methods for drug and driving research were discussed. The relationship between informational needs for decision-making at the policy level to the type of study required to satisfy them was defined.

4.0 CONSTRAINTS ON EPIDEMIOLOGIC RESEARCH IN DRUGS AND DRIVING

Of all areas of research in drugs and driving, epidemiology is perhaps the most difficult. Technical and policy issues converge, causing conflicts between various principles that the federal government is trying to follow at present. On one hand, increased interest in problems related to drugs has produced pressure to act, with the concomitant pressure to better define the drug and driving problem. On the other hand, attempts to decrease interference with the public have led to sharp restraints on survey research. This acutely affects research and the development and prevention programs in highway safety. Finally, efforts by NHTSA to select for work only problems that are high priority items have led to a low priority for research on drugs other than alcohol. This is the milieu today for epidemiologic research in drugs and highway safety.

This section describes present constraints on epidemiologic research as perceived by participants of Workshop III. First, two categories of constraints—**policy** and **technical or methodological**—are outlined. Their combined effect on research is then discussed in terms of feasibility. In other words, how feasible today are various approaches for studying the relationship between drugs and highway safety?

4.1 Policy Constraints

Participants identified constraints based on policy in several areas, including the Department of Transportation, the Office of Management and Budget, and state and local agencies. Also included in this category were certain current legal constraints, which may not be essentially law-based constraints, but which really represent present interpretations of laws and regulations. One example of this latter type of constraint is departmental regulations forbidding uniformed officers from stopping traffic without

cause.

Administrative sources of constraints exist. One is the U.S. Office of Management and Budget (OMB). In general, this office has tried to limit surveys. Difficulty in obtaining approval for survey research in highway safety has been noted. This policy stance apparently stems in part (1) from the perception that the public resents such research and (2) from such specific questions as "Does use of law enforcement officers in the roadside-stop approach constitute apparent government coercion inappropriate for research based on voluntary cooperation?"

Participants questioned this view of the public's reaction to research and suggested that the official perception of the public attitude may be at odds with reality. (However, see "refusal rates," below.) They also suggested that this problem may be one of education.

Another constraint imposed by the OMB was noted. One participant suggested an approach in which NHTSA would include questions about drug use and highway safety in a national survey, e.g., one sponsored by the National Institute on Drug Abuse. Another participant pointed out that the OMB's mechanism for clearing interagency efforts to collaborate erects almost insurmountable barriers to such research. This despite the intent of regulations to facilitate such interaction.

Administrative constraints are also apparent in prospective and retrospective studies based on surveys of drug use. For example, the use of existing survey data may be limited for record-based studies. Demands for confidentiality may have led to complete removal of information identifying a respondent. This thwarts attempts to link driving records and self-reported drug use. Participants also perceived administrative resistance to the idea of additional uses of data on drug use. Because subjects must be completely informed, asking their permission, e.g., to examine their driving records, might lower the response rate on a survey.

Other policy constraints may exist at state and local levels. Two examples were given.

Special regulations exist for confidentiality in alcoholism and drug abuse programs. Clinical agencies may refuse to cooperate with researchers

seeking to compare drug use data and driving records of patients. The Drug Abuse Control Act of 1970 did provide for an absolute grant of privilege--by the Attorney General or the Secretary of the DHEW--for researchers. Proposed regulations to promulgate that authority were not given until late 1976, however. A person with a grant of privilege can **receive** information that is confidential. But, in the opinion of one participant, some clinical agencies may not accept that these regulations enable them to **give out** such information. There may be at present a difference between what was intended and what is practiced.

The question was raised whether state Department of Motor Vehicles would cooperate with record-based surveys using driving records. This kind of inquiry might be held by some officials to be an invasion of privacy or a violation of confidentiality. Such constraints do exist; however, at present, it is believed the legitimacy and purpose of the study would allow researchers access to this information.

The other group of constraints, more associated with survey designs and methods, is described in the next subsection.

4.2 Technical and Methodological Constraints

Even if all the policy constraints were removed, the ideal survey could not be done; technical and methodological limits also constrain research in this area. Participants often stressed that, assuming the fact of overinvolvement of drugs in traffic crashes, no one study can control all other variables, many of which may be factors in their overrepresentation. The relatively low prevalence of particular drugs expected in a sample of traffic crashes also poses a problem. The ratio of the number of variables to the number of cases simply becomes too small for study. Therefore, questions containing multiple variables must be answered either in a series of surveys or must await in-depth investigations of accidents at a deeper level of inquiry. But other, less global constraints beset the conduct of surveys in drugs and driving.

Perhaps the greatest of these constraints, manifest in high rates of missing data, is the lack of complete cooperation by the subjects of

surveys. One participant described the problem this way for studies of relative risk. Any single substance will appear with a very low frequency in the at-risk population. To determine its degree of overrepresentation in the crash population requires many times the number of accident-involved drivers in the sample of cases. The error in measurement becomes crucial. If the percentage of drivers at-risk who refuse to cooperate is substantial, the noncompliant group and assumptions about their use of the drug can inflate—or deflate—the calculated risk factor "astronomically."

In past household surveys of drug use, for example, the last five to ten percent of the sample that initially did not respond contained a high proportion of drug users. In surveys of drug use in schools, **absentees**, who may be more likely to use drugs, are of interest. In the roadside surveys of the driving population, therefore, the drivers who refuse to supply information by interview or specimens for analysis are the focus of concern.

Participants discussed factors that may affect the rate of missing data. The requirement for informed consent by subjects of a study was believed one factor that increases the number of refusals. Statements made to subjects clearly point out to each that participation is totally voluntary. Increased resistance to cooperation has been observed recently. Methods to increase rates of response include substantial payments to subjects and even to interviewers. The setting for collection of data may also be important. Thus, refusals at roadside may be greater and have more significance than refusals in a household survey. Participants recommended that studies of various methods to decrease rates of missing data be carried out **before** large-scale surveys of relative risk are attempted.

In surveys based on chemical analyses of body fluids, other sources of missing data include the lack of full cooperation by medical examiners and coroners and hospitals. Failure to supply specimens might occur for a number of reasons, among them professional ethics and the privileged status of medical information. Participants saw little difficulty in gaining the cooperation of medical examiners and coroners for a study of fatally injured drivers. Obtaining specimens from injured drivers taken to

emergency rooms, however, presents more of a problem.

Participants also noted specific constraints that pertain to methods used in surveys. In studies based on questionnaires, limits on the number of questions asked prevent adequate differentiation among classes of drugs. Unlike chemical analyses, specific drugs are not usually identified (exceptions are marijuana and a few other prominent illicit drugs). The reliability and lack of face validity of statements in a survey based on self-reports constitute a significant constraint.

The most subtle constraint is the **state of knowledge** itself. As yet, only global findings linking drug use and accidents have been reported. The empirical basis for establishing epidemiologic hypotheses is limited. For example, little is known about which factors belonging to environment or subject should be studied along with drugs in surveys of relative risk. Which age groups are most at risk is not known. The meaning of drug concentrations in body fluids, crucial variables for interpreting the findings of studies that collect such data, is not known with great certainty. Studies of the causal role of drugs in traffic crashes, which must be based on a body of knowledge not yet in existence, are precluded for the most part. Sources of data for secondary analyses—to support the call for relative risk studies—must still be found. The present state of knowledge appears to limit near-term research to descriptive surveys and to the most basic of relative risk studies—those that indicate risk by establishing overrepresentation.

Not so subtle is the **lack of funding** for survey research in drugs and driving. This dilemma is circular. Drugs are "precrash, individual" risk factors. Because there is only fragmentary evidence to date, this area has trouble competing for available funds. The emphasis now is on programs with "high-payoff," and areas with this prospect have higher priority. The issue of drugs and driving does not have the priority necessary to obtain the funding needed for systematic research. Thus, the drug and driving problem is ill-defined, of unknown magnitude, and may remain so.

4.3 Feasibility of Research Linking Drug Use and Highway Safety

Constraints in epidemiologic research act as a potent force in the choice of survey designs and methods. They establish, in effect, a hierarchy of feasibility for ranking various approaches. Although not formally defined, two kinds of feasibility were discussed. One kind of feasibility involves technical issues. For example, comprehensive analyses for drugs in breath and saliva are not yet possible. Methodological problems must be solved before these body fluids can be used for drug analysis in surveys of drug use among drivers. The other kind of feasibility pertains to socio-political issues. Factors of cost, approval of research, and likely outcomes of studies may be included here.

Participants did not rate each approach on a subjective scale. Neither did they discuss at length specific methods of research in terms of their feasibility. Instead, statements emerged during the course of the workshop that suggest, at least, an outline of their feasibility, given current conditions of research. Paragraphs below summarize these statements.

The Grand Rapids study by Borkenstein et al. (1964, 1974) stands as a bench-mark survey, albeit for alcohol. For the near-term, a similar approach for other drugs appears very unlikely. Practical, political, and legal constraints seem to preclude obtaining and analyzing specimens of body fluids, especially blood and urine, at least in a federally sponsored study. Are these constraints insurmountable? They do not appear absolute, if such a study were not under sponsorship of the U.S. Government. This condition does erect a real funding barrier for a type of research quite costly to begin with. But rates of missing data found in earlier studies using the roadside-stop approach also darken prospects for this type of survey.

Even less feasible are more involved studies such as a longitudinal, prospective survey (a cohort study), and causal studies (in-depth investigations of accidents). Their cost, their dependence on knowledge that does not now exist, the commitment they demand in terms of time and purpose—these factors fully preclude these approaches. Their priority must proceed from studies of relative risk and this depends entirely on

findings indicating that a substantial drug and driving problem exists.

Certain methods appear to stand a better chance of approval than others. For example, technical considerations aside, collection of breath and saliva specimens are more feasible than collection of blood and urine. Interviews may be more feasible yet. But even interviewing ("interrogating," as one participant described this approach) may run afoul of the same constraint that hinders collection of body fluids—a question of civil liberties. Unfortunately, high rates of missing data also plague household surveys. Perhaps most feasible are the least rigorous of studies, for example, record-based surveys of drug use and accident experience.

Driving populations themselves differ in feasibility for study. Fatally injured drivers are most easily studied, if not necessarily the most appropriate. Less accessible are other accident-involved drivers and drivers arrested for moving violations. Practical constraints dictate the order of their study. Participants stressed that driving populations other than fatally injured drivers must be studied to fully define the drug and driving problem.

4.4 Summary

Participants identified various constraints that hamper epidemiologic research on drugs and driving and discussed their combined effect on the design and conduct of studies.

Policy constraints include laws and regulations at federal, state, and local levels as well as interpretations of laws that do not explicitly rule out research efforts. Methodological constraints stem in part from the inherent difficulty of studying the relationship of drug use and traffic crashes. Low cooperation rates among subjects of research also contribute to problems in this research area. The present, limited state of knowledge constitutes another constraint, restricting research hypotheses to questions about the overrepresentation of drug use among crash-involved drivers. The lack of adequate funding prevents the development and implementation of a comprehensive, systematic program of research to define the drug and driving problem.

These constraints affect the feasibility of possible research designs, the scope and depth of drug and driving surveys, and the ability of researchers to do the studies necessary to answer policy questions related to drugs and highway safety.

5.0 SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Present knowledge poorly describes the relationship between drugs and highway safety. The field remains in a state of infancy. At this stage of research, only basic questions are asked, such as these:

- What evidence now suggests that a problem of drugs and driving exists?
- What evidence can be produced to show there is a problem?

NHTSA has already engaged the process of problem definition. Ongoing and planned projects promise to return some much needed information. The findings of these studies may demand additional, perhaps more involved, research. Should exploratory studies produce such results, surveys that estimate actual highway safety risk are among the kinds of research required to further advance the state of knowledge.

Epidemiologic research, especially that beyond the descriptive survey, is neither simple nor cheap. Methodological and other issues hinder progress in an area of highway safety not straightforward to begin with. As an aid to planning, this workshop dealt with phases of research beyond the one now at hand but not yet complete. Basically, the central concern of this effort was how to obtain more refined data, given the current climate of research in drugs and driving.

Three major topics focused discussion:

1. the nature of epidemiologic research;
2. epidemiologic approaches to describe the relationship between drugs other than alcohol and highway safety; and
3. constraints on this kind of research.

In general, epidemiologic research in drugs and driving compares samples from populations of accident and nonaccident drivers for the

presence and absence of drugs. Four groups of drivers (accident + drug; accident + no drug; no accident + drug; no accident + no drug) are required to study the overrepresentation of drugs in the accident sample. But the cells in the 2 X 2 table (as shown in Table 3-3) really represent more one cell each. There are different sets of cases (fatalities, injuries, property damage only), and different samples from the control population provide a number of contrast groups for comparing them. Alternative designs and methods provide different measures of drug use and accident experience.

Participants described the epidemiologic approach as applied to research in drugs and driving along several dimensions:

- technical rigor;
- control over variables other than drugs;
- the conclusiveness of research;
- levels of refinement within and among different approaches;
- the desirability of types of surveys; and
- the feasibility of types of surveys.

In general the sequence of research follows the degree of technical rigor in types of surveys. Because other factors may intervene between drug use and accident experience, the study of multiple variables and the conclusivity of research are directly related. Studies based on various designs and methods form a hierarchy of control. One can establish the relative risk of drugs with various degrees of confidence and under conditions of more or less control. Levels of refinement in research depend on the design of surveys and the methods used to collect data. In the end, the broader the definition of the problem, the greater potential error inherent in the final estimate. Also, less certain will be the choice of action measures to counter the problem as defined.

Specific approaches in epidemiologic research differ greatly in the kind of variables studied and in how they are measured. The desirability and feasibility of research needed to define the problem of drugs and driving are not congruent. Three related forces—not entirely distinct—set the limits of inquiry, the sequence of studies, and the choice of survey designs

and methods:

- past and present levels of funding;
- present knowledge of drugs and driving; and
- specific policy and research constraints.

Together, they impose severe conditions on the planning and conduct of research in this area.

Taking them into account, participants concluded that case-control studies like the Grand Rapids study for alcohol are ultimately required for other drugs, despite their present infeasibility. Such a roadside-stop approach should match cases and their controls for important environmental and subject variables. Chemical analyses of body fluids and collateral data to aid in interpreting analytical results are essential elements in this approach. Nevertheless, given its problems and constraints, this kind of survey on a national scale was not recommended until preliminary research provides a firmer foundation for its undertaking.

Among issues to resolve is the refusal of subjects to cooperate. Possibly, this is a function of setting and incentives. More refined approaches in future studies may produce acceptable rates of missing data. Participants concluded that feasibility studies should be done to find the best ways to obtain better cooperation by drivers from populations at risk.

While knowledge of the populations at risk seems absolutely required for most types of action, studies indicating risk depend on findings from exploratory research. Initial attempts to define the problem should include studies of the prevalence of drugs in populations not only of fatally injured drivers but also of cases of injury and property damage. One key point here is their degree of refinement. Collateral data is crucial, given problems in interpreting the meaning of drug concentrations in body fluids. The predominant finding may even be one of "polydrug use." The presence of drugs combined with alcohol compounds the difficulty of assessing the problem of drugs and driving. Do drugs increase the relative risk of alcohol use in driving populations, and, if so, how significantly? Refined data from descriptive surveys may indicate the need for further research along these lines.

Although participants gave case-control studies high priority, they recognized that no one study can give all the answers. For example, retrospective studies, or post hoc surveys, usually lead to inappropriate contrast groups. A series of studies will be needed to describe the nature and extent of this problem. The more effort directed toward factors other than drugs, especially factors antecedent to the accident, the more credibility findings will have, and the more concrete the basis for action will be.

As one participant pointed out, all science can ever determine is sequence and, then, infer cause. A prospective study can enhance the inferential capacity of research. A question facing decision-makers in highway safety is this: How much assurance do you want against the alternative hypothesis that both drug taking and accidents have a common origin? With its greater control over some variables, the prospective study has the power to examine hypotheses with respect to the common origin of cause and effect. For instance, the influence of a quality of personality, e.g., proneness to risk-taking, might be studied as a common cause of both drug use and accidents in a driving population. This option is usually not available in the post hoc case-control approach.

Nonetheless, it is difficult to imagine a longitudinal, prospective study that can measure the presence and amount of drugs in body fluids. Although validity of self-report data may be better than thought, the perceived reliability of information based on self-report is low. This hinders use of these data in developing action programs. Participants felt that this level of refinement does not suffice for decisions on policy more involved than programs of public information and education. Before existing laws on drug-impaired driving are enforced on a large scale, studies objectively showing drug use while driving must be done. That is, body fluids must eventually be obtained and analyzed as the sequence of research approaches the level of refinement needed for the development and implementation of large-scale programs dealing with any drug and driving problem.

Assessing the prospects for the near term, participants concluded that

the best hope is for the piecemeal accumulation of evidence. The central problem in this regard is how to disaggregate (in terms of specific studies) the convergent lines of evidence needed to describe the relationship between drugs and highway safety. The panel recommended three kinds of activity:

- a national survey of the prevalence of drugs in fatally injured drivers;
- studies to resolve methodological problems both present and future; and
- studies to identify sources of existing data and their utility for secondary analyses.

A national survey of drug use among fatally injured drivers has been funded by NHTSA. Participants recommended, however, that a national study of relative risk not be tried without support of adequate pilot studies. In addition to the planned national survey, participants suggested the possibility of adding questions on drug use and driving to future national surveys, such as those of the National Institute on Drug Abuse. Alternatives to federally sponsored studies include smaller scale, commercial surveys. Also, surveys based on interview or questionnaire by mail could supply information on other, less accessible populations, such as injured drivers. In studies based on the analysis of body fluids, rates of missing data may be too high for these kinds of cases.

Participants also recommended that a series of methodological studies be carried out in one area over a long period of time. Their purpose would be two-fold: (1) to develop methodology for a national survey of relative risk as well as the series of interlocking studies needed to fully define the problem; and (2) to better define interrelationships among driver, environment, vehicle, and drugs. Data flowing from these cross-sectional surveys might identify variables that correlate with drug use and accidents and that might be included in later longitudinal surveys of multiple variables.

Participants recommended one approach to this activity. A long-term

research project, or even a center for research, could be established in a locality with the interest and capability. Limited jurisdictions may yet exist in the United States for pilot studies to prepare for a national survey to estimate relative risk.

Another function of the proposed center for research on drugs and driving might be **secondary analyses of existing data**. Whether or not such a center is established, participants recommended that these kinds of studies be pursued. Secondary analyses can yield high payoffs. For example, they may provide insight into the problem and into the effect of variables other than the use of drugs. Thus, they can help to form a better basis for the expensive case-control studies.

First, however, sources of data must be identified. Sources include past surveys, ongoing studies of drug use among drivers at state and local levels, existing records, and medical information systems. The value of available data must be assessed. Next, of course, funding for their analyses must be forthcoming. Participants recommended a workshop be conducted to focus on this line of research. Representatives of data systems, secondary archives, and their potential users should be brought together. This kind of workshop would provide a forum for researchers to find out what kind of data now exists and to evaluate its utility.

Final comments by participants summed up the findings of this workshop. Progress in epidemiologic research will come hard. Comprehensive knowledge will only result from strands of evidence entwined over time. Studies forming a series of successive refinements must be done as they become feasible and as funds are justified for further research. To build toward surveys of relative risk, especially case-control studies of the Grand Rapids type, participants recommended that exploratory and methodological research of the kind suggested in this workshop be carried out in the near-term future. In this way, future efforts to define the relationship between drugs and highway safety stand a better chance of approval and, if approved, succeeding.

APPENDIX A

Review of Findings of
Workshops I and II
By Participants of Workshop III

APPENDIX A

REVIEW OF FINDINGS OF
WORKSHOPS I AND II
BY PARTICIPANTS OF WORKSHOP III

The Drug Research Methodology project includes a series of workshops on distinct but related areas of research. Section 1.1 of this report briefly describes how input on issues in other workshops was obtained from participants. Thus, the panel of the third workshop was asked to review and comment on findings of Workshops I and II. The ensuing discussion centered almost entirely on the list of drugs of interest developed in the first workshop. (As defined in Section 1.1, the phrase "drugs of interest" is used in a very general sense to include all substances—licit and illicit—whose use by drivers may increase highway safety risk.)

At the request of participants, the purpose, approach, and findings of Workshop I were briefly outlined to provide a frame of reference for comments on the list of drugs of interest. (For a detailed discussion of these topics, the reader is referred to the report on Workshop I [Joscelyn and Donelson 1980]. See also Section 1.2 of this report.) Table A-1 presents the list of drugs of interest in the rank ordering identified in Workshop I.

In addition to general questions about the process used to produce the list of drugs of interest, some participants in Workshop III had deep reservations about the use of numbers in rating risk criteria and in ranking drugs of interest. They said that this approach was misleading, implying greater objectivity and certainty than is presently possible. Other participants expressed concern over how the list would be perceived—and used—by "nonexperts." For example, they were concerned that this list might be considered a rank ordering of drugs based on their **actual** highway safety risk; programs at state and local levels might focus on highly ranked drugs of interest and miss others that may be as much of a

TABLE A-1

A RANK ORDERING OF THE DRUGS OF INTEREST

RANK ORDER	DRUG OR DRUG GROUPING	EXAMPLES *
1	ethanol	alcoholic beverages
2	diazepam (Antianxiety Agent, Group I)	
3	cannabis sativa	marijuana, hashish
4	codeine (Narcotic Analgesic, Group I)	
5	Volatile Solvents	xylene, gasoline, toluene, butylnitrite, trichloroethylene
6	flurazepam (Sedative-hypnotic, Group I)	
7	d-propoxyphene (Narcotic Analgesic, Group I)	
8	Antihypertensives	reserpine, propranolol, hydralazine, methyldopa, digoxin
9	oxycodone (Narcotic Analgesic, Group II)	
9	Sedative-hypnotics, Group IIa	secobarbital, pentobarbital, amobarbital (inclusive)
10	chlordiazepoxide (Antianxiety Agent, Group I)	
11	Antihistamines, Group I (over-the-counter)	diphenhydramine, chlorpheniramine, methapyrilene, doxylamine

TABLE A-1

A RANK ORDERING OF THE DRUGS OF INTEREST (Continued)

RANK ORDER	DRUG OR DRUG GROUPING	EXAMPLES *
12	pentazocine (Narcotic Analgesic, Group I)	
13	Narcotic Analgesics, Group II	methadone, pethidine, morphine, hydromorphone
14	Antipsychotics	chlorpromazine, prochlorperazine, chlorprothixene, haloperidol
15	Hallucinogens	LSD, DMT, mescaline, psilocybin
15	caffeine	caffeinated beverages, OTC stimulants
15	carbon monoxide	automobile emissions, cigarettes
15	glutethimide (Sedative-hypnotic, Group I)	
15	methaqualone (Sedative-hypnotic, Group I)	
16	nicotine	tobacco products
17	Anesthetics (outpatient therapy, dental surgery)	lidocaine, procaine, thiopental, methohexital, halothane, nitrous oxide
18	Sedative-hypnotics, Group IIb	other barbiturates, e.g., butabarbital, butalbital, mephobarbital, metharbital
19	heroin	

TABLE A-1

A RANK ORDERING OF THE DRUGS OF INTEREST (Continued)

RANK ORDER	DRUG OR DRUG GROUPING	EXAMPLES *
20	Antihistamines, Group II (prescription)	diphenhydramine, pyrilamine, chlorpheniramine, pheniramine
20	Stimulants	d-amphetamine, methamphetamine, phenmetrazine, methylphenidate
20	ethchlorvynol (Sedative-hypnotic, Group I)	
20	chloral hydrate (Sedative-hypnotic, Group I)	
20	Antianxiety Agents, Group II	oxazepam, prazepam, lorazepam, hydroxyzine, meprobamate
21	Anticonvulsants	phenobarbital, phenytoin, primidone, carbamazepine, ethosuximide, trimethadione
22	cocaine	
23	Antidiabetics	insulin, phenformin, tolbutamide

* The examples listed in column two of this table arose from one or two sources. The agents either were mentioned in the course of discussion or were selected by HSRI staff following the workshop. Before completion of this report, workshop participants had the opportunity to review this table. Additions and deletions of drugs under Examples were made based on their comments. The purpose of including examples is to represent members or subclasses of drugs within each grouping ranked. Some drugs given as examples, therefore, may themselves be rarely used by drivers. The examples are intended to illustrate the groups of drugs evaluated by the panel, not necessarily to identify specific drugs of interest within each group.

problem or more so. These concerns were addressed in the report on Workshop I, which stressed the subjective, heuristic nature of the list of drugs of interest and which stated that their rank order can only be validated by epidemiologic research (Joscelyn and Donelson 1980, pp.32-35).

Participants in Workshop III also had specific comments on the findings of Workshop I. For example, noting that criteria for ranking drugs of interest were grouped under the headings of "Exposure and Effects," some participants wondered if the characteristics of users were taken into account. They emphasized that who uses certain drugs may be an important factor in assessing their potential impact on highway safety. In fact, some criteria in the category exposure directly pertained to the user. For example, the range of age for users of a drug was noted to show their relation to the driving population. Information on where a drug might be used was also included, if known. On the whole, however, the ranking was achieved with little regard to the "human" factor. It was stressed that research has not progressed much beyond environmental factors in highway safety. Even for alcohol, characteristics of users and nonusers involved in accidents have only recently been compared. Information on the characteristics of users of other drugs by and large represents a level of inquiry not yet reached in the area of drugs and driving. This information has unknown import for highway safety and does not now supply an adequate empirical basis for assessing the relative importance of drugs for study.

In response to a question on possible **negative** risks associated with the use of some drugs (that is, a decreased likelihood of traffic crashes), one assumption underlying the list of drugs of interest was made explicit: every psychoactive substance has some **positive** risk associated with its use. In making this assumption, the panel of Workshop I recognized the variability of response among individuals. That is, some drugs may enhance performance in some individuals. They acknowledged the complexity of interaction between drug, disease, and performance; impaired driving might even result from the **absence** of certain drugs whose use—acute or chronic—might improve performance under adverse conditions of

disease or fatigue (e.g., antidiabetic agents, psychostimulants). Thus, the ratings of Exposure and Effects took into account data concerned mainly with the positive aspects of risk, the potential of a drug to increase the likelihood of a traffic crash and associated losses.

Some participants questioned the inclusion of caffeine and nicotine among the drugs of interest. The rationale was two-fold. First, the panel of Workshop I tried to make the list comprehensive. Caffeine and nicotine have been studied for their effects on performance related to driving, both for enhancement and, in their absence following chronic use, for impairment. Second, by ranking such drugs as caffeine and nicotine, the panel wished to emphasize the relative importance of other drugs. For example, some drugs or classes of drugs have in the past been suggested automatically for investigation, among them cocaine and anticonvulsants. Ranking these along with others in common use--but not of popular concern--points up those that appear to warrant higher priority for near-term research.

Unlike most data from questionnaire-based surveys, Table 2-1 separately lists agents within classes of drugs. Some participants asked whether this implied that an epidemiologic approach based on the analysis of body fluids was favored. It was stressed that this was not the case. The ranking did focus on single agents or on drugs sufficiently alike to permit their rating as a group. Differentiation among drugs was based on criteria pertaining to exposure, effects, or both. This approach was intended primarily to aid discussions in Workshop II, where issues in drug analysis tend to center on specific agents. The disaggregation of drugs addressed the concern that all highly ranked drugs be screened; this still allowed their aggregation if methods that detected other, similar drugs were available.

In summary, the panel of Workshop III agreed that the list of drugs of interest was comprehensive. They stated that the accuracy of the rank ordering awaits studies that indicate the actual highway safety risk of drugs in different driving populations. As one participant observed, if this ranking is viewed as an hypothesis, then epidemiologic studies will provide its test. This observation led to consideration of topics central to Workshop III--how to indicate the actual highway safety risk of drugs.

APPENDIX B

List of Workshop Participants

APPENDIX B
DRUG RESEARCH METHODOLOGY

EPIDEMIOLOGY IN DRUGS AND HIGHWAY SAFETY:
THE STUDY OF DRUG USE AMONG DRIVERS AND
ITS ROLE IN TRAFFIC CRASHES

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