Alcohol-Problem Prevention Research Policy: The Need for a Phases Research Model

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INTRODUCTION

INAPPROPRIATE use of alcohol is a major contributor to morbidity and mortality worldwide. The National Health Promotion and Disease Prevention Objectives put forth in Healthy People 2000 include 13 specific objectives relevant to the prevention of alcohol-related problems. These objectives include: reducing alcohol-related morbidity and mortality; reducing the amount and prevalence of alcohol consumption among underage persons; reducing the average consumption by adults; strengthening alcohol-related policies; and changing knowledge levels and attitudes regarding alcohol (1).

Existing data strongly support the view that "alcohol problems arise through a complex interaction of individual, interpersonal, and social factors" and not from any single mechanism or risk factor (2, 3). Therefore, a public health perspective—one that considers the interacting roles of the individual (host), physical and social contexts of drinking (environment), and the properties and availability of alcohol (agent)—is more appropriate for developing prevention strategies. The public health perspective on alcohol problems is significant in fundamental ways (4). First, alcohol abuse is seen as the destructive use of alcoholic beverages in any situation by any person. Therefore, alcohol abuse includes not only drinking by people who use alcohol compulsively and without control (i.e., alcoholics), but it also includes any use of alcohol by any drinker that endangers the drinker or others. Anyone who drinks can be at risk for a problem outcome depending upon the drinking situation, the amount of risk inherent in the activity, and the level of alcohol impairment. Alcoholic beverages

are high-risk beverages if used inappropriately. As mood-altering drugs, they require unique attention on behalf of the public's well-being and safety.

Public health problems are not isolated in individuals; they are a part of the social system in which we all live and work. The growing body of research data on alcohol-related problems has led us to see that alcohol problems arise through a complex interaction of individual, interpersonal, and social factors—not from a single determining mechanism (5).

Public health policy should be based on sound scientific research. But many prevention interventions or activities are undertaken with little or no scientific basis. Even if considerable basic scientific knowledge exists, prevention interventions may not incorporate such knowledge. One can envision a continuum wherein the plan for research always forces one to think in terms of the ultimate objective of reducing alcohol-involved problems. Thus, prevention interventions should be carried out in a practical fashion and based upon what is known scientifically. In alcohol-abuse prevention research today, a methodology is needed to enable researchers to assess the current state of knowledge and to plan, in a rational manner, future prevention research that reflects a public health perspective. We contend in this paper that a phases research model for alcohol-problem prevention should be developed which is analogous to models developed for studies in cardiovascular disease, cancer, and drug testing.

National leadership in scientific prevention research in the alcohol area comes from more than one federal agency. However, none of these agencies have well developed models that articulate a logical set of research phases. For example, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health is responsible for research on the causes, consequences, prevention and treatment of alcohol-related problems. NIAAA establishes national policy for prevention research, including development and testing of effective interventions. The National Highway Traffic Safety Research Administration (NHTSA) of the Department of Transportation conducts research on policies and programs to prevent alcohol-involved traffic crashes and associated injuries and fatalities. Yet both NIAAA and NHTSA lack a phases model like the models available in cardiovascular disease and cancer prevention research. In this paper we discuss the rationale for the development of a phases

model in alcohol problem prevention research, and we describe the special features of alcohol research that must be accommodated in developing a phases model.

Alcohol as a Contributing Factor

Alcohol obviously is a major contributor to alcohol-related problems, but it is often not the only contributor. For example, alcohol plays a major role in car crashes; however, road conditions, the condition of the car, and other drivers on the road are also contributing factors. As the National Research Council concluded, the amount and frequency of drinking combined with the characteristics of the social and physical environment make drinking more or less risky (6). In other words, a very intoxicated person is at greater risk for an alcohol-related problem in a dangerous environment (e.g., one where machinery is being operated) and at less risk in a safer environment (e.g., at home in front of the television). Similarly, a light or moderate drinker in an unsafe environment is also at risk. The interaction of the level of intoxication and environmental characteristics suggests that alcohol-related problems are not limited to heavy drinkers. Everyone who drinks is at some risk, and even people who do not drink may become victims in alcohol-related incidents, such as violent crimes or car crashes.

Vital Role of Prevention Research

If the goal of prevention is to reduce alcohol-related problems, then in principle any research that aids us in this goal could be called prevention research. For example, the study of the metabolism of ethanol, the active ingredient in alcohol, could help researchers determine the rate of potential cognitive and behavioral impairment resulting from drinking. This knowledge, in turn, could be used by prevention program designers to educate people about alcohol impairment before they drink in conjunction with risky activities, such as driving.

However, in this paper, prevention research begins with the definition of a social and health problem in which alcohol is a contributing factor. As in other public health fields, basic research for the prevention of defined alcohol-related problems includes the study of risk factors at the individual, group, and societal levels. Basic studies may focus on physiological (including genetic) factors; individual-level variables including personality, life experience, and age; group factors

including family, peers, and work groups; social and economic factors including social values and norms about drinking as well as the cost and affordability of alcohol; the physical environment including convenience of access to alcohol beverages; and larger societal and cultural factors.

However, basic research alone is not sufficient for several reasons. First, basic science does not necessarily tell us how to put new knowledge into practice. Even if research is able to determine a causal link (for example, between genetics and a potential for alcohol dependency), we do not necessarily know how to use this information or where to intervene. The most effective point for prevention action is unlikely to be determined solely from knowledge of basic causal connections, for example, identifying at risk individuals based on genotype.

Second, basic research does not necessarily identify effective strategies or interventions to reduce a specific alcohol problem. For example, knowledge that a large number of drinking drivers come from public drinking establishments does not tell us how best to intervene with such drivers to reduce traffic crashes (7). It is not obvious what types of interventions will be most effective in reaching this population and reducing their blood alcohol concentration on the highway. The training of alcohol beverage servers (8) is one program response to this basic research finding, but it did not automatically follow from that finding.

Third, some of the important factors identified as contributing to alcohol consumption or even to alcohol problems may not be appropriate targets for a prevention strategy. For example, personal disposable income has been shown to be strongly related to consumption (9, 10); and consumption levels have been shown to be related to alcohol problems (11,12,13). However, it is unlikely that future prevention programs will seek to reduce personal income as a means of reducing alcohol problems. Similarly, a determination of genes which contribute to risk of alcohol dependency does not imply that genetic engineering is the most appropriate intervention.

Prevention research is developmental, which provides the means to transform basic knowledge into components of prevention systems and identifies the settings and situations which may be most appropriate for interventions. Developmental or phased research is therefore concerned with identifying appropriate target groups and endpoint or outcome variables; planning feasible intervention approaches aimed at

the individual (host), the agent (alcohol), and/or the social, economic, political, and cultural environment; identifying potential mechanisms for cost-effective delivery of interventions; and selecting, adapting (or constructing), and pretesting appropriate measuring instruments. It is also concerned with assessing the feasibility of particular intervention approaches, including their potential effectiveness and cost.

The Need for Prevention Research Planning

The rationale for a phases model for alcohol-problem prevention research is based on the need for prevention research planning in the alcohol area. Planning for effective use of research resources is essential. And the phases research approach used in other fields provides important planning precedents.

Traditionally, the impetus for prevention research in the various fields of health has come from the investigators themselves, from public or private funding and policy-making bodies, or from organizations and individuals involved in prevention activity. When government research agencies (such as the National Institutes of Health) request grant applications or contract proposals, they establish guidelines and evaluation criteria for the requested research. However, these solicitations do not necessarily reflect an integrated research plan that places the current research request in some overall perspective.

Themes for solicited research frequently represent a response to mandates from Congress, interests of senior members of the executive branch of government, or popular emerging social and cultural objectives. Solicited research may also reflect an idea "whose time has come," because it appears to evolve logically from previous work. Occasionally requests for research may take advantage of naturally occurring policy initiatives in the prevention area, such as the Request for Applications, "Measuring the Impact of Alcohol Warning Labels," that was issued by NIAAA in the Winter of 1989, prior to the required implementation of warning labels on all containers of alcoholic beverages in the U.S.

A more systematic approach to initiating prevention research is clearly needed, given limited resources and the urgency of the alcohol problems to be addressed. For a number of definitive reasons, researchers and funding organizations need a planning methodology: (a) to assess scientific knowledge relevant to alcohol prevention across a variety of research paradigms and disciplines; (b) to decide

when existing basic research in a particular area supports a transition toward more applied research; (c) to guide the allocation of resources among a variety of research opportunities; (d) to anticipate future research needs; and (e) to provide the research structure for formulating a coherent national strategy for preventing alcohol abuse and alcohol-related problems. A phases approach to prevention research can supply this planning methodology.

Phases Models of Prevention Research in Other Health Fields

The National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the Food and Drug Administration (FDA) have all adopted phases research models to guide their programmatic activities. These models establish a logical progression of research from basic to more applied investigations. Movement to more advanced phases of research must be justified in terms of completed work in the earlier phases. Only when each relevant building block has been put in place can researchers legitimately move forward. Otherwise, investigators are admonished to return to prior research phases and to confront unresolved issues.

The NCI Model. In its most complete form, the NCI sequence of phases (14,15,16) constitutes a complex flow chart. Its sets of decision-making junctures provide guidelines for systematically conceived research policies. The five defined phases of cancer prevention research, in sequence, are hypothesis development, methods development, controlled intervention trials, defined population studies, and demonstration and implementation studies. Before researchers initiate this sequence, basic research must already have provided them with an understanding of disease progression and prevalence as well as the utility of certain technologies such as chemo prevention therapies (17). After the research sequence ends, it is anticipated that nationwide prevention and health services programs will follow and that they will be monitored on an ongoing basis. At this point in the process, research demonstration projects give way to service demonstrations, and research gives way to monitoring.

The first two phases in the NCI model (hypothesis and methods development) correspond to pre-intervention research. The hypothesis development phase, according to Greenwald and Caban (15), includes bringing together the available scientific evidence about cancer and possible interventions that could be applied to its prevention and

reduction. In this phase, extensive use is made of basic scientific findings, and a hypothesis is formulated about possible reductions in cancer that might result from a specific intervention.

In the methods development phase, researchers determine factors that must be controlled or monitored during implementation of an intervention, and they develop reliable methods to deliver the planned strategy. This phase can include pilot projects to assess feasibility and acceptability of the intervention among target populations, studies of alternative methods to deliver the defined intervention, and field testing of data collection methods and instruments.

Intervention research (the controlled testing of preventive interventions or policies) is carried out in phases III, IV, and V: controlled intervention trials, defined population studies, and demonstration and implementation studies. The three phases describe a progression from a highly controlled test of an intervention under optimal conditions to evaluation of the intervention when it is implemented on a large scale under "real world" conditions. This means that intervening outcomes and processes are of concern as well as final outcomes; and as one progresses along the phases continuum, research methodology shifts from controlled testing of an hypothesis to various types of evaluation.

The NHLBI Model. NHLBI has also set forth a five-step series of research phases: basic research, applied research and development, clinical investigations, clinical trials, and demonstration and education research (18). Basic research seeks new knowledge about "normal and abnormal functions of the heart, lungs, and blood and the etiology and pathogenesis of the related diseases," which makes the category relevant to the full range of explorations germane to these organ systems. At the opposite point, demonstration and education research includes testing intervention effectiveness "designed to promote healthful behaviors and to prevent or ameliorate disease in defined populations."

The FDA Model. The FDA's drug development and approval process embodies a well-established sequence of research phases (19, 20). The FDA process preceded those already described and has accommodated changing social realities. The process begins with extensive preclinical laboratory and animal testing of promising agents that takes one to two years to complete. Only about 5 out of every 4000 compounds that are evaluated move forward to human testing. The human (i.e., clinical) testing is conducted in three phases, from

determination of safety and dosage levels through efficacy studies, to extensive clinical trials to verify effectiveness and monitor possible side effects.

In response to the AIDS epidemic and other concerns of health practitioners and patients, the FDA has implemented an Expedited Drug Approval plan to speed the approval of drugs for life-threatening and severely debilitating diseases. The plan involves closer collaboration between the FDA and pharmaceutical companies to hasten the drug development and clinical trial process, enabling expanded availability of drugs during completion of the second rather than third phase of human studies (20). It also permits the research phases to be appropriately combined to expedite the scientific testing of new drugs (21). This flexibility in responding to current events by modifying the pace and structure of research sequences is noteworthy. Prevention researchers face similar circumstances. There are times when, due to public demand, intervention efforts cannot be deferred until scientific certainty has evolved. It then becomes necessary to adapt ideal models of the progression of scientific knowledge to meet the challenge of social reality.

A Health Promotion Model. A phases sequence for prevention research proposed by Flay (22) addresses prevention (or health promotion) research in greater detail than either the NCI or NHLBI models, and it draws an important distinction between studies of intervention efficacy and effectiveness. Flay's eight-phase agenda begins with basic research (phase I) and hypothesis development (phase II). It continues through pilot (III) and small-scale (IV) tests of strategies and programs, larger studies of experimental interventions that are delivered under optimal conditions (efficacy trials—V), and effectiveness trials (VI and VII) carried out under real-world conditions. The sequence ends with demonstration studies (VIII) that resemble those of the NCI. Flay' s model recognizes two levels of effectiveness testing. In phase VI the delivery and implementation process is standardized as much as possible, while in phase VII it is allowed to vary, naturally or deliberately.

Flay defines an *efficacy* trial as one that provides a rigorous test of (a) a well-specified and standardized intervention that (b) is uniformly implemented (or delivered or made available or enforced), within standardized contexts or settings, to a specified target audience, which (c) completely adopts (or accepts, participates in, com-

plies with, or adheres to) the intervention as delivered (22). The most rigorous and easily interpretable efficacy trials of fully implemented and standardized interventions are randomized controlled trials (RCTs). They may be experimental studies of one intervention versus a control, or they may compare two or more planned variations of an intervention and control(s).

On the other hand, *effectiveness* studies assess or demonstrate the effectiveness of interventions under real-world conditions. Real-world conditions include variability in implementation (or enforcement or availability) and in adoption (acceptance or compliance). Interventions of proven efficacy may or may not perform well under real-world conditions. Intervention efficacy is necessary for effectiveness, but efficacy is by no means a sufficient condition for effectiveness (22). It is possible that the conditions necessary to optimize implementation or adoption in the efficacy study are not easily obtained when the intervention is widely implemented. For example, staff under the control of a researcher implement the intervention during an efficacy study; but in the "real world," non-research staff carry out the implementation and may not adhere faithfully to the intended protocol. Thus, it is necessary to demonstrate program effectiveness once an intervention is disseminated beyond the original research site, assuming that the conditions of implementation are changed.

Natural Experiments or Studies of Program-Driven Interventions

The existing phases of research models all incorporate systematic progressions from basic to more applied research. For the most part, such studies focus on research-driven or investigator-initiated interventions. The greatest potential benefit from studies of investigator-initiated interventions is the opportunity for long-term research involving a full set of planned developmental steps. In the developmental phases, a problem is analyzed and defined, risk factors are identified, and possible strategies for reducing these risk factors or their impact are formulated and specified. Interventions developed in this way can then be carefully tested through a set of efficacy and preliminary effectiveness studies before being tested in real-world effectiveness trials. However, it is important to recognize that the range of preventive interventions worthy of being studied is not always controlled by investigators themselves.

Prevention researchers do not always have the luxury of engaging

in carefully designed controlled studies or of proceeding systematically through all the steps of a logical research sequence. Important research opportunities occur without researcher involvement or planning, i.e., they occur naturally. This is particularly true in the area of alcohol-problem prevention research. Prevention programs and policies often are implemented on the basis of popular "wisdom" without full benefit of thorough formative and evaluative research. Additionally, public policies that affect alcohol consumption patterns may be instituted for non-prevention reasons. For example, increases in alcohol taxes raise state and federal revenues, but the resulting net increase in the price of alcohol can have other effects as well. Decreases in per capita alcohol consumption may occur, particularly among youth (23), leading to subsequent decreases in the number of traffic crash fatalities (24) and in deaths from cirrhosis (25).

Alcohol abuse prevention research has made important use of naturally occurring public policy interventions by conducting so-called "natural experiments," i.e. studies of interventions which are beyond the control of the investigators. Evaluations of program- or policy-driven interventions have distinct advantages. They can provide better estimates of "real world" effectiveness, i.e., results can be more readily generalized to the population at large. Moreover, the interventions to be tested are already in place and do not have to be financially supported by the research endeavor. Thus, they provide cost-effective opportunities to evaluate policy effects and are by definition policy-relevant.

However, program-driven or natural experiments also have methodological disadvantages, primarily because traditional experimental approaches are not feasible. There is so little opportunity to carry out randomized controlled trials that non-experimental or "quasi-experimental" designs are generally the only option (26, 27). When multiple sites are involved, there may be considerable variation among them in the levels of implementation and acceptance. Identifying appropriate comparison groups can be especially difficult, and the universality of certain existing interventions, such as minimum drinking-age laws or warning labels, may make it impossible to find appropriate control groups. It is also not likely that an efficacy study can be undertaken.

Existing phases of research models do not address the special characteristics of natural experiments and program-driven research. Because

program-driven studies figure prominently in alcohol prevention research, it is essential that a phases model for alcohol prevention studies recognize and accommodate such "real world" research. Environmental interventions are a central focus of natural experiments and are possible primarily because of cross-sectional and time-series variations in public policies and programs that influence alcohol use and abuse. For example, excise tax rates on alcoholic beverages, regulations concerning the distribution and sale of alcohol, minimum drinking age laws, and laws to deter drunk driving have varied among states and over time in a given state or the nation as a whole. Examples at the national level include the increase in the Federal excise tax rate on distilled spirits at the beginning of fiscal 1986, the Federal Uniform Drinking Age Act of 1984 that resulted in a minimum legal drinking age of 21 in all states by July 1988, and the January 1991 Federal excise tax increases on all forms of alcoholic beverages (enacted as part of the Deficit Reduction Act of 1990).

Randomized controlled trials are particularly unlikely in research on governmental policies. Even where multiple jurisdictions are to be involved in implementing a new program, there is little possibility of randomizing the application of that program. For example, a unique opportunity for a federally-sponsored randomized trial experiment in traffic safety was provided by the Alcohol Safety Action Project (ASAP), which ultimately established projects in 35 communities in the United States (28). However, because agreements to participate from police departments, courts, prosecutor's offices, and treatment agencies were necessary for program implementation, communities could not be selected at random. Rather, an application procedure was established; and only communities sufficiently motivated to apply were eligible. Although each applicant was required to identify an appropriate comparison community, this did not constitute a randomized control. Such unavoidable selection bias is often inherent in natural experiments and program-driven research. Therefore, statistical controls for potentially confounding variables become necessary.

Another example is provided by the California Farr-Davis Driver Safety Act of 1986 which called for vehicular interlocks for DUI offenders. As a part of this act, the state legislature allowed an experimental period before statewide implementation of the intervention and permitted a controlled evaluation of interlock programs undertaken in specific geographical areas of the state (29). The selection of

the experimental counties was the responsibility of the Office of Traffic Safety, but the adoption of the program by judges within those counties varied significantly. Moreover, the legislature allowed judges in non-participating counties to use the interlock device if they so desired, thus biasing the experiment in ways that had to be accounted for in evaluating intervention effectiveness.

Most natural experiments are best described as effectiveness studies, and few existing program-driven interventions have been subjected to an efficacy trial. However, under some conditions, natural experiments can come close to efficacy testing. For example, Ross (30) concluded that the adoption of laws that increase the probability of apprehension and conviction for driving after drinking can lead in the short run to significant reductions in motor vehicle fatalities and other measures of drunk driving. These effects tend to diminish over time, however, due to a decline in the public's perception that the laws will be enforced. The short-term results reflect effects achievable under optimal (efficacy) conditions, when the public perceives that the laws are being enforced, while the long-term results reflect real-world effectiveness after public perceptions become more realistic. It is essential that research opportunities involving naturally occurring interventions be supported by mechanisms that permit rapid reviews of study proposals and rapid deployment of funds. Resources need to be readily available for studying sudden changes in alcohol policy and for obtaining quality baseline data before a policy is implemented.

In an extreme case, a funding agency may have to collect baseline data preceding a policy change which might never occur, for example, a tax referendum or a legislative change. Time constraints may force the researcher to gamble that the policy will actually be implemented and proceed with the collection of baseline information or forever lose the opportunity to gather these data.

Integrated Approaches to Prevention Research

Studies of research-driven interventions (initiated by the investigator) and studies of program-driven interventions or natural experiments are both integral to the advancement of knowledge about the prevention of alcohol-related problems. Each approach has its advantages, disadvantages, and special methodological considerations.

Research driven by investigator-initiated interventions is generally more amenable to the use of randomized controlled trials than pro-

gram-driven or natural experiments because the researcher has more control over the design and implementation of the intervention. However, control diminishes with increased size and complexity of the study population and the use of non-laboratory settings, which may reduce the integrity of randomization, the equivalence of comparison groups, and the ability to systematically manipulate levels of adoption and implementation. Frequently, studies conceptualized as randomized controlled trials are revealed, upon closer examination, to be in reality quasi-experimental. Sophisticated multivariate techniques are needed; and at the level of effectiveness testing, studies of investigator-initiated interventions and program-driven research may share many features in analytic approach.

Like natural experiments, studies of investigator-initiated interventions may also focus on environmental strategies, singly or in combination. Server training is a prime example of a promising environmental intervention that has moved in ad hoc rather than systematic fashion through various phases of a research sequence. Almost simultaneously, in the 1980s, a diverse group of studies attempted to assess effects of training servers of alcoholic beverages to control customer consumption and reduce intoxication. These studies included: small-scale tests of the impact of server training on actions toward and BAC levels of "pseudopatrons" (31), a larger pilot efficacy trial using a quasi-experimental design (32), a more extensive community-based effectiveness trial (33) that had equivocal results, and two so-called demonstration/evaluation studies (34, 45). More recently, a state-mandated server training program has been evaluated as a natural experiment, using an interrupted time-series design (36).

A number of community prevention trials relevant to cardiovascular disease and cancer have tested investigator-initiated interventions and have shown notable successes in reducing the targeted risk factors (37, 38). These trials were undertaken to test programs among diverse populations, to develop methods useful for dissemination and implementation in community settings, and to provide an opportunity to evaluate interventions of appropriate scope for implementation as public health policy (39).

In research involving investigator-initiated interventions, the research team has more control over the selection of intervention and control communities than with program-driven community research. In the Minnesota Heart Health Program, matched pairs of com-

munities were selected for inclusion on the basis of demographic, geographic, and political structure considerations, but without solicitation from or prior agreement with the communities themselves. Assignments to intervention or control were made for reasons of logistics and feasibility (40). Similar considerations determined the selection of intervention and control communities in the Stanford Three Community Study and Stanford Five City Project (41, 42).

In contrast, the Community Intervention Trial for Smoking Cessation (COMMIT) (43), funded by the National Cancer Institute, follows traditional clinical trial methodology, with random assignment of communities to intervention or control conditions. This approach is also being used in community-based research to prevent alcohol problems. The NIAAA is currently funding several community trials of research-driven and program-driven interventions which use a variety of methodological approaches, including randomization. Both the individual and the environment have been targeted, and multiple components of the programs could potentially provide a synergism that multiplies effectiveness.

A phases model for research on the prevention of alcohol problems must accommodate both investigator-initiated and naturally occurring interventions. Methodologies associated with the later phases of research (such as effectiveness studies) must be sensitive to changes in the implementation and adoption of the intervention itself.

Role of a Phases Model for Alcohol-Problem Prevention Research

Preplanning of research independent of investigator initiative is problematic. However, effective use of scarce federal and other resources for prevention research cannot depend solely upon the curiosity of individual researchers. They rarely have the exposure to the entire field of prevention to determine, on their own, what the prevention field requires next. This in no way discounts the central importance of a researcher's interest or pursuit of a particular research direction which builds upon prior work. A phases model of prevention research does not limit researcher initiative. Rather, it can be used to enhance and guide research.

In general, a phases model of prevention research can provide a road map to assist both researchers and funding sources in: (1) locating how far prevention research has moved along the continuum from basic or pre-intervention studies to partial or full intervention

research in specified areas; (2) identifying gaps in existing research which may not be obvious to individual researchers or even to the field of prevention researchers without systematic assessment; and (3) determining how much empirical support (proof, if you will) exists for the effectiveness of one or more specific prevention strategies before widespread dissemination takes place. We will discuss each of these in turn.

First, a phases model is essential in determining at any point in time how far specific prevention research has progressed toward identifying and confirming an effective prevention strategy for a specific alcohol problem. One of the major purposes of basic science is determining underlying causal mechanisms for particular problems and identifying associated risk factors as well as potential protective factors. For example, in alcohol-related traffic crashes, basic science has been used to understand driver impairment with varying amounts of alcohol consumed and how gender, body weight, and prior drinking experience can influence the level of alcohol impairment. In addition, basic science has determined what age groups and drinking styles as well as drinking locations contribute to greater risk of alcohol-involved impairment and thus traffic crashes. Given this information, researchers can then turn to various fields of basic and applied science to consider the development of preventive interventions and procedures for their implementation and measurement. When these tasks are completed, they can embark on pilot or more complete efficacy and effectiveness studies, focusing upon both educational (or socialization) and social control strategies.

A phases model provides a continuum for evaluating the extent of scientific knowledge at any point in the process. In the above example, such a model could be used to determine or document the state of science in addressing the questions raised and in identifying necessary research to move the process successfully forward.

Second, a phases model can be used to identify gaps in research. To date, prevention research for alcohol problems has been largely stimulated by researcher initiative or by naturally occurring interventions. Although funding organizations issue requests for certain types of studies, alcohol prevention research is stimulated in large measure by the researchers themselves. This has resulted in a patchwork of prevention research on alcohol problems and a tendency for behavioral scientists to forego intervention studies for pre-intervention research.

Rarely has there been a concerted effort to systematically study and perfect an intervention under optimal conditions and then move its testing into real-world environments. Almost by definition, a phases research model can help investigators think beyond the boundaries of their own work. Further, by inherently specifying long-term goals for prevention research, phases models can help funding agencies to systematically identify critical gaps in such research and studies needed to close these gaps. These assessments could prevent premature application of basic research findings to prevention practice and overemphasis on basic research at the expense of applied intervention research. Both are necessary.

Third, a phases model can provide guidelines or standards for determining "how much proof" is needed before proceeding to the next logical step in the process. These standards can also be used to assess whether a sufficient mass of evidence exists to move beyond phases of research on interventions to phases of their applications. For example, causal relationships established in the laboratory with animals or with human subjects, where high standards of rigor are possible, do not necessarily transfer to the outside world with many interacting and intervening variables that cannot be controlled. Therefore, testing to confirm risk factors or processes outside of the laboratory, where uncontrolled factors exist, is an important step before researchers design a prevention activity around a basic finding. Premature prevention interventions can fail because (a) the causal mechanism underlying the intervention is not sufficiently understood and therefore the designed intervention may not work, and/or (b) the effectiveness of the intervention is unproven and may have been flawed even if the causal model on which the intervention was based was sound.

A phases model can be used by an individual researcher to determine how his or her particular interest fits into the larger field of prevention research on alcohol problems. Does one's research contribute to an improved understanding of the causal mechanisms and risk factors, and/or the development of more rigorous methodologies or measurements, or the development and testing of prevention interventions?

From the perspective of prevention practitioners in various jurisdictions, and distinct from prevention researchers, a phases research model could also be useful. It could: (a) help guide the selection of prevention strategies that have a sufficient scientific base for wide appli-

cation and (b) provide a mechanism for such professionals to identify the needs of science. Unfortunately, too often the various prevention program professionals and prevention researchers in the alcohol field do not interact or share common values about "what is needed next?" Researchers often advise a delay in prevention programs because they conclude that doubt exists and "more research is needed." On the other hand, field professionals feel pressure to act and sometimes confuse popular approval of an intervention with proof of its effectiveness.

CONCLUSION

Alcohol-related problems are a major threat to public health and safety, a threat to which policy makers and the prevention community are impelled to respond. Government organizations, such as NIAAA, NHTSA, the Centers for Disease Control and Prevention, and other federal agencies are charged with responsibility for: conducting and supporting research that will advance understanding of the causes, mechanisms, and consequences of all or specific types of alcohol-involved problems; identifying feasible strategies to prevent or ameliorate such problems; testing interventions that are most promising; and promoting dissemination of those found to be effective. Given limited available resources, systematic guidelines are needed to assess the state of alcohol problem prevention research in all its diversity and to provide appropriate direction for future research.

A phases research model is a promising approach, but it must accommodate the special characteristics of alcohol prevention research. As in phases models developed for the fields of cardiovascular disease and cancer prevention, the phases of research for alcohol problems ideally progress from basic research, through pre-intervention research, efficacy testing, effectiveness testing, and demonstration projects. However, studies of naturally occurring and program-driven interventions, which are prominent in alcohol research, provide special opportunities to advance understanding of intervention processes in "real world" settings. Opportunities to evaluate "natural experiments" abound, and guidelines are needed to help identify those experiments that can make the greatest contribution to the research field, given inherent limitations in investigator control over study designs.

The concept of research which follows a developmental phasing is gaining popularity in the alcohol prevention field, but its meaning

and scope are still being defined. A detailed phases model would essentially operationalize the notion of such research and permit investigators and funding agencies to determine whether and when the building blocks for intervention research are in place. Given limited resources for large-scale alcohol prevention studies, it is imperative that these funds be spent as wisely as possible. The availability of a systematic phases model should make the decision-making process considerably more efficient.

In any diverse culture, such as American society, differences in socioeconomic levels, racial and ethnic differences, and variations across cultures and subcultures must be taken into account in developing and designing intervention research. The authors believe that possibilities for subgroup variation must be recognized along the whole continuum of the phases model, especially when there are reasons to expect subgroup differences. For example, if an intervention proves to be effective for a community or group as a whole but not for a special subgroup within the entirety, then it may become necessary for researchers to move back to earlier phases of research and to focus on the special group of concern. The new research guidelines of the National Institutes of Health regarding minorities and women highlight the importance of including diverse populations in human research as early as possible so that findings and generalizations can apply to all members of society.

In alcohol prevention studies, an appropriate phases model should be able to incorporate research on single investigator-initiated interventions, which are more easily accommodated by a traditional phases research approach; community-based trials and research on community systems, which involve multiple interventions; evaluations of program-driven interventions; and evaluations of "naturally occurring" policies. As prevention research moves from the laboratory to the "messier" milieus of the real world, extra threats to scientific validity may ensue. Research necessarily becomes more complex; "pure" control groups become more difficult or impossible to locate; the number of potential analytic units may become so large that sampling procedures are required; and, perhaps most important, the targets of the intervention (e.g., demarcated communities) may generate their own stakes in research outcomes. To meet these challenges, the development of appropriate study designs and analytic/evaluative methodologies must evolve in conjunction with the research phases.

A research phases perspective will require attention to what works as well as how the most effective intervention is implemented. The disciplines of anthropology, political science, community psychology, media studies and law all provide valuable methods for developing effective prevention strategies. Case study research, formative and process evaluation research, and other more qualitative research, should be an integral part of research proposal reviews. Research representing a variety of disciplines with experience in qualitative as well as quantitative methods is necessary in support of a phases model. Such considerations should be explicit and implicit in a phases model. For example, process evaluation permits one to determine if the intervention which actually occurred is the one which is being evaluated with outcome research.

The phases model envisioned here could serve as a guide for the logical genesis of new projects in alcohol prevention research, taking account of necessary and sufficient conditions for emergent research in specified areas. However, it is not anticipated that a phases research model will usurp investigator independence by rigidly defining parameters of acceptable research. The model should not become a management tool for restricting research initiative and creativity. Rather, it should assist funding agencies in fulfilling their commitment to research on the prevention of alcohol-related problems by supporting a planning process for strategic and efficient utilization of available resources. The model should be publicly and openly discussed, evaluated, tested and changed over time, as circumstances require, to make it as viable and useful as possible.

A phases model to be most effective in organizing research should incorporate incentives for sequenced research processes. In this way, all researchers are encouraged to follow the logical protocol of this model and avoid a situation where only less innovative researchers comply. Research agencies might organize meetings and dialogues about this topic at which a number of prevention researchers could come together to discuss and debate the phases model. Discussions might address the pros and cons of such a model and its application to research practice and priorities in the complex U.S. society and culture. Key review/overview papers could be invited to summarize what has been accomplished. Examples of issues which could be considered include: encouraging research where there are timely opportunities; serious gaps in evolution of our knowledge base; or new direc-

tions for research that are relevant to evolving prevention opportunities on the horizon. A published phases model for alcohol-problem prevention research can bring scientists into a dialogue with the staff of funding organizations about the operationalization of phases and the placement of specific research into the phases model.

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ABSTRACT

This paper describes the need and rationale for developing a phases model for guiding alcohol-problem prevention research. A phased approach to prevention research is consistent with such models developed for other health areas including heart disease, cancer, and drug testing. Such a model in alcohol prevention research can provide a means for (1) locating how far research has progressed along a continuum from basic or pre-intervention research to full implementation of preventive action, (2) identifying gaps in research, and (3) determining the level of empirical proof which exists for one or more prevention strategies prior to widespread dissemination.