Phases of Alcohol Problem Prevention Research

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We build on precedents from other health research to present a phases model of research for alcohol problem prevention that accommodates the special characteristics of this research. We propose a five-level model, in which research moves along a series of relevant continua: from basic to more and more applied research; from descriptive hypothesis-generating pilot studies to full-fledged, methodologically sophisticated, hypothesis-testing studies; from smaller to larger samples for testing; from greater to lesser control of experimental conditions; from more artificial "laboratory" environments to real-world geographically defined communities; from testing the effects of single prevention strategies to more complex studies of multiple strategies integrated into intervention systems; and from research-driven outcome studies to "demonstration" projects that evaluate the capacity of various types of communities to implement prevention programs based on prior evaluations. The five phases of research are: (1) foundational research to define and determine the prevalence of specific alcohol-involved problems, establish causal factors and processes that yield the specific problems or increase the risk of a problem, and provide the foundations for the development of effective prevention interventions; (2) developmental (preliminary effectiveness) studies to develop and test the likely effectiveness, safety, and costs of new interventions or to assess the effectiveness, safety, and costs of an existing intervention; (3) efficacy studies to determine the effects, safety, and costs of an intervention under optimal conditions of implementation (or availability or enforcement) and acceptance (or adoption at the community, organizational, or group level; or participation, compliance, or adherence at the individual level); (4) effectiveness studies of the real-world effectiveness of preventive interventions with purposeful or natural variation in implementation and acceptance; and (5) demonstration studies of the effects of interventions when widely disseminated. The proposed phases model for alcohol problem prevention research presented herein differs in significant ways from the models established by other National Institutes of Health agencies. Greater emphasis is placed on natural experiments, on methods development along the whole research continuum, on collapsing or combining research phases when appropriate, on recognizing the critical importance of behavioral parameters early as well as late in the research sequence, and on extending the research continuum to embrace diffusion and dissemination (i.e., technology transfer) studies. We also include examples of phased research in existing alcohol studies and a discussion of relevant issues, including cost, special populations, methods, and dissemination. If systematically followed, this model has the potential to contribute to wider testing and dissemination of prevention interventions of known effectiveness.

Key Words: Prevention, Phases, Innovation, Dissemination, Sequence.

Alcohol is involved in a number of health and safety problems in society. The most cost-effective approaches to preventing alcohol-involved problems are those based on a systematic approach to developing and testing prevention strategies that themselves are based on scientific knowledge. The impetus for most alcohol problem prevention research has come from investigators themselves and/or research program announcements by public and private funding and policy making bodies. However, such actions do not necessarily reflect an integrated research plan that places current research in some overall perspective. In addition, state-level and national alcohol policy changes provide natural experiments for studying intervention effectiveness.

Phased models for prevention research establish a logical progression of research from basic to more applied investigations. Each phase builds on prior research phases. Movement to more advanced phases must be justified in terms of completion of research in earlier phases. In general, only when relevant building blocks have been completed should research proceed forward.

Holder et al. (1995) previously presented a rationale for a phases model of alcohol problem prevention research) and noted at least three major contributions of a phases approach: (1) locate existing prevention research along the continuum from basic or preintervention studies to partial or full intervention; (2) identify gaps in existing research that may not be obvious to individual researchers without systematic assessment; and (3) determine how much scientific support (proof, if you will) exists for the effectiveness of specific prevention strategies before widespread dissemination takes place.

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SPECIAL CONSIDERATIONS FOR ALCOHOL PROBLEM PREVENTION RESEARCH

The desirability of systematic phases of prevention research has been clearly articulated by other areas of health research, including the Food and Drug Administration, the National Cancer Institute (NCI); the National Heart, Lung, and Blood Institute (NHLBI) (NHLBI, 1987); the National Institute of Mental Health; and Flay (1986), who translated the NCI model into more extensive phases of health promotion research and placed greater emphasis on behavioral processes and outcomes. Holder et al.'s conclusion that modifications were necessary to accommodate the special characteristics of alcohol problem prevention research.

First, natural experiments (or studies of policy-driven interventions outside the control of the investigator) are an essential aspect of alcohol problem prevention research. Natural experiments can be referred to as "program-driven" studies, as opposed to studies that are traditionally "research-driven." Examples of successful prevention strategies that were program-driven include: raising the legal minimum drinking age to 21 years, establishing per se definitions of drunk driving based on blood alcohol levels, mandating administrative license revocation for drunken drivers, increasing the price of alcoholic beverages through taxation, and restricting the availability of spirits by the drink in bars and restaurants.

Second, methods development in many prior phases models have been implicit or time-bounded. The phases model presented herein recognizes the dynamic nature of learning as research moves across the spectrum of phases from more basic to more applied studies. A sequential ordering of phases as presented herein is a practical means to express levels of evidence that is to be accumulated and that builds a base for subsequent phases.

Third, in alcohol problem prevention research, a relatively small amount of money has been allocated to prevention research and even less to actual prevention interventions. Thus, collapsing and combining phases of research to maximize resource utilization can be particularly important. One approach is to test multiple strategies simultaneously in community-based studies as a means of determining their combined impact as a "critical mass," as well as to gain some insights about their independent effects. Nesting investigator-initiated experiments within natural experiments can enable researchers to learn whether and how the effects of government policies [such as zero tolerance blood alcohol concentration (BAC) laws for youth] can be enhanced by special community initiatives.

Fourth, basic research in many other phases models is definitely biomedically oriented (e.g., seeking "new knowledge about normal and abnormal functions of the heart, lungs, and blood and the etiology and pathology of the related diseases"). In contrast, research on the prevention of alcohol-involved problems embraces physiological factors, as well as behaviors, that are not necessarily disease driven (e.g., consumption of alcohol by underage drinkers, drinking and driving, and alcohol-related sexual risk taking). Thus, foundational and developmental studies in the field of alcohol prevention research focus on the antecedents of behavioral, social, organizational, and environmental change. It is essential in preintervention foundational research to develop working causal models that inform prevention intervention design. This involves understanding the problem and its risk factors or determinants, and understanding the mechanisms of psychological, organizational, or environmental change. It is not expected that foundational research is complete or completed before intervention testing. Actually disturbing the system with a prevention intervention also informs research about the system (i.e., adds to foundational knowledge).

Fifth, studies of technology transfer are particularly important in the field of alcohol problem prevention research, because the interventions are always targeted toward behavioral change. Unlike medications and other biomedical technologies, behavioral change strategies can undergo profound transformations in the process of their implementation and diffusion. For example, the implementation of minimum legal drinking age laws in different states had different outcomes, depending in part on variation in levels of enforcement. Thus, the proposed phases model for alcohol problem prevention research presented herein differs in significant ways from the models established by NCI, NHLBI, the National Institute of Mental Health, the Food and Drug Administration, and Flay.

PHASES OF RESEARCH IN DEVELOPING AND TESTING ALCOHOL PROBLEM PREVENTION INTERVENTIONS

We propose a five-level model of alcohol problem prevention research, in which research generally moves along a series of relevant continua from basic to more and more applied research, from descriptive hypothesis-generating pilot studies to full-fledged methodologically sophisticated hypothesis-testing studies, from greater to lesser control of experimental conditions, from more artificial "laboratory" environments to real-world geographically defined communities, and from testing the effects of single prevention strategies (or first order interactions) to more complex studies of multiple strategies integrated into intervention systems.

The five phases of research proposed herein are:
Table 1. Phases of Research in the Development and Testing of Alcohol-Involved Problem Prevention Interventions

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>I. FOUNDATIONAL RESEARCH</td>
<td>Basic studies to define and determine the prevalence of specific alcohol-involved problems, establish the causal factors that yield specific problems or increase the risk of a problem, and provide foundations for the development of effective preventive interventions:</td>
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<tr>
<td>1. Definition of the problem: prevalence, incidence, and documentation of problems (epidemiology).</td>
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<tr>
<td>2. Establish working causal models of the problem, including potential risk and protective factors (etiology).</td>
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<tr>
<td>3. Identify potential behavioral, social, and environmental changes—models of change based on causal models.</td>
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<tr>
<td>II. DEVELOPMENTAL STUDIES</td>
<td>Preliminary studies to develop and test new interventions or to assess the effectiveness of an existing intervention.</td>
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<tr>
<td>A. RESEARCH-DRIVEN INTERVENTIONS</td>
<td>That are researcher-developed and designed.</td>
</tr>
<tr>
<td>1. Intervention design (with documentation).</td>
<td></td>
</tr>
<tr>
<td>2. Pilot studies of limited application.</td>
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<tr>
<td>3. Feasibility studies to determine potential effects and costs.</td>
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</tr>
<tr>
<td>B. PROGRAM-DRIVEN INTERVENTIONS</td>
<td>That were not researcher-initiated, but are program- or policy-driven.</td>
</tr>
<tr>
<td>1. Documentation of an existing intervention (and, where possible, its development).</td>
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<tr>
<td>2. Preliminary evaluations of the process and effects of existing interventions.</td>
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<tr>
<td>III. Efficacy Studies</td>
<td>Rigorous studies (of maximized internal validity) of the intervention under optimal conditions with maximal implementation (availability or enforcement) and acceptance (participation or compliance).</td>
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<tr>
<td>1. Controlled trial of a research-developed intervention.</td>
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<tr>
<td>2. Controlled trial of planned variations of the intervention.</td>
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</tr>
<tr>
<td>3. Nonexperimental test of an existing, but optimally implemented, intervention.</td>
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<tr>
<td>2. Experimental or nonexperimental tests of variations of a well-implemented existing intervention.</td>
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<tr>
<td>IV. EFFECTIVENESS STUDIES</td>
<td>Studies of the real-world effectiveness of preventive interventions with purposeful or natural variation.</td>
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<tr>
<td>Demonstration effectiveness study</td>
<td>Test of the effectiveness of an intervention of proven efficacy when both acceptance and implementation vary.</td>
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<tr>
<td>Program evaluation</td>
<td>Evaluation of the quality and levels of acceptance and implementation, and of the overall effects of the intervention under real-world conditions (i.e., variation occurs naturally).</td>
</tr>
<tr>
<td>V. DIFFUSION STUDIES</td>
<td>Studies of the effects of different levels or types of implementation or acceptance on effectiveness.</td>
</tr>
<tr>
<td>Acceptance trials</td>
<td>Tests of planned variations in acceptance of or compliance with an efficacious intervention.</td>
</tr>
<tr>
<td>Implementation trials</td>
<td>Tests of planned variations in the implementation, availability, and enforcement of an efficacious intervention.</td>
</tr>
<tr>
<td>Maintenance trials</td>
<td>Tests of planned approaches to the diffusion and maintenance of the efficacious intervention.</td>
</tr>
<tr>
<td>Acceptance evaluation</td>
<td>Evaluation of the levels of acceptance of a fully implemented intervention (i.e., with minimal concurrent variation in implementation) and effects under such conditions.</td>
</tr>
<tr>
<td>Implementation evaluation</td>
<td>Evaluation of the levels of implementation of an accepted intervention (i.e., with minimal concurrent variation in acceptance) and the ultimate effects under such conditions.</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Assessment and continued monitoring of the diffusion pattern and maintenance of an effective intervention.</td>
</tr>
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</table>

I. Foundational Research: Basic studies to define and determine the prevalence of specific alcohol-involved problems, establish working causal models of factors and processes that yield the specific problems or increase the risk of a problem, and provide the foundations for the development of effective prevention interventions.

II. Developmental (preliminary effectiveness) Studies: Preliminary studies to develop and test the likely effectiveness, safety, and early cost estimates of new interventions or an existing intervention.

III. Efficacy Studies: Rigorous studies (of maximized internal validity) of intervention effects, safety, and costs under optimal conditions with maximal implementation (or availability or enforcement) and acceptance (or adoption at the community, organizational, or group level; or participation, compliance, or adherence at the individual level).

IV. Effectiveness Studies: Studies of the real-world effectiveness of preventive interventions with purposeful or natural variation in implementation and acceptance.

V. Dissemination/Diffusion Research/Evaluation: Studies of the effects of different levels or types of implementation or acceptance on effectiveness, safety, or costs.

The proposed phases accommodate the need to (1) develop and evaluate both research-driven interventions and program-driven interventions; and (2) allow for the systematic development of interventions that target social change at community or society levels (e.g., price adjustments, taxation policies), as well as interventions that target individuals (e.g., public information campaigns, school-based education). At the outset, we acknowledge that the distinction between research-driven and program-driven interventions in practice is not absolute. Research-initiated interventions give investigators more options in designing and implementing scientifically rigorous evaluations. Yet, studies that move beyond the laboratory into real-world communities mirror to a greater or lesser degree natural experiments, because implementation and acceptance of the intervention (and perhaps the choice of methodologies) depend on persons or groups that cannot be completely
controlled by the research team. Thus, in the field, prevention studies are often a mix of both, and one can argue that there exists a continuum bounded at each end, along which prevention interventions can be arrayed.

Table 1 shows the five phases and summarizes the types of research conducted at each phase. In the left-hand column of Table 1 are those programs based on foundational research where development and associated research and evaluation tend to be research-driven (i.e., initiated by scientifically trained investigators). Such researchers usually work from one or more explicit working "causative" theories or models linking type of intervention with a change in a behavior or environment.

In the right-hand column of Table 1 are those programs that are designed in the field by practitioners or policy makers (or already exist) to meet an immediate need. The prevention intervention tends to be program-driven (i.e., determined by the laws, policies, and norms regarding public solutions to a problem). Even while program-driven, foundational research can and is used in practice for such efforts. For example, the basic research evidence concerning the effects of alcohol availability on adolescent drinking was used to support national legislation that mandated a drinking age.

In conducting community studies, considerable similarity between investigator-driven and natural experiments or program-initiated interventions exist. Within a community-initiated prevention program, the community may decide to implement one or more alternatives or design new ones. Even if the study is researcher-driven, the community is often mobilized and empowered to make decisions about alternative strategies for prevention. Thus, community choices may produce a situation more like a natural experiment (where the researcher had no control over the intervention selected or the integrity and timing of implementation). For example, when you train and energize ("stir-up" if you will) a community, then the intervention may only be to mobilize and see what actions are taken naturally by the community (see description by Wagenaar et al., 1994). Prevention strategies that communities select may not have been previously tested.

We now discuss each of the proposed phases of research in some detail. In doing so, we point out the similarities and differences between research-driven and program-driven studies within phases.

**Phase I: Foundational Research**

The first phase of prevention research for alcohol-related problems helps build the foundation for later developmental and intervention research. The foundational phase is applicable to both natural experiments and investigator-initiated interventions, and emphasizes basic social or behavioral as well as biomedical research. Foundational research is the basic research that provides the cornerstones for the development of preventive interventions, and it may well be conducted by scientists who do not consider themselves to be prevention researchers or even alcohol researchers. Foundational research in the alcohol phases model can involve a synthesis of available information, as well as empirical research in its own right. Most foundational research will be conducted before the development and testing of interventions. However, studies in later phases may illuminate areas where further foundational study is needed, which may then be undertaken during the course of the intervention study or after it has been completed.

**Define The Problem.** As an introductory step, it is critical to define the alcohol problem that needs to be remedied. Generally, this requires an assessment of the incidence and prevalence of the alcohol-involved problem and its boundaries. In certain situations, this effort may constitute a major study in itself (e.g., determining the prevalence of fetal alcohol syndrome and other alcohol-related birth defects in specific types of Native American tribes, as a prelude to implementing and testing an intervention program). Where relevant, it may also be deemed necessary to determine or estimate the economic and social costs of the problem as a means of justifying prevention research priorities.

**Establish Working Causal Models.** Alcohol-involved problems are usually not the result of a single causal factor, but the consequence of the interaction of many factors or mediating variables. To help set the stage for later intervention studies, research must determine the causal contribution of biomedical, psychological, sociocultural, environmental, and economic factors to the alcohol-involved problem of interest.

Risk and protective factors in individuals, groups, and environments can shed light on causal processes, but such factors easiest to identify often tend to be immutable (e.g., age, gender, race/ethnicity, religiosity, and family history). Thus, prevention research needs to consider prevention strategies that can affect mediating factors that are capable of being changed. For example, whereas income is highly associated with drinking levels, it is unlikely that prevention will seek to lower income to reduce drinking.

Although it is helpful to understand the causes of a problem before designing prevention strategies, complete knowledge is not a necessary condition for developing effective interventions. Disentangling multiple types of causes and correlates can be a time-consuming process that could unnecessarily delay systematic prevention intervention studies. Complete research on all interrelationships between alcohol abuse and unsafe sexual practices and between heavy drinking and violent victimization or perpetration cannot delay the exploration of potentially effective prevention strategies. Sometimes the prevention research field must embark on intervention research, while simultaneously striving to increase knowledge of the etiologic process. Theory-driven and empirically tested prevention strategies that prove effective can validate (and invalidate) existing etiological theories and introduce new ones—indeed, well-designed evaluations of preventive interventions can provide the strongest tests of theories of causation.
In like manner, causal models can also address change strategies for prevention as well. In such models, appropriate theories of intervention can also be postulated or designed.

Identify Potential Behavioral, Social, and Environmental Changes. This dimension of foundational research is directed toward the identification of change variables, as well as intervention strategies that can be tested in development studies. The knowledge to make these choices comes from basic and applied research, tested and untested theories, and extant hypotheses in the behavioral, biological, and social sciences, education, communication, organizational development, and other relevant disciplines. Also germane is technological development, such as alternative alcohol breath sensors and ignition interlock devices, that can be used to prevent an alcohol-impaired driver from starting his/her automobile. The review and evaluation of potential intervention strategies may focus on investigator-initiated interventions or on (naturally occurring) prevention policies implemented by various levels of government or the private sector. Prior evaluations also provide knowledge of any prior tests of change models on which interventions can be designed.

Phase II: Developmental (Preliminary Effectiveness) Studies

Knowledge of potential change factors (i.e., intermediate variables or mediators that can alter risk) is not equivalent to knowing prevention strategies or interventions that can produce change. For example, a determination of the price sensitivity of alcohol consumption (basic econometrics foundational research) is not the same as determining the purposeful means to alter price as a prevention policy to reduce consumption. A determination of the contribution of genetics to increased risk of alcohol dependency cannot specify the prevention strategies to address this risk. Therefore, a major purpose of the developmental phase is to design potential strategies and interventions that can be tested for effects on intermediate causal factors, other effects (both good and bad), costs, and feasibility of implementation (i.e., practicality).

The essential test during the developmental phase is a determination of changes made in intermediate variables via specific interventions. It is possible that changes in distal outcomes (specific alcohol-involved problems) can also be assessed, but it is not essential. The research method selected depends on current knowledge and, to some extent, on whether a new intervention is researcher designed or is a program-driven intervention. Multiple studies might be necessary to complete essential requirements of the developmental phase. Each successive study can add to previously accumulated knowledge and still not extend beyond the developmental phase.

Preliminary evidence of potential effectiveness in reducing a specific alcohol problem should be demonstrated before conducting large-scale efficacy or effectiveness studies or disseminating the strategy broadly. Developmental tests also provide opportunities for the testing of appropriate methods for future research and the evaluation of similar interventions. Note that methods and assessment of process, side-effects, and cost-effectiveness are themes that continue through all phases.

Developmental (Preliminary Effectiveness) Studies of Research-Driven Interventions. The developmental phase is the first step in prevention research where basic knowledge can purposefully be used to design and/or test interventions, actions, strategies, or policies by researchers that have the potential to change key variables in the causal chain. Any newly designed intervention should be subjected to careful formative research to ensure that it is as refined as much as possible. Small-scale pilot studies are a simple means to undertake formative research. Prototype studies, or studies that are more formal than most pilot studies, may also be undertaken as a test of feasibility in this phase.

Developmental (Preliminary Effectiveness) Studies of Program-Driven Interventions. The evaluation of interventions that are program- or policy-initiated cannot usually be as formal as or as strategically planned as research-driven interventions. The formative research phase may have been skipped. However, information from other types of studies can be used in a formative sense (i.e., to suggest that a program-driven intervention might be effective or improve future iterations of an existing intervention). For example, new laws can provide opportunities for developmental research.

Studies by Bigelow and Liebson used two male, skid row, chronic alcohol volunteers residing in Baltimore to show that alcohol-dependent persons reduce their alcohol consumption as a function of beverage costs. Babor et al. recruited 20 adult male volunteers with a prior history of casual drinking and 14 adult male volunteers with a prior history of heavy drinking to conduct an experimental study of price reductions during afternoon “happy hours” in Boston. Results of these two studies suggested that alcohol consumption is responsive to price in general and with heavy or heavy-dependent drinkers. These results are a compliment to macroeconometric studies of the price elasticity of alcohol, some of which have demonstrated that price changes or price differences can contribute to reducing alcohol problems and could be used to suggest a social policy intervention to reduce problem drinking (e.g., increasing taxes on alcohol).

During the 1970s, a number of U.S. states lowered their legal drinking ages in response to a national desire to make 18 a legal age for adulthood, including giving 18-year-olds the right to vote. Studies of this change on a state-by-state basis demonstrated that (1) youth drinking practices were affected by the law and (2) lowering the legal age produced increased drinking and alcohol-involved traffic crashes. The research results of such studies were used in planned
incremental increases in some states of the legal age that demonstrated that each year of increase reduced alcohol-involved traffic crashes among youth.\textsuperscript{15}

**Phase III: Efficacy Studies**

Efficacy studies test whether an intervention, when delivered under the most optimum conditions possible, actually reduces a specific alcohol problem. The efficacy study examines alcohol-involved problem outcomes (i.e., tests the effect of the intervention and thus the causal relationship between distal outcome and intermediate variables). Before widespread adoption and implementation of new interventions, it is essential to have information about their level of efficacy. They provide information on: (1) whether or not an intervention can have desired effects, (2) estimates of the potential maximum effects of an intervention, (3) the potential costs of implementation, and (4) if more good than harm is achieved.

Optimum conditions refer to a situation, setting, or system in which there exists the best opportunity for the intervention to be effective (i.e., to produce the expected changes). Two major factors are relevant to defining optimum or ideal conditions: (1) level of actual implementation, and (2) acceptance of the intervention. Implementation refers to how well an intervention is delivered or used in practice. For example, if a special DUI enforcement is poorly implemented by law enforcement or the enforcement protocol is weakly or incompletely conducted in practice, a true test of effect in reducing drinking and driving may not be possible. Implementation can also refer to how well teachers, physicians, or other professionals deliver an intervention; how well-trained the providers of an intervention are; how well a policy or legal intervention is enforced; or how readily available service or assistance is to those who need it.

Acceptance refers to how well the intervention is accepted by its intended receivers. This may be at the level of an organization or community, in which case it might be assessed by community readiness to adopt a policy or program, and is a precursor to good implementation. Readiness refers to the openness or preparedness of an organization or society for the intervention. For example, if a special roadblock or random breath testing for drinking and driving enforcement is to be tested, research should determine if the police department and/or the community is ready or open to this new intensive enforcement. Thus, the setting for the efficacy test is not selected at random but where there already exists good or optimum opportunity for adoption. It must be noted that an aspect of community acceptance is the fidelity between the intervention and its cultural acceptability. The burden of acceptability lies with the researcher, not the community, in designing a culturally relevant intervention.

Efficacy trials require that both implementation and acceptance be optimized and standardized. Variation in either of these can influence the estimate of possible intervention efficacy. If the intervention seems to be ineffective, variation in implementation or acceptance could be the cause, rather than lack of inherent efficacy of the intervention itself. The good versus harm comparison is essential to a complete evaluation of an intervention at this phase. Only examining the effects on a specific alcohol problem can overlook other untoward or unexpected consequences. For example, raising alcohol prices to a very high level could reduce the consumption of legal retail alcohol while stimulating illegal alcohol and the development of a criminal system for production and distribution.

**Efficacy Trials of Research-Driven Interventions.** An efficacy trial initiated by an investigator provides a rigorous test of (1) a well-specified intervention that (2) is uniformly implemented within consistent or standardized contexts, and (3) with high acceptance.\textsuperscript{7} Efficacy studies may be experimental studies of one intervention versus a control, or more than one control type, or they may compare two or more planned variations of an intervention (plus a control or controls). When testing the efficacy of a new intervention, the comparison condition may consist of the best-known available intervention, rather than a placebo. The test of efficacy is then concerned with whether or not the new (or experimental) intervention can have better effects than the existing intervention.

**Efficacy Studies of Program-Driven Interventions.** Efficacy studies of existing interventions are rigorous evaluations of fully implemented and standardized interventions that have the benefit of early data suggesting their effectiveness. For example, a law could not be subjected to an efficacy study unless it is well implemented [i.e., adopted by the local community and fully enforced (or, at least perceived to be fully enforced)]. If either of these conditions are not fulfilled, then only a limited form of effectiveness study will be possible.

Nonexperimental designs are more realistic when assessing the efficacy of an existing or real-world intervention. Although few existing program-driven interventions have been subjected to an efficacy trial, longitudinal designs that rely on time series archival data can provide a means to test the effects of an “universal” intervention. For example, Ross\textsuperscript{10} found that the adoption of DUI enforcement, which increases the probability of apprehension and conviction for driving after drinking, leads to significant reduction in motor vehicle fatalities and other measures of drunken driving in the short run. These effects tended to taper off, however, in the long run due to a decline in the public’s perception that the laws would be enforced. Short-term results reflected the maximum achievable (efficacy condition), when the public initially perceived that the laws were enforced, whereas long-term results reflect effectiveness conditions after the public’s perception changed (became more realistic).

The initial evaluation of a higher drinking/purchase age in Michigan\textsuperscript{14} demonstrating a significant effect, occurred
within a state with a high level of enforcement and compliance, and thus was close to an efficacy trial. Alternatively, an effectiveness study of the minimum age change in Massachusetts with low enforcement, and thus lower compliance, did not find an effect.\(^\text{17}\)

**Phase IV: Effectiveness Studies**

Effectiveness studies assess or demonstrate the effectiveness of interventions under less than optimal conditions. Where implementation and/or acceptance vary, interventions of proven efficacy may or may not perform well. Effectiveness studies provide the evidence of effectiveness in the real world.

**Effectiveness Studies of Research-Driven Interventions.** Investigator-initiated prevention interventions that prove effective in an efficacy study cannot be assured to have similar impact in less controlled situations. It is possible that the conditions necessary to optimize implementation or acceptance in the efficacy study are not easily obtained in less “friendly” situations. Sometimes, well-trained and personable staff under the control of researchers implement the intervention during an efficacy study, and nonresearch staff may not implement it as well in real-world conditions. The effectiveness of an intervention will be maximized if an efficacious program or strategy is implemented fully by providers and accepted completely by the target.

**Effectiveness Studies of Program-Driven Interventions.** Program-driven interventions can also show effectiveness because the setting for the strategy was optimal with naturally occurring high implementation and acceptance. Within effectiveness studies, randomized trials are one means to provide rigorous, interpretable, and credible results. However, real-world constraints often force the use of nonexperimental designs where threats to validity must be carefully controlled for through design and/or statistical analysis.\(^\text{18}\) The national evaluations of minimum drinking age provided the opportunity for a natural experimental test of the overall results of increased legal drinking/purchase age\(^\text{19}\) across states. A complete effectiveness study requires a careful documentation of the actual time and level of program/policy implementation. Blose and Holder,\(^\text{20}\) for example, determined that the dates of actual implementation of a state law that permitted individual counties to issue licenses to sell spirits for consumption at bars and restaurants lagged considerably behind the legal date.

**Phase V: Diffusion**

Diffusion and dissemination studies examine the robustness of intervention effectiveness given systematic variations in implementation and/or acceptance and may operate at two levels: level 1—programs and policies that directly impinge on the target population (e.g., drivers, or youth, alcohol vendors, or environments); and level 2—programs and policies that effect the delivery systems themselves. For example, in school-based prevention programs, the second level of intervention includes procedures for recruitment of schools and teacher training, whereas level 1 is the intervention as delivered to students. In a study of server training, the training delivered to bartenders would be a level 2 intervention, necessary for the implementation of policies regarding underage or inebriated patrons, level 1 interventions.

Organizational or community readiness, and adoption of an intervention, are important antecedents to high levels of implementation. For example, do school systems purchase the curriculum or do bars agree to institute server training? Implementation refers to what is actually delivered and to whom. Acceptance and participation describe adoption in the target, and they determine levels of exposure, compliance, or utilization. Participation can be manipulated through varying recruitment efforts and incentives.

Cost implications are the primary criterion for deciding when and whether to conduct dissemination studies. For example, if less intensive training of program deliverers (teachers, bartenders, police, etc.) does not diminish effectiveness, this makes the intervention easier and less costly to disseminate. Similarly, knowing the optimal level for enforcement of policies and the decay curve for publicity effects greatly influences the cost of their effective implementation. The maintenance of an intervention and its effects over time are important, and maintenance studies are needed to determine the conditions of institutionalization, implementation, and other variables that maximize the continuation of program effectiveness. Well-established programs may be monitored to ensure that institutionalization, implementation, acceptance/participation, and effects are maintained at cost-effective levels.

Natural experiment dissemination and diffusion research may be initiated in response to findings from monitoring or surveillance activities and addresses the general question, “What went wrong?” For example, observed differences in accident fatalities among states with similar drunk driving laws might prompt inquiry into differences in adoption and implementation, as well as cultural conditions.

**EXAMPLES OF PHASES OF ALCOHOL RESEARCH**

Although not necessarily progressing in a systematic sequential fashion, there are examples of alcohol-involved problem prevention research that illustrate how the phases described in this paper can be used to document and assess the state of research in this field. Unique placement of individual research studies in Table 2 (Refs. 21–62 herein) are for illustration and should not be considered absolute.

**ISSUES AND QUESTIONS RELEVANT TO ALL PHASES**

A number of issues and considerations apply to all phases and appear in some form as one progresses from one phase to the next. These are discussed herein.
Movement Across Phases Can Be Dynamic

Under ideal circumstances, research-driven interventions would be suggested or supported by existing foundational research and theory. Developmental studies would be conducted before intervention development, formative research and pilot studies would inform development, at least one efficacy trial would establish the maximum potential effects of the intervention, and subsequent effectiveness and dissemination/diffusion trials would establish the best or most cost-effective conditions under which to disseminate the intervention. Similarly, program-driven interventions would be subjected to rigorous assessments of their maximum potential, but only after some level of evidence is available to suggest intervention efficacy, followed by ongoing assessments of intervention implementation, acceptance, and effects.

In practice, movement across and within phases is dynamic and both forward and backward movement is possible. Factors that may affect sequencing include: (1) opportunity to actually conduct research in the next sequence, (2) cost of conducting the research and the parsimony of moving to a higher level phase, and (3) public pressure to “do something” about a health problem before all phasing requirements have been completed.

Phases Can Be Mixed

Aspects of two or more phases may be included in one project. For example, in an efficacy trial of a community-based intervention to prevent alcohol-involved trauma, five basic prevention strategies were implemented that had been tested separately in both previous developmental and efficacy phases but not combined together. For some strategies, developmental aspects involving new training manuals and training techniques had to be tested, whereas for other strategies, approaches from the developmental phase were sufficient.

There is a downside risk for skipping phases or taking them out of order. If an intervention fails during a later stage, the researcher may not know why it failed or if the intervention could actually work if tested in developmental or efficacy studies. Even if positive effects are observed, the researcher may also not know why the intervention worked. What constitutes sufficient proof of effects during one phase to move to another phase is an important aspect of any phases model. For example, a review of existing studies (or even a meta-analysis if there are sufficient controlled studies for such an analysis) may be required to conclude that there is a level of proof of effectiveness at one phase to
proceed to the next phase. In the end, there is no absolute standard of proof at any level or phase.

Variations in Implementation and Acceptance Across Phases

Effective utilization of a phases approach to alcohol problem prevention research will require greater attention to levels of implementation and acceptance. These elements can vary across efficacy, effectiveness, and dissemination phases of research under at least three conditions: optimal, planned variation, and natural variation. Optimal refers to the “best possible” conditions. When both implementation and acceptance are optimized, the study is one of efficacy. When both vary naturally, the study is an effectiveness evaluation.

Methods

Development and testing of methods runs throughout all phases and include (1) techniques and processes for program implementation as well as (2) design, measurement, and data analysis. Methods are constantly revised and redesigned as new experiences and problems arise. For example, formative research using qualitative methods, such as focus groups to explore program elements or processes, can be essential in the developmental phase. Formative research methods may be less appropriate during the more rigorous implementation of later phases.

For example, methods for delivery of server training within a scientific setting or in a specific bar or restaurant as a developmental test of a training technique are likely customized to that alcohol serving setting. Saltz, in his early test of server training at U.S. Navy on-base enlisted men’s bars, established a training and alcohol serving protocol unique to that situation. Based on a demonstration of effects for this unique establishment type (i.e., an on-base bar), Saltz and associates carried server training into the civilian world of two communities as a further developmental test with specific targeted licensed establishments. Herein, the demands for training and serving compliance were different from the Navy experiment. Whereas the fundamentals of server intervention were the same, the training approaches were different and had to be modified for civilian application.

A new phase brings new demands on implementation and evaluation methods. The requirements for implementation of a developmental test are different from those of an effectiveness test. Each phase has unique objectives for research, different measurement needs, and different conditions for testing. For example, because drivers who survive crashes are often not tested for BAC, the contributing role of drinking to nonfatal crashes is often unknown; therefore, one surrogate uses single vehicle nighttime crashes because such crashes are known to have high alcohol involvement.

The requirements of subject permission and full disclosure can make randomization to treatment or placebo conditions difficult or impossible. Differences in communities and the dynamic nature of communities can make randomization to treatment condition particularly difficult. In addition, randomization is not a complete protection against uncontrolled variance.

Similarities Between Natural Experiments and Investigator-Initiated Interventions in Communities

Essentially all evaluations of the effectiveness (and occasionally the efficacy) of environmental interventions at the state level are natural experiments. Illustrations include assessments of the effectiveness of state alcohol monopolies, administrative license revocation, state-mandated server training programs, increases in taxes on alcoholic beverages, increases in the legal minimum drinking age, and reductions in legal BAC levels for drinking drivers. Researchers have also measured the impact of naturally occurring multidimensional prevention programs, such as the so-called “Saving Lives Program” that was implemented in six Massachusetts communities.

By definition, researchers who evaluate naturally occurring community-based interventions do not have control over the design, initiation, or implementation of the intervention. When multiple intervention sites are involved, the level of implementation or acceptance of the intervention may vary greatly in uncontrolled ways. Selection or self-selection of the intervention groups can be biased (in statistical terms) in ways that may escape detection, causing uncertainty about criteria for choosing controls. And appropriate control or comparison groups or communities may be difficult or impossible to find, especially when the intervention is universally implemented.

Community intervention studies that encourage “participatory research” have been defined to mean that members of the target population become full partners with investigators in research planning, implementation, evaluation, and dissemination. Advocates of participatory research in minority communities assume that it helps ensure validity of the findings, cultural sensitivity, and researcher accountability. Certainly, this can result. There are also reasons for caution in that participatory research can erode and even subvert the scientific integrity of a study. It may be difficult to effect randomization of communities or subcommunities to the intervention and control strategy in these situations and empowered members of the community may not wish to wait for proof. In addition, on their own initiative, control patients in clinical trials frequently “drop into” the intervention group, and the same has occurred for control communities.

Cost

The cost of implementation, as well as effects of any prevention strategy, should be considered. In preventing alcohol problems, like any area of public health prevention, alternative strategies for reducing problems are available.
Costs to actually implement a prevention alternative are an essential research consideration alongside with effectiveness and must also be considered at each phase. At the extreme, an effective prevention strategy that is too costly to be implemented by a community or state is not likely to be actually used, and a low-cost but ineffective strategy has no practical prevention value.

**Age, Gender, and Racial/Cultural Differences**

Alcohol problems are not evenly distributed across all age, gender, and cultural/racial groups. A prevention strategy that is effective overall for a general population is likely to have differential effectiveness for subgroups based on their patterns of alcohol use, the cultural values assigned to drinking, drinking style, and abstinence. Therefore, differential effectiveness of prevention strategies for subgroups are an important consideration in a phases research model. In general, cultural and racial appropriateness of interventions within a community are essential factors in any effective prevention strategy that is designed and tested by research.

**Foundational Research Throughout**

Foundational research forms the base on which all subsequent phases rest. In practice, foundational research can be done anywhere along the way such that additional foundational research can be added throughout later phases. No requirement exists herein that all basic knowledge is in hand before other research phases are undertaken. Unanticipated basic research needs are often identified in later phases leading to the concurrent conduct of basic science along with the applied research necessary for prevention testing. However, if the basic knowledge is totally inadequate to conduct the research of the later phase, then the research should go back to earlier phases, including foundational research, before the later phase is undertaken.

**OBSERVATIONS AND CONCLUSIONS**

An important aspect of any phases model is the development and testing of appropriate and effective prevention strategies at any point in the phased continuum. A sequential phasing and testing of individual elements or methods that make up a prevention intervention accomplish both (1) a controlled testing and subsequent improvement of individual methods before full implementation, and (2) facilitate an interpretation of any observed effects of a prevention program.

A failed prevention strategy may result from a specific method included in the overall strategy. If this method has not been previously tested, one cannot rule out this method as an explanation of failure. For example, if a strategy of responsible beverage service for bars and restaurants to reduce the level of alcohol impairment of customers fails when the materials used to train servers and managers have not been individually tested and shown to be effective, then these training materials cannot be ruled out as the explanation for failure.

Timely dissemination of the results of every stage of research/evaluation is essential for a phases model of research to be successful. The sequential or developmental aspect of prevention research, as established by this model, is dependent on wide dissemination and review of the research results at any stage. Within a phases-of-research approach, negative findings, which are not as attractive or desired by research journals, could be more widely disseminated. Within a phases model, research results can become community property, and widely shared and used by researchers, funding agencies, and prevention practitioners.

By using a phases research structure to alcohol problem prevention, funding agencies can collect and summarize the ongoing research that could integrate their programs into a common structure, providing a more complete picture of prevention research in the area of alcohol problem prevention. This structure would assist in avoiding duplication of research efforts. Finally, the development of a phases structure for prevention research can be used to inform the efforts of individual researchers. The phases structure can also provide a framework for literature reviewed and for acquainting new investigators with the status of any particular prevention field.

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