

A Case for Braided Prevention Research and Service Funding

Over the past decade, the nation's investment in prevention research has provided impressive evidence that prevention programs can both reduce mental disorders, substance use, and related problem behaviors and promote youth competence and resilience (Elliot, 1998; Greenberg et al., 1999; Institute of Medicine (IOM); Mrazek & Haggerty, 1994). Most of the evidence supporting the effectiveness of these programs has been generated through randomized controlled trials. This has fueled awareness that rigorous research can be used to examine the impact of complex health, behavioral, and social service interventions.

Positive research findings from the field of prevention are now influencing public policy. Federal, State, and local governments increasingly are calling for schools and communities to use empirically validated preventive interventions with children and families. Perhaps most importantly, the Office of Management and Budget (OMB) recently issued its new Performance Assessment Rating Tool (PART) for FY06, which OMB will use to evaluate federal programs government-wide (<http://www.whitehouse.gov/omb/part/>). This new set of standards calls for the use of randomized controlled trials to evaluate government programs whenever appropriate and feasible. Public funding increasingly will be dependent upon findings from rigorously conducted research. Thus, there is urgent need to increase the quantity of programs tested using randomized controlled trials and other rigorous research methods, and especially to test programs in community contexts (Flay et al., 2004). There also is an urgent need to better understand the community and organizational conditions that encourage the selection and faithful implementation of effective programs.

Research Progression from Studies of Efficacy to Effectiveness and Dissemination

The scientific approach to prevention research is modeled after that used in cancer control (Greenwald & Cullen, 1984) in which interventions are carefully developed and tested initially under well-controlled randomized experimental trials and then evaluated as delivered in increasingly naturalistic conditions. While the use of randomized trials is highly desirable in determining the effects of preventive interventions, many of the findings reported to date are based upon a special type of study known as an *efficacy trial*, which, while critical to learning about the effects of the program under ideal conditions, often has limited application to real-world settings. In the majority of efficacy trials conducted to date, the researcher has been closely affiliated with the program developer who has enjoyed a high degree of control over most aspects of the implementation process. Consequently, most of these interventions still require a second stage of research known as an *effectiveness trial*, in which an intervention with demonstrated effects in an efficacy trial is tested in community contexts both to see how it performs under real-world conditions and to understand how to optimize its broader use. Effectiveness trials can test the effects of naturally occurring or planned variations in implementation, and they also can be used to evaluate interventions that emerge from ongoing service delivery settings. While these studies can use a range of designs, randomized designs provide the basis for strongest inferences. *Dissemination studies* examine factors that affect the successful dissemination of effective preventive interventions. Rogers (1995) describes five stages in the diffusion of innovations: Gaining knowledge about the innovation; being persuaded to use the innovation; deciding to use the innovation; implementing it in a reasonably rigorous fashion; and confirming the decision, including integrating it into one's routine. Dissemination

research is designed to test (ideally, using randomized trials) variations in strategies for achieving each of these stages of diffusion of effective prevention practices, and the process by which disseminated programs are sustained as ongoing services in community settings.

Trials of Promising Community Programs

Another model for the development of prevention programs is where innovative interventions are originally developed in community rather than research settings. There is an abundance of wisdom and clinical insight embodied in many community-based prevention programs, the vast majority of which have not been tested with the most rigorous, feasible research methods. These programs represent a resource that might be employed to accelerate the process of developing a wider array of evidence-based programs. The challenge is to focus scarce research dollars on testing those programs that show the greatest promise. Programs that are most mature in terms of their explicit operationalization in the form of manuals, logic models, and thorough training, and that have preliminary data from quasi-experimental studies or pretest – posttest findings, in our view, deserve the highest priority. These are the programs that have the greatest chance of being replicated reliably and producing desired effects. One of the greatest attractions of such programs is that they already exist in community settings, and have been developed by practitioners who are deeply knowledgeable about effective program delivery. Programs with these characteristics, therefore, may be ready for research collaboration in the conduct of randomized trials to rigorously test their effects.

Effectiveness Trials are Crucial for Transporting Promising Models to Practice

Effectiveness trials are carried out in community contexts, serving entire populations, and because of this are critical in transporting promising research-based models to practice. Ideally, the essential elements of a program model and methods of measuring them will have been established in the efficacy phase of the research. It is possible that some features of the program may require adaptation as it is implemented in new practice settings. Effectiveness studies can be designed to provide guidelines on how to support the widespread implementation of a program by providing insight into factors such as what populations the intervention helps the most, the optimal characteristics of service providers, and the kinds of program adaptations that can be made without losing program impact. Gaining insight into the degree to which critical features of the model and its organizational supports are modifiable is an important focus of this type of research. For prevention models that have been initially generated in the community context, the effectiveness trial provides the opportunity to operationalize the intervention so that it might be systematically implemented by others, and to rigorously assess its effects.

While the science of how to implement evidence-based programs in real time and under naturally occurring conditions is beginning to emerge, only a modest knowledge base currently exists on the measurement of implementation, on factors that influence its quality, and on the relationship between implementation quality and outcomes obtained. When evidence-based interventions are implemented in community settings, careful monitoring of program implementation is needed to ensure a high degree of program fidelity, given that there are many factors related to the intervention, the system that supports it, the population it targets, and its environmental context that can undermine the implementation process. It is almost inevitable that communities implementing evidence-based interventions will want to make purposeful changes to the content or structure of the model in order to increase its fit to their particular needs. Without adequate

effectiveness research, these decisions will be made arbitrarily and, thus, will have the potential to attenuate the effectiveness of the intervention.

Dissemination Research

Dissemination Research also is needed to guide future attempts at getting organizations and individuals in “real world” settings to adopt policies, programs, and practices that have been shown to be efficacious. These studies can examine the efficacy of various dissemination strategies in experimental studies. In these studies, the outcome of interest is the quality of implementation and substantive effects of research-based policies and practices. Early dissemination research might examine the effectiveness of different dissemination approaches for improving the quality of implementation of the prevention practice. Eventually, this research can be extended to examine the effects of these approaches on prevention outcomes and cost-benefit ratios.

While in the context of effectiveness trials, implementation is carefully measured, documented, and related to outcomes, dissemination research may deliberately manipulate factors thought to improve implementation and outcomes. Little is known about the characteristics of organizations, their staffs, or their community contexts related to implementation quality. Likewise, information is lacking on characteristics of prevention practices, training and dissemination strategies, and technical support structures that might influence implementation quality. Research is needed to understand the characteristics of providers who are “ready” to implement prevention activities in ways that are likely to produce positive effects.

Dissemination research also might experimentally assign prevention activities (policies or programs) to different points along the continuum of local adaptation vs. adherence to prescriptive research-supported models and test the effects of this manipulation on prevention outcomes. Alternatively, tests might be conducted that compare programs or policies that have been locally developed using “principles of effectiveness,” and control conditions. The results of this type of research could lead to major changes in the current level of acceptance among practitioners of evidence-based programs.

Challenges in Mounting Effectiveness Trials and Dissemination Research.

Effectiveness and dissemination research involves both research and service provision. However, there are significant challenges to conducting such research, as funding for program implementation and evaluation traditionally have been provided categorically by different agencies with different missions, often acting without coordination. Effectiveness and dissemination research requires large-scale studies in order to answer key research questions regarding program impact in community contexts. Multiple sites are desirable for these types of studies: having a multiplicity of organizations and communities can help sort out how factors at those levels affect program implementation and outcomes.

These requirements make effectiveness trials and dissemination research considerably more expensive than efficacy trials currently funded through National Institutes of Health mechanisms. The recruiting process for multiple sites is also more difficult than in smaller scale efficacy trials. Service grants like those supported by the Substance Abuse and Mental Health Services Administration, the Administration for Children and Families, the Health Resources Service

Administration, the Department of Education, or Department of Justice, on the other hand, are of larger scale but present their own challenges. They provide funding for intervention activities but typically often only minimal support for evaluation. The individuals who serve as local evaluators on these projects may have limited resources to take advantage of the opportunity afforded by NIH-type of grants. The review processes for research and service grants also are sufficiently different that it often is difficult for individuals or teams accustomed to one system of review to successfully compete in both arenas.

The typical federal grant cycle, research or service, also is too short for effectiveness and dissemination research. A greater amount of time – often a year or more - is needed to prepare at the beginning of these trials. This includes understanding the settings and potential participants in which the intervention or the dissemination strategy is to be tested. The real-world conditions of the trial mean that more collaboration and negotiations have to take place among the researcher, program developer and service provider. This includes the design, recruitment, data collection procedures, staff training, and numerous other practical and philosophical aspects of the process. Further, allowance must be made for longitudinal follow-up to determine if and how effects may persist or attenuate over time. These practical and philosophical concerns have great importance for the outcomes of effectiveness and dissemination research, particularly if the community involved differs from the original study group. This process, then, might be considered a research focus in itself - translational research - with the primary focus on collaborating with communities to assure that an effective program is appropriate for a given community.

A unique opportunity exists to build collaborative partnerships between researchers and service providers so that effectiveness trials and dissemination research can be conducted well. Federal agencies that focus on research and those that focus on service delivery have the ability to overcome barriers to high quality effectiveness research by coordinating their funding efforts in the service of effectiveness and dissemination research. The Society for Prevention Research is supportive of efforts to braid funding in this way across funding agencies. Given our organization's knowledge of the research activities that would be necessary to advance this next stage of prevention research and our knowledge of the different priorities of the NIH agencies, we believe that we have much to offer to the development of effective procedures to help inform this process. Below, we describe some initial ideas about a framework for the discussion of braided funding, based on a conceptual overview of the kinds of activities that are likely to occur in efficacy, effectiveness and dissemination research.

A Working Model for Studying Program Effectiveness and Dissemination

Effectiveness research requires careful implementation of tested program models in new community settings. Much of the debate about transporting effective programs to practice settings and to larger scale has centered so far on topics such as whether training and on-going technical support for service deliverers are needed, what type of training is most important, and whether programs require operations manuals. We start from the proposition that if we are concerned about quality implementation, enduring impact on functional outcomes, and program sustainability, then effective training, technical assistance, and clear articulation of the program in manuals are needed, but insufficient in themselves. All effectiveness trials should include these elements.

Further, we hypothesize that each site choosing to implement an effective program also needs favorable organizational and community conditions to operate and sustain it with high quality, ideally expanding it gradually to reach a significant portion of the target population. These conditions might include having 1) a favorable policy environment that gives access to sustainable funding appropriate to the program's design; 2) strong levels of community support among relevant health and human service providers and community leaders; 3) an adequate supply of competent service providers; 4) an organization that is deeply knowledgeable and supportive of the program and that possesses a culture and set of operating procedures conducive to the implementation of the program; 5) a receptive staff that has appropriate skills and that can be well trained and supported in the conduct of the program model; and 6) real-time information systems on program implementation and benchmark outcomes to guide efforts in continuous quality improvement. These conditions are consistent with the literature on the transportability of preventive interventions (Schoenwald and Hoagwood, 2001).

Research that experimentally manipulates one or more of these factors will produce a better understanding of the extent to which selection of strong programs in the first place and high quality implementation can be improved. We expect that these outcomes depend upon the degree to which replicating communities and organizations either meet these conditions or support their development when they are absent. Tested programs are likely to gain greater scale to the extent that they are implemented well, that they achieve their goals of improving functional outcomes, and that their impact is communicated effectively to policy makers.

Proposed Role for Federal Service Agencies

We are not asking service agencies to become research agencies, but rather to use their resources to support in community settings the replication of programs that meet the highest evidentiary standards, i.e., that have been tested and found to be effective in efficacy and effectiveness trials, and to integrate some of their funding with NIH to focus on a research agenda designed both to increase the number of programs tested in effectiveness trials and to experimentally manipulate factors related to the transfer of evidence-based programs into community practice.

Specifically, federal service agencies can play a crucial role in improving prevention practices by setting aside a portion of its resources to engage in the following activities:

- promoting the adoption of evidence-based programs, using criteria consistent with those promoted by the Society for Prevention Research and the Coalition for Evidence-Based Policy;
- encouraging its grant recipients to partner with researchers to conduct effectiveness trials of promising programs already tested in efficacy trials;
- coordinating its funding with NIH to support research aimed at testing promising strategies for improving dissemination of evidence-based programs;
- coordinating funding with NIH to support the testing of methods to maintain a high quality of implementation of evidence-based prevention programs and to evaluate aspects of implementation that relate to desired preventive outcomes
- supporting the development of information systems that monitor critical features of program implementation and outcomes in the conduct of evidence-based programs;

- supporting service providers' time devoted to partnerships with researchers aimed at improving the replication of evidence-based programs;
- support research on methods and policies that affect the sustainability of evidence-based prevention programs in community agencies.

With information systems built into every effective model to be adopted in new communities, and with staff time devoted to partnerships with researchers, program directors will be in a position to monitor the successes and challenges of implementation, to use that information for continuous quality improvement, to share their successes with policy makers, and to contribute to the ongoing development of effective programs. We believe that braided funding in which the resources of NIH and services supporting agencies are necessary to pursue a broad program of collaborations for a broad program of collaborative service and research programs to test, disseminate and implement effective prevention programs in the community.

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