Behavioral and social intervention research at the National Institute of Dental and Craniofacial Research (NIDCR)

Ever since the National Dental Research Act of June 24, 1948 established a dental health research institute at the National Institutes of Health (NIH), behavioral and social aspects of oral health have been important considerations in the institute's mission. Even during these early years, the Institute recognized the importance of epidemiological studies in understanding dental disease, and of the role of behavior in disease prevention efforts. Early studies of dental caries explored patients' diet and nutrition behavior, toothbrushing with fluoridated dentifrice, and a shared family context, in order to understand better the etiology and treatment of caries. Early studies of periodontal disease identified variations by socioeconomic status, and drew from the prevailing behavioral concepts of that time to understand "psychosomatic" contributors to periodontal disease. Subsequent oral and dental research has become increasingly sophisticated in its investigations of behavioral and social factors. The modern-day National Institute of Dental and Craniofacial Research (NIDCR) and its constituent researchers stand on a strong foundation of empirical evidence about the roles of psychosocial factors in oral health, including individual and social behavior, the social and built environments, the health delivery system, and many other factors (1). Cutting-edge investigators have translated some of this basic knowledge into effective behavioral and social interventions targeting these psychosocial factors. The NIDCR hopes to encourage investigators to continue this work, drawing on state-of-e4the-science methods and approaches, and providing the tools and other resources necessary to conduct high-quality research.

As part of its efforts to encourage advances in oral health behavioral and social intervention research, the NIDCR convened a meeting in June, 2009 to seek recommendations about future directions from a multidisciplinary group of experts, hereafter called "the expert consultants" (2). The expert consultants identified six essential elements of behavioral and social intervention research that need more attention: intervention planning models, health behavior theory, mechanisms of action, fidelity, acceptability, and sustainability. Those essential elements informed the structure of this supplemental issue, as well as serving as guiding principles for the NIDCR behavioral and social intervention research program. Below is a brief discussion of those essential elements, followed by a description of how the NIDCR behavioral and social intervention research program incorporates those elements.

Intervention Planning Models

The article by Crosby and Noar describes the difference between a health behavior theory and an intervention planning model, and illustrates nicely the utility of the latter in guiding a program of intervention research. Different uses of the terms "theory" and "model" across disciplines, and by different theory and model developers, has led to difficulties in tracking and integrating findings in health research. For instance, public health researchers are likely to be familiar with the concept of the intervention planning model, with models such as PRECEDE-PROCEED and RE-AIM being core elements of public health training. In contrast, researchers from the behavioral sciences are likely to use the term "model" in the context of health behavior theories such as the Health Belief Model, Transtheoretical Model, and the Precaution Adoption Process Model. Our expert consultants noted that intervention planning models are sometimes referenced in publications as the theory upon which an intervention is based, and most had experience reviewing grant applications that mixed intervention planning models with theories.

Despite the use of different terminology, most intervention-development traditions identify a process for moving from early intervention development to widespread dissemination of the intervention. For instance, in the United States, the Food and Drug Administration defines four "phases" of research for the development of drugs, medical devices, and other products. The National Institute on Drug Abuse (NIDA) defines an analogous process for the development of behavioral interventions. The NIDA model defines three "stages" of research, guiding the systematic progression of behavioral intervention research from early, idea stage through large-scale efficacy testing, and to preparing an intervention for implementation in varied community settings (3,4). The field of epidemiology identifies a similar process for moving from early intervention development to broad dissemination, using the terms efficacy, effectiveness, and efficiency to describe different research activities. The NIDCR does not mandate the use of any particular intervention planning model, but we recommend

that investigators follow some sort of systematic approach to guide their programs of intervention development.

Health Behavior Theory

The article by Bartholomew and Mullen makes a compelling case that the use of health behavior theory is essential to behavioral and social intervention research. The article provides important guidance for the thoughtful use of health behavior theory in behavioral and social research, including strategies for drawing from empirical evidence and from multiple health behavior theories, to develop the most potent interventions possible. Inherent in drawing from multiple theories to inform a particular intervention is the idea that a single theory may not lead to the optimal intervention. Stated another way, existing health behavior theories may not be sufficiently useful in developing psychosocial interventions relevant to oral health. This concern was expressed by our expert consultants too, who suggested that existing theories may be too general to specify testable – and falsifiable – hypotheses. If theories are too broadly specified, and hypotheses cannot be refuted, a theory is not of much use in guiding intervention research. Our expert consultants also suggested that some health behavior theories may not translate well across health conditions or intervention types. For instance, the Transtheoretical Model (5) has been widely used in smoking cessation interventions but has been criticized for being an ineffective health behavior theory in alcohol and drug addiction treatments (6). Existing theory may explain those behaviors from which the original theory was designed. In translation to other health conditions, the theory may not be ideally suited to identify the pertinent variables. Consequently, this may lead researchers and practitioners to intervene in a less-than-ideal way.

These concerns about the limitations of existing health behavior theory in guiding behavioral and social interventions for oral health lead to a clear recommendation: where existing theories are inadequate, researchers should base their interventions on their own, strong theoretical rationales. Researchers may find existing theories especially inadequate in explaining complex oral health behaviors or conditions, or in integrating multiple influences on a particular oral health condition. The NIDCR recognizes the need to develop innovative, explanatory complex conceptual models or theories. In 2008, the NIDCR announced a Funding Opportunity Announcement (FOA) encouraging research that "develops and tests new conceptual frameworks, models, and theories that explain the complex relationships between behavioral and social factors and oral health" (7). Although this particular FOA has closed, the NIDCR's commitment to supporting research that develops such explanatory models remains strong.

Mechanisms of Action

MacKinnon and Luecken provide a detailed overview of mediation analysis methods, which are important tools in identifying how behavioral or social interventions produce desired changes, i.e., their "mechanisms of action." Traditionally, those interested in improving health outcomes have not focused their attention on identifying mechanisms of action, focusing instead on producing efficacious interventions, regardless of how they work. Recent guidelines about evaluating evidence-based practices to improve health and mental health echo this focus on efficacy, omitting mechanisms of action data from the determination of whether interventions are ready for dissemination to "real-world" settings (8,9).

Kazdin and Nock (10) have been strong voices in support of mechanisms of action research, arguing that understanding how interventions work is a complementary and essential activity to developing interventions that work in the "real-world." Far from being simply an academic exercise, understanding the mechanisms of action of interventions allows both for preservation of key ingredients when disseminating the intervention, and for adaptation of ancillary ingredients to boost utility in different settings and for different populations. Understanding the mechanisms of an intervention also allows for the development of even more efficacious interventions because research efforts can focus on improving techniques to catalyze those mechanisms, rather than on intervention features that do not improve outcomes.

Understanding how interventions work also affects the degree to which intervention research can build an iterative science of behavior and social change. If interventions are developed as multi-component programs, without a clear understanding of how they produce change, the product of research efforts is an increasingly large catalog of idiosyncratic interventions with limited utility. In contrast, if interventions are developed with an understanding of how they produce change, each intervention study contributes to a deeper understanding of how to produce behavior or social change. Subsequent intervention studies can draw from previous lessons learned to adapt interventions to meet specific needs, or to develop new interventions where existing ones are inadequate. From the point of view of intervention research funding, a focus on mechanisms of action allows for a much more efficient investment in research to improve the public health. Kazdin and Nock propose that "study of mechanisms of treatment is probably the best short-term and long-term investment for improving clinical practice and patient care" (p. 1117).

Multiple institutes at the NIH agree that studying the mechanisms of behavior change is a top research priority. In 2010, the NIH directors underscored their support of mechanisms of behavior change research, announcing a trans-NIH

scientific meeting and FOA focused on mechanisms, and developed as part of the NIH Common Fund program (7). Likewise, the NIDCR Behavioral and Social Sciences Research Program considers mechanisms of action an essential element of intervention research, integrating it into FOAs, sponsored symposia, and the branch's conceptual framework for approaching intervention research.

Fidelity

Borrelli provides a strong rationale for the importance of ensuring fidelity in behavioral and social intervention research, and gives comprehensive guidance for state-of-the-science fidelity methods. There is an ongoing debate about how amenable these gold-standard methods are to "real-world" settings, and for "real-world" psychosocial interventions. For instance, this discussion was the focus of several sessions at the 2010 Dissemination and Implementation Research Conference, sponsored by the NIH (11). Important questions were raised by one think tank session chaired by Dr. Sonja Schoenwald of the Medical University of South Carolina, including how to balance the priorities of different stakeholders, who may differentially value internal validity and generalizability (12). One potential resolution to this debate is to distinguish fidelity methods in the context of developing and testing an intervention versus quality assurance once an intervention has been adopted outside the context of research. Rigorous fidelity methods are essential to conducting intervention research; these same methods may not be necessary once an intervention with established efficacy is adopted. Researchers in behavioral treatment for drug abuse have studied this question in depth, testing different quality assurance methods for community behavioral interventions (13,14).

Nonetheless, explicating the measures, procedures, and statistical analyses used to monitor intervention fidelity, including specifying intervention training and implementation protocols, has become a virtual requirement of behavioral and social intervention research in other fields. Without this detail, it is difficult for other investigators and practitioners to reproduce the interventions. Hence, we recommend that oral health researchers similarly give careful attention to intervention fidelity in their studies.

Acceptability

The best designed intervention will fail if it is not acceptable to the target population. The paper by Ayala and Elder in this issue provides several important tools for developing interventions that will be acceptable to the target population, and so increasing the chances of success. For behavioral and social intervention research, "target population" refers to those individuals to whom the intervention will be delivered, as well as providers or other interventionists, external stakeholders, and in some cases, to third-party payers.

Establishing the acceptability of behavioral and social interventions occurs at the intersection of two communities – members of a target population, and members of an academic or research community. Cultivating productive collaborations between these two communities can be challenging, with each community bringing potentially different priorities, resources, areas of expertise, governance, and other characteristics to the proverbial table. A recent survey of research faculty conducting community research highlighted some of these challenges from the perspective of the academic community (15). Almost all (90%) of faculty respondents agreed that involving members of the target population improves the relevance of their research, although the majority (60%) also acknowledged that they had not done so in their own research. Researchers were more likely to involve members of the target population in all stages of research when interventions were delivered in community settings (as opposed to recruiting the target population to a study conducted in an academic setting). Importantly, faculty researchers cited the need for more institutional support and for better skills in involving members of the target population in intervention research.

Approaches aimed at establishing productive partnerships between researchers and members of a target population have been developed, including Participatory Action Research and Community-Based Participatory Research (CBPR). These approaches involve members of the target population from the beginning of the research, assuming an equitable partnership between researchers and members of the target population. Approaches such as CBPR are not without their own challenges, though. For instance, a recent case study illustrates the challenges of reconciling a CBPR approach with necessary oversight by a research ethics committee (16), and another study highlights the challenges of allocating credit through co-authorship in CBPR collaborations (17). A survey of "advocate-scientist" collaborators in federally funded breast cancer research centers detailed the need to define collaborators' roles clearly from the beginning of a project, citing differences in perceived roles as a challenge to productive collaborations (18).

Clearly, there is not yet a satisfying answer to the question of how best to develop partnerships between members of a target population and researchers. The tools outlined in the Ayala and Elder paper are starting points for developing interventions that are both relevant and acceptable to the population(s) for which they are intended. We recommend that investigators include these tools as they develop and pilot test interventions before larger expenditures of resources are used to test interventions that might not be sufficiently acceptable to those they intend to assist.

Sustainability

Sustainability involves determining the extent to which interventions work when used in real-world settings, and understanding the necessary factors that promote the effective use of interventions once external research funds have been removed. O'Connell and Griffin describe critical cost considerations that impact the sustainability of interventions. Equipment needs, training and supervision requirements, staff credentials, and intervention duration are just some of the many factors that impact the cost of delivering interventions, and the relative value of the interventions must be weighed by how effective they are and what additional benefits they confer. Inclusion of economic analyses in behavioral and social intervention research can greatly aid practitioners and policy makers in deciding how to effectively allocate scarce resources. Simple and informative economic analyses can be added to most intervention studies, particularly those examining the effectiveness and efficiency of interventions. We recommend that investigators include economic analyses in their behavioral and social intervention research, and that they integrate the related methods into the study design early into the research planning process.

Psychosocial interventions of known efficacy are not always utilized by practitioners. There can be a number of reasons that new evidence-based interventions are not quickly adopted, including lack of knowledge, a level of comfort with existing interventions, or the belief that the new intervention is not markedly better than the current practice. Effective dissemination is a key component of sustainability and involves a complex multi-stage process, with multiple pivotal points in which strategies for enhancing the dissemination process might be used. Simpson describes one such model for disseminating innovative and efficacious oral health interventions to community practices. We encourage investigators to identify dissemination processes that influence the adoption, implementation, and maintenance of evidence-based oral health interventions, and to study strategies that foster the use of these innovations in the field.

The NIDCR Behavioral and Social Intervention Research Program

The current NIDCR Behavioral and Social Intervention Research program integrates the essential elements of behavioral and social intervention research discussed in this supplemental issue. The Behavioral and Social Intervention Research program also proposes that particular intervention planning models may dictate that the relative emphasis on each of these essential elements may change, depending on the stage, phase, or step (hereafter referred to as "stage") of intervention research. In an effort to accommodate the most commonly used intervention planning models, we use the terms "exploratory," "efficacy," "effectiveness," and "efficiency" to describe the stages of intervention development. We provide potential definitions of the activities appropriate in each of these stages, recognizing that even defining the terms has been a topic of fervent debate (19-26). We do not attempt to settle the debate here, but hope to provide a general guideline for investigators to approach behavioral and social intervention research with the best tools available.

Figure 1 depicts the guiding principles of the NIDCR Behavioral and Social Intervention Research Program in graphic form.

Borrowing heavily from John Last's dictionary of epidemiology (27), we make the following distinctions:

- Exploratory Research: the extent to which a new or adapted intervention, service, policy, or procedure demonstrates promise in being acceptable to the target population, and working in ways consistent with predictions based on the theoretical rationale. Exploratory research focuses on innovative theories and/or methods, new or unmet clinical needs, etc. Some exploratory research questions do not involve tests of significance, and in such cases, statistical power is not relevant. However, when exploratory research questions do involve tests of significance, adequate statistical power is expected.
- Efficacy Research: the extent to which an intervention, service, policy, or procedure produces a beneficial result under ideal circumstances in the target population. "Ideal circumstances" refer to the intervention being delivered with strict adherence to the designed intervention (i.e., high fidelity), by trained interventionists, to a well-defined population, with sound measurement of outcomes. Efficacy research is intended to identify causal relationships between the intervention and target outcomes. Efficacy research questions almost always involve significance testing, and so adequate statistical power is expected. While some efficacy questions are best answered via a randomized controlled trial (RCT), there is no requirement that an RCT design be used. The research question(s) should determine the research design.
- Effectiveness Research: the extent to which an intervention, service, policy, or procedure of known efficacy, and deployed under routine circumstances, produces a beneficial result to the target population. "Routine circumstances" refer to the intervention being delivered by the intended end-users, to a broadly defined population, with sound measurement of outcomes. In effectiveness research, there is likely to be variability in the delivery of the intervention, making fidelity monitoring essential. Rather than requiring the intervention be delivered with high fidelity as in efficacy research, fidelity monitoring in effectiveness research identifies situations in which the end-user adapts the intervention. Follow-up research can identify why the end-user chose to adapt to the intervention, and whether a change in the intervention or delivery system is needed. Effectiveness research is not meant to be a return to "black box" intervention research, but rather

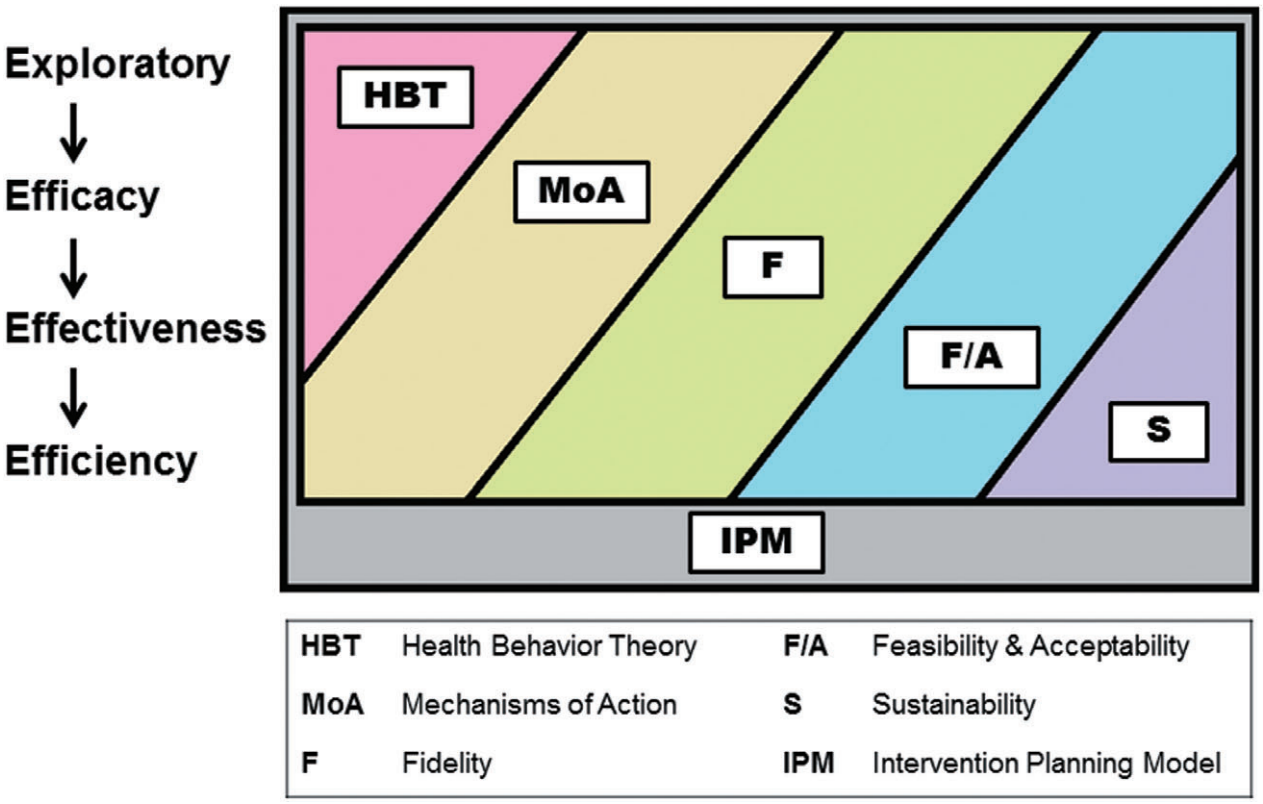

Figure 1 National Institute of Dental and Craniofacial Research Behavioral and Social Intervention Research Program.

a systematic investigation of how an intervention can be delivered in a "real world" setting.

- Efficiency Research: the extent to which an intervention, service, policy or procedure of known efficacy and effectiveness can be successfully delivered to the target population using the least amount of resources. These are often dissemination and implementation studies with emphasis on cost-benefit, cost-effectiveness, and cost-utility.

The left column of the graphic refers to the spectrum of study types being conducted. Reading from left to right, the relative emphasis on the essential elements of behavioral and social intervention research changes, depending on the type of research being conducted. For instance, in exploratory research, we propose that there should be a heavy emphasis on health behavior theory, identification of mechanisms of action, ensuring fidelity, and acceptability to the target population. While sustainability of the intervention can be considered during this early stage, it need not be a primary focus. In other words, early intervention development could focus on building a highly efficacious intervention that would not be sustainable as-is, but would require either intervention or delivery-system adaptations to be sustainable in community settings.

Moving down the left column, efficacy studies emphasize the use of health behavior theory, understanding mechanisms of action, ensuring fidelity, and building interventions that are acceptable to the target population. Effectiveness studies emphasize mechanisms of action, monitoring (but not ensuring) fidelity, acceptability to the target population, and beginning to consider long-term sustainability. Efficiency studies emphasize long-term sustainability and acceptability to key stakeholders, while monitoring fidelity. By the time an intervention reaches this point, it should have already incorporated health behavior theory, and identified mechanisms of action.

Finally, the entire process of moving from early, exploratory intervention research to efficiency research should be governed by a sound intervention planning model. This governs the activities appropriate at each stage of intervention development, and helps investigators to plan for a *program* of research that builds on past successes, and appropriately addresses challenges along the way.

The graphic representation of the Behavioral and Social Intervention Research program illustrates the ideal, systematic progression of intervention development research through a series of research activities, as well as the elements

and activities that are essential along the way. Incorporating these elements into behavioral and social intervention research to improve oral health secures a leadership role for the oral health research community in making efficient and potent improvements in public health, and in understanding behavior and social change. It is our hope that the expert guidance provided in this supplemental journal issue equips our community with the tools necessary to produce even greater advances in behavioral and social intervention development, and ultimately, to improve oral health for the public we serve.

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Conflict of interest

The authors declare no conflict of interest.

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