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Advances in EBI Development for Diverse Populations: Towards a Science of Intervention Adaptation

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Abstract

This introduction examines major issues and challenges as presented in this special issue of Prevention Science, "Challenges to the Dissemination and Implementation of Evidence Based Prevention Interventions for Diverse Populations." We describe the Fidelity-Adaptation Dilemma that became the origin of dynamic tensions in prevention science. It generated controversies and debates and new perspectives on the dissemination and implementation of evidence-based interventions (EBIs) within diverse populations. The five articles in this special issue address many of these challenges. These dynamic tensions have culminated in a reframing of this dilemma, that now argues that fidelity and adaptation are both equally important imperatives. These five articles also examine the abiding challenges of engagement and sustainability. Also, two commentaries from expert research investigators reflect on these five articles and their contributions to prevention science. The current introduction describes this "second generation" of EBI's as they may contribute towards a reduction of the health disparities and inequities that disproportionately affect sectors of the major ethnocultural populations in the U.S. We also present a systems analysis of approaches and challenges in the dissemination and implementation of EBI's within the contemporary integrative care environment. Finally, we mention an initiative for, "building a science of intervention adaptation," that proposes systematic research and the creation of an archive of scientific data on the benefits and problems of intervention adaptation. Collectively these new directions can integrate scientific rigor and sensitivity to cultural factors, for enhancing the effectiveness and reach of this second generation of evidence-based interventions with diverse ethnocultural populations.

Keywords

Interventio	on Adaptation;	Implementation;	Dissemination;	Health I	Disparities	

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Reflections on Scientific Advances

In the field of prevention science, the "Fidelity-Adaptation Dilemma" serves as a naturalistic episode in which two important prevention science constructs have evolved across time. This dilemma inspired controversy and discussion, in time shaping related research, and practice. Reframing a scientific dilemma, such as this one, can reveal new perspectives to be considered and re-considered with the usual scientific skepticism. These new perspectives have emerged from the accumulation of empirical results that reveal new and distinct patterns that suggest new approaches towards resolving this dilemma. This special issue captures many of these patterns and directions, leading to the reconceptualization of this Fidelity-Adaptation Dilemma.

Historical Origins and a Reframing of the Fidelity-Adaptation Dilemma

The compelling dilemma

Within the past two decades, issues and approaches regarding the cultural adaptation of original evidence-based interventions (EBIs) have been examined extensively (Barrera, Castro, Strycker, & Toobert, 2013; Castro, Barrera & Martinez, 2004; Elliott & Mihalic, 2004). The "Fidelity-Adaptation Dilemma" was originally framed as a mutually-exclusive imperative, arguing that *complete fidelity* to an EBI's *core components* is essential, and that EBI modifications are <u>not</u> negotiable. Complete fidelity was regarded as the "gold standard" to which interventionists must adhere, and adaptations were regarded as detrimental to EBI effectiveness (Elliott & Mihalic, 2004; see Mejia, Leijten, Lachman, & Parra-Cardona, 2016, this issue).

Nonetheless, Elliott and Mihalic, strong proponents of total fidelity acknowledged the occasional need for adaptations, provided that they remain consistent with the intervention's *theoretical foundations*, and that they be re-tested for effects on targeted program outcomes under controlled experimental trials (Elliott & Mihalic, 2004). This perspective on the importance of an EBI's *theoretical foundations* underscored the importance attributed to the EBI's theoretically-derived *core components*, the essential operating mechanisms believed to produce the intervention's targeted behavioral changes (Rohrbach, 2014). Historically, it must be noted that when examined retrospectively across almost two decades, despite shifts in contemporary views of the utility of cultural adaptations, their emphasis on adherence to the EBI's theoretical foundations, as proposed by Elliott and Mihalic, is as relevant today as it was almost 20 years ago.

Within this context, the *cultural adaptation* perspective argued that EBI implementation in "real world" settings often requires adjustments in response to emerging conditions or situations. One aim was to eliminate "cultural mismatches," between the EBI's established protocol and aspects from three domains: (a) *the participants*, when EBI contents conflict with participants' cultural beliefs or values, (b) the *intervention delivery staff*, and/or (c) the *local community environment* (Castro, Barrera, & Martinez, 2004). Moreover, considerable evidence accrued from school-based community studies on the pervasiveness of teacherinitiated adaptations (Barrera, Berkel & Castro, 2017, this issue; Ringwald, Vincus, Ennett, Johnson, & Rohrbach, 2004).

Subsequently, research to measure and operationalize *fidelity* emerged that conceptualized it as a multi-dimensional construct. These dimensions of fidelity were: (a) *adherence* - closely following the intervention's prescribed curriculum and activities; (b) *dosage* – the amount of intervention content that is presented; (c) *quality of delivery* – implementer skills in the implantation of EBI material based on a thorough understanding of the intervention; (d) *engagement* – high participant involvement in the intervention's activities; (e) *program differentiation* - the intervention's unique contributions to behavior change; as well as (f) *adaptation* itself, which was regarded as, "the least studied factor of the complex fidelity construct" (Hansen, 2014, p. 342). *Adaptations* have been described as, "modifications in an intervention's content or methods in response to specific consumer needs and preferences," with the recognition that adaptations, have "the potential to improve program outcomes," (Hansen, 2014, p. 343).

Contemporary conceptualization

The original "either-or" conceptualization of fidelity has now transitioned into a "both-and" conceptualization (Mejia, Leijten, Lachman, & Parra-Cardona, 2016, this issue). Currently and in principle, given a thorough understanding of the original EBI's theory-based goals, both fidelity and adaptation can be attained under well-planned modifications (*strategic adaptations*) that resolve emerging implementation problems, while still adhering to the EBI's core goals (*theoretical congruence*). Ideally, such adaptations can also increase *engagement* among participants, and increase intervention *effectiveness*.

Linking EBIs to the Elimination of Health Disparities and Inequities

The widespread dissemination and implementation of EBIs in Type 2 translations (Spoth, Rohrbach, Greenberg, Leaf, Brown, Fagan, et al., 2013) is a major goal that has the potential for reducing or eliminating several health disparities that disproportionately affect disadvantaged sectors of the major ethnocultural populations in the United States (Department of Health and Human Services [HHS], 2016). Thus, a major public health goal is to disseminate tested-and-effective EBIs for availability nationwide (Spoth, Rohrbach, Greenberg, Leaf, Brown, Fagan, Catalano, Pentz, Sloboda, & Hawkins, 2013).

Ideally, when implemented with fidelity, an original EBI will exhibit the same or similar effectiveness across diverse cultural groups, and within various service delivery and community settings. By definition, an EBI's effectiveness is determined by its capacity for, "producing Y outcomes for X population at time T, [and] in setting S." (Gottfredson, Cook, Gardner, et al., 2015, p. 286). However, when an EBI exhibits a lower effectiveness across one or more of these factors, this would indicate an erosion in the EBI's *social validity* as implemented within a new population (Burlew et al., 2013; Lau 2006). As a remedy, *strategic modifications* would be indicated to improve the original EBI's performance because it: (a) exhibits lowered effectiveness in changing targeted outcomes for a subcultural group, or (b) the new subcultural group exhibits unique social or clinical problems that are not addressed by the original EBI (Barrera & Castro, 2006; Lau, 2006).

Cultural and local adaptations

A major premise of the landmark the 2001 Surgeon General's report was that "culture counts," (USDHHS, 2001). Cultural factors can be important for engaging individuals and families from many sectors of the major ethnocultural populations of the United States: African Americans, Latinos/Hispanics, Asian Americans, Native Americans. *Cultural adaptations* have been described as modifications to an original EBI's *contents* or *activities*, to fit the needs, preferences, or the life contexts of a particular subcultural group (Castro, Barrera, & Holleran Steiker, 2010), or for intervention adoption to improve fit within a new human service organization (Wisdom, Chor, Hoagwood, & Horwitz, 2014). Cultural adaptations have also been defined as EBI modifications for promoting "cultural fit," when developed prior to broad-scale implementation (Barrera et al., 2016, this issue). Nonetheless, some teachers and other implementers have conducted culturally-focused and *impromptu adaptations* to an original EBI's established curriculum during the process of implementation (Miller-Day, Pettigrew, Hecht, Shin, Graham, & Krieger, 2013).

By contrast, *local adaptations* have been defined as, "modifications made by implementing organizations and communities that are not part of the intervention as described by the developer." Local adaptations typically involve changing the contents or activities from intervention sessions to improve fit in response to here-and-now local conditions (Barrera et al., 2016, this issue). Depending on the adaptive changes made, local adaptations of noncore aspects can erode EBI effectiveness. Conversely, local adaptations are now also regarded as useful for eliminating, "likely barriers to recruitment, acceptance, participation, and high-quality implementation" (Gottfredson et al., 2015, p. 917), and that they can also increase EBI effectiveness.

Common limitations in EVTs and EBIs

Findings from the NIDA Clinical Trials Network have identified three major limitations of *empirically validated treatments* (EVTs), the tested-and-effective programs developed for treating drug dependence within clinical treatment settings. These limitations are: (a) *low engagement and retention*- conditions that limit full exposure and benefits offered by substance abuse treatment; (b) *limitations in dissemination and implementation*- whereby these treatments have not been broadly disseminated nor adopted across communities, and that they have not been implemented with fidelity by program staff; and (c) *limited sustainability* – limited financial, staff, and supervisory resources that are needed to sustain these programs across time (Carroll, Ball, Jackson, Martino, Petry, Stitzer, Wells, & Weiss, 2011; Donovan, Daley, Brigham, Hodgkins, Perl, & Floyd, 2011). These EVT limitations are strikingly similar to the limitations that affect preventive EBIs.

About the Contributing Articles

Mejia and colleagues: Diverse approaches for cultural adaptation

Mejia and collaborators refer to the "fidelity-adaptation debate," asserting that this dilemma should be reconceptualized from an "either-or" conceptualization to a "both-and," conceptualization. That is, beyond framing fidelity and adaptation as antithetical imperatives, these investigators argue that a more useful approach is to reframe these

imperatives as equally-important, essential, and complementary. They note that "... cultural adaptations can be a flexible process, [and] should be informed according to existing local resources, and remain responsive to specific cultural contexts," (Mejia, Leijten, Lachman, & Parra-Cardona, 2016, this issue). These investigators present three case studies that utilize surface level, deep structure, or culturally focused adaptations illustrating this localized flexibility when conducting cultural adaptations.

Barrera and colleagues: Local adaptations, engagement, and sustainability

Barrera and collaborators examine three contemporary issues in the cultural adaptation of preventive interventions: (a) *local adaptation*, (b) *engagement*, and (c) *sustainability*. These investigators argue that more data now suggests the beneficial effects of cultural and local adaptations (Barrera, Berkel, & Castro, 2016, this issue). Nonetheless, a remaining challenge is to, "improve reach, engagement, and sustainability of interventions by making modifications to fit ethnocultural groups' languages, cultural values, lifestyles, and unique risk/protective factors," (Barrera et al. 2016, p. x, this issue). Culturally adapting original EBIs has the potential for increasing EBI engagement, intervention efficacy, adoption within community agencies, and sustainability. Establishing and maintaining intervention sustainability remains as a major challenge that requires further research to identify and leverage the factors that can enhance sustainability within diverse human service organizations. These investigators also offer several recommendations for conducting local adaptations, promoting engagement, and increasing sustainability.

Kumpfer and colleagues: Views from decades of cultural adaptation research

Kumpfer and collaborators impart their knowledge and experiences from over two decades of development and implementation worldwide of the Family Strengthening Program within 36 countries (Kumpfer, Magalhaes, & Xie, 2016; this issue). Kumpfer and collaborators examine barriers to cultural adaptation and existing cultural adaptation frameworks, also providing recommendations on best approaches for the cultural adaptation of family EBI's.

These investigators indicate that most family evidence-based interventions (FEBIs) have been designed for English-speaking families. Thus, when disseminated to diverse communities within the U.S., and internationally, various forms of cultural adaptation are often necessary. Despite evidence regarding the efficacy of FEBIs in reducing several adolescent behavioral health problems, FEBIs, "have not been widely adopted for the prevention of ethnic children's behavioral or physical health disorders in the U.S.A. and around the world." (Kumpfer et al., 2016, p. x, this issue).

Kumpfer and collaborators note that racial/ethnic and low-income families who reside in high-stress environments are at high risk of developing familial and youth problems, yet they are also the most difficult to enroll and graduate from FEBIs. To promote their engagement, an original EBI often must be modified to accommodate their needs. Otherwise, these efficacious interventions will remain, "underutilized in addressing health disparities in ethnic populations," (Kumpfer, Magalhaes, & Xie, 2016, p. x, this issue).

These investigators also describe their Planned Adaptation Approach in which stakeholders are invited to participate in the planning and implementation of well-reasoned adaptations of

an original EBI. Within this context, Kumpfer and colleagues indicate that future EBIs will benefit from ongoing "consumer feedback" on the EBI's strengths and weaknesses, as assessed by *continuous implementation quality* assessments (Kumpfer, Magalhães & Xie, 2016, this issue).

Dawson-McClure and colleagues: Creating community for responsive parent education

Dawson McClure and collaborators describe issues and approaches in the delivery of an innovative school-based parent education intervention, the *ParentCorps* intervention (Dawson-McClure, Calzada, & Brotman, 2017, this issue). This intervention has been implemented with culturally-diverse groups of low-income parents who reside within an urban environment. *ParentCorps* incorporates the core components from major parent education interventions and focuses on, "placing culture at the center," of this intervention. This approach promotes parental engagement, retention, and sustained participation, and ultimately aims to maximize beneficial intervention outcomes. Rather than utilizing an ethnic-specific adaptation, culture is captured by accepting the values and beliefs endorsed by participating parents, which enables the intervention to be sensitive to the evolving needs of multicultural families and communities.

Henry and colleagues: Methodological alternatives to RCTs

From a methodological perspective, Henry and collaborators describe three alternative methodologies for conducting rigorous tests of the efficacy of a prevention intervention, in cases where a randomized controlled trial (RCTs) is not feasible for logistical, political, cultural, or ethical reasons (Henry, Tolan, Gorman-Smith, & Schoeny, 2016, this issue). Furthermore, some investigators have noted that RCTs are designed to maximize *internal validity*, and that this often attenuates the design's *external validity* (Leviton, 2017). In community-based RCTs, establishing narrow inclusionary criteria in sample selection, among other RCT design features appears to reduce the design's external validity, thus limiting *generalizability* of study results, and the *transferability* of the intervention's protocol for implementation within new organizations and with new ethnocultural groups, particularly among those from culturally distinct communities and from hard-to-reach populations.

RCTs still prevail as the scientific "gold standard" for testing EBI efficacy and effectiveness. Nonetheless, Henry and collaborators indicate that often alternate research designs and measures of causal inference are necessary for rigorous tests of intervention efficacy in instances in which conventional RCTs cannot be utilized. Although RCTs remain the "gold standard" for testing intervention effects, often they are less informative for providing indepth evidence on ways to adapt and refine the EBI's curriculum or protocol. For this purpose, other research approaches, such as mixed methods research designs can provide this important evidence (Curry & Nunez-Smith, 2015; Palinkas, Aarons, Horwitz, Chamberlin, Hurlburt, & Landsverk, 2011).

Bernal commentary: Novel assumptions for cultural adaptations

Dr. Guillermo Bernal is a senior investigator who has published extensively on the topic of cultural adaptations and has developed models that examine important components of

cultural adaptations. In their commentary, Bernal and Adames (2017, this issue) question the adaptation strategy of maintaining the EBI's "core components," arguing that limited empirical evidence exists regarding the effects of an EBI's putative core components as essential influences on targeted behavior change outcomes. Bernal and Adames also describe a conceptual framework that distinguishes an EBI's *propositional model* (theory of change) from its *procedure model* (action and methods) (Bernal & Adames, 2017, this issue). This analysis underscores the importance of *theoretical congruence* in conducting adaptations that can also retain fidelity to the EBI's core intervention aims.

Bernal and Adames also argue that interventions should recognize how an EBI's proposed model (theory of change) can conflict with the worldview of persons from certain ethnocultural groups. In these cases, adherence to that EBT's or EBI's theoretical foundations when in conflict with a client's cultural "world view," could impose culturally-dystonic values that can be detrimental to the client's well-being (Bernal & Adames, 2017, this issue). These investigators also note that future adaptations research may identify new emergent principals and guidelines for increasing intervention effectiveness. Such research may also examine the stability of each emergent principal as observed across diverse subcultural groups.

Gonzales commentary: Expanding cultural adaptations to address health disparities

Dr. Nancy Gonzales is a well-recognized research investigator who has published extensively in the areas of preventive interventions for Latino families and children. Dr. Gonzalez indicates that the approaches presented in this special issue are novel and responsive to the growing population diversity occurring within the U.S. She reviews and comments on three major trends involving EBI dissemination and implementation: (a) an expanded conceptualization of fidelity and adaptation, (b) the need for broader systemic analysis of EBI delivery within systems of care, and (c) new ways to adapt and evaluate this new generation of preventive interventions as designed for efficacy in this increasingly diverse society (Gonzales, 2017, this issue). Gonzales encourages new research that can produce a broad-spectrum population impact, as this includes coordinated efforts among research investigators and health service providers, and that is responsive to shifting population trends.

Systems EBIs and Community Partnerships for Reducing Health Disparities

Historically, complex economic, environmental, political, and social conditions have produced the health inequities and health disparities that disproportionately affect large sectors of the major ethnocultural populations in the U.S.: African-Americans, Native Americans, Hispanic/Latinos, and Asian Americans. The reduction or elimination of these health disparities will require the design, dissemination, and implementation of coordinated systemic multi-level interventions that promote community engagement and mobilize various forms of social support to help community residents practice healthy lifestyles (American Diabetes Association, 2017). These multi-level EBIs would be designed to provide resources and support at three distinct levels of the social ecology: (a) the *macro* (federal, state and policy), (b) the *exo* (local community or health clinic) level, and (c) the

micro (individual behavior change intervention) level, also establishing trusting relationships and secure commitments to engage individuals and families from underserved ethnocultural groups and communities (Belgrave, & Abrams, 2016).

One example of this multi-level EBI is the Strong African American Families (SAAF) intervention that has been implemented within low-income rural communities in Georgia (Kogan, Lei, Brody, Futris, Sperr, & Anderson, 2015). This study conducted extensive outreach to establish connections with schools, faith-based organizations, and local stakeholders. Program staff trained local implementers, to formulate, refine, and troubleshoot problem, to thus develop a locally effective intervention (Kogan et al., 2015). This study also underscores the emerging view that, "... simply handing off on evidence-based program and assuming it continues to produce the desired outcomes is not a tenable position," (Supplee, & Meyer, 2015, p. 940). To the contrary, the integration of a study within a local community or community-based organization requires building, "a culture of continuous improvement with shared responsibility between the community-based organization, the founder, and the developer of the evidence-based program," (Supplee, & Meyer, 2015, p. 940).

Challenges in Integrating Preventive Interventions within Primary Care Settings

A new frontier in the design, development, and implementation of a new generation of treatment and preventive interventions is to design and develop interventions that can be integrated and implemented within various community-based agencies (see Gonzales, 2017, this issue), including primary care settings. "Integration is a key feature of health system reform that promises to improve the access, quality and value of care for all patients..." (Walley, Tetrault & Friedman, 2012). Presently, the *integrative care* approach has focused on incorporating substance abuse and mental health services within primary care settings (Padwa, Teruya, Tran et al., 2016; Walley, Tetrault & Friedman, 2012). Many challenges exist for effectively integrating these treatment modalities within local community agencies, with perhaps greater challenges facing the integration of preventive interventions (Franz, Stemmler, Hahlweg, Pluck, & Heinrichs, 2015).

In planning this integrative approach, systems level-analyses are essential for coordinating intervention activities within macro and micro-level organizational structures and processes (Aarons et al., 2011). One conceptual model examines the influences of: (a) "inner context factors" (micro-level factors internal to the organization that include organizational characteristics and organizational leadership), and (b) "outer context" factors (macro-level factors external to the organization that include funding, social policy, and interorganizational networks). These contextual factors exert differential effects across four progressive phases of the implementation process that occurs in *evidence-based practice* (EBP): (a) exploration, (b) adoption decision/preparation, (c) active implementation, and (d) sustainment.

As contrasted with the conventional acute care model practiced for decades within health settings, a contemporary health and wellness model emphasizes the value of *prevention* and

health promotion as proactive approaches to health care that involve: (a) clinical information systems for making empirically-based patient-specific and population-based decisions to promote healthy lifestyles, (b) support that is informed by evidence-based information, (c) support for patient self-management and decision making, (d) sources and policies to promote a quality-oriented health culture (American Diabetes Association, 2017). These approaches can be guided by new emerging multilevel, multi-domain and multistage systems models that describe dynamic process that occur among major components of a service delivery system, and as influences on targeted health outcomes (Holden, McGregor, Thandi, Fresh, Sheats, Belton, Mattox, & Satcher, 2014, Lowenson & Simpson, 2017).

Building a Science of Intervention Adaptation

Currently limited data exists on best approaches for integrating EBIs within educational, social services, and health care agencies. Chambers and Norton (2016) have advocated for the development of, "a science of intervention adaptation," as developed within the context of intervention implementation. This initiative would, "fully explore the range of ways in which adaptation can affect patient outcomes both positive and negative," (Chambers & Norton, 2016, p. S126). A central aim in this science of adaptation is to conduct rigorous implementation research for creating guidelines for an improved development and implementation of efficacious and adaptive EBIs that can evolve over time (Chambers & Norton, 2016, p. S130).

A future aim of this science of intervention adaptation is identify robust principles and guidelines for conducting effective cultural adaptations. These principles and guidelines could guide decision making during implementation and in conducting strategic adaptations. Strategic adaptations would localize the EBI to improve EBI responsiveness to local conditions to promote cultural relevance and acceptability among local community residents. These strategic adaptations would also seek to preserve the integrity of the original EBI by tempering adaptations with the reminder, "but don't change too much" (Botvin, 2014). In summary, strategic adaptations would seek to maintain fidelity to the EBI's original theoretical foundations (theoretical congruence), while also engaging in problem solving adaptations that allow the EBI to operate effectively within new environments and with new subcultural groups.

Integrating Scientific Rigor and Cultural Flexibility

Prevention science holds the promise for reducing health disparities, to reduce the burden of disease and disability that disproportionately affect several sectors of major ethnocultural populations. This promise can be met through rigorous and culturally-informed applications of prevention science theory and empirical knowledge, to inform EBI adjustments, adaptations, and continuous quality assessments for refining an original EBI, ideally for also augmenting the EBI's effectiveness. The goal is to significantly improve the health and well-being of disadvantaged sectors of the U.S. population by significantly reducing the existing health disparities and inequities.

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