

# Evidence and Equity: Challenges for Research Design



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## INTRODUCTION

The value of scientific evidence in providing guidance on what strategies are most likely to promote positive health and developmental outcomes has gained considerable traction among policymakers and federal, state, and private funders of intervention efforts. Growing emphasis on evidence-based interventions (EBIs) is reflected in reviews of evidence and official lists of programs and practices that meet rigorous criteria for demonstrated effectiveness (Administration for Children and Families, 2017; Substance Abuse and Mental Health Services Administration, 2017; U.S. Department of Health & Human Services, 2017). Funding for service provision may be restricted to programs and practices included on such lists, with emphasis placed on investing resources in proven methods, and reducing resource allocation for programs that prove ineffective or, in some cases, harmful to participants. Opportunities to make programmatic decisions based on evidence reflect important progress in promoting positive health outcomes. Evidence-based practice holds promise for promoting health equity when effective practices can be focused within populations at greatest risk. That particular promise, however, is not being fully realized because evidence is lacking for populations most at risk.

This brief is based on a presentation at a meeting titled *Building strong evidence in challenging contexts: Alternatives to traditional randomized controlled trials*, held in September 2016 (<http://www.opremethodsmeeting.org/2016topic.html>).<sup>1</sup> The purposes of this brief are (1)

<sup>1</sup> The meeting focused on understanding what kinds of research questions can be addressed using alternatives to traditional randomized control trials (RCTs), the special considerations involved with these types of approaches, and the tradeoffs between using alternative and traditional

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to discuss research disparities between easier-to-study populations and harder-to-study, more marginalized groups and (2) to present four strategies to address these research disparities. It draws on work with American Indian and Alaska Native (AIAN) populations as a motivating example.

## THE EVIDENCE GAP

Established lists of EBIs typically include few, if any, interventions for specific ethnic or cultural minority communities because few interventions within these populations have met strict criteria for rigorous evaluation.

Ethnic and cultural minority communities are too often left behind in efforts to build evidence to inform effective interventions.

As an example, the scarcity of evidence regarding effective interventions is salient for AIAN populations. A search of the Substance Abuse and Mental Health Services Administration National Registry of Evidence-Based Programs and Practices

impact designs and analyses. Speakers shared their experience and knowledge around innovative, applied examples of alternatives to traditional RCTs and the theoretical and statistical models underlying those designs.

(<https://www.samhsa.gov/nrepp>) returned 419 interventions but only six with any evidence of effectiveness within AIAN populations. The U.S. Department of Health and Human Services' Home Visiting Evidence of Effectiveness Review (Sama-Miller et al., 2017) identified 20 home visiting models with evidence of effectiveness; only one of which has effectiveness data specific to cultural groups. The Tribal Home Visiting Evidence of Effectiveness Review (Del Grosso, Kleinman, Mraz Esposito, Sama-Miller, & Paulsell, 2012), also funded by the U.S. Department of Health and Human Services (DHHS), specifically examines evidence of effectiveness within tribal communities, a population at particular risk for health and developmental inequities. This report (last updated in 2014, anticipated to be updated again in September 2017) identified one model that meets DHHS criteria for an evidence-based early childhood home visiting service delivery model for tribal populations (Barlow et al., 2015; Mraz Esposito, DelGrosso, Kleinman, Sama-Miller, & Paulsell, 2014). This evidence gap reflected the need for systematic studies of home visiting within tribal communities.

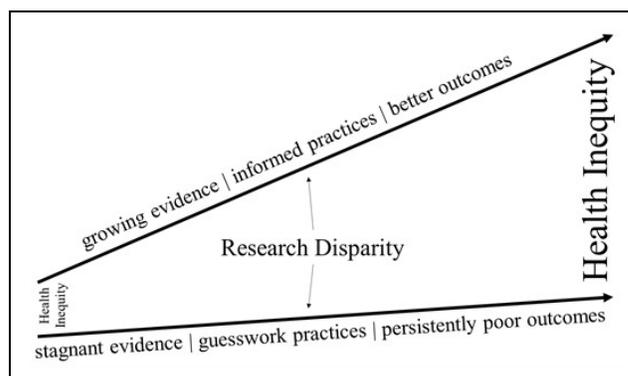
## RESEARCH DISPARITIES

Gathering evidence on the effectiveness of interventions within diverse community and cultural contexts is an undeniably complex undertaking. Community-based participatory research is an approach meant to improve rigorous designs and valid data in community settings (Israel et al., 2003). The approach relies on sustained partnerships between community and research partners and genuine engagement of diverse stakeholders in all phases of research, from identification of study goals through study design, implementation, analysis, interpretation, and dissemination (Viswanathan et al., 2004). Intervention research is difficult; community-engaged intervention research can be even more challenging (Wallerstein, Duran, Oetzel, & Minkler, 2017; Whitesell, Sarche, Keane, Mousseau, & Kaufman, 2017). Standard research designs are often challenging and sometimes impossible to implement. Timelines are extended. Funding is difficult to secure. Partnerships can take years to build and effort to sustain. Costs can be prohibitive. Researchers often understandably shy away from doing this kind of research. Academic pressures for publication and promotion are often at odds with community pressures for genuine engagement, local dissemination, and creative thinking about the meaning of

evidence (Thompson, Whitesell, Galliher, & Gfeller, 2012). These challenges may help explain the relative shortage of evidence about effective interventions across diverse communities and populations.

While research disparities are thus understandable, if the trajectory of evidence continues to build for populations easiest to engage and study while continuing to lag for marginalized or hard-to-reach communities, equity gaps are likely to widen. For example, research is relatively easy in communities that are in close proximity to universities, in urban areas where large samples are comparatively easy to obtain, and in middle-class neighborhoods where participants are well-educated and tend to hold favorable views of research. However, research is markedly more challenging in remote rural communities or among populations that have been subject to unethical research practices in the past.

**Figure 1** illustrates this scenario of divergent evidence across populations over time—what could happen if research equity is not pursued with intention. In the figure, the top trajectory represents the easier-to-reach populations, projecting continued accumulation of evidence about effective health interventions. The populations represented in this research will reap the benefits of EBIs, with choices of programs and practices that can be used “off the shelf” with some confidence that they will impact outcomes. The lower trajectory in the figure illustrates a future of modest gains for communities that continue to be underrepresented in the intervention literature. When, as noted above, evidence is harder to generate, studies take longer and require more resources, or do not occur at all. As a result, rigorous science falters and remains stagnant. In this scenario, intervention efforts would fail to benefit from accumulating evidence and inequities would persist.



**Figure 1.** An illustration of the potential for growing health inequity related to research disparities.

Research disparities are evident on lists of vetted EBIs and the uneven guidance they provide to different population groups (Mraz Esposito et al., 2014; Sama-Miller et al., 2016; Substance

If current research disparities continue, underrepresented communities are at risk of being left behind in the push for evidence-based practice.

Abuse and Mental Health Services Administration, 2017). The holes in these lists reflect the uneven evidence base and arguably exacerbate health inequities by limiting both resources and guidance to communities.

Communities that find no approved EBIs appropriate to their populations face a dilemma. To obtain funding for needed services, they may be required to adopt an EBI with evidence largely irrelevant to their community, implementing it in the hopes that it will be effective, often despite concerns about cultural or contextual alignment. Otherwise, they may be ineligible for funding that could bring critical resources to addressing health concerns in their communities. Even when resources are available, communities trying to address health concerns are left without sound guidance for choosing among potential approaches. With the need for timely intervention, they must move forward without the benefit of evidence that research affords to other populations (i.e., they cannot select a proven program from a list), at risk of squandering resources or even doing harm.

## ADDRESSING RESEARCH DISPARITIES

To ensure that ethnic and cultural minority communities can benefit from what science has to offer, research disparities must be reduced. To bridge this gap, researchers should utilize strategies that (1) engage with communities throughout the research process, from identification of study aims through dissemination of study findings; (2) use the most rigorous research design appropriate for a given setting; (3) acknowledge and address challenges to research within at-risk communities; and (4) implement flexible and innovative methods.

### 1. Engaging Community Partners in Research

First and foremost, rigorous intervention research within communities requires engaging the community. Community-based participatory research approaches have gained significant momentum and represent an important strategy for ensuring the

validity of intervention research (Wallerstein et al., 2017). Close partnerships with communities contribute to rigorous intervention science, beginning with the collaborative identification of the problem to be addressed, through the selection or creation of an intervention, implementation, evaluation, dissemination, and sustainability plans. Sustained partnerships between communities and researchers can improve the relevance of questions, appropriateness of design, and feasibility of implementation and data collection. Together, partners bring state-of-the-art scientific methods and deep knowledge of the local community and culture to prevent problems and promote health equity.

### 2. Prioritizing Rigor over Rigidity.

Misalignment between standard evaluation designs and community values and priorities can be a significant impediment to rigorous intervention research in AIAN communities and other ethnic and cultural minority communities. This divergence can ultimately undermine the quality of evidence produced. The literature supporting the value of randomized controlled trials (RCTs) as the gold-standard method for evaluating the effectiveness of an intervention is weighty. It is hard to argue with the value of this method *under circumstances where it can be appropriately applied*. The qualifying phrase is key here. There are circumstances under which RCTs cannot be appropriately applied, and these circumstances often appear in contexts of marginalized communities.

For example, assignment to intervention and comparison groups is problematic in the tightly interconnected contexts of AIAN communities; spillover of intervention may be inevitable, rendering the comparison useless. Similarly, random

When an RCT fits, it deserves its gold-standard status. When it does not fit, forcing it will either provide questionable data or preclude the collection of any data at all.

assignment in a setting where the community considers it unethical may be undermined when staff find ways to deliver the intervention to those perceived to be in greatest need, thus compromising the design and invalidating results but aligning with local priorities. The goal of rigorous science is to obtain high quality, trustworthy data, invulnerable (as much as possible) to threats to both internal and external validity. RCTs applied without careful thought to context protect against

neither threat and are especially vulnerable to threats to external validity.

### 3. Acknowledging Challenges to Community-Based Intervention Research

It is useful to acknowledge a number of challenges encountered by researchers partnering with communities to design, implement, and evaluate interventions intended to reduce health inequities. Highlighted here are illustrations from work with AIAN communities; while these challenges are often shared across other contexts, their relevance undoubtedly varies and additional challenges are likely encountered in other populations. The goal of these limited examples is to highlight some of the contextual challenges that require prevention scientists to bring the best scientific tools they have available but also to think creatively and flexibly about how to utilize those tools in partnership with communities.

*Small samples.* A fundamental beauty of randomization in RCTs is the ability to create comparison groups that are equivalent at baseline, with nothing but random variation to distinguish them on key characteristics. It is an efficient way to create equivalent groups, but only when group sizes are large. Many community intervention trials cannot engage large samples; often the populations are themselves small (e.g., tribal communities with as few as 1,000 members). In these contexts, random assignment may not be effective in ensuring an equivalent comparison group. Reliance on RCTs is also complicated when studying community-level interventions, place-based initiatives, and when measuring intervention effects across multiple levels (individual, family, school, community, etc.). In the case of multi-pronged interventions delivered at the community level (e.g., Communities that Care (Rhew et al., 2016)), small numbers of comparable communities call into question the value of randomization in equating intervention and control groups at the community level.

*Ethical concerns.* Random assignment can be problematic in many community settings due to ethical concerns. For example, AIAN communities experience suicide rates among youth that far exceed the national average (Suicide Prevention Resource Center, 2013). These high suicide rates often blind community members—desperate to find solutions for their youth—to the value of a comparison, especially when establishing a control group means withholding a potentially life-saving intervention

from at-risk youth. Sometimes, researchers can effectively communicate the value of withholding an intervention of unknown effectiveness from a comparison group (at least for the period of the evaluation) to examine the effects of the intervention. This is more likely to occur when the researcher has a strong and sustained commitment to partnering with communities over time, and building trust and research literacy. In such cases, randomization to treatment and comparison groups may be feasible (when sample sizes are sufficiently large).

*Implementation challenges.* Significant roadblocks to successful effectiveness trials are often encountered, regardless of the intervention study design. Three of these that are particularly problematic include contamination or diffusion of intervention across groups, logistical challenges, and resistance to research.

- ❖ In small, tight knit communities, *contamination or diffusion* is a serious threat to the validity of any comparison design. My research team has had the experience of delivering one arm of a family-based intervention program to families in one reservation town on Tuesday night, only to have families in a different arm in a different town show up Wednesday night telling us what they had heard from the Tuesday night session. This sort of “contamination” is effective for diffusing interventions within and across communities but poses a significant challenge to research designs looking for differential impacts based on intervention delivery.
- ❖ *Logistical challenges* are common to all intervention studies. Delivering interventions and collecting the data necessary to evaluate their effectiveness always involves a well-choreographed dance of recruitment, retention, implementation, and data collection. This dance becomes so intricate in some community contexts, such as remote AIAN communities where services are scarce, that it challenges the capacities of even the most well-prepared research teams. Because of these challenges, complex research designs that might be feasible in urban settings close to research hubs can become intractable in rural or remote settings, or in under-resourced urban communities.
- ❖ Finally, *resistance to research* can be pervasive in communities that have been the subjects of unethical research histories that have ignored participant and community rights and

disseminated findings in ways that fostered negative stereotypes of populations while offering little information to benefit communities. This is evident in AIAN communities, as described by Manson and Norton (Norton & Manson, 1996), but pertains to other communities as well. Engaging with research-wary communities, understanding and respecting their fears and questions, and proceeding in an authentic and equitable partnership to bring research to bear on their health priorities is an intensive process that requires considerable time and unwavering commitment of research partners.

*Funding priorities.* The priorities of funders, both public and private, shape the collective research agenda. Research requires resources, and obtaining those resources requires responsiveness to funder agendas. This can be a barrier to building evidence within communities facing the most significant health inequities. The National Institutes of Health (NIH), for example, increasingly prioritize transformative science over incremental science and the value placed on “overall impact” in grant review has grown in recent years. Where does this leave disadvantaged communities, where building evidence is challenging? The broad overall impact of developing interventions specifically for these communities is questioned. Evaluations of the adaptation of mainstream interventions for these contexts are often deemed incremental and not of high priority. There are notable exceptions to such funding priorities, however, as in an NIH initiative to fund intervention research in AIAN and Native Hawaiian communities (<https://cancercontrol.cancer.gov/nativeamericanintervention/>) and the work of the Administration for Children and Families to rigorously evaluate the implementation of Maternal, Infant, and Early Childhood Home Visiting programs in tribal communities (Lyon et al., 2015).

*Evaluating adaptations.* Evidence supports the importance of ensuring the cultural fit of an intervention to maximize effectiveness (Botvin, Schinke, Epstein, Diaz, & Botvin, 1995; Schinke & Matthieu, 2003). Despite this, we have little evidence about the effectiveness of many EBIs within particular cultural contexts. Official reviews value evidence generated with diverse samples, but analyses typically demonstrate average impact across subgroups rather than effectiveness within them, often because subgroup samples are too small to examine subgroup effects.

Another challenge arises when cultural or contextual adaptations are made to fit the local community, and measures of fidelity to the EBI become nuanced. In some cases, adaptations are relatively minor, core components of the parent EBI clearly preserved, and fidelity assessment is straightforward. When adaptations are deeper and more responsive to the local community, or when core components are not clearly articulated within the original model, re-envisioning fidelity is often necessary. Communities often push for integrating culture within interventions; however, using a scientific lens to understand how cultural mechanisms function (in regard to impact and measurable outcomes) can move into the realm of reductionism (Gone, 2012). For example, cultural practices often occur within sacred spaces, and forcing them into logic models and operationalized measures is a tenuous process at best. Thus, while it is clear that culture should be considered in the fit and implementation of interventions, and while it is important to study the impact of cultural modifications on intervention effectiveness, respect for boundaries between cultural practice and evidence-building efforts is critical.

#### 4. Utilizing Innovative Research Designs

It is clear that RCTs are not always appropriate. Fortunately, rigorous alternatives to RCTs are continually being developed and improved to address the challenges outlined above, as exemplified by the presentations at the convening. When sample sizes are small, techniques for single case design, optimization, and Bayesian analyses are increasingly recognized and significant strides have been made in developing these methodologies in recent years (Bertsimas, Johnson, & Kallus, 2015; Fienberg, 2011; Fok, Henry, & Allen, 2015; Horner et al., 2005; Lane, Ledford, & Gast, 2017). When including a control group that does not receive an intervention is unacceptable, we should consider alternatives that capitalize on the strengths of random assignment with designs that ultimately deliver the intervention to all participants. These include stepped wedge designs, dynamic wait list designs, and other roll-out designs, which have all benefited from both increased methodological attention in the past decade as

If an RCT does not fit, the story should not stop there. Evidence can be built, incrementally, by utilizing innovative techniques that are responsive to the particular priorities and challenges encountered in community contexts.

well as increased implementation in practice (Fok et al., 2015; Hughes, Granston, & Heagerty, 2015). When randomization is not possible, options for leveraging information from preference trials are being explored (Corrigan & Salzer, 2003; He, Gewirtz, Lee, Morrell, & August, 2015; Marcus, Stuart, Wang, Shadish, & Steiner, 2012). Other alternatives to random assignment include comparative regression discontinuity designs, comparative interrupted time series designs, use of simulated instrumental variables, and innovative matching techniques (Angrist & Rokkanen, 2015; Wing & Cook, 2013).

These designs may bring their own practical challenges for application within many community contexts. They do, however, offer a broader and more flexible repertoire of options.

## GOING FORWARD

Significant strides in reducing health inequities will depend on the identification of effective interventions for diverse communities, particularly those at highest risk for health challenges. Intervention scientists must embrace rigorous but *flexible* evaluation methods, committing to partnering with communities to obtain valid data to support well-founded conclusions. Compromises will be required. Research designs that are feasible in community contexts may not handle threats to internal validity as well as RCTs do *under optimal conditions*. Researchers at the forefront of developing and testing interventions to address the most significant health inequities are, however, rarely operating under optimal conditions. They are on the ground in diverse communities, working with community partners in a wide range of contexts and cultures.

Inflexible allegiance to RCTs under these circumstances is misguided and ultimately hampers efforts to build quality evidence of what works within communities, contributing to research disparities. Application of alternative designs should be done with awareness of limitations but also with recognition of the potential to contribute incrementally to the evidence base around effective intervention practices for specific populations. Using a variety of methods to get the best data possible *under realistic conditions* will be critical to supporting health equity.

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