

IMPLEMENTATION RESEARCH METHODOLOGIES FOR ACHIEVING SCIENTIFIC EQUITY AND HEALTH EQUITY

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Implementation science has great potential to improve the health of communities and individuals who are not achieving health equity. However, implementation science can exacerbate health disparities if its use is biased toward entities that already have the highest capacities for delivering evidence-based interventions. In this article, we examine several methodologic approaches for conducting implementation research to advance equity both in our understanding of what historically disadvantaged populations would need—what we call scientific equity—and how this knowledge can be applied to produce health equity. We focus on rapid ways to gain knowledge on how to engage, design research, act, share, and sustain successes in partnership with communities. We begin by describing a principle-driven partnership process between community members and implementation researchers to overcome disparities. We then review three innovative implementation method paradigms to improve scientific and health equity and provide examples of each. The first paradigm involves making efficient use of existing data by applying epidemiologic and simulation modeling to understand what drives disparities and how they can be overcome. The second paradigm involves designing new research studies that include, but do not focus exclusively on, populations experiencing disparities in health domains such as cardiovascular disease and co-occurring mental health conditions. The third paradigm involves implementation research that focuses exclusively on populations who have experienced high levels of disparities. To date, our scientific enterprise has invested disproportionately in research that fails to eliminate health disparities. The implementation research methods discussed

INTRODUCTION

Implementation research “is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.”¹ More broadly, implementation science focuses on how to apply research advances in real-world service systems.² Too often, however, evidence-based interventions (EBIs) are applied inequitably across various settings and populations, skewing application of

best available practices toward communities and organizations with high capacity and resources. When this occurs, it can further exacerbate health disparities based on race/ethnicity, gender, sexual orientation, socioeconomic status, and other factors.³ This scientific inequity⁴ begins with the underrepresentation of historically disadvantaged populations in clinical/preventive research⁵ and persists into wide-scale implementation of EBIs across settings and systems, where innovations can be slow in reaching or responding to the needs of populations who expe-

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rience avoidable health disparities.

Our methodologic perspective focuses on rapid ways to gain knowledge on how to design and conduct research and share, adapt, and sustain implementation and health care successes in partnership with communities in order to diminish health inequities. In this article, we examine methodologic approaches to advance our understanding of both scientific equity in terms of what historically disadvantaged populations would

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need, and how this knowledge can be applied to produce health equity. We begin with consideration of the term health equity and health disparities; we then discuss principles for the formation of partnerships between implementation researchers and community entities; and, finally, present three complementary methodologic paradigms that can inform research to reduce health disparities. Exam-

ples of each paradigm are presented from diverse fields of medicine and behavioral health with documented scientific and health inequities.

HEALTH EQUITY AND HEALTH DISPARITIES: CONCEPTUAL AND METHODOLOGICAL CONSIDERATIONS

Health equity and health disparities emerged in the academic literature around the same time in the early 1990s.^{6,7} While the two concepts are intertwined, health equity has roots in social justice and human rights, defined as “the state in which everyone has the opportunity to attain full health potential and no one is disadvantaged from achieving this potential because of social position or any other socially defined circumstance.”^{7,8} It can be seen as assurance of the conditions for optimal health for all people⁹ and represents a striving for the best possible standard of health.^{6,10} Health disparities are typically the metrics by which two different groups are compared. There are challenges to the use of health disparities as a metric that drives inquiry and any subsequent policy, rather than a focus on health equity where the goal is for all to achieve a certain level of health. While it is beyond the scope of this article to discuss the limitations of a health disparities perspective, we focus on health equity as a framework that allows for resilience and health promotion as guiding principles for implementation science.

BUILDING PARTNERSHIPS FOR HEALTH EQUITY

Partnership building is a crucial strategy for implementation research.¹¹⁻¹³ By building partnerships between key community and health system stakeholders, researchers can establish equal voices with legitimate power and oversight concerning the conduct of implementation research.¹³ Partnerships are essential to addressing social justice issues that result from intentional and unintentional discriminatory policies and social structures that create and perpetuate health inequities. Community-based participatory research (CBPR) and community-partnered participatory research (CPPR) are two well-known approaches devoted to the development of processes for engagement and continued participation of communities in research.¹⁴⁻¹⁶ Through these approaches, community engagement exists along a spectrum from community-as-advisors to full shared decision-making. Arriving at a shared research agenda in partnership with communities requires the development of a shared partnership culture, which will depend on the level of trust, the perceived benefit from the research, and researchers’ ongoing engagement and commitment to the community’s priorities.¹⁷

IMPLEMENTATION RESEARCH METHODS FOR ADDRESSING HEALTH INEQUITIES

We present and then illustrate three methodologic paradigms for

conducting implementation research to address health inequity. We use the term “methodologies” broadly to encompass trial designs, measurement metrics, and implementation strategies. The three paradigms differ in their objectives, as well as the amount of new data required, and consequently in the expense and resources needed to carry out such studies. While these paradigms are distinct, they are complementary in that each can be used to inform and advance the others. Notably, examples of these paradigms exist in the literature; our goal is to better apply them as the science dictates and to increase their use to further equity.

Paradigm 1: Using Existing Data

The first paradigm is the simplest: make efficient use of existing data by applying epidemiologic and simulation modeling to understand what drives disparities and how they can be overcome. This analytic approach relies on already existing data from either administrative records or formal research studies, or both, that elucidate: 1) the extent of population-level disparities; 2) mechanisms that can explain them; and 3) the likely impact of specific implementation strategies on reducing disparities. The first two steps have long been examined using descriptive and analytic epidemiologic methods (eg, regression analysis) that can quantify the extent of disparities in the prevalence or incidence of a disorder for a minority population against a standard. When rates are clustered over a region (eg, counties) and/or longitudinally (eg, histories of acute myocardial infarctions), mixed

effects models can account for such clustering across place or time.¹⁸⁻²⁰ The second step can be examined by conducting regression models with hypothesized mediator and moderator variables^{21,22} and the interaction between moderators and baseline variables.²³ However, the third step involving implementation strategies typically requires more complex systems-level modeling.²⁴ In this step, the use of specific EBIs can be measured through a variety of scenarios, allowing development and simulation of implementation strategies to optimize desired clinical outcomes and ensure that the chosen intervention, as well as the delivery of the intervention, results in reduction, rather than worsening, of health disparities.

One systems-science modeling approach is agent-based modeling (ABM), which we can use to model the impact of implementation strategies. ABM is a method of building computational models that simulate complex systems^{25,26} by describing the entities (called ‘agents’) of a system and the behavioral rules that guide their interactions.²⁷ These agents, which can be any element of a system, interact with each other and the environment to produce emergent, system-level outcomes.²⁸⁻³¹ In principle, these models can account for individual-level attitudes and health behaviors, as well as social determinants of health and of equity, including stigma, sexism, and individual and structural racism.^{32,33} The increased amount of data collected across the health care system presents new opportunities to better understand what drives disparities and how they can be overcome, but also to understand how

various implementation strategies affect the dynamics that result in disparities at the individual and system levels. For example, we have applied ABM to the sexual activity of men-who-have-sex-with-men (MSM) in Chicago in order to support the Chicago Department of Public (CDPH) in their current efforts to eliminate HIV transmission. The specific question facing CDPH is whether it is more effective to focus efforts on improving viral suppression, improving PrEP (pre-exposure prophylaxis) uptake, or some combination of the two. The effectiveness of these interventions is relatively well understood; however, the optimal combination for achieving maximum impact on the system and achieving health equity remains an open question.

To explore these questions, we built an ABM simulating the full population of MSM in Chicago. Three data sources were combined to calibrate the model by creating a population of agents that reflects the demographics of the MSM population, and to simulate the sexual behavior of the population. This model was then used to infer the impact of various combinations of interventions. In particular, we explored inequity in the predicted effects on the African American and Latino MSM populations, and we analyzed the input parameter space to determine which combinations of EBIs were most effective in reducing HIV incidence in these populations.^{34,35} As the ABM is a mechanistic model, we were consequently able to identify the implementation drivers that should be leveraged to most effectively achieve this predicted impact in practice.

Paradigm 2: Including Populations with Health Inequities in New Implementation Research

The second methods paradigm involves designing new implementation research studies that include, but do not focus exclusively on, populations with a history of health disparities, such as multi-lingual, racial/ethnic minority, and low-income communities, ideally in a prospective manner and in a proportion that is representative of the degree of the health disparity. This includes both multicultural and minority communities.

To date, the majority of research includes a smaller number of racial/ethnic, gender, and sexual minorities experiencing historical health disparities despite higher rates of disease burden compared with advantaged populations. According to the latest NIH report, the proportion of racial and ethnic minorities enrolled in domestic clinical trial research studies is substantially less than that in the general population, especially for Hispanics (29% less than the population percentage) and Native Americans (77% less), but also for African Americans (10% less).³⁶ Implementation research is not immune to this problem. Consequent to these lower numbers of minorities in research, implementation inferences based on a smaller underrepresented population (eg, transwomen) or linguistic group would be less precise than those pertaining to the majority population. Single research studies that do little to recruit minorities or recruit blindly by not asking questions such as sexual orientation or linguistic background often contribute little to health equity.

Implementation research commonly results in heterogeneous populations within a study sample due to the testing of implementation strategies on higher-level units, such as health department jurisdictions and state and national policies. Unlike trials that target individual-level change and can recruit a defined population, the reality of testing implementation strategies is that they are likely to be administered to a more heterogeneous population. Thus, implementation researchers would ideally design studies with units that contain a large proportion of the target disadvantaged populations. Even if this is not the case, this paradigm provides a way of generating information that increases scientific equity. In the following examples, we illustrate implementation research that targets a high proportion of disadvantaged populations, though not exclusively.

The Collaborative Care Model

Designed for patients with depression in primary care clinics in the Northwestern Medicine system, researchers on our team (JDS, IBZ, CHB) are conducting a randomized rollout implementation trial. Socio-economically disadvantaged, racial/ethnic minority adults are at increased risk for psychiatric conditions, such as stress, depression, and anxiety, which are closely linked to chronic health conditions such as obesity, diabetes and cardiovascular disease; all of which are more prevalent among Black and Hispanic adults.³⁷ However, Black and Hispanic adults are 40%-60% less likely than Whites to receive mental health treatment^{38,39} and less likely to receive

adequate treatment^{38,39} or treatments that are consistent with their preferences.⁴⁰ Antidepressant medication is the cornerstone of the Collaborative Care Model, which is highly efficacious,⁴¹ but Black and Hispanic adults are less likely than Whites to find antidepressants acceptable, less likely to be adherent and more likely to hold negative beliefs about them.⁴⁰ Thus, there is a need to consider the role of alternative EBIs that might be more palatable than antidepressants for Blacks and Hispanics.⁴²⁻⁴⁴ Although the Northwestern Medicine system serves predominantly White patients, we focus on the experience of participants from disadvantaged backgrounds to inform a subsequent implementation trial of this model in practices serving majority Black and Hispanic patients by examining heterogeneity in effects, engagement, adherence, and program satisfaction.

Implementation Research in Co-Occurring Cardiovascular Disease and Mental Health

Health care in the United States has witnessed a significant push toward models of care in which interdisciplinary services are coordinated, comprehensive, and delivered in one setting.⁴⁵ Integrating mental and behavioral health care into safety-net primary care settings could facilitate greater access to care for those who are unable to access, or prefer not to use, specialty behavioral health care, while reducing the systemic and psychological barriers that contribute to treatment disparities among underserved individuals. One such study by members of our investigative team (JDS, CG) is an effectiveness-imple-

mentation hybrid trial testing a family-based behavioral intervention for the prevention of obesity in pediatric primary care. This trial, including a majority of Hispanic families, was designed to test two strategies for implementation in primary care: integrated/co-located care and referral to external service providers.⁴⁶ This trial aims to identify implementation strategy differences in engagement, effectiveness, acceptability, costs, and other salient outcomes that would impact the population benefit of the program for families experiencing disparities and perhaps even widen the disparity compared with White participants. In this example, designing a trial to test various strategies to implement integrated care models for behavioral health services in primary care holds promise for achieving health equity.

Technology to Adapt a Behavioral Intervention to Populations Experiencing Health Disparities

Interventions delivered via Internet, text messaging, and mobile phone apps (ie, eHealth, mHealth) have the potential for rapid and efficient scale up with widespread reach into diverse populations, in particular touching minority groups who might not seek treatment through traditional health care service systems. Guy2Guy (G2G) is a technology-delivered peer-based text messaging intervention that can be tailored to diverse groups based on shared linguistic features. It is used to engage and deliver HIV prevention content to adolescent MSM aged 14 to 18 years.⁴⁷ In a randomized trial, G2G was shown to improve HIV testing but not reduce condomless sex acts

in adolescent MSM—demonstrating the potential of the intervention.⁴⁷

Subsequent analysis of text messages in the peer-to-peer platform showed that the linguistic style of texters could predict engagement,⁴⁸ demonstrating the feasibility of monitoring engagement and optimizing peer matching based on language. Tailoring the intervention based on the linguistic profile of each participant may prove important to improving engagement and outcomes of technology-based EBIs for populations experiencing disparities. For instance, Hispanics are experiencing an increased HIV incidence,^{49,50} which requires researchers to deliver adequate interventions in a linguistically and culturally suitable manner.⁵¹ Rather than creating entire interventions for specific populations, this individual tailoring approach can be an alternative to address the heterogeneity of the target population.

Paradigm 3: Implementation Research Focused Exclusively on Populations Experiencing Inequities

The third methodologic paradigm involves conducting implementation research that brings EBIs to populations that have experienced high levels of disparities. There is no substitute for this type of study when the context of living in a community of low opportunity plays a major role in awareness, availability, or access to care. Stratification of opportunities is the norm in many US cities; 50% of African American children in Chicago are living in such neighborhoods compared with only 2% of those who are White.⁵² Similarly,

stratification of risk factors by neighborhood has been documented; in one study, 39% of the sexual partners of young Black MSM lived in neighborhoods of high HIV prevalence, whereas that was the case for only 5% of the partners of young White MSM.⁵³ By not accounting for such social determinants, an implementation strategy that functions well in a neighborhood with high opportunity may have no or even detrimental effect in one with low opportunity. In such cases as low-opportunity neighborhoods, a distinct implementation strategy that addresses these contextual barriers would need to be tested.

Delivering EBIs to populations experiencing high levels of health disparities remains challenging, particularly when populations most in need have been underrepresented in effectiveness trials, and furthermore may be less likely to access the traditional health care system. Some implementation science methods have developed to expand the reach of an EBI by scaling up to similar settings and populations as used in the original effectiveness studies. In contrast, methods for scaling out—that allow for adapting EBIs to new populations, new health care systems, or both—for highest public health impact need to consider specific factors of the target group in order to reach those populations.⁵⁴

PrEP: Scaling Out of a Biomedical Intervention

HIV pre-exposure prophylaxis, or PrEP, has been shown to be highly effective for preventing HIV.⁵⁵ We know that young Black MSM (YBMSM) have the highest rate of HIV diagnoses in the United States,

yet few participate in trials and they are among the least likely to use PrEP.^{56,57} This may be due, in part, to the guidelines for PrEP initiation and monitoring that can be prohibitive for key populations.⁵⁸⁻⁶¹ Scaling out of PrEP to YBMSM will require considering novel and adapted delivery methods. One strategy to address barriers involves expedited (same day start) PrEP, both within and outside of traditional health care settings. A “one size fits all” method for PrEP delivery should be reassessed since younger populations may need more frequent interactions to encourage adherence, while older populations may not.^{60,61} Implementation research methodologies can be applied to test these hypotheses and provide “differentiated” care based on individual client needs.

Scaling Out Known EBIs for CVD to People Living with HIV

Morbidity and mortality in persons living and aging with HIV is now primarily due to non-HIV/AIDS related causes, including cardiovascular diseases (CVD) such as cardiomyopathy and coronary artery disease.^{62,63} Persons living with HIV (PLWH) in the United States, who are disproportionately represented by racial and sexual/gender minorities, have higher incidence of hyperlipidemia, hypertension, and metabolic abnormalities than the general population.⁶⁴⁻⁶⁶ Accordingly, care for PLWH has shifted to detection, prevention, and treatment of these comorbidities.⁶⁷ While existing guidelines and EBIs apply to the prevention of CVD in the general population, it is not as well known if

these guidelines and other interventions are appropriate for PLWH.⁶⁷ As an implementation research methodology, scaling out of known EBIs for the prevention and treatment of CVD will involve adapting them to PLWH.⁶⁸ For instance, interventions that increase adherence to antiretroviral medications, thereby decreasing inflammation caused by HIV, may be more effective in reducing CVD among PLWH, perhaps in combination with interventions that aid in smoking cessation and treatment of hyperlipidemia and hypertension. Implementation trial designs, including sequential multiple assignment randomized trial (SMART) designs and adaptive approaches, afford the flexibility to compare combinations of interventions and implementation strategies to determine differential effects and optimal delivery across populations.⁶⁹⁻⁷² Interventions that have been shown to reduce cardiovascular disparities in Blacks may be especially salient to adapt and scale out for populations living with HIV in order to achieve health equity.⁷³

DISCUSSION

Health disparities continue to exist in the United States and around the world. Despite the availability of EBIs for many of the conditions with the greatest disparities, there remain significant gaps in implementation that thwart achieving health equity. The three paradigms we have described offer insight into implementation research methods to address the persistence of health inequities and should be used in concert

for maximum effect. Focusing exclusively on a disadvantaged population (Paradigm 3) can be informed by the results of studies that included a proportion of that population (Paradigm 2) that found differential effects of the EBI as a result of its implementation. In addition, studies that would fall within Paradigm 3 can be informed by existing data (Paradigm 1), with modeling incorporated into the study design phase. With the advancement of these methodologies, there are new opportunities to address health inequities through de-

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livery of EBIs to populations most in need. There has been renewed focus on addressing health inequities within the medical community, which provides opportunities for researchers who seek to make an impact in this area. In addition, implementation research is garnering more widespread attention as crucial to the success of EBIs and now has support through dedicated funding sources.

Despite these opportunities, challenges remain overall and within each of the paradigms described

here. While the use of existing data may appear to be low hanging fruit, the data necessary for such models are not always readily available and relying on data that are primarily from populations that do not experience disparities is perilous. This is particularly true for different implementation strategies, as much of the effectiveness and implementation research being done either lacks specificity in reporting of the strategies being used or has not yet reached that area of inquiry (eg, for newer interventions). The lack of an intervention effect can be due entirely or in part to the implementation. If there is poor reach into the population, low engagement, or poor fidelity, the overall impact will inherently be low as well.⁷⁴ In addition, we must consider the typical 17 years it takes for EBIs to go from initial development and testing to the intended communities who might benefit, and the time required to successfully sustain them once implemented.⁷⁵ This lag contributes to generations of people impacted by health inequities receiving little direct benefit from research. This, in turn, affects trust when trying to build community partnerships. Implementation researchers must be committed to understanding and addressing the needs of communities in these contexts. When effective interventions for disadvantaged communities are identified, there needs to be an explicit endeavor to more rapidly disseminate and implement. Scaling out should be the guiding methodology to achieve more rapid implementation that can ultimately reduce health disparities.

CONCLUSIONS

Implementation is inherently messy, in that many variables play a role in the final outcome, making it challenging to discern the root cause of an outcome if the proper measures are not considered from the beginning. Thus, implementation must be recognized as a key component from inception of every research initiative. Given the multiple variables of implementation that contribute to an overall effect, it is critical to go beyond simple effect size comparison and delve deeply into the implementation processes that contribute to health disparities and inequities. While appreciation of implementation research has grown, the field needs to gain more momentum to address scientific and health inequity. This requires that the field of implementation science acknowledges the need for equity, so that trainees and established researchers are continually encouraged to address disparities that will deepen if new technologies are implemented disproportionately and only offered to communities and organizations with the most resources.

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CONFLICT OF INTEREST

No conflicts of interest to report.

AUTHOR CONTRIBUTIONS

Research concept and design: McNulty, Smith, Villamar, Burnett-Zeigler, Vermeer, Benbow, Gallo, Wilensky, Hjorth, Mustanski, Brown; Data analysis and interpretation: Gallo, Wilensky, Hjorth, Schneider, Brown; Manuscript draft: McNulty, Smith, Villamar, Burnett-Zeigler, Vermeer, Benbow, Gallo, Wilensky, Mustanski, Schneider, Brown; Statistical expertise: Smith, Vermeer, Wilensky, Hjorth, Schneider, Brown; Acquisition of funding: Smith, Burnett-Zeigler, Mustanski, Brown; Administrative: McNulty, Villamar, Gallo, Mustanski, Brown; Supervision: McNulty, Benbow, Gallo, Schneider

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