

# Implementation Science Perspectives and Opportunities for HIV/AIDS Research: Integrating Science, Practice, and Policy

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**Background:** Disparities in the incidence and mortality of HIV/AIDS persist, challenging researchers, practitioners, and communities to develop improved strategies to reach vulnerable and marginalized populations.

**Methods:** The emerging field of Implementation Science, with its focus on context, external validity, and innovative design approaches, is well suited to respond to this challenge. We provide an overview of Implementation Science, including its frameworks, tools, and strategies, and how they can inform the response to HIV/AIDS.

**Results:** We summarize pioneering Implementation Science frameworks, and then present examples using newer models, including RE-AIM (Reach, Effectiveness/Efficacy, Adoption, Implementation, Maintenance) and the Evidence Integration Triangle, a framework for combining research and practice using participatory and adaptive processes in a multilevel context.

**Conclusions:** Although still developing, the international field of Implementation Science can offer helpful perspectives for facilitating the more rapid integration of HIV/AIDS research, practice, and policy.

**Key Words:** implementation Science, external validity, framework, dissemination, HIV/AIDS, evaluation

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## INTRODUCTION

Although the HIV/AIDS epidemic seems to be stabilizing,<sup>1</sup> policy experts note that the HIV virus is being transmitted faster than efforts to control it.<sup>2</sup> Therefore, achieving an “AIDS transition”<sup>2</sup> will require a simultaneous focus on both treatment and prevention on a large scale. Furthermore, examination of HIV/AIDS in specific communities and populations does not necessarily reflect the same trend of stabi-

lization. Disparities linked to gender and geography,<sup>1</sup> as well as to race, ethnicity, and sexual orientation persist.<sup>3</sup> Controlling the epidemic will not only require bringing successful interventions to scale but also tailoring them to vulnerable and marginalized populations and understanding the social, cultural, and institutional contexts in which interventions are delivered. Treatment strategies in vulnerable populations have reported success in controlled research, but it is unclear whether the interventions are feasible and sustainable outside the research environment, where financial resources have contracted.<sup>4</sup> In these cases, adequate knowledge has been developed; the challenge is in translating it to practice. As Woolf<sup>5</sup> argues, the health impacts of this translation might be larger and more far-reaching than any additional laboratory discovery.

We term this application and integration of research evidence to in practice and policy Implementation Science. In this article, we provide an overview of the emerging field of Implementation Science. We present Implementation Science frameworks and strategies that can inform the response to the HIV/AIDS epidemic. Finally, we advance the Evidence Integration Triangle as a coherent framework and Implementation Science tool for integrating research, policy, and practice to prevent and control HIV/AIDS.

## FRAMEWORKS AND TOOLS FOR AN EMERGING FIELD

Developments among many of the world’s biomedical and public health institutions have pointed to the importance of practical application and integration of research findings.<sup>6–9</sup> Although Implementation Science is a relatively new and evolving field,<sup>10</sup> important lessons have been learned and helpful frameworks have been developed to conceptualize its essential characteristics and strategies. A brief summary is presented in Table 1, as space precludes lengthy discussion of all frameworks and models.

## EARLY IMPLEMENTATION SCIENCE MODELS

Early influential models that provided much of the impetus for the current field include PRECEDE–PROCEED<sup>11</sup> and Diffusion of Innovations.<sup>12</sup> Diffusion of Innovations is particularly useful to the process of disseminating interventions because it emphasizes characteristics of an intervention (an “innovation”) that can enhance or discourage its uptake. These characteristics include comparative advantage and

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**TABLE 1.** Implementation Science Frameworks, Characteristics, and Methods

Frameworks/Theories	References
Diffusion of Innovations	Rogers <sup>12</sup>
RE-AIM	Glasgow et al <sup>18</sup>
PRECEDE-PROCEED	Green and Kreuter <sup>11</sup>
T1-T4 Translation	Khoury et al <sup>14</sup>
Evidence Integration Triangle	Glasgow et al <sup>10</sup>
Characteristics	Highlights
Contextual and Interactive	Customizing approaches to fit the specific public health issue and local context
Multilevel	Understanding the complexity of the issue while tackling every level of the problem
Evolving, adaptive, flexible	Using malleable designs that allow for changes and modifications to achieve best and most rapid results
Sustainable	Establishing evidence-based foundations ensuring that the intervention is sustainable over time
Transdisciplinary	Using an integrated spectrum of expertise to address the multiple facets of a public health problem
Methods	Example
Flexible and adaptive designs	Spielberg et al <sup>38</sup> ; Use of iterative quality improvement evaluation in a counseling and testing program to address health disparities
Stakeholder involvement and participation/community-based participatory research	Decroo et al <sup>39</sup> ; Involvement of self-forming groups of patients
Enhanced focus on external validity	Collins et al <sup>13</sup> ; Diffusion of Evidence Based Interventions (DEBIs), development and evaluation of interventions with a range of applications in mind; analyses of robustness across subgroups, settings, and conditions

cost (what advantage does the innovation have over old ways of doing things? what are the risks and benefits that will be incurred?), trialability (can the innovation be tested first with low risk?), simplicity (how difficult will it be to implement this innovation?), observability (how readily can we “see” the results of the innovation?), and compatibility or congruency (can the innovation “fit” in a given organization, system, or culture?). Diffusion of Innovations has been widely applied and has influenced almost all later applications. It has also served as the theoretical underpinning of Diffusion of Evidence Based Interventions (DEBI), the pioneering dissemination initiative of the US Centers for Disease Control and Prevention.<sup>13</sup>

### T1-T4 MODEL

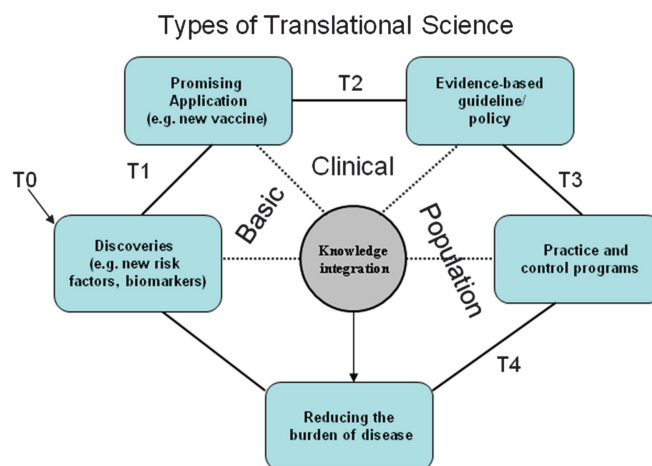
Khoury et al<sup>14</sup> have developed a classification framework of translational research for the field of genomic medicine,

which is also relevant to HIV/AIDS and other health fields. The framework categorizes 4 types of translational research, T1 through T4, which describe the development of knowledge from basic discovery to the development of applications and interventions (T1), to evidence-based guidelines (T2), to practice (T3), and ultimately to improved population health (T4). A modified schematic of this framework was developed by Schully et al,<sup>15</sup> and we present an HIV/AIDS adaptation in Figure 1.

Although acknowledging that the categories of translational research are neither completely discrete nor linear, Khoury et al estimate that most published research (approximately 97%) in genomic medicine could be categorized as T1. An analysis of the distribution of HIV/AIDS research along this continuum is beyond the scope of this article. However, achieving an AIDS transition will likely only occur with increased investment in the latter types of translational research (T2, T3, and T4). These latter types provide the opportunity to investigate how interventions will play out on a larger scale, in specific contexts, and for specific populations. Furthermore, T3 and T4 translation allows for an examination of multiple levels of intervention, going beyond individual behavioral interventions to examine the influence of policy, history, health systems, organizations, as well as economic and cultural factors. These types of translational research will become increasingly important, as a recent systematic review documented the limited and unsustainable efficacy of individual-level behavioral HIV prevention interventions for women in low and middle income countries.<sup>16</sup>

### RE-AIM FRAMEWORK

A third tool available from the growing field of Implementation Science is the RE-AIM (Reach, Effectiveness/Efficacy, Adoption, Implementation, Maintenance) Framework.<sup>17,18</sup> RE-AIM identifies critical elements, beyond intervention efficacy, that support public health programming with the capacity to make substantial health impacts. An application of the framework to the dissemination of a hypothetical HIV



**FIGURE 1.** Types of Translational Science. Modified from Khoury et al *Genetics in Medicine* 2007.

vaccine is presented in Table 2, which illustrates the sequential steps required to take an evidence-based intervention to scale. It shows the corresponding “voltage drop” in percent of the target population impacted as one moves from 1 step to another in the dissemination cascade. We use the “the law of halves” to demonstrate that a hypothetical vaccine with 50% efficacy (a major achievement) could still experience diminishing impact, even when using very optimistic estimates of the penetration of the innovation, where 50% of the target population is engaged at each stage. The essential point is that all steps in Table 2 and their corresponding RE-AIM concepts are important for successful translation of research to practice. Yet, traditional efficacy research tends to focus almost exclusively on the “E” or effectiveness dimension. A much broader focus is needed and, as with the T1-T4 model, more attention should be directed to other RE-AIM dimensions (especially Reach, related to health disparities and Adoption, related to organizational and contextual factors).

Noar<sup>19</sup> has recently applied the RE-AIM model to the review of computer-assisted technologies for HIV prevention. He concluded that the framework was useful in evaluating the literature and identifying needs for future research, and that the interventions to date seem effective. However, additional research is needed, congruent with the hypothetical scenario in Table 2, especially, to determine the reach, adoption, and long-term maintenance of computer-assisted interventions for HIV.

## RESEARCH DESIGN CONSIDERATIONS

As the frameworks above have illustrated, Implementation Science emphasizes the need to consider multiple levels of intervention and the importance of addressing factors beyond clinical efficacy. In essence, context is at the heart of Implementation Science. In the case of HIV/AIDS, context can both drive the epidemic and shape the response to it. For the past several years, the United Nations Joint Programme on AIDS<sup>20</sup> has encouraged countries to “know your epidemic; know your response,” and to tailor control strategies to the local drivers of the epidemic. Interventions may also be hampered or supported by the local social context. As just 1 example, intervention strategies in Cuba and Jamaica are very different, impacted by the level of homophobia and AIDS-related stigma in each country.<sup>21,22</sup> Such differences in the social perceptions of the disease require a customized intervention strategy that addresses the unique social characteristics of each region or country.

**TABLE 2.** RE-AIM Application Model: Impact of Hypothetical New HIV Vaccine

Dissemination Step	Concept	% Impacted
50% of clinics use	Adoption	50
50% of clinicians prescribe	Adoption	25
50% of patients accept medication	Reach	12.5
50% follow regimen correctly	Implementation	6.2
50% of those taking correctly benefit	Effectiveness	3.2
50% continue to benefit after 6 mo	Maintenance	1.6

## EXTERNAL VALIDITY

Understanding of context will facilitate the dissemination of evidence-based programs and policies because it addresses external validity. In Implementation Science, external validity is relevant in 2 ways, which are highly related but play out differently depending on one’s role. A policy maker is concerned with the generalizability of a program or the range of conditions, including staff, settings, and patients across which a given intervention is effective. An individual practitioner’s concern is “local,” namely “will X intervention work in settings such as mine for the types of patients I have and the settings and resources with which I have to work?”<sup>23</sup> These questions, concerned with “what,” “where,” and “how” are different from those of traditional scientific inquiry focused on mean effects across samples because the principle questions are different, it follows that methods should also be different.

## FLEXIBLE AND ADAPTIVE DESIGNS

Although traditional biomedical and public health research regard the randomized controlled trial as the “gold standard,” Implementation Science includes other types of research design because the focus is on external validity and practical issues in addition to efficacy. These designs include natural experiments, pragmatic trials, interrupted time series designs, economic analyses, and cost-effectiveness research, systems dynamics and simulation modeling, and continuous quality improvement strategies. For example, an innovative approach that has recently gained traction in oncological drug development is a Bayesian<sup>24</sup> or adaptive<sup>25</sup> trial design. Such trials feature a flexible modifiable design that can be changed as new information is learned, influencing arm assignment and the therapeutics offered to trial participants. The drug development process is streamlined as investigators simultaneously attempt to discover cancer biomarkers and develop effective drugs, identifying promising therapeutics early in the clinical trials process. These types of designs have recently been endorsed for the development of an HIV vaccine.<sup>26</sup>

Adaptive trial designs could also be useful for the implementation of behavioral interventions. For example, observers<sup>27</sup> of the DEBI initiative note that the rollout of evidence-based interventions has sometimes appeared top-down and insufficiently concerned with the organizational and community context of implementation. As a solution, those observers propose “comprehensive dynamic trials,” which combine process and outcome evaluation, resulting in an iterative feedback loop between researchers and communities. The designs described above provide more flexibility and are more contextually sensitive and responsive to initial results than the traditional expensive, time consuming, and static RCT.<sup>28</sup>

## PARTICIPATORY APPROACHES

The iterative research processes that result in feedback loops between communities and researchers underscore the importance of community participation in all phases of research and implementation. If an intervention was not



designed for a particular population, implementers must undergo a challenging adaptation process,<sup>29</sup> and attempt to manage the tension between maintaining fidelity to the intervention and making the intervention suitable to a given setting. At the same time, the privilege bestowed on the randomized controlled trial can exclude local knowledge or “practice wisdom” originating in local communities and organizations from the domain of legitimate practice.<sup>27</sup> Coates et al<sup>30</sup> observe that it is precisely local “ground-up” approaches that often use the needed multilevel perspective or that support calls to “know your epidemic” through community assessments and local epidemiological surveillance. With recent announcements that DEBI will be disseminated globally,<sup>31</sup> such issues will become even more important. A wealth of local knowledge and expertise has been developed in Africa in response to the HIV/AIDS epidemic, and this reality will lead to a change in the directionality of knowledge transfer about effective practice to control HIV/AIDS.<sup>32</sup> Researchers, communities, and practitioners will have to establish different ways of collaborating, including the use of transdisciplinary and participatory approaches. Although the principles of these collaborative approaches have been articulated,<sup>33–35</sup> their application has been less well articulated in actual practice. For example, “participation” can mean anything from simply being intervened on, to tokenism, to empowerment.<sup>36</sup> Determining the “best partnership processes”<sup>10</sup> of community engagement will be fundamental to successfully integrating research, practice, and policy.

### EVIDENCE INTEGRATION TRIANGLE

Elsewhere,<sup>37</sup> we have suggested that an Evidence Intervention Triangle (EIT) (Figure 2A) can help guide public health efforts. The EIT could be particularly useful in HIV/AIDS control and prevention, as it draws attention to 3 interacting components of effective translation: (1) practical evidence-based interventions, (2) practical measures of progress, and (3) participatory implementation processes. As shown, the EIT also acknowledges the presence of a multilevel context. It includes individual actors, organizations, and the broader social milieu and places stakeholders in the center of this ongoing interaction. Taken together, these components can lead to the successful implementation of an evidence-based intervention.

The DEBI initiative of CDC offers an example of the type of interventions that fit at the apex of the Evidence Integration Triangle (Intervention Program/Policy). These interventions have undergone extensive and rigorous evaluations of their efficacy and suitability for dissemination.<sup>13</sup> Later, guidance was issued and a framework developed to help community organizations choose, adapt, and implement the appropriate intervention and to tease out the components that could or could not be modified.<sup>29</sup> That is, the interventions are clearly evidence-based, but there is also consideration of the local context and needs of implementing organizations. In addition, Coates et al<sup>30</sup> advocate for combination interventions that address multiple behavioral risk factors with multilevel intervention strategies. Figure 2B presents an example of comprehensive, multilevel, intervention approaches.

A second component of the EIT is the use of Practical Progress Measures. The measures provide regular feedback, allowing implementers to monitor the progress and effectiveness of implementation. These types of measures, which strike a balance between validity and feasibility, can quickly indicate where tweaks should be made, or where components can be modified. A recent application<sup>38</sup> of these types of measures and evaluation can be observed in a mobile HIV counseling and testing program. This program used quality improvement evaluation to make modifications to the program design, which resulted in reaching more people of color than clinic-based testing and counseling.

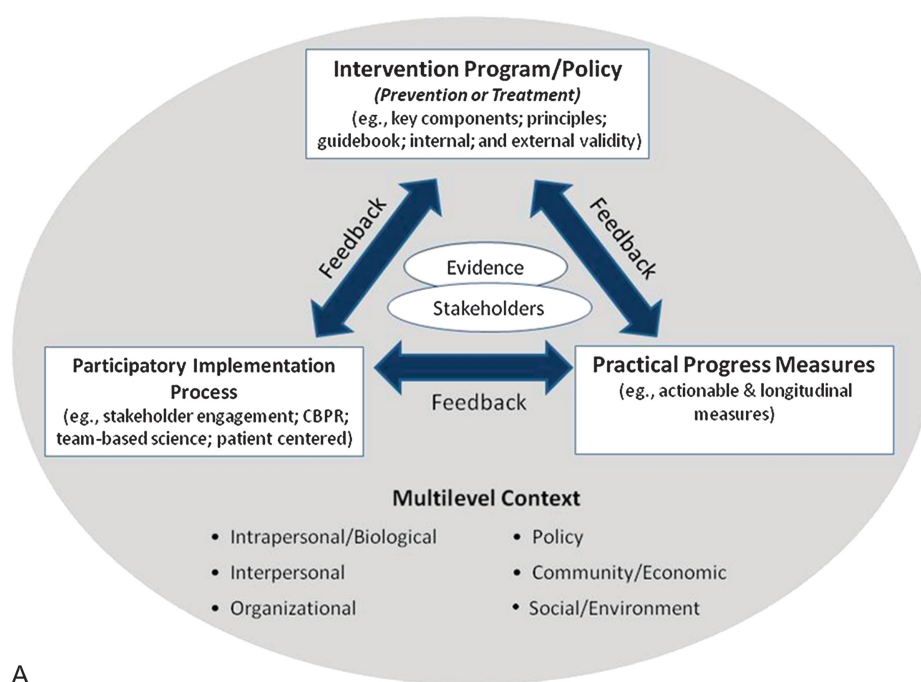
The third component of the EIT is the use of participatory implementation processes, as discussed above. An example of a practice-based innovation was recently reported in this journal.<sup>39</sup> It described the development of a community group ART adherence strategy for patients in Mozambique, who were struggling to regularly obtain their medicines. This strategy was not only implemented by community members but they were also responsible in part for the genesis of the idea. Furthermore, patients were responsible for much of the monitoring and evaluation.

The above examples of the application of EIT components are not meant to be exhaustive or systematic. Rather, we have highlighted the types of knowledge, innovations, and solutions that can be developed when context and external validity become a central focus.

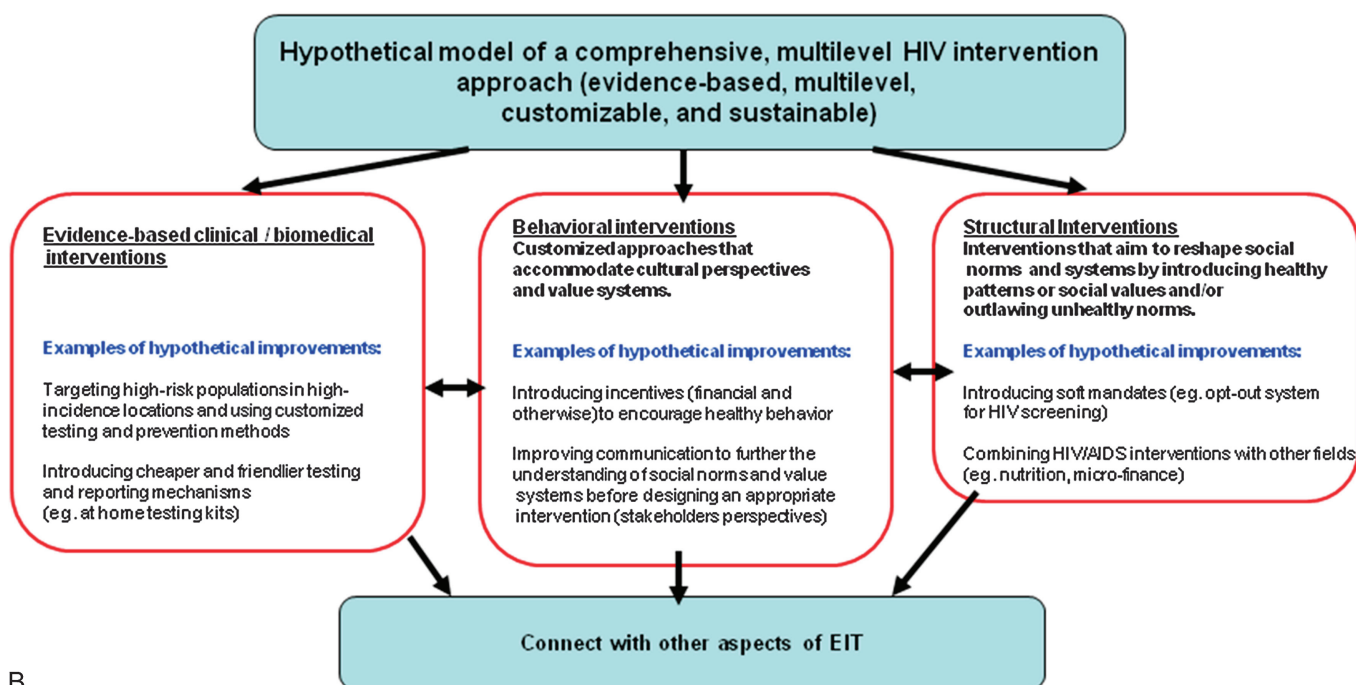
We note 5 specific implications of the EIT for HIV applications. (1) The process should begin and end with engagement of local stakeholders, as well as consideration and analysis of the multilevel context as shown in Figure 2A. (2) It is unusual for an implementation effort to be immediately completely successful. Rather, success is more often the result of iterative cycles, based on feedback from the practical tracking measures, and successive iterations and adaptations. (3) Each of the 3 elements of the EIT are necessary but not sufficient. Most funding agencies have devoted the vast majority of their resources to the identification of effective programs and much less to practical measures of progress or to participatory implementation processes. (4) The EIT presents an iterative, dynamic, and continuous process. Therefore, dissemination and its sustainability should be critical considerations from the outset. Planning for dissemination means that the concerns of potential adoptees (who, what, when, where, and how much will it cost) should be primary considerations, rather than an afterthought. (5) The iterative nature of the EIT means that implementing organizations could benefit from several waves of technical assistance and guidelines.

### CONCLUSIONS

A summary of the key characteristics, methods, and frameworks of Implementation Science is presented in Table 1. We have discussed some of the key models and frameworks of Implementation Science, including Diffusion of Innovations, T1-T4, RE-AIM, and the EIT. Some of these models have already been applied to the dissemination of HIV/AIDS interventions, whereas others are from other



A



B

**FIGURE 2.** A, Evidence Integration Triangle. B, Illustrative model of evidence-based multilevel interventions.

health fields. Utilization of these models can guide the challenges of disseminating effective and contextually appropriate treatment and prevention interventions. We have also explained that Implementation Science will require a different approach to evaluation and evidence. The randomized controlled trial is an important method to determine the clinical efficacy of interventions. However, the field cannot rely

solely on it to solve complex problems like HIV/AIDS, which is driven by a myriad of contextual factors at a variety of different levels. Innovative research designs will be necessary to adequately respond to these complexities. In particular, adaptive trials and participatory implementation processes show promise for creating solutions that address the local context of an HIV/AIDS epidemic.

We have advanced the EIT, a framework to guide policy and practice that brings together stakeholders and scientific evidence. The EIT necessitates a flexible process that inherently considers the rich context and multilevel nature of a health problem and appropriate responses. It is the synergy of these components that will lead the development of effective, relevant, and implementable interventions to control and treat HIV/AIDS.

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