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Importance of Rigorous Implementation Science Studies to Scale-up Evidence Based Interventions to End the HIV Epidemic in the United States

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'Ending the HIV Epidemic' is a bold plan that aims to curb the spread of HIV in the United States (US) by 2030 by focusing on advancing the science of HIV prevention, diagnosis, treatment and outbreak response in 57 HIV high burden areas ^[1, 2]. The integration of evidence based interventions and science into routine practice in these communities will require focused efforts. Implementation science is used to facilitate the spread of evidence based interventions ^[3] and can be defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services."^[4] Implementation science is key to understanding not only which interventions to deploy but how to deploy them.

Shangani and colleagues conducted the first systematic review of the early adoption of implementation science for HIV prevention and treatment studies in the US ^[5]. Despite over a decade of investment in implementation science research by the US National Institute of Health (NIH),^[4] the authors only identified 39 studies—none of which used formal theoretical frameworks. Frameworks are necessary to document and explain how and why implementation of interventions succeeds or fails; this documentation enhances the generalizability and replicability of research and is essential to maximizing the collaborative impact of investments in HIV research.^[6]

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Most of the studies included in the review were limited to assessing feasibility or acceptability of HIV prevention and treatment interventions. Appropriateness and fidelity were not reported in any study and reports of penetration, adoption and sustainability were very limited. Failure to report on these elements as well as the limited description of interventions, also noted by the authors, prevents implementation science from achieving its aim of promoting evidence-based practices into routine use. The authors also note that most studies came from urban settings in the Northeast or California, which limits the generalizability of findings to other hot spots in the South or Midwest of the US. Further, most of the studies identified focused on sexual minority populations including gay, bisexual, transgender or men who have sex with men—with few focusing on women.

HIV prevention interventions were more commonly described than those describing treatment interventions. The authors found that the majority of implementation science studies focused on prevention (27) and not treatment (10). Additional focus on the application of implementation science on treatment outcomes—especially viral suppression, is essential to meet the UNAIDS "third 95" goal of having 95% of those on ART to have viral loads suppressed below levels of detection by 2030. ^[6]

We agree with the authors' conclusions that implementation science is key to scaling up evidence based HIV prevention and treatment interventions. An additional notable finding is the lack of any "Type 3" hybrid research studies in the review. The authors found no studies that evaluated the impact of interventions in real-world settings and the implementation strategy. This type of design is typically used with well-established interventions and ensures translation of findings into practice. When used appropriately, implementation science is a new field—a bridge from the world of rigorously controlled RCTs to widespread implementation guided by program monitoring. The full range of implementation science tools should be used or the field risks falling back into old patterns of repeatedly replicating costly and time consuming trials and failing to learn how to apply knowledge from one setting to another. The use of theoretical frameworks and implementation outcomes are key to achieving the ambitious goals set out in the ending the HIV epidemic plan. Rigorous study designs and implementation science frameworks will broaden the reach and generalizability of implementation research^[6].

Further, to scale interventions, implementation studies are necessary. Clinical trials or studies that demonstrate impact in improving HIV diagnosis, prevention uptake, linkage to treatment and viral suppression in a population should be evaluated in the context of implementation science to determine how best it can be brought to scale. HIV implementation studies must do better to provide detailed and clear descriptions of interventions to ensure others can replicate the work and achieve similar results.

As Shangani et al state, the NIH has dedicated over \$11.3 million to 23 institutions across the US to work with community partners to develop "locally relevant plans for diagnosing, treating, and preventing HIV in areas with high rates of new HIV cases". However, without implementation science frameworks and rigorous study designs, what is found in one local area or small study, may not be replicable in others. Similarly, without reporting on interventions that fail, we risk wasting some of the investment in HIV prevention and

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treatment. Strong implementation science studies are essential to achieving the ambitious Ending the HIV Epidemic plan in the US, with potential reach to other parts of the world with heavier HIV burden. The NIH and other funders must hold their grantees accountable for producing the most rigorous, framework-based implementation research.

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