The Importance of Context in Implementation Research

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Abstract: This article describes the pertinence of context in HIV/AIDS implementation research. Without attending to context and how it interacts with interventions, national protocols for HIV/AIDS interventions are likely to fail or underperform. With its focus on what works, for whom, under what contextual circumstances, and whether interventions are scalable, implementation research yields context-sensitive designs and enhances the likelihood of scale-up for equitable outcomes. A framework for implementation science is presented alongside a review of published HIV/AIDS protocols for complex interventions. A case study of the South African Prevention of Mother-to-Child Transmission of HIV program highlights the application of complex system improvement principles in developing adaptive and context-sensitive scale-up designs. Preliminary recommendations are provided that can be used to characterize context when reporting interventions and describing how context can be accounted for in implementation strategies.

Key Words: implementation science, context-sensitive research, HIV/AIDS

INTRODUCTION

Although due attention is given to rigorous cause-and-effect fixed-protocol designs for efficacy and effectiveness research, the usefulness of these studies to health system planners and implementers is limited in the more complex settings and systems that are encountered outside of controlled study environments. Like much of the efficacy and effectiveness literature, many studies of HIV interventions have incomplete descriptions of the contextual environment in which the studies are conducted, in part due to the lack of a common typology to elucidate its features. Consequently, context is rarely and inconsistently mentioned in systematic reviews, creating difficulties for decision makers and program planners who play a key role in contextualizing interventions. The purpose of this article is to describe the pertinence of context in implementation research, propose some preliminary recommendations that can be used to characterize context when reporting interventions, and describe how context can be accounted for in implementation strategies.

RATIONALE AND KEY CONSIDERATIONS

Implementation science examines what works, for whom, under what contextual circumstances, and whether interventions are scalable in equitable ways. The intervention includes the “what”—typically, a biomedical activity (eg, a drug given in a specific format to a defined population) or behavioral activity (eg, counseling using a theory-informed approach)—as well as the “how”—the implementation activities that are required to achieve full (equitable) coverage of the biomedical or behavioral intervention. The schemata in Figure 1 show the progression of knowledge from efficacy to full-scale implementation on 3 dimensions: determinants and their pathways, framing the research question, and design of the intervention. As described below, each of these dimensions is represented by a continuum.

The first axis of implementation has proximal and sociostructural determinants as its end points. Proximal determinants are individual characteristics such as socioeconomic status, household income, or education level. Sociostructural determinants reflect embedded social conditions such as class, stigma, or discrimination, and power relationships. Even when officially repealed or abolished (eg, Apartheid in South Africa and residential schools for aboriginal children in Canada), these determinants may continue to drive inequities.

The second axis concerns the framing of research questions, with causal questions at 1 end of the continuum (eg, Does a particular intervention produce a specific outcome in heterogeneous implementation contexts?), and adaptation questions at the other (eg, What adaptations and improvements to the intervention are required so that the intended outcomes are achieved in heterogeneous implementation contexts?). These adaptation processes may produce new emergent properties of the intervention, as well as the system and related subsystems into which they are introduced.

The third axis focuses on the intervention, contrasting contextualized versus standardized interventions. Efficacy studies are typically conducted with fixed protocols applied in controlled environments; fidelity to the protocol is key. Adherence to the underlying theory (eg, behavior change theory) underpinning the intervention is considered essential, but that adherence is challenged the moment the intervention strays into environments that are different from those of the original studies. Various approaches (eg, protocols, manuals) are used by researchers and implementers to try to ensure interventions are delivered as planned. Effectiveness studies often examine the causes of deviation from fidelity to
the protocol (eg, provider/patient adherence). In contrast, adaptive interventions adjust, purposefully or otherwise, through contextual interactions with interventions and systems feedback processes to replicate the desired outcomes of the intervention in a more heterogeneous set of external influences. Contextualized interventions are guided by a theory of change, with an emphasis on understanding how the intervention and context interact as interventions are implemented and scaled up, aiming to achieve high degrees of effectiveness in heterogeneous complex environments.

These 3 axes highlight the pertinence of context to implementation science and the different ways in which context is understood, examined, and addressed across efficacy, effectiveness, and adaptive implementation studies. With respect to efficacy and effectiveness studies, context is considered a nuisance factor, a cointervention or confounder that must be controlled or adjusted. In contrast, implementation science questions can only be answered when the intervention is tested in a heterogeneous mix of contextual settings, since the adaptability of the intervention to different settings will test the limits of its scalability. Both proximal and more distal elements of context are considered relevant. Furthermore, what is relevant is determined by what contextual elements (both static and dynamic) interact with the intervention, shaping and modifying it, rather than how context is defined a priori by the research team.

Although efficacy studies aim to reduce the signal-to-noise ratio by controlling for context, implementation science seeks to understand and examine context, how it shapes and interacts with interventions, and how interventions are modified/adapted by patients, providers, organizations, and communities in response to shifting contextual circumstances.

It follows that key features of implementation science are the purposeful selection of heterogeneous contexts (systems, organizations, and populations), understanding the interaction between interventions and context through an adaptation lens, and the transposition of findings to other contexts and systems.

**SCALABILITY AND REPLICABILITY OF INTERVENTIONS**

Although this review focuses on the importance of context in the scalability of an intervention, we must differentiate between scalability and replicability. Scalability concerns the equitable reach of the intervention. The rate, pace, and reach of scalability is determined by many political, infrastructural, and personnel factors as well as the characteristics of the populations themselves.

The field of HIV implementation is notable for the profusion of effectiveness studies. Many are not scalable, however, either because they require a level of resources and infrastructural elements that do not currently exist in the broader health system, or they lack the methods and capability to adapt the intervention into complex environments that may be very different from the original study environments.

It is problematic to simply replicate most efficacy and effectiveness studies. Replicability implies disseminating the intervention without further adaptation and is unlikely to succeed unless the new environment is very similar to the test environment. Thus, rapid spread can only occur once testing and adaptation of the delivery process has occurred in multiple contexts likely to be encountered in a complex scale-up environment. Only when adapted to work across multiple contexts can an intervention be replicated with little further adaptation. This approach was used during the latter stages of the scale-up of the South African Prevention of Mother-to-Child Transmission (PMTCT) program. At the same time, key attributes of the intervention itself (eg, relative

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**FIGURE 1.** Progression of knowledge from efficacy to full-scale implementation.
advantage, compatibility, simplicity) can increase the likelihood of dissemination.

Similarly, strategies for preparing an environment for change and advice on promoting rapid spread of a new intervention (eg, leadership roles for change, packaging the new ideas, communication strategies, strengthening the social system of the adopter community, measurement and feedback, and knowledge management) have been well described. However, much less attention has been given to describing context and the accommodation of context in implementation research designs.

**ASSESSMENT OF CONTEXT IN HIV/AIDS STUDY PROTOCOLS**

A number of authors have identified limitations in how context is reported within studies, leading to subsequent difficulties in operationalizing the interventions. To survey how much attention is directed toward context as a factor in evaluation of HIV implementation studies in complex environments, we reviewed articles describing study protocols related to HIV/AIDS, identified through a search of the BioMed Central database of study protocols. We identified any articles with the key words “HIV” or “AIDS.” Nineteen articles were found. These were then screened using the following inclusion criteria: (1) protocol is for an intervention (17 articles), (2) study was to be undertaken in at least 1 low- or middle-income country (15 articles), and (3) the intervention described was deemed complex, defined as multistrategy and/or multilevel, resulting in 6 articles that were used for the final review.

We (N.E. and C.A.) read each article in its entirety and extracted any text that described context (Table 1). The pertinent text was then grouped into 2 categories: contextual elements and the ways in which these contextual elements had been used or would be used in relation to the study protocol. The first author also reviewed the articles for any explicit reference of a guiding framework used to identify contextual parameters for study. With the exception of gender analysis and domains of care provision, none of the protocols referred to a framework that had been explicitly used or would be used to guide the identification of contextual characteristics. The types of contextual characteristics described varied considerably and tended to focus on the study settings (ie, communities or facilities where study would be undertaken rather than the health system as a whole). Thus, descriptions of health system features such as financing, governance, leadership, human resource capacity, health information systems, and universal access to health services were largely absent.

**A CASE STUDY OF THE SOUTH AFRICAN PMTCT PROGRAM**

The South African health system has started more patients on antiretroviral treatment than any other nation and has successfully scaled up its PMTCT. The South African PMTCT program is a leading model where a complex intervention was implemented at full national scale across a large number of different geographic and sociocultural contexts. By 2012, the nationally reported transmission rate for Mother-to-Child Transmission (MTCT) was less than 3%, close to the reported transmission rates under clinical trial conditions. But the South African rollout of the PMTCT program underwent significant evolution, from a typical largely ineffective, context-insensitive, cascaded-training approach to a sophisticated health systems intervention that used modern adaptive designs.

Major social and political drama preceded the launch of the South African PMTCT program in 2002. The program was initiated when the epidemic had been underway for at least 10 years, by a reluctant administration that had been forced to do so by public action and court order. The reasons for the delay, which occurred in the early postapartheid era, were complex, and undoubtedly the government’s antipathy toward PMTCT reflected the slow start and initial poor performance of the program. Although efficacy studies showed single-dose nevirapine decreased MTCT of HIV by more than half, more than 2 years after full deployment of the PMTCT program (training of nursing staff at all clinical sites across the country, and universal availability of the nevirapine), an impact study in KwaZulu-Natal province showed the program was minimally effective. This prompted several demonstration projects that used more adaptive designs to improve the performance of the PMTCT program.

These designs, increasingly being promoted for improving performance of health systems at a large scale, followed principles of complex system improvement adapted from manufacturing processes. The approach, known collectively as Quality Improvement (QI), seeks to improve performance by developing a common simplified view of the components and linkages of the system, real-time data feedback to track system performance, understanding the psychology of system change, and crucially, the testing and incorporation of ideas for performance improvement from the front-line practitioners, managers, and customers in a broader range of contexts.

After successful demonstration of the effectiveness of this approach, the South African government adopted the method and tested its wider application before rapidly scaling up key elements of the approach across the country. This scale-up was promoted by significant political shifts resulting in crucial senior governmental leadership support for urgent solutions to the HIV epidemic for the first time. Other key determinants were more efficacious drug regimes, deployment of mobile treatment teams, and policy changes that allowed nurses to initiate antiretroviral therapy. As a result, within a few years, the MTCT rate across the South African public health delivery system fell to levels that were unprecedented in a public system of this size.

There were additional lessons in the effect of context on the rate and success of efforts to implement and scale the program. One of the demonstration projects was designed as a cluster randomized trial (CRT) of 2 levels of health systems support—a QI intervention with and without the use of a face-to-face collaborative learning system to promote context-sensitive improvement ideas. The project was implemented simultaneously in 3 districts, using a step wedge design, with clusters of clinics and their supervisors. The clusters included clinics from the same district but ignored natural and well-established referral and administrative linkages outside the boundaries of the cluster.
Leadership attributes and management functionality had a major impact on the ability to effect change. One district was led by a highly functional, energized district manager who was already using systems thinking to organize health program activities in his district, whereas the second district had weak leadership and was driven by a power struggle for control of clinic activities between municipal and district management structures. The third district had moderate strength of leadership, but a shortage of personnel led to the disbanding of the cadre of nurse supervisors that formed the basis of the cluster randomization. Within the districts, there was some urban/rural variation in sociocultural and economic characteristics, but there was ethnic and racial homogeneity and uniformly high clinic attendance (>90%).

The CRT design was abandoned after 12 months because of a failure of this design to accommodate key context-driven issues that were essential to the integrity of the study:

- The randomization forced a sequence of scale-up that did not use the interest and good will of an early adopter community that could have supported the innovation phases of the scale-up; instead, we were forced to start the implementation with a spectrum of willing and unwilling participants.
- The randomization unit in 1 district was destroyed when an administrative decision removed the key nurse–supervisor role around which the randomization was constructed.
- The support of the participants for the project was severely tested when the study design prevented the spread of the intervention along natural lines of clinic aggregation and patient referral.

**TABLE 1. Contextual Elements and Their Application in Selected HIV/AIDS Complex Intervention Protocols**

<table>
<thead>
<tr>
<th>Articles Where Contextual Elements and Their Application Were Explicit</th>
<th>Contextual Elements and Examples</th>
<th>Application of Contextual Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warren et al16; Abramsky et al17; Andersson et al18</td>
<td>Cultural practices and gender norms</td>
<td>Shaped intervention design (eg, gender-focused intervention)</td>
</tr>
<tr>
<td>Harding et al19; Abramsky et al17; Hayes et al20; Andersson et al18</td>
<td>Characteristics of the study population and/or communities where the study was going to be undertaken</td>
<td>Shaped intervention design</td>
</tr>
<tr>
<td>Harding et al19; Warren et al16; Tomlinson et al21</td>
<td>Characteristics of health facilities where research was to be implemented</td>
<td>Shaped intervention design</td>
</tr>
<tr>
<td>Harding et al19; Tomlinson et al21</td>
<td>Sources of funding for the intervention</td>
<td>Shaped intervention design</td>
</tr>
<tr>
<td>Warren et al16; Abramsky et al17; Tomlinson et al21; Hayes et al20; Andersson et al18</td>
<td>Characteristics of formal and informal health workers including traditional healers</td>
<td>Shaped intervention design</td>
</tr>
<tr>
<td>Warren et al16; Abramsky et al17</td>
<td>Sociopolitical influences expected to impact on intervention delivery</td>
<td>Shaped intervention design</td>
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Equally important, the CRT, through its inherent design characteristics, assumes a homogeneity (or control) of the external environment and resists any change of the intervention design. As such, the CRT design is destined for failure when attempting to evaluate complex interventions being applied in ever-changing, heterogeneous environments. Like any large complex administrative unit, a health district includes multiple shifting and interlinked human networks. Any implementation study has to account for these deep linkages, the tendency for the linkages and resources that nourish them to change repeatedly over time, and the wide variation in competencies of leaders, managers, and front-line workers. This mismatch between CRT design and the contextual properties of the health systems in which interventions are being implemented and scaled up is particularly acute at the start of a scale-up process, when new contexts are being encountered and the theory of change and the intervention itself are evolving in response to these new contexts. Some argue CRTs can be used to evaluate the replication phase of scale-up. By contrast, adaptive designs are better suited to generate and study novel strategies that are required to implement and scale-up interventions in complex environments. The 3-district PMTCT project in KwaZulu Natal thrived when the randomization was abandoned and a more context-sensitive scale-up design was adopted. Each district pursued the same common objective (decrease MTCT to <5%) but used a different implementation and scale-up strategy. The project resulted in numerous innovations for PMTCT that were collated and rapidly scaled across the province. The QI approach provided a template for a rapid national scale-up that required minimal further modification since it had already been tested in multiple contexts. This experience provoked questions on whether cluster randomized designs are appropriate if they disrupt naturally occurring networks or disregard the system properties of administrative structures (eg, districts) and whether they are appropriate for testing scale-up of complex health system interventions. There is growing consensus that adaptive designs are required so that the interventions can remain highly effective across large-scale heterogeneous implementation contexts.

Rapid implementation and scale-up of complex interventions into heterogeneous environments requires a clear aim (outcome); a core set of measures that track key processes and progress toward that outcome; and a theory of change that incorporates anticipating, learning from, and adapting to local context. For PMTCT in South Africa, the aim was to reduce MTCT to less than 5% by 2013. A core set of 7 indicators tracked the continuum of care from early antenatal care through to early testing of the infant for HIV and became the basis of a quarterly report. The theory of change was that success would require a combination of motivated leadership, data feedback systems, and rapid-cycle testing of local ideas applied to a simplified care pathway for PMTCT that was clearly understood from leadership to the front line. After successful demonstrations, the tested change package was modified in a range of different contexts, and the national Department of Health was then able to move quickly to implement well-tested, context-sensitive changes at scale.

**RECOMMENDATIONS**

A framework for understanding and describing context, as well as an adaptive approach for implementing and scaling up interventions in a context-sensitive way, are essential to advance the field of implementation science in HIV/AIDS. Addressing context involves the development of well-informed assumptions regarding the context for delivery, not just in the setting where the study will take place but also in the wider health system that is the target for scale-up. Contextual parameters must include what health personnel (formal and informal) are in place, whether health services are accessible and affordable for those in need, how the health system is financed and governed, and how health information systems are operating. Implementation science protocols and articles describing study results should make explicit reference to the contextual framework being used. Effort is needed to identify common typologies, but in the meantime, frameworks such as the WHO health systems framework or the Greenhalgh framework for organizational change offer good starting points.

Learning from the South African experience, a framework for context-sensitive implementation and scale-up should attend to the sequencing of scale-up components. These include the following: (1) provide a deep understanding of the dimensions of context to plan scale-up, develop a theory of change, and design a feedback measurement system and an adaptive strategy for implementation; (2) undertake prototype testing of the theory of change and early development of implementation ideas; (3) implement early scale-up testing in various complex environments reflecting anticipated variations in the scale-up area; and (4) follow-up with rapid scale-up, ensuring full (equitable) coverage with replication and minor further adaptation of implementation strategies that have been well tested across multiple contexts.

Finally, a receptive environment to facilitate scale-up is also needed. This involves building support for change with leadership, managers, front-line practitioners, and the target population. It also includes ensuring that the environment is prepared with data systems, commodities such as supplies and essential drugs, clinical knowledge.

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