CME

Qualitative Contributions to Implementation Research on HIV Prevention and Treatment

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Background: The advantages of conducting implementation research as part of the development, as well as delivery and use of HIV prevention and treatment interventions, are increasingly being recognized. Qualitative methods are gaining recognition in implementation-oriented research on HIV as vehicles for examining particular implementation outcomes and for identifying barriers and facilitators to intervention uptake. However, they have more to offer. This article presents 3 case examples illustrating the use of qualitative research to explain intervention processes and outcomes, with the goal of clarifying "how and why" they work.

Methods/Case Examples: The first example identifies active ingredients in an intervention aimed at improving antiretroviral therapy (ART) adherence. The second proposes an explanation of the processes through which community-based HIV testing with follow-up support may bring about linkage to care and prevention services. The third unpacks the dynamics of a novel strategy of delivering oral pre-exposure prophylaxis and ART to HIV serodiscordant couples, showing how the organization of services positively impacted participating couples, enabling them to use oral pre-exposure prophylaxis and ART effectively to prevent HIV transmission.

Results/Discussion: Qualitative methods contribute to implementation research for HIV intervention development by (1) offering an alternative to framework-driven investigation, (2) providing tools for understanding user experience of interventions, and (3) developing local explanations of intervention processes and outcomes.

Conclusion: In various ways, qualitative methods contribute to implementation research by deepening and "thickening" conceptualization of implementation problems. Stronger conceptualizations lead to stronger implementation strategies and, thus, to increased use of evidence-based interventions for HIV prevention and treatment as they are made available to the public worldwide.

Key Words: qualitative research, implementation science, HIV prevention, HIV treatment sub-Saharan Africa

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INTRODUCTION

Implementation science in global health seeks to close the gap, preventing interventions known to be effective from being widely used. Investigators are now advocating for conducting implementation research earlier on in the evidence-generating phase of the knowledge production process.[1] Approaches to combining implementation and clinical effectiveness research designs are attracting increasing interest.[2]

Qualitative research refers generally to systematic approaches to investigations that rely on non-numerical data.[3] There is no single method or "recipe" for conducting qualitative research; rather, the design, data collection methods, and approach to data analysis are selected case-by-case to fit the question or problem being addressed. Rigor lies in the quality of the data (how detailed and specific?) and the quality of the argument or interpretation based on the data rather than in adherence to a standard set of procedures.

Qualitative methods are gaining recognition in implementation-oriented research on HIV as vehicles for examining particular implementation outcomes, such as intervention acceptability[4–7] and user perceptions and/or preferences.[8–10] Qualitative designs are also considered the methods of choice for investigating "barriers and facilitators" to acceptance/use of novel HIV prevention and treatment interventions.[11–13]

Much more can be accomplished with qualitative approaches. Our team has used qualitative data to explain processes and outcomes of HIV prevention and treatment interventions in sub-Saharan Africa. In what follows, we present 3 case examples from this work.

CASE EXAMPLES

Case Example #1: ART Adherence

The first case example involves the development of an intervention aimed at improving adherence to antiretroviral therapy (ART). Real-time electronic monitoring devices (Wisepill Technologies, Cape Town, South Africa) were used for adherence measurement. The monitoring devices recorded the date and time each time the device was opened (ie, to remove a pill) and transmitted the information over cellular phone networks to a central location. Failure to receive a signal centrally suggested a missed dose.

The intervention combined short message service (SMS) text message reminders with SMS notifications to individuals who could provide adherence support. Two forms of the intervention were investigated. In the first, participants

received reminders on a schedule, that is, daily for one month and then weekly for 2 months. In the second, participants received SMS reminders "triggered" by the absence of an expected signal confirming opening of the monitoring device. In both instances, SMS notifications were sent to adherence supporters if no signal was received from a monitoring device for more than 48 hours after a participant's designated dosing time.

The intervention was evaluated through a small randomized trial (NCT01957865) and a qualitative study. The trial assessed the impact of each of the 2 intervention variants upon adherence outcomes; the qualitative study sought to explain how the intervention worked by characterizing its active ingredients. The intervention study took place in rural southwest Uganda.

Sixty-three Ugandan adults initiating ART at Mbarara Regional Referral Hospital in Mbarara, Uganda, were randomized 1:1:1 to receive (1) scheduled SMS reminders, with social support for missed doses and real-time electronic adherence monitoring; (2) "triggered" SMS reminders, with social support for missed doses and real-time electronic adherence monitoring; or (3) real-time electronic adherence monitoring only (control condition). Results revealed higher adherence in the scheduled SMS study arm, compared with real-time electronic adherence monitoring only. Adherence was similar in the triggered study arm and the control condition.[14]

Trial participants took part in open-ended interviews as part of the qualitative study. The interviews elicited information on intervention experiences. Inductive analysis of the qualitative interview data pointed to 2 active ingredients likely contributing to intervention effectiveness. First, interviewees credited scheduled SMS reminders with helping them to establish a "habit" of adherence. With regular, frequent reminders, individuals beginning ART grew accustomed to taking pills at the same time every day. As time passed, they were able to rely less on the reminders, remembering without prompting to take ART at dosing time.

The qualitative data also revealed a role for the electronic monitoring device in facilitating adherence. Understanding the device transmitted reports of openings immediately; in real time, participants experienced monitoring as "being seen adhering" by clinic and study staff. They interpreted this as an opportunity to show staff they appreciated the care they were receiving by demonstrating their commitment to treatment. They sought to demonstrate their commitment through good adherence. Thus through the qualitative research, a component not initially considered part of the intervention was revealed to have an effect on the outcome of interest.[15]

Case Example #2: Linkage to HIV Prevention and Treatment After Home HIV Testing and Follow-up Support

The Linkages Study (NCT020385582) was a randomized community intervention trial investigating the impact of community-based HIV testing with follow-up support on subsequent linkage to HIV treatment and prevention services. The study took place in rural southwest Uganda and in KwaZulu-Natal, South Africa. Trained and supervised community health volunteers conducted HIV testing in homes and mobile vans. In addition to testing, volunteers provided counseling to explain HIV disease and the testing procedure and to interpret the test results. Individuals testing positive and not already taking ART were randomized to one of 2 follow-up strategies to support linkage to HIV care or to a control condition. Uncircumcised men testing negative received information about the benefits of male medical circumcision (MMC) for HIV prevention; they were randomized to one of 2 interventions to support MMC uptake or to a control condition.

Linkage support interventions for individuals testing HIV-positive were as follows: (1) home follow-up visits by community health volunteers or (2) help from volunteers in navigating the initial clinic visit (eg, being met at the clinic entrance on the day of the initial visit or being introduced to clinic staff). Linkage support interventions for men referred to MMC were as follows: (1) home follow-up visits by volunteers or (2) SMS text message reminders.

Study results revealed 98% of individuals offered HIV testing in communities were tested. Linkage to clinics for HIV care and treatment for HIV-positive participants was high overall and higher for the "clinic navigation" arm than for controls. ART initiation was higher in the "home follow-up visit" arm than in controls. Linkage to MMC services was high overall, without significant differences between study arms.[16]

Qualitative research was conducted alongside the Linkages Study to unpack intervention dynamics and advance propositions about the processes through which intervention components may have produced an impact. Qualitative data collection consisted of 99 individual interviews with trial participants and 3 focus groups with 16 community health volunteers. We examined the details of HIV testing and counseling and of follow-up visits, clinic navigation, and SMS text-message reminders from the points of view of Linkages Study participants and implementers to understand how these activities were conducted in practice and how and why they resulted in linkages to MMC and to HIV care.

Inductive analysis of the qualitative data yielded a set of linked propositions that together explain how community-based HIV testing with follow-up support may have worked to bring about linkage to care and prevention services. It was clear that HIV testing generated enthusiasm for services, either to treat infection so as to preserve health (for those testing HIV positive) or to remain free of HIV (for uncircumcised men testing negative). The initial enthusiasm was eroded, however, by the difficulties of getting to a clinic site. These difficulties—disentangling oneself from day-to-day tasks and responsibilities, securing transport, and summoning the courage to face life-long daily medication or surgery—over time led to discouragement and disconnection from what had been a positive testing experience.

Follow-up support functioned to renew interest in linkage and inspire action. Counseling by volunteers during home follow-up visits improved morale and provided additional information about HIV. Repeated visits were

interpreted as signs of caring, invigorating their recipients and inspiring a desire to reciprocate for visits by seeking services. Many volunteers were local to communities—some highly respected leaders—which helped overcome fears and provide reassurance that services could be trusted. In these ways, intervention activities strengthened confidence and moved people to action, fueling determination to overcome obstacles and succeed in linking to care. Overall, these observations point to the importance of interpersonal interactions with volunteer implementers as a mechanism contributing to the intervention's ultimate effect.[17]

Case Example #3: The "Bridging Strategy" of Delivering ART and PrEP to HIV Serodiscordant Couples

The "bridging strategy" is a novel, integrated approach to delivering ART and oral pre-exposure prophylaxis (PrEP to HIV serodiscordant couples in African public health settings. The strategy offers time-limited PrEP to HIV-negative partners in serodiscordant couples as a "bridge" to long-term ART in HIV-positive partners. HIV-negative partners use PrEP until HIV-positive partners have taken ART for 6 months, when they are considered virally suppressed and not infectious.[18–20] In the absence of contraindications, HIV-negative partners discontinue PrEP at this point.

The Partners Demonstration Project (NCT02775929) was a prospective, implementation research study evaluating the bridging strategy. One thousand thirteen heterosexual, higher-risk serodiscordant couples at 4 sites in Kenya and Uganda participated. Results revealed the strategy to be highly successful. Rates of uptake of PrEP and ART were 97% and 91%, respectively. PrEP adherence was high. Only 4 HIV infections occurred across the study population during the 2-year follow-up period, for an observed HIV incidence of 0.24 per 100 person-years. This represented a reduction of 95% in the rate of expected new infections, compared with a counterfactual simulation in which expected HIV incidence was calculated to be 4.9 per 100 person-years.[21,22]

We conducted a qualitative evaluation aimed, again, at unpacking intervention dynamics and proposing a process through which the intervention may have produced its effect. Two hundred seventy-four in-depth qualitative interviews eliciting experiences of PrEP, ART, and the bridging strategy were completed with Partners Demonstration Project participants at the Kampala, Uganda site. Interviews were conducted at different points in interviewees' progress through the bridging strategy follow-up period. In addition, trained Ugandan research assistants observed activities of clinical care taking place as part of the bridging strategy. Interactions between participants and clinical staff were observed in the context of screening and enrollment visits, follow-up visits, and study exit visits for a total of 55 observations lasting an average of 2 1/2 hours each.

Inductive analysis of the qualitative data yielded a set of linked propositions in 3 conceptual domains: (1) how services were organized to implement the bridging strategy in the Partners Demonstration Project; (2) how couples experienced the services; and (3) how couples managed the tasks of the bridging strategy, for example, medication uptake and medication adherence.

We proposed first that the couples-focused services comprising the bridging strategy brought partners in serodiscordant couples closer to each other.

The discovery of serodiscordance threatened couples because partners could see no way of avoiding HIV transmission other than to dissolve the relationship. The couple was the "unit of service" in the bridging strategy. Participants were required to attend clinic visits as a couple, which created opportunities to spend time together. They also received counseling, which often included advice on how to manage serodiscordance and remain together, as well as more formal and standardized information about prevention of HIV. As a result of services being "couples-focused" in these ways, participants found ways of repairing their estranged relationship. Reunited, they were able to adopt a "couples' orientation" to the management of PrEP and ART, as explained below.

This "couples' orientation" to PrEP and ART in the bridging strategy manifested itself in various ways. HIV-positive partners initiating ART gave concern for the negative partner's continued well-being as a reason for accepting treatment. Similarly, reinforcing the partnered relationship was cited as a reason for accepting PrEP. Some couples devised joint strategies for adhering to their respective medication regimens, mutually reinforcing each other's adherence success.

In short, we proposed that couples' experiences of "couples-focused services" in the bridging strategy led to the development of a "couples' orientation" to its tasks. The "couples' orientation," in turn, may have increased capacity for ART initiation, PrEP acceptance, and ART and PrEP adherence, lowering HIV transmission rates and making the bridging strategy a success.[23]

DISCUSSION

These 3 case examples illustrate the use of qualitative research to characterize intervention processes. One approaches this by identifying and describing active intervention ingredients (the adherence monitoring device in Case Example #1: ART adherence) and the other 2 through formulating linked propositions that together explain how the intervention may produce an effect. In addition to illuminating intervention processes, these and other qualitative studies also contribute to implementation research in the ways described below.

An Alternative to Framework-Driven Investigation

First, qualitative studies offer an alternative to framework-driven investigation.

Conceptual frameworks for implementation research are designed to integrate relevant research constructs into comprehensive configurations.[24–26] These configurations standardize data analytic strategies and set the stage for broad understandings. By providing a general a priori structure,

conceptual frameworks foster a deductive, "top–down" approach to thinking about data in which results are mapped onto, or otherwise shaped by, pre-designated categories and interrelations. Qualitative approaches to data analysis, by contrast, rely on an inductive approach.

An inductive approach to data analysis systematically develops broad concepts from an understanding and representation of detail.[27] Inductive analysis proceeds by iteratively grouping bits of data based on observed similarities to form larger categories. Relationships among categories are suggested by associations among specific "data bits," identified as the analysis proceeds. An inductive analytic process moves from specific to general without reference to a predesignated framework, but arriving at the same general conceptual level. It does so by following the "conceptual trail" that emerges from the data, free from the constraints imposed by a framework, thus opening the door to new insights and ideas.

User Experiences and Intervention Meaning

Qualitative studies also contribute to implementation research by offering a way of understanding user experiences of intervention content.

As a research construct, "experience" is distinguished from behavior, for example, through the inclusion of the subjective. Subjectivity refers to individual consciousness, sense of agency, emotions, and other qualities that make up the internal world of the person. Because they are open-ended and flexible, qualitative data collection methods provide access to this internal world—the world of experience. Done well, these methods make it possible to represent an intervention, or other object of inquiry, "through the eyes" of users.

The study of user experiences of an intervention leads to an understanding of what the intervention means to them. Not infrequently, in inquiring into experience, we discover that what an intervention means to users extends well beyond the goals and purposes of intervention developers and implementers. For example, as we have seen, saving their relationship was the larger meaning of preventing HIV through the bridging strategy of PrEP delivery for couples participating in the Partners Demonstration Project. Adherence and Linkages Study participants experienced these interventions as meaning they were "cared about" by health care staff. What an intervention means to people, we propose, impacts whether and how well it will be used.

Local Explanations

Finally, qualitative investigation contributes to implementation research by proposing explanations of how and why interventions work (or do not work). These are "local explanations," aimed at proposing a set of interactions through which a particular intervention, implemented in a particular set of circumstances, produces the outcomes it does.

"Local explanations" are similar in some ways to the "middle-range theory" associated with Robert K. Merton and the analytical sociology approach to understanding the social world.[28,29] Like local explanations, middle-range theories are empirically grounded and developed inductively to construct more general propositions about "how the world works." Middle-range theories are generic statements intended to be verifiable through empirical data. Local explanations refer specifically to the contexts that gave rise to them but can be tested in other circumstances and modified to develop more general claims. Both local explanations and middle-range theories can be usefully applied to strengthen empirically grounded explanation and theorizing in implementation science and have clear implications for the formulation of effective implementation strategies.

Local explanations of intervention outcomes may be formulated as "mechanisms of effect." A "mechanism of effect" (also termed "mechanism of change," "mechanism of action," and "mechanism of impact") may be believed of as the process or processes through which intervention components interact to produce a particular result.[30,31] Mechanisms of effect served as the medium for proposing explanations in the 3 cases presented here. Another example is a recent theory-driven analysis from Uganda highlighting the interaction of the following: (1) coaching by opinion leaders, (2) new resources and restructuring of services, and (3) ongoing performance feedback to participating clinics to yield a substantial increase in rapid ART initiation ("START-ART," NCT #01810289).[32] The notion of a "spoiled identity" brought about by HIV-related stigma, but "redeemed" through publicly recognized involvement in advocacy for HIV treatment, is posited as a mechanism contributing to initiation of ART in qualitative analyses embedded in the START-ART and SEARCH clinical trials (Sustainable East African Research in Community Health, NCT# 01864603).[33]

Local explanations may also be derived from analyses of the sociocultural contexts in which interventions are implemented. A qualitative contextual analysis conducted again, in conjunction with the SEARCH clinical trial, identified cultural and structural factors accounting for the disproportionately lower number of men taking part in community-based HIV-testing campaigns early in the intervention's follow-up period.[34] As a result, adjustments were made to the way campaigns were conducted, and the number of men taking part correspondingly increased.

CONCLUSIONS

Through a combination of case examples from our own work and references to other pertinent studies, this article identifies at least 3 ways in which qualitative designs and methods contribute to implementation research, in addition to generating data on implementation outcomes (eg, acceptability and preferences) and on facilitators and barriers to intervention use. First, they offer an alternative to framework-driven investigation, substituting inductive analytic strategies for "top–down" approaches, while arriving at comparable conceptual ends. Second, they offer tools for eliciting and understanding users' subjective experiences of interventions and the meanings that arise out of these experiences. Third, they provide "local explanations" of

intervention processes and outcomes to shed light on how and why interventions work.

Each in a different way, these contributions deepen, "thicken," and thus strengthen the conceptualization of implementation problems through a grounding in the details of users' lives. Stronger conceptualizations lead to stronger, more informed implementation strategies and, thus, to increased uptake and use of evidence-based interventions for HIV prevention and treatment of HIV infection as these are made available to the public worldwide.

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