Published in final edited form as:

J Acquir Immune Defic Syndr. 2015 March 1; 68(0 2): S107–S113. doi:10.1097/QAI.0000000000000438.

Evaluating Respondent-Driven Sampling as an Implementation Tool For Universal Coverage of Antiretroviral Studies among Men who have Sex with Men Living with HIV

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Abstract

Introduction—The TRUST model based on experimental and observational data posits that integration of HIV prevention and universal coverage of antiretroviral treatment (UCT) at a trusted community venue provides a framework for achieving effective reduction in HIV-related morbidity and mortality among men who have sex with men (MSM) living with HIV as well as reducing HIV incidence. The analyses presented here evaluate the utility of respondent-driven sampling (RDS) as an implementation tool for engaging MSM in the TRUST intervention.

Methods—The TRUST integrated prevention and treatment model was established at a trusted community center serving MSM in Abuja Nigeria. Five seeds have resulted in 3–26 waves of accrual between March, 2013 and August, 2014 with results presented here characterizing HIV burden and engagement in HIV care for 722 men across study recruitment waves. For analytic purposes, the waves were collapsed into five groups; four equally spaced (0–4, 5–9, 10–14, 15–19) and one ranging from the 20 to the 26th wave with significance assessed using Pearson's chi-squared test.

Results—In earlier waves, MSM were more likely to have reported testing for HIV (82.9% in waves 0–4, 47.7% in waves 20–26, $p < 0.01$). In addition, biologically-confirmed HIV prevalence

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Conflict of Interest: None noted

decreased from an average of 59.1 to 42.9% ($p<0.05$) in later waves. In earlier waves, about 80% of participants correctly reported their HIV status as compared to less than 25% in the later waves ($p<0.01$). Lastly, participants reporting being on ART decreased from 50% to 22.2 % in later waves ($p<0.01$).

Conclusions—Implementation science studies focused on demonstrating impact of universal HIV-treatment programs among people living with HIV necessitate different accrual methods than those focused on preventing HIV acquisition. Here, RDS was shown to be an efficient method for reaching marginalized populations of MSM living with HIV in Nigeria and engaging them in universal HIV treatment services.

Introduction

Emerging experimental and observational data have catalyzed an evolution in HIV prevention approaches highlighting the importance of the continuum of HIV care ranging from being aware of one's diagnosis to viral suppression¹. To date, the experimental data highlighting the link between lower viral load and decreased risk of onward transmission of HIV has focused on preventing vertical and heterosexual transmission with data from several prevention of mother to child HIV transmission (PMTCT) studies and also HPTN 052²⁻⁴. However, there is a far broader base of observational data highlighting the benefits of lower community viral load through the universal coverage of antiretroviral therapy (UCT) (79). Observational data include classic studies from Rakai, Uganda where after adjustment for a series of HIV-related determinants, each log increment of plasma viral load was associated with a 2.45 times relative risk of HIV transmission (95% CI 1.85 to 3.26) (25;80). Ecologic observational studies have also been completed comparing incident HIV infections in HIV-uninfected partners in long term heterosexual serodiscordant relationships before and after the scale up of antiviral therapy (ART). The results demonstrated that after adjusting for key determinants, the HIV-uninfected partners were 86% less likely to become HIV infected if their partner was receiving ART (aOR 0.14, 95% CI 0.03–0.66)⁴. While the majority of studies have focused on the prevention of heterosexual transmission, there are also emerging observational data highlighting the potential benefits of the universal coverage of ART for men who have sex with men (MSM)^{5,6}. However for this benefit to be achieved, optimal strategies to engage marginalized MSM living with HIV are needed.

Observational data at the individual and community level highlight the benefits of UCT to impact HIV transmission among MSM^{7,8}. There is a gap in evidence concerning the efficacy of systemic ART on HIV acquisition in relationship to the route of exposure. Although experimental data related to the protective effects of UCT for heterosexual transmission are available, the per-coital act transmission risk of penile-anal intercourse compared to penile-vaginal intercourse is far higher. Consequently, in the absence of clinical trial or well-conceived observational data the effectiveness of UCT for MSM is still unproven^{9,10}. In many parts of the world, MSM have been characterized as being disproportionately affected by HIV given biological, behavioral, and structural risks¹¹. And while the majority of epidemiologic data characterizing HIV risks among MSM have traditionally come from higher income settings, there are consistent data highlighting that the risks for HIV acquisition and transmission among MSM and subsequently the higher

burden of HIV are more similar than they are different across all studies from high and low income areas of the world^{12,13}.

In the context of the most broadly generalized HIV epidemics affecting countries within Sub-Saharan Africa, data consistently highlight the high burden and incidence among MSM¹⁴. This is especially the case in West and Central Africa, where the epidemics appear to be more concentrated among key populations^{12,15}. Nigeria has a mixed HIV epidemic including both concentrated epidemics within key populations as well as a more generalized epidemic among reproductive age adults. Multiple rounds of biobehavioral surveillance studies across urban centers of Nigeria have demonstrated that MSM have a significantly higher burden of HIV than the approximately 3.6% prevalence observed among all reproductive age adults in the country^{16–19}. Moreover, using conservative static approaches for population attributable fraction, it is estimated that key populations including MSM account for about 40% of the 300,000 incident HIV infections in the country every year²⁰. Furthermore, while the burden of HIV is high among these men, accruing appropriate MSM for HIV treatment or prevention impact studies is often challenged by prevalent stigma in the communities^{21–25}. Taken together, these data suggest the need for novel approaches to explore the effectiveness of UCT among MSM in stigmatized settings, including appropriate implementation designs, and the study of facilitators and barriers to the uptake of ART among these men. To operationalize impact studies, accrual strategies need to be in place to accrue appropriate candidates for UCT interventions specifically supporting MSM.

There are several methods that are in use to accrue MSM participants for research studies that have evolved out of active HIV surveillance approaches²⁶. These methods include venue-based accrual where men potentially at higher risk of acquiring or transmitting HIV may be engaged including health service facilities, social venues specifically for gay men and other MSM, and at public events such as Pride Events²⁷. Another common approach includes the engagement of community based organizations (CBOs) that serve MSM to advertise and support the direct accrual or referrals of participants to study venues. However, engagement with CBOs and disclosure of sexual orientation or same-sex practices is limited in contexts with significant enacted and perceived stigma. While the extreme situation may be scenarios whereby same-sex practices or membership in CBOs is criminalized such as with the recent legislation in Nigeria, stigma appears to limit disclosure of same-sex practices to providers across a range of settings. In response, HIV surveillance programs have evolved to explore populations that tend to be systematically undercounted in passive case-based surveillance including venue-day time sampling (VDT) and respondent-driven sampling (RDS). While there are several advantages to VDT sampling, in many settings where MSM are stigmatized, there are no or very few established venues to use for accrual. It is in these settings that RDS has emerged as an effective HIV surveillance strategy leveraging social networks to drive accrual rather than physical venues^{28,29}.

The analyses presented here evaluate the utility of respondent-driven sampling (RDS) as an implementation tool for engaging MSM in the TRUST intervention focusing on providing UCT for MSM living with HIV combined with prevention programs to minimize HIV acquisition among MSM in Abuja, Nigeria.

Methods

Overview

The TRUST study is a prospective cohort evaluating RDS-based recruitment of gay men and other MSM into a comprehensive model of HIV prevention, treatment, and care services co-located with a community-based organization (CBO) that is a trusted venue for MSM in Abuja. The central hypothesis is that RDS will reach populations of MSM not engaged in services and thus be a feasible strategy for engaging marginalized MSM in the TRUST service delivery model. The study is implemented as a collaboration between the Institute of Human Virology at the University of Maryland, Johns Hopkins University, the International Center for Advocacy on the Right to Health (ICARH) a Nigerian CBO, IHV-Nigeria (PEPFAR implementing partner and Nigerian research center of excellence), and the Military Health Research Project (MHRP).

Study Population

The inclusion criteria for the study include presenting to the study site with a valid RDS coupon, assigned male sex at birth, the ability to provide informed consent in English or Hausa, and a history of insertive or receptive anal intercourse in the previous 12 months. Men had to be aged 15 or older and men under the age of 18 were considered emancipated minors exempt from parental consent for the purpose of this study. The men had to be willing to enroll and participate in follow up for 18 months, including completion of quarterly structured interviewer-administered questionnaires and HIV and sexually transmitted disease testing and treatment monitoring.

Study Accrual and Procedures

RDS methods have been previously described²⁹. Briefly, seeds were identified representative of different sociodemographics including Yoruba and Hausa men, as well as geographically across neighborhoods in Abuja, Nigeria. Seeds participated in the study and then were given three coupons with which to recruit other MSM to complete the structured survey instrument and biological testing. The initial visit included informed consent and the administration of several modules of the structured instrument, together with referral to a peer from the co-located community-based organization (ICARH). The second visit included the administration of the remaining modules of the survey instrument together with serial rapid HIV screening tests. If the HIV tests were positive, the participant then completed phlebotomy for further HIV and sexually-transmitted infection (STI) testing. Ultimately, five seeds recruited participants in Abuja from March 2013 to August 2014 resulting in between 3 and 26 recruitment waves by seed and 722 baseline recruits. For the current analysis 706 participants with complete data are analyzed.

Analytic Approach

The waves of accrual are not necessarily related to time of accrual in the study, but relate to the position of the recruit in relationship to the initial seed (rounds of subsequent coupon distribution by subsequent seeds. To characterize HIV burden and engagement in HIV care across study recruitment waves, we collapsed the waves into five groups; four equally

spaced (0–4, 5–9, 10–14, 15–19) and one ranging from the 20 to the 26th wave. In waves 0–4, there were 114 participants including 5 seeds, in waves 5–9, there were 166 participants, 10–14 included 224 participants, 15–19 included 131 participants, and waves 20–26 included 87 participants for a total of 722 participants. We computed baseline (visit 0) self-reported HIV testing and HIV status, and a self-reported history of CD4 testing by wave. HIV test results and ART status measured at follow-up visits are also presented across waves. Cumulative proportions of the above variables are presented graphically across strata of enrollment waves and distributions were compared using Chi-squared statistics. Statistical analysis was conducted using Stata 13.1 (College Station, Texas).

Ethics

This study was approved by the State Ethics Board of the Federal Capital Territory in Nigeria, and Institutional Review Board of the University of Maryland in the United States which both accepted enrollment of age 15 – 18 participants as emancipated minors not requiring parental consent.

Results

Sociodemographic and HIV-Related Characteristics of Participants, By Wave

In earlier waves, participants with tertiary or higher levels of education were more likely to be accrued whereas in later waves those with primary or less education were significantly more likely to be accrued (Table 1). In addition, the average age also decreased among participants from earlier waves to that of later waves. Despite this age gradient, there was no significant difference in the marital status among participants. While employment levels initially increased across the grouped waves of participants, this decreased to similar to baseline levels towards later waves. The majority of men identified as bisexual (66%); this was similar across waves. However, condom use during last anal sex with another man decreased across groups of waves (from 77% to 68%, $p<0.05$) whereas MSM who had sex with other women during the past month increased from 35% to 46% ($p<0.05$).

Reported Engagement among MSM in the HIV Treatment Cascade by Accrual Wave

In earlier waves, MSM were more likely to have reported prior testing for HIV with the prevalence of average testing being 82.9% in waves 0–4 down to 47.7% in waves 20–26 ($p<0.01$ for trend) (Table 2). Throughout the waves, biologically confirmed HIV prevalence also decreased from an average of 59.1% among MSM in waves 0–4 to 42.9% in waves 20–26 ($p<0.05$ for trend). The most significant drop in HIV prevalence was observed up until approximately wave 14 after which equilibrium was reached (Figure 1). Among the total sample, those who self-reported to be living with HIV decreased from nearly 50% to just over 10% of volunteers ($p<0.01$) (Table 2). Consequently, in the earlier waves, about 80% of people correctly reported their HIV status as compared to less than 25% in the later waves ($p<0.01$). In addition, those who reported being on ART among those reported to be living with HIV similarly decreased from exactly 50% in waves 0–4 to 22.2% in later waves. Lastly, there was a trend towards those reported to be living with HIV to have had CD4 tests in earlier waves as compared to later waves (81.0% to 50.0%), though this did not reach statistical significance ($p=0.127$).

Markers of Social Support and Engagement among Participants

While ever disclosing same-sex practices to a health care worker was limited at baseline to 48.2% of participants in waves 0–4, it decreased significantly to just 11.6% of participants in later waves (Table 2, Figure 2). Moreover, having ever disclosed same-sex practices to a single family member was similarly limited at baseline with less than a quarter of participants reporting in the affirmative. This type of disclosure also decreased precipitously in the later sample to just 6% of participants. Finally, the average network size represented by the number of MSM known by the participant went from 120 MSM to 28.5 from earlier to later waves.

Discussion

This study aimed to assess the utility of respondent-driven-sampling (RDS) to accrue MSM in Abuja, Nigeria who represent appropriate candidates for the evaluation of UCT for people living with HIV. While traditional programmatic interventions have leveraged CBOs, venue-based peer outreach, targeted marketing approaches, and social networks to drive accrual for programs and research, these programs tended to focus nearly exclusively on preventing HIV acquisition or the reduction of HIV incidence as the outcome³⁰. However, the last three years have witnessed a transition from the near exclusive focus of HIV prevention focused on the prevention of primary HIV acquisition, to studies focused on better addressing the needs of those already living with HIV³¹. Given the high baseline prevalence and the high force of HIV transmission among MSM, anti-retroviral based prevention and treatment approaches are absolutely necessary components of prevention packages focused on changing the trajectory of these often growing HIV epidemics⁸. The TRUST study presented here is equally focused on evaluating the impact of UCT for people living with HIV. Overall, these data highlight the utility of RDS as a feasible implementation tool for reaching key populations in need of ART-based prevention and treatment approaches.

This study reinforced the high prevalence and risk for incidence of HIV among young MSM in Abuja. Moreover, participants from earlier waves were more likely to be living with HIV, but these same men were also significantly more likely to report awareness of positive HIV serostatus and be on ART than those accrued in later waves. Participants from later waves in this study appeared to be more marginalized from services and at higher risk for HIV acquisition as they had lower HIV prevalence, and reported lower levels of condom use with male partners. Given that MSM in earlier waves were more likely to be aware of their status, it is reasonable to assume that they are better connected to the CBOs as they are seeking HIV-related services. In addition, these men were more likely to have larger social networks of other MSM which is also likely related to their engagement with CBOs and the subsequent networking that tends to happen in these settings. While the HIV prevalence was the highest among these men, they may not actually be the men at highest risk of onward HIV transmission given the higher uptake of ART. While the focus of epidemiologic studies and ultimately the interventions trying to address the HIV epidemic among MSM have been concentrated in higher income settings, data such as these reinforce the need to examine meaningful approaches for MSM across Sub-Saharan Africa⁷. The implementation across

different settings requires contextualization for each setting, however, there are commonalities in the need to decrease blood and semen viral load among those living with HIV for their own health and to decrease onward sexual transmission as well as to ensure sufficient antiretroviral blood or rectal tissue levels among those at particularly high risk of HIV acquisition^{6,32}. For an impact study evaluating UCT, the men in the first few waves of accrual in this study may not represent ideal candidates for UCT evaluations given the relatively high engagement in care and treatment observed at baseline. Furthermore, the data presented here suggest that men at least 5 or more waves from the original seeds were more marginalized from existing HIV care and treatment services thus representing optimal candidates for impact studies of UCT. Arguably more importantly, these data suggest that it is these men where the impact of treatment interventions may be the highest and would have been potentially missed with traditional programmatic accrual approaches.

These data characterizing differential level of engagement by wave of accrual are also relevant in informing power and sample size calculations for UCT studies. Studies in high, medium, and low income settings focused on MSM may face similar issues in that the early recruitment may oversample potential participants most closely linked with community groups that have a higher burden of HIV, but also already be linked to existing HIV treatment and retention services. The TRUST study described here is focusing on biomedical and behavioral interventions implemented at the level of the individual with the focus on increasing the uptake and retention in ART services, as well as to minimize the risk of HIV acquisition. However, increasingly, programs and studies are implementing interventions addressing health system delivery or policies which utilize clinics or communities as the unit of analysis³³. Evaluation of these studies often necessitates cluster randomized controlled trials, stepped-wedge approaches, or pre-post designs^{34,35}. While the unit of analyses for these studies are not individuals, it is still individual participants that drive sample size considerations. Consequently, if studies do not account for the bias of oversampling participants with higher baseline engagement in HIV treatment when calculating sample sizes for these studies, they may be underpowered for primary outcomes of UCT studies.

Ultimately, the collective goal of UCT studies is to better understand how to implement programmatic treatment scale up programs serving MSM, and other key populations, in the context of significant stigma and even criminalization. The WHO has recently made recommendations to provide UCT for key populations in combination with increased access for treatment among other reproductive age adults³⁶. However, this study highlighted that those who would benefit most from these programs are the same people are the least likely to access services and the most difficult to reach. While RDS has traditionally been used as a tool in the realm of HIV surveillance and research, the data presented here suggest that programmatic implementing agencies should consider the use of RDS as a tool in reaching those populations of MSM where treatment impact could be the greatest.

There are several limitations with the analyses presented here. While multiple different design effects have been proposed to inform sample size calculations for RDS studies, a general tenet is that when equilibrium (distribution of key study parameters is similar across waves) is reached, then the sample size is sufficient³⁷. Here, there was still some lability of

characteristics in later waves which may limit the generalizability of these findings to the broader population of MSM in Abuja from which the participants were sampled. However, the goal of these analyses is not to adjust the observed proportions for network size and homophily to calculate unbiased estimates that are more representative. These analyses were focused on observing the characteristics and engagement in HIV prevention and treatment programs by wave to inform future research and implementation. In addition, this study was implemented in the context of a country which criminalizes same-sex practices and in earlier 2014, enacted legislation adding additional penalties to existing punitive laws^{16,19}.

Consequently, the interpretations focused on optimal accrual strategies for UCT studies are most appropriate for these settings. However, it should be noted in that in higher income settings, HIV among MSM is often disproportionately higher among minority MSM³⁸. While same-sex practices are not criminalized, these men may experience similar enacted and perceived stigma within their communities which may challenge traditional approaches especially for accrual of MSM living with HIV for UCT studies³⁹.

The high incidence and prevalence of HIV among MSM necessitate further study of the implementation of effective packages of ART-based HIV prevention and treatment approaches combined with behavioral and structural interventions⁷. Moreover, while the study of these interventions is complicated by stigma and criminalization of same-sex practices, there remains equipoise for studying how best to serve the unmet needs of these men. This study highlighted the differential engagement in HIV treatment services across wave of accrual suggesting the need for future investigation of other treatment related characteristics by wave of accrual including prevalence of resistance mutations, HIV superinfections, and viral load. Here, RDS was shown to be an efficient method for reaching marginalized populations of MSM living with HIV in Nigeria and engaging them in universal HIV treatment services.

Acknowledgements

Funding sources:

The research reported in this publication was supported by the U.S National Institutes of Health under award number R01MH099001-01. This study is also supported by funds from the U.S. Military HIV Research Program (Grant No. W81XWH-07-2-0067), Fogarty AITRP (D43TW01041), and the President's Emergency Plan for AIDS Relief through cooperative agreement U2G IPS000651 from the HHS/Centers for Disease Control and Prevention (CDC), Global AIDS Program with IHVN. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or other funders.

The study team would like to acknowledge the participants for taking part in this study given the significant stigma that exists affecting gay men and other men who have sex with men in Nigeria. We would also like to acknowledge Sara Kennedy for her leadership support in implementing the study. Marcy Gelman and Dr. Kevin Kapila from Fenway Health completed training to increase the cultural and clinical competency of study and clinical staff for the TRUST Study. In addition, Ashley Grosso supported instrument development and Erin Papworth provided training on respondent driven method implementation.

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Figure 1.
Proportion of Men who have Sex with Men in Abuja, Nigeria Engaged in the HIV Care Cascade by Wave of Accrual in the Trust Study

Figure 2.
Average levels of disclosure of same-sex practices to either family or health care workers
among MSM in Abuja by wave of accrual

Table 1

Sociodemographic Characteristics of Men who have Sex with Men in Abuja, Nigeria by wave of accrual.

Variable	Distribution of characteristics across grouped wave number (row %)					Chi-square p-value	Total sample percent (n)
	0-4	5-9	10-14	15-19	20-26		
Education							
Primary or less	5.83	10.68	23.3	40.78	19.42	<0.001	14.7(103/700)
Junior school	10.0	11.0	48.0	13.0	18		14.3(100/700)
Secondary school	14.47	27.01	35.05	13.5	9.97		44.4(311/700)
Tertiary or beyond	25.27	27.96	21.51	16.13	9.14		26.6 (186/700)
Religion							
Christian	18.64	30.02	37.53	9.2	4.6	<0.001	58.7 (413/703)
Muslim	10.34	11.72	23.79	31.03	23.1		41.3(290/703)
Marital Status							
Single/cohab man	15.02	23.6	32.51	17.33	11.55	0.184	85.7(606/707)
Married/cohabitating	18.99	13.92	24.05	25.32	17.72		11.2(79/707)
Divor/sep/wid	22.73	18.18	36.36	13.64	9.09		3.1(22/707)
Employment							
Unemployed	9.09	31.17	39.61	15.58	4.55	<0.001	21.8(154/707)
Self or formal employ	20.45	20.2	23.23	19.19	16.92		56.0(396/707)
Studying	10.19	19.11	45.22	17.83	7.64		22.2(157/707)
Age group in years							
16-19	2.0	15.2	55.0	15.9	11.9	<0.001	21.4 (151/707)
20-24	13.8	26.4	29.0	18.2	12.6		38.1 (269/707)
25-29	20.3	26.6	20.8	21.4	10.9		27.2 (192/707)
30-34	36.8	12.3	31.6	7.0	12.3		8.1 (57/707)
35+	29.0	15.8	13.2	26.3	15.8		5.4 (38/707)

Table 2
Key Parameters Related to engagement with the HIV Treatment Cascade and Accrual Wave among MSM in Abuja, Nigeria

	Distribution of characteristics across grouped wave number (row %)					Chi-square p-value	Total sample percent
	0-4	5-9	10-14	15-19	20-26		
Wave number							
Self-reported HIV testing	82.9	67.1	52.0	43.0	47.7	<0.001	58.1 (410/706)
HIV VCT results	59.1	52.8	36.7	40.0	42.9	<0.05	46.3 (187/494)
Self-reported living with HIV *	47.8	33.3	18.6	18.5	10.5	<0.001	28.3 (113/399)
Ever had a CD4 test *	81.0	64.7	50.0	60.0	50.0	0.127	67.3 (74/110)
ART status *	50.0	27.7	20.9	19.2	22.2	<0.01	30.6 (57/186)
Disclosure of sexual practices to healthcare worker	48.2	24.0	11.0	14.8	11.6	<0.001	20.5 (144/701)
Disclosure of sexual practices to family	24.3	19.0	6.7	10.2	6.0	<0.001	12.8 (90/705)
Average network size	120.0	58.9	51.8	18.6	28.5	<0.001**	55.3**

Notes:

* among those reported to be living with HIV,

** nonparametric test for trend p-value