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Men & HIV: insights from sub-Saharan Africa

Guest Editors: Wole Ameyan, James Ayieko, Anna Grimsrud, Tanya Shewchuk
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EDITORIAL

Shifting the narrative: from "the missing men" to "we are missing the men"

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Thirty years into the HIV response, there is growing recognition that engaging men will be key to reaching the global UNAIDS fast-track targets of 90-90-90 by the end of 2020 – whereby 90% of people living with HIV know their status, 90% of those who know they are positive are on antiretroviral therapy (ART) and 90% of those on ART are virally suppressed [1]. The most recent global HIV data through 2018 show that progress towards the 90-90-90 targets for men lags behind at 75-74-85 compared to 84-81-87 for women [2]. Looking at the second 90, ART coverage is considerably lower for men than women globally (68% vs. 55%), and consistently lower in all of the seven World Health Organization (WHO) regions except Latin America [3].

Since the 2017 UNAIDS publication of "Blind spot: Reaching out to men and boys," the global trend of poorer outcomes across the HIV care cascade for men has gained traction and focus from PEPFAR programmes, national departments of health, implementing partners and global normative agencies [4-8]. Furthermore, recent guidance from the WHO does highlight gender differences in HIV outcomes, including the substantial gap in reaching men with HIV testing services [9].

Our call for abstracts for this supplement highlighted this growing attention and sought to collect and promote approaches to reaching men with HIV testing, prevention, treatment, care and support services. The interest in this topic was reflected in the over 100 abstracts that we received, which emphasized several salient points on where the gaps are and where we should be headed.

First and foremost, it is time to shift away from a narrative that looks at men from a "safe" distance, blames men for poor health-seeking behaviour and focuses on men solely to improve the health of their partners and children. Men need and are willing and deserve to have access to services for their own health. Engaging men in health services for their own health can further provide an entry point for programmes that may have a positive impact on improving the health of their families and communities.

Our second takeaway is that the current system is not working for anyone – all populations are negatively impacted by the current gender norms. As highlighted by The Lancet in their recent series on gender, equality, norms and health, "rigid gender norms undermine the health and wellbeing of all people – girls and women, boys and men, and gender minorities" [10]. This is true in HIV where, as outlined, men are not accessing and benefiting from ART in the same way as women, while at the same time, incidence rates among adolescent years girls and young women remain unjustifiably high [11] and outcomes among key populations, including men who have sex with men and transgender people, remain disturbingly poor [3].

Thirdly, given the global HIV response and the current spotlight on men, HIV programmes may be uniquely positioned to drive a larger men's health agenda and plans within countries that are adapted to different settings. Data highlighting worse outcomes for men compared to women are not unique to HIV. The global burden of disease data sheds light on mortality rates presenting sex-disaggregated data across geographies and notes that improvement is less pronounced, particularly for adult males where in several countries progress in mortality was "stagnant or increasing" [12]. There is evidence of increased morbidity among men from infectious diseases including tuberculosis (TB) [13,14] and other conditions including cardiovascular diseases, respiratory diseases and injuries [15]. Higher rates of co-infection with TB were demonstrated by Osler *et al.* in this supplement where men living with HIV were twice as likely to have TB compared to women living with HIV [16]. The experiences of the "Khotla" male-centred services in Lesotho highlight both the importance of having a physical space within the health system for men and that a non-vertical, comprehensive men's health services offering is appealing to men [17].

Despite the large number of abstracts reviewed for this supplement, there were limited data and evidence to show what works. Much of the data describes challenges or current

pilot programmes (often focused on HIV testing), with few examples highlighting where men's health has been mainstreamed and health systems have been responsive to their needs.

Despite this, there is a strong case for health systems that are people-centred and can be sensitive and responsive to the attributes of clients [18]. Put differently, we need differentiated service delivery for different populations. There are increasing calls for "x-friendly services" which all include integration, service hours that work for patients, are offered by educated and sensitive staff and involve peers. This is universal – for men, for adolescents, for key populations, for women – the bottom line is that people, including men, want and need services that respond to their needs. The balance is to ensure these services can be offered within a public health approach and in resource-constrained settings.

In this supplement, four key themes emerged. First, health systems are structurally gendered to address women's health needs. Second, while there are considerable efforts, including through the MenStar Coalition [19], to reach younger men, there is a large number of "older" men (those over 35 years old) who require HIV services. The third theme is that programmes are going to need to be more creative and strategic to access and test men who truly do not know their HIV status. Some of the interventions studied around testing may be retesting those who know their status instead of reaching men who are unaware of their HIV-positive status. This insight underscores not only the need for testing interventions to reach those unaware of their status but also corresponding services adapted so men start and stay on treatment. Finally, as described above, it's time for a narrative shift away from "men as the problem" to one that views men as a group that is interested in health and able to be part of the solution where health systems adapt to meet men where they are.

1 | RECOGNITION AND ENGAGEMENT OF MEN BY HEALTH SYSTEMS

In many resource-limited settings, health systems are largely designed to address critical maternal and child health needs. This point is described in detail by Dovel *et al.* in relation to Malawi [20] and complements earlier work highlighting that during adulthood, women (excluding pregnant women and those with children under two years of age) have 19 hours per year of interaction with the health system compared to just three for men [21]. The gendered health services are further exacerbated by the reality that in many high HIV prevalence countries, women are the majority of the health workforce. Men are therefore absent from the health system both as patients and as providers. As a start, programming and global guidance on HIV should include and recognize men as a critical group that requires HIV prevention, care and treatment. Engagement and involvement of men, by health systems, primarily as a group that is interested in their own health is a reasonable first step in addressing the glaring gaps. The "men gap" needs to be closed to achieve the 90-90-90 global targets by 2020 and to end the HIV epidemic by achieving 95-95-95 by 2030.

2 | HIV SERVICES ARE NEEDED FOR OLDER MEN

Historically, efforts to reach men with services have been done to ensure services for their partners. As such, there are considerable efforts to reach men with HIV programming, reduce HIV infections among their partners and/or improve outcomes for their partners who are living with HIV. However, when looking at HIV population pyramids it is clear that the largest numbers of HIV-positive men currently not engaged in services are among those over 35 years of age, which aligns with the age bands of highest prevalence. In the work by Gottert *et al.*, 20% of the sample was "older high risk groups" [22] highlighting the critical need for services focussed on older men. It is also critical to reach these men sooner, before they are acutely ill. In data from Western Cape province in South Africa, 39% of the men first presented with a CD4 count below 200 copies/mL, had increased probability of death compared to women and were less likely to start ART compared to women [16]. The lowest uptake of ART was among men not co-infected TB, 26% less likely than men coinfected with TB.

3 | ENHANCING HIV TESTING TO REACH THOSE WHO HAVE NOT BEEN REACHED

The advent of HIV self-testing (HIVST) has accelerated interest and modalities to reach men with HIV testing [23]. Data from the Kwa-Zulu Natal province in South Africa in this supplement highlights how both oral and blood-based HIVST are reaching men [24]. In the study by Barnabas *et al.*, HIVST reached a high number of men with the majority having a suppressed baseline viral load suggesting that there are unanswered questions on retesting behaviours as they were already active on treatment and knew their HIV status [25]. In Zambia's Community Impact to Reach Key and Underserved Individuals for Treatment and Support (CIRKUITS) project, the index testing approach was successful in reaching both a high volume and yield of HIV-positive men [26]. It is critical to interrogate this data, given than 75% of the traced contacts had an unknown HIV status. By comparison, Zambia's population-based HIV impact assessment data from 2016 estimated the first 90 gap among men to be only 29% [27]. Therefore, it is important to consider the proportion of men in the CIRKUITS project not disclosing their HIV status to the CIRKTUS staff. HIVST is a critical intervention to reach those who would not otherwise test, and the evidence of this is further bolstered by the findings of Napierala *et al.* In this study, women at increased vulnerability to HIV did secondary distribution of HIV self-test kits – each woman gave HIVST to a median of three partners with 94% offering a kit to their primary partner [28].

4 | REFRAMING THE NARRATIVE

As outlined above and stated in the viewpoint of Makusha *et al.* [29], now is a critical moment to change the discussion

and acknowledge the unique and underserved health needs of men. We call on national ministries of health to consider a "men's health agenda" and how to ensure the health system is inclusive of men. Importantly, the narrative needs to consider men in their diversity and across the life course. Bhattacharjee *et al.* [30] described the HIV cascade among a sample of Kenyan men who have sex with men, comparing those who use physical sites, physical and virtual sites and virtual sites to meet sex partners. On life course, there needs to be a recognition that the harmful norms and behaviours that drive negative health outcomes among men are likely to be internalized during adolescence. Health systems need to address the needs of adolescent boys with a view to harnessing the triple dividend of benefits for adolescents now, for their future adult lives, and for the next generation [31].

In conclusion, at this juncture the HIV response should support HIV programming for men from prevention to testing, care and treatment by considering their needs. To improve services, it is essential that health services acknowledge that we have been missing men, and that it is our collective responsibility for health systems to be people-centred to address the needs of all people.

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COMPETING INTERESTS

None of the authors have competing interests.

AUTHORS' CONTRIBUTIONS

AG wrote the first draft. WA, JA and TS authors provided comments and input. All authors approved the final submission.

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RESEARCH ARTICLE

Population-wide differentials in HIV service access and outcomes in the Western Cape for men as compared to women, South Africa: 2008 to 2018: a cohort analysis

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Abstract

Introduction: Few studies have systematically described population-level differences comparing men and women across the continuum of routine HIV care. This study quantifies differentials in HIV care, treatment and mortality outcomes for men and women over time in South Africa.

Methods: We analysed population-wide linked anonymized data, including vital registration linkage, for the Western Cape Province, from the time of first CD4 count. Three antiretroviral therapy guideline eligibility periods were defined: 1 January 2008 to 31 July 2011 (CD4 cell count <200 cells/μL), 1 August 2011 to 31 December 2014 (<350 cells/μL), 1 January 2015 to 31 August 2016 (<500 cells/μL). We estimated care uptake based on service attendance, and modelled associations for men and women with ART initiation and overall, pre-ART and ART mortality. Separate Cox proportional hazard models were built for each outcome and eligibility period, adjusted for tuberculosis, pregnancy, CD4 count and age.

Results: Adult men made up 49% of the population and constituted 37% of those living with HIV. In 2009, 46% of men living with HIV attended health services, rising to 67% by 2015 compared to 54% and 77% of women respectively. Men contributed <35% of all CD4 cell counts over 10 years and presented with more advanced disease (39% of all first presentation CD4 cell counts from men were <200 cells/μL compared to 25% in women). ART access was lower in men compared to women (AHR 0.79 (0.77 to 0.80) summarized for Period 2) over the entire study). Mortality was greater in men irrespective of ART (AHR 1.08 (1.01 to 1.16) Period 3) and after ART start (AHR 1.15 (1.05 to 1.20) Period 3) with mortality differences decreasing over time.

Conclusions: Compared to women, men presented with more advanced disease, were less likely to attend health care services annually, were less likely to initiate ART and had higher mortality overall and while receiving ART care. People living with HIV were more likely to initiate ART if they had acute reasons to access healthcare beyond HIV, such as being pregnant or being co-infected with tuberculosis. Our findings point to missed opportunities for improving access to and outcomes from interventions for men along the entire HIV cascade.

Keywords: HIV/AIDS; gender; access; mortality; antiretroviral therapy; South Africa

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1 | INTRODUCTION

South Africa has the largest antiretroviral therapy (ART) programme in the world [1,2]. Coverage of those eligible for ART is improving year-on-year [3] but men living with HIV continue to have inferior access to HIV care and treatment outcomes compared to women[4,5]. Improvements in mortality on ART are slowing, losses to care happen at all levels of the HIV cascade and a large number of patients, predominantly men, continue to present with advanced HIV disease in spite of the widespread access to ART [6,7]. Identifying patients who are less likely to test, present to care, start ART and remain on effective ART, provides opportunities to adjust service delivery models to be more responsive to the needs of these patients.

A range of studies have shown that men living with HIV in South Africa are less likely to access care than women, and present with more advanced disease [1,4,8]. Across the region, men on ART also have higher mortality than women after initiating antiretroviral drugs [5,9]. Any exploration of differential access to care requires consideration of the changing eligibility criteria for ART access. While patient cohorts and randomized trials have demonstrated reduced morbidity and mortality risks in patients accessing ART at higher CD4 cell counts [10],

there is limited real-world data from high HIV-burden countries exploring the impact of changing treatment guidelines on differential outcomes by sex.

The aim of this analysis is to describe in the Western Cape Province of South Africa, population-wide differences of men compared to women in presentation with HIV, access to ART and mortality on ART around the successive CD4 cell count eligibility thresholds as guidelines evolved.

2 | METHODS

2.1 | Setting and data sources

The Western Cape is one of nine provinces in South Africa, with a population of 6.7 million, an estimated 439,136 people living with HIV and 260,734 people on ART in 2018 [11]. The vast majority of people living with HIV seek care in the public sector. ART was first available in pilot projects as of 2001, and coverage accelerated after 2004 when ART provision became national policy [12]. CD4 cell count monitoring of all HIV positive patients has been provided since programme inception. In March 2013, CD4 cell count monitoring after one year on ART among virologically suppressed and clinically-well patients with CD4 ≥200 cells/μL was no longer recommended.

Full details of the ART programme evolution are described elsewhere [12-14]. From 2004 to March 2010, an adult was eligible for ART with a CD4 cell count <200 cells/μL or a World Health Organization (WHO) stage IV illness. In April 2010, national guideline revisions increased ART eligibility to include CD4 cell counts of 350 cells/μL for pregnant women and those with active tuberculosis (TB) [15]. In August 2011, eligibility was expanded to include all patients with a CD4 cell count <350 cells/μL [16]. In April 2013, all tuberculosis (TB) patients and pregnant women were eligible regardless of their CD4 cell count [17]. In January 2015, guidelines were changed again to expand eligibility to all patients with a CD4 < 500 cells/μL [18]. Finally, in September 2016, universal access was introduced, and all HIV infected people were eligible to start ART regardless of CD4 cell count as per WHO guidelines [2,19]. These changes for patients without other health conditions conferring ART eligibility are summarized into three CD4 cell count ART-eligibility eras in Tables 1 and 2 and referenced throughout this paper, period 1: 1 January 2008 to 31 July 2011 (CD4 cell count <200 cells/μL), period 2: 1 August 2011 to 31 December 2014 (CD4 cell count <350 cells/μL), period 3: 1 January 2015 to 31 August 2016 (<500 cells/μL).

All public-sector laboratory testing was done by the National Health Laboratory Service and province-wide digitized results were available from 2007 onwards. The province has successfully established a patient registration system which shares a unique health identifier and Patient Master Index (PMI) across both hospital and ambulatory services [20]. This has facilitated the linkage of data from hospital, laboratory and pharmacy sources, as well as electronic disease registers such as those for HIV and TB [3]. Information on deaths was extracted from the National Population Register (NPR) [21], which classified deaths as either natural or unnatural. The process of linking all data to the PMI is formalized through the Provincial Health Data Centre [22]. All data provided for analyses are pre-anonymized but linkable based on a privacy-preserving random key.

The study was approved by the Western Cape Department of Health and the University of Cape Town Human Research Ethics Committee. A waiver of consent was issued by the committee due to the use of anonymized data.

2.2 | Study population

The study population consisted of all patients seeking HIV treatment and care in the Western Cape public-sector health services with their first pre-ART CD4 cell count between 1 January 2007 and 31 August 2016. We followed up the study population for three years from their first CD4 cell count, with the last follow-up data in 2018. We excluded children and adolescents less than 16 years of age on the date of their pre-ART CD4 cell count, people without a CD4 test result prior to the ART start date, any record with a first CD4 specimen taken at hospital, and anyone recorded as having an unnatural death. We intentionally excluded patients tested in hospital to focus on patients with ambulatory-care CD4 cell counts who would be evaluated for ART eligibility based on CD4 cell count rather than co-morbidities (Figure 1).

2.3 | Study design and key variables

The study comprises a cohort survival analysis by sex of time to ART and time to death from natural causes. The survival analyses were restricted to patients with a South African identification (SA ID) number (57% of the total cohort), a requirement for linkage with data from the NPR [21]. A separate model was fitted for each eligibility time period and outcome.

HIV testing is often done outside healthcare facilities using point of care tests which do not get recorded into routine digital health records, therefore the first CD4 cell count for each patient was defined in this study as the first presentation to HIV care services. We have defined the proportion of patients utilising HIV services as the number of unique patients having a recorded encounter at health care facilities (lab test, visit data, medication pick up) divided by the number of prevalent cases for the same annual time period (2009, 2012, 2015, 2018), stratified by sex. Data from the NPR distinguish natural from non-natural causes. Mortality was defined as death from natural causes. Survival analyses were restricted to three years after first presentation with HIV.

We included sex, age, first CD4 cell count, TB and pregnancy as baseline variables in adjusted models for the survival analyses of time to ART and time to death after presentation or ART initiation. The data in the variable sex were split into three categories, men, non-pregnant women and pregnant women. Both CD4 cell counts (0 to 49, 50 to 99, 100 to 199, 200 to 349, 350 to 499, ≥500 cells/μL) and age (16 to 24, 25 to 34, 35 to 44, 45+) were analysed in the described categories. We added one day to death dates if the patient was recorded as dying on the date of entry into the analyses.

2.4 | Statistical analysis

The baseline characteristics of people living with HIV and with a SA ID recorded were described by sex with summary statistics (absolute number, proportions, medians and interquartile ranges (IQR)).

Table 1. HIV status and CD4 cell count results for the Western Cape population and the study population

CD4 count threshold time period	Western cape population							Study population				
	Men, N (%)		Women, N (%)		Total	Men, %	Women, %	Men, N (%)		Women, N (%)		Total
Incident cases[a]						Incidence (/100 py)[a]						
2009	9,219	(39)	14,180	(61)	23,399	0.48	0.71					
2012	8,491	(40)	12,882	(60)	21,373	0.42	0.62					
2015	7,874	(40)	11,826	(60)	19,700	0.37	0.54					
2018	6,457	(40)	9,830	(60)	16,287	0.28	0.43					
Prevalent cases[a]						Prevalence (%)[a]						
2009	103,334	(37)	173,366	(63)	276,700	5.10	7.99					
2012	123,565	(37)	210,192	(63)	333,757	5.73	9.18					
2015	143,662	(37)	246,777	(63)	390,439	6.25	10.11					
2018	161,050	(37)	278,086	(63)	439,136	6.62	10.75					
Unique patient visits/year						% of cases						
2009	47,268	(33)	94,111	(67)	141,379	46	54					
2012	74,889	(33)	148,671	(67)	223,560	61	71					
2015	96,386	(34)	190,914	(66)	287,300	67	77					
First CD4 count, per person												
Period 1	66,351	(34)	130,584	(66)	196,935			30,892	(29)	74,809	(71)	105,701
Period 2	56,664	(38)	93,929	(62)	150,593			31,303	(33)	60,368	(67)	91,671
Period 3	29,084	(39)	45,786	(61)	74,870			15,269	(34)	27,979	(66)	43,248
First CD4 count categories						% in period						
0 to 199												
Period 1	27,962	(44)	35,923	(56)	63,885	42	28	12,645	(40)	19,221	(60)	31,866
Period 2	20,780	(49)	21,235	(51)	42,015	37	23	11,568	(46)	13,408	(54)	24,976
Period 3	10,557	(52)	9,842	(48)	20,399	36	21	5,519	(49)	5,824	(51)	11,343
200 to 349												
Period 1	17,899	(33)	35,949	(67)	53,848	27	28	8,383	(29)	20,573	(71)	28,956
Period 2	15,085	(39)	23,381	(61)	38,466	27	25	8,217	(35)	15,009	(65)	23,226
Period 3	7,804	(41)	11,245	(59)	19,049	27	25	4,059	(37)	6,833	(63)	10,892
350 to 500												
Period 1	10,810	(28)	27,969	(72)	38,779	16	21	5,150	(24)	16,567	(76)	21,717
Period 2	10,373	(33)	21,106	(67)	31,479	18	22	5,692	(29)	13,605	(71)	19,297
Period 3	5,387	(34)	10,560	(66)	15,947	19	23	2,777	(30)	6,483	(70)	9,260
>500												
Period 1	9,680	(24)	30,743	(76)	40,423	15	24	4,714	(20)	18,448	(80)	23,162
Period 2	10,426	(27)	28,207	(73)	38,633	18	30	5,826	(24)	18,346	(76)	24,172
Period 3	5,336	(27)	14,139	(73)	19,475	18	31	2,914	(25)	8,839	(75)	11,753
Tuberculosis at first CD4						% in period						
Period 1	15,445	(53)	13,798	(47)	29,243	23	11	7,170	(50)	7,179	(50)	14,349
Period 2	12,870	(58)	9,261	(42)	22,131	23	10	7,359	(56)	5,802	(44)	13,161
Period 3	6,551	(61)	4,246	(39)	10,797	23	9	3,603	(58)	2,577	(42)	6,180
Pregnancy at first CD4						% in period						
Period 1			28,258	(100)	28,258		22			20,764	(100)	20,764
Period 2			17,348	(100)	17,348		18			13,335	(100)	13,335
Period 3			9,499	(100)	9,499		21			6,880	(100)	6,880
New ART enrolment												
Period 1	37,381	(32)	80,806	(68)	118,187			22,061	(28)	57,857	(72)	79,918
Period 2	36,738	(35)	67,089	(65)	103,827			22,743	(32)	47,974	(68)	70,717
Period 3	19,506	(36)	34,551	(64)	54,057			10,847	(33)	22,277	(67)	33,124

Table 1. (*Continued*)

CD4 count threshold time period	Western cape population						Study population				
	Men, N (%)		Women, N (%)		Total	Men, %	Women, %	Men, N (%)		Women, N (%)		Total
Deaths												
Period 1	12,951	(46)	15,346	(54)	28,297			8,895	(44)	11,468	(56)	20,363
Period 2	8,108	(52)	7,631	(48)	15,739			6,103	(50)	6,114	(50)	12,217
Period 3	2,646	(53)	2,300	(47)	4,946			1,888	(52)	1,756	(48)	3,644

[a]Thembisa Model outputs v4.2 for all > 14 years old (estimates for June each year) [28], (ART) antiretroviral therapy; (py) person years; (cs) cases; (Period 1) 1 January 2008 to 31 July 2011 [CD4 count eligibility <200 cells/μL]; (Period 2) 1 August 2011 to 31 December 2014 (CD4 count eligibility <350 cells/μL); (Period 3) 1 January 2015 to 31 August 2016 (CD4 count eligibility threshold <500 cells/μL). Please note: Absolute numbers are divided by the number of first CD4 count presentations in the same year for tuberculosis, pregnancy and CD4 count indicators.

Time to ART and time to death were analysed from the date of the first CD4 cell count. Time to death for those on ART was analysed from their ART initiation date, whereas the baseline CD4 count was at initial presentation and not necessarily ART initiation. We used Cox proportional hazards to assess crude and adjusted associations between baseline characteristics and mortality. Results are presented as adjusted hazard ratios with 95% confidence intervals. The proportional hazards assumption was tested using graphs and Schoenfeld residuals for sex, TB and pregnancy.

Data were analysed using STATA 14.2 (STATA Corporation).

3 | RESULTS

Men 15 years of age and older comprised 49% the population and constituted 37% of the population living with HIV in the Western Cape from 2008 through 2018 (Table 1). In the total cohort, men were less likely than women to be newly diagnosed with HIV by the health services (Table 1), although more recently the sex distribution of first-ever CD4 cell counts has tracked population prevalence more closely. Men were less likely (8% or more) to utilize health care services annually, with 46% of men estimated to be living with HIV recorded as attending health care in 2009, rising to 67% in 2015 (in comparison to 54% to 77% in women respectively). Men presented with more advanced HIV disease than women (39% of first-ever CD4 cell counts in men were <200 cells/μL over the entire study period in comparison to 25% in woman).

Men living with HIV and first accessing care were more than twice as likely as women to be co-infected with TB throughout the entire study period (23% of men vs. 10% of women) (Table 1). The co-infection proportion remained at 23% throughout each period for men but decreased slightly over time among women presenting to HIV care. The number of women pregnant at first CD4 test was about double that of women co-infected with TB in each period. Across all three eligibility eras, in the general and study populations, men were less likely to start ART than women. Overall, 62% of men and 67% of women who presented for their first CD4 test during the study started ART within three years of their first CD4 test.

Men were less likely to start ART and more likely to die, regardless of whether they started ART, throughout the study (Table 2), when compared to non-pregnant women. Illustratively, after adjusting for age, CD4 cell count, TB and pregnancy at baseline, men were 22% (adjusted hazard ratio [AHR] 0.78, 95% CI 0.76 to 0.79) less likely to start ART in comparison to woman during Period 1. Men had higher mortality overall (AHR 1.17, 95% CI 1.09 to 1.25 in the 200 cell/μL threshold), higher mortality in the first eligibility period prior to initiating ART (AHR 1.12, 95% CI 1.07 to 1.17) and higher mortality on ART (AHR 1.17, 95% CI 1.09 to 1.25 in the first era). Mortality pre-ART and mortality overall appear to be decreasing over time in comparison to women, narrowing the mortality difference.

Access to ART by sex was confounded by pregnancy, initial CD4 cell count and TB, with a proportion of women presenting pregnant, and men more likely to present with advanced disease or TB, each independently associated with ART access (Tables 2 and 3a). When considering crude hazard ratios, men, non-pregnant and pregnant women all had similar uptake of ART services. However, the adjusted hazard ratios in Period 2 for example, show that men who were not co-infected with TB had the lowest uptake, 21% less than non-pregnant women. TB and pregnancy remained independently associated with starting ART (34% and 17% more likely to initiative ART respectively), while there was a consistent inverse association after adjustment between CD4 count and starting ART (Table 3).

Mortality in people living with HIV was highly confounded by their baseline CD4 cell count, TB, pregnancy in women, and age (Tables 2 and 3b,c). Although men in Period 2 for example had higher mortality risk during pre-ART care compared to non-pregnant women prior to adjustment, this difference did not persist after adjustment (Tables 2 and 3b). Co-infection with TB was independently associated with a 55% increase in pre-ART mortality. As shown in (Table 1), men were twice as likely to be infected with TB when presenting to HIV care and therefore more likely to die during this interval prior to initiating ART. This association between TB and mortality persisted for all mortality outcomes in all periods. By contrast pregnancy and higher CD4 counts reduced the risk of mortality pre-ART, on ART and regardless of ART.

Table 2. Mortality for men, baseline characteristics and crude and adjusted hazard ratios as compared to non-pregnant women

Survival analysis	Threshold time period	Adults N (% men)	Median CD4 (M:W)	Median Age (M:W)	Deaths N (% men)	Men, crude HR (95% CI)	Men, AHR (95% CI)
Starting ART	Period 1	104,472 (29)	247:332	35:29	47,907 (31)	1.03 (1.01, 1.05)	0.78 (0.76, 0.79)
	Period 2	87,131 (35)	273:368	35:29	55,758 (34)	0.98 (0.96, 0.99)	0.79 (0.77, 0.80)
	Period 3	38,465 (39)	278:378	35:29	28,235 (37)	0.94 (0.91, 0.96)	0.80 (0.78, 0.82)
Survival analysis	**Threshold time period**	**Adults N (% men)**	**Median CD4 (M:W)**	**Median Age (M:W)**	**Deaths N (% men)**	**Men, crude HR (95% CI)**	**Men, AHR (95% CI)**
Pre-ART mortality	Period 1	104,472 (29)	247:332	35:29	8,914 (45)	1.71 (1.63, 1.78)	1.12 (1.07, 1.17)
	Period 2	87,131 (35)	273:368	35:29	4,919 (50)	1.47 (1.39, 1.56)	1.03 (0.97, 1.09)
	Period 3	38,465 (39)	278:378	35:29	1,532 (51)	1.24 (1.12, 1.38)	0.92 (0.83, 1.02)
ART mortality	Period 1	79,918 (28)	227:313	35:29	3,651 (45)	1.85 (1.73, 1.98)	1.17 (1.09, 1.25)
	Period 2	70,717 (32)	242:344	36:29	4,243 (50)	1.83 (1.72, 1.95)	1.14 (1.07, 1.21)
	Period 3	33,124 (33)	246:359	36:29	2,020 (52)	1.85 (1.69, 2.02)	1.15 (1.05, 1.26)
Mortality, irrespective of ART	Period 1	105,701 (29)	247:332	35:29	10,134 (46)	1.75 (1.68, 1.82)	1.17 (1.13, 1.23)
	Period 2	91,671 (34)	273:368	35:29	8,325 (50)	1.70 (1.63, 1.78)	1.13 (1.08, 1.18)
	Period 3	43,248 (35)	278:378	35:29	3,536 (52)	1.66 (1.55, 1.78)	1.08 (1.01, 1.16)

(Period 1) 1 January 2008 to 31 July 2011 (CD4 cell count eligibility <200 cells/μL); (Period 2) 1 August 2011 to 31 December 2014 (CD4 cell count eligibility <350 cells/μL); (Period 3) 1 January 2015 to 31 August 2016 (CD4 cell count eligibility threshold <500 cells/μL). Adjusted for baseline CD4 cell count and age categories, tuberculosis and pregnancy at first CD4 test. The analyses covered 3 years from first CD4 cell count or ART initiation (for ART mortality only). AHR, Adjusted hazard ratio; ART, antiretroviral therapy; CI, confidence interval; HR, Hazard Ratio; M:W, men vs. women; CD4, CD4 cell count in cells/μL; (N) number of people.

4 | DISCUSSION

Using clinical, laboratory, pharmaceutical and vital registry data linked at patient level for all adults with HIV in the Western Cape, we analysed differences for men and women in the HIV cascade over the past decade. Overall, men were less likely to present for HIV care than women, represented in this analysis by their first recorded CD4 cell count, and more likely to be diagnosed due to concurrent TB infection. In analyses limited to patients with SA IDs, across all three eligibility eras, men consistently had both lower health care utilization and enrolment on ART and higher mortality across the entire cascade.

4.1 | Presenting with HIV and accessing HIV care

Late presentation has been cited as one of the main reasons for ongoing HIV-associated morbidity and for mortality after starting ART, especially in men [5-6,9]. Although women and men presented earlier to HIV care over time based on first CD4 cell count values, the trend was more pronounced in women.

Whereas our findings in the earlier periods concur with other studies which have found men less likely to access HIV care in similar settings [23,24], we observed a narrowing of this differential in later periods of this study, approaching what would be expected based on sex-specific HIV prevalence estimates. Men continued to present with lower CD4 cell counts and have a larger proportion of TB co-infection, which seems to be increasing over time. In addition, numerous studies have found that women, via reproductive health services, have more opportunities to test for HIV and therefore present earlier for care and treatment while not otherwise symptomatic [23-25]. This study's results validate that finding, showing pregnant women were 38% more likely to access ART in comparison to men not infected with TB. Recently scaled-up interventions that increase uptake of HIV and TB testing and care by men, such as community-based mobile testing units, may be contributing to the gains in access to HIV care seen in men in recent eligibility eras of this study [24,26,27]. Model results by Johnson et al. in 2019, have also estimated lower HIV testing among men (84.5% vs. 91.2% in women), as well as lower testing (irrespective of sex) in adolescent age groups compared to adults. The MicroCOSM model results suggest home-based testing coupled with the opportunity of self-testing will most likely yield the greatest increase of newly diagnosed people infected with HIV by 2030 and increase the fraction of both men and young adults tested [28]. Changes may also be due to a saturation effect being reached in women earlier than in men, due to the higher proportion of women who already know their HIV status [29].

4.2 | Antiretroviral therapy access

Men continue to have lower rates of ART enrolment after their first eligible CD4 cell count. Across all three time periods, men were 20% to 22% less likely to start antiretroviral drugs and therapy and that estimation held relatively stable regardless of eligibility era. In the adjusted model, the divergence to poorer ART initiation in men was largely driven by

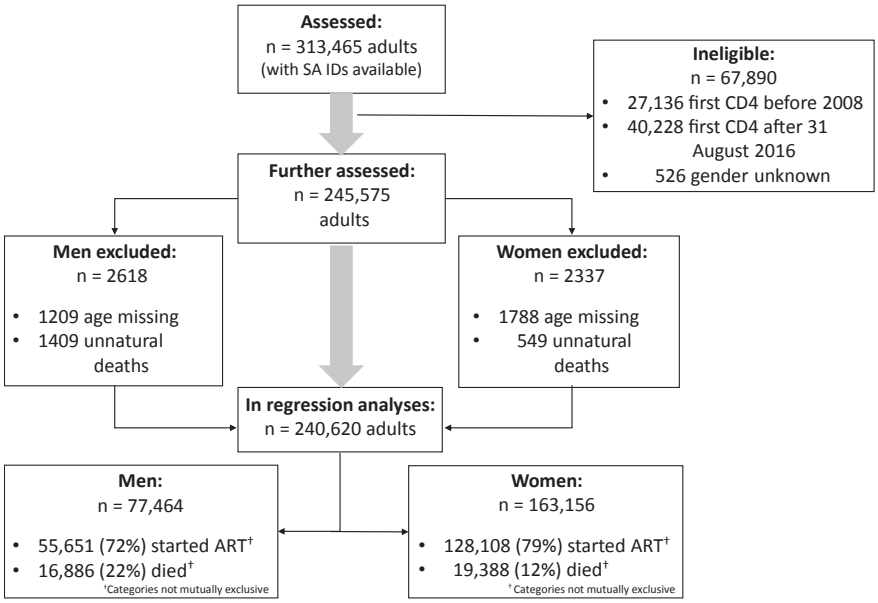

Figure 1. Patient flow chart describing the cohort of patients included in the survival analyses.

TB co-infection (largely among men) and pregnancy amongst women. Men not co-infected with TB were 21% less likely to start ART than non-pregnant women, and 38% less likely than pregnant women (summarized for Period 2). When comparing men with and without TB co-infection, men not co-infected were 26% less likely to start ART. Pregnancy and TB infection provide a natural entry point to health care as well as HIV testing and treatment. Poorer access for men to treatment has been widely noted [24,28,30]. This study provides strong evidence of the need for clinical service interventions oriented to assisting men (specifically those not accessing health services for other reasons) link to ART care after initial presentation.

4.3 | Mortality after initial CD4 cell count assessment

Although men had increased pre-ART mortality compared to women in Period 1 of the study, this difference narrowed over time as CD4 cell count criteria widened to include people earlier in HIV disease progression. As men continue to present to HIV services with more advanced HIV disease [6], specific diagnostic interventions for co-morbidities associated with advanced HIV disease are needed. These include a Lipoarabinomannan (LAM) antigen tests for TB and cryptococcosis (CrAg) antigen tests, which could be guided by immunodeficiency represented by CD4 cell count testing [31]. Alternatively, in countries where routine CD4 cell counts are not done at baseline, interventions could be based on algorithms for advanced disease risk in which sex may play a role.

4.4 | Mortality after ART initiation

Men continued to have inferior mortality outcomes on ART over the ten years of this study. Similar results have been widely published [5,8,30,32]. In our analyses, deficits in life expectancy appear largely related to HIV and TB [32], with men showing higher rates of TB co-infection across all eligibility eras. Although similar or greater mortality differentials were observed even in those who were HIV uninfected [5], interventions targeting men, their retention in care, and the co-morbidities associated with their advanced disease at ART initiation, are warranted.

4.5 | Interventions to address the access and treatment gaps for men

There have been some successful interventions designed to increase uptake by men carried out in the Western Cape such as the clinics for men [33,34] in the services run by the local authority, and the after-hours clinics in Khayelitsha and other areas [35]. These types of services should develop best practice guidelines and be considered for scale-up where appropriate across South Africa. Nationally and regionally, a range of interventions have been tested to address gaps in the supply and demand side of men's access to, and uptake of, HIV services [36]. On the supply side, community-based projects include testing at home and in the workplace, in index patients, partners of pregnant patients, shebeens, sports centres, shopping centres, mobile facilities and through campaigns including the provision of incentives [37], although many of the pilot projects are not scalable, and linkage to care remains challenging. The high uptake of HIV self-testing within facilities by men suggests a possible universal entry point for testing, given that in Malawi, 80% of those who needed testing had visited a facility within the last two years [38]. On the demand side, most interventions are community-based, integrated with work on gender equity and reducing gender-based violence [36], and focus on individual-level behaviour change. At an international level, UNAIDS launched a report 'Blind spot: reaching out to men and boys' and held a regional consultation in May 2019 to workshop a plan to accelerate men's uptake of HIV services in the region. In July 2019, the IAS convened the first-ever Men and HIV Forum prior to the 10th IAS Conference on HIV Science, the WHO has

Table 3. Cox proportional hazard models for associations with starting ART and with mortality in HIV and ART care

	Period 1				Period 2				Period 3			
	HR	95% CI	AHR	95% CI	HR	95% CI	AHR	95% CI	HR	95% CI	AHR	95% CI
a. Starting ART												
Sex												
Women	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
Men	1.03	(1.01, 1.05)	0.78	(0.76, 0.79)	0.98	(0.96, 0.99)	0.79	(0.77, 0.80)	0.9	(0.91, 0.96)	0.80	(0.78 to 0.82)
Pregnant	0.62	(0.60, 0.64)	0.82	(0.80, 0.84)	1.00	(0.97, 1.02)	1.17	(1.14, 1.20)	1.2	(1.20, 1.29)	1.36	(1.31, 1.41)
Tuberculosis	2.05	(2.00, 2.10)	1.16	(1.14, 1.19)	1.96	(1.92, 2.01)	1.34	(1.31, 1.37)	1.61	(1.56, 1.67)	1.36	(1.32, 1.41)
Age												
15 to 24	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
25 to 34	1.48	(1.44, 1.52)	1.20	(1.17, 1.23)	1.13	(1.11, 1.16)	1.01	(0.99, 1.04)	1.06	(1.02, 1.09)	1.00	(0.97, 1.03)
35 to 44	1.84	(1.79, 1.89)	1.33	(1.29, 1.37)	1.27	(1.24, 1.30)	1.08	(1.04, 1.10)	1.15	(1.11, 1.29)	1.07	(1.03, 1.11)
≥45	1.80	(1.74, 1.86)	1.25	(1.21, 1.30)	1.20	(1.16, 1.23)	1.02	(0.99, 1.06)	1.12	(1.08, 1.17)	1.07	(1.03, 1.11)
First CD4												
0 to 49	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
50 to 99	1.07	(1.03, 1.11)	1.09	(1.05, 1.13)	1.08	(1.03, 1.12)	1.10	(1.06, 1.15)	1.07	(1.00, 1.14)	1.11	(1.04, 1.18)
100 to 199	0.94	(0.91, 0.98)	1.00	(0.96, 1.03)	0.90	(0.87, 0.94)	0.96	(0.93, 1.00)	0.98	(0.93, 1.04)	1.07	(1.02, 1.13)
200 to 349	0.46	(0.45, 0.48)	0.50	(0.48, 1.03)	0.75	(0.72, 0.77)	0.81	(0.78, 0.84)	0.87	(0.83, 0.92)	0.97	(0.92, 1.02)
350 to 499	0.20	(0.19, 0.21)	0.22	(0.21, 0.23)	0.36	(0.35, 0.38)	0.39	(0.38, 0.41)	0.79	(0.75, 0.83)	0.87	(0.82, 0.92)
≥500	0.09	(0.08, 0.09)	0.10	(0.09, 0.10)	0.23	(0.22, 0.24)	0.25	(0.24, 0.26)	0.40	(0.38, 0.42)	0.43	(0.41, 0.46)
b. Pre-ART Mortality												
sex												
Women	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
Men	1.71	(1.63, 1.78)	1.12	(1.07, 1.17)	1.47	(1.39, 1.56)	1.03	(0.97, 1.09)	1.24	(1.12, 1.38)	0.92	(0.83, 1.02)
Pregnant	0.43	(0.40, 0.47)	0.70	(0.65, 0.75)	0.34	(0.92, 0.39)	0.60	(0.52, 0.69)	0.41	(0.30, 0.54)	0.70	(0.52, 0.94)
Tuberculosis	3.40	(3.24, 356)	1.43	(1.36, 1.51)	4.25	(4.00, 4.53)	1.55	(1.44, 1.66)	4.83	(4.35, 5.37)	1.86	(1.66, 2.10)
Age												
15 to 24	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
25 to 34	1.96	(1.82, 2.10)	1.50	(1.39, 1.61)	2.08	(1.85, 2.32)	1.61	(1.43, 1.80)	2.57	(2.03, 3.25)	1.91	(2.51, 2.42)
35 to 44	3.60	(3.35, 3.88)	2.19	(2.02, 2.36)	3.84	(3.43, 4.30)	2.43	(2.16, 2.73)	4.91	(3.89, 6.20)	3.00	(2.37, 3.80)
≥45	6.60	(6.12, 7.11)	3.49	(3.23, 3.78)	7.49	(6.70, 8.34)	4.26	(3.79, 4.78)	8.97	(7.15, 11.26)	5.03	(3.99, 6.35)
First CD4												
0 to 49	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
50 to 99	0.79	(0.73, 0.85)	0.85	(0.78, 0.91)	0.84	(0.76, 0.93)	0.90	(0.81, 0.99)	0.75	(064, 0.89)	0.85	(0.72, 1.00)
100 to 199	0.46	(0.43, 0.50)	0.59	(0.55, 0.64)	0.45	(0.41, 0.50)	0.58	(0.54, 0.63)	0.40	(0.34, 0.46)	0.55	(0.47, 0.65)
200 to 349	0.21	(0.20, 0.23)	0.32	(0.30, 0.35)	0.21	(0.19, 0.23)	0.33	(0.30, 0.36)	0.17	(0.15, 0.20)	0.30	(0.25, 0.35)

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Table 3. (*Continued*)

	Period 1				Period 2				Period 3			
	HR	**95% CI**	**AHR**	**95% CI**	**HR**	**95% CI**	**AHR**	**95% CI**	**HR**	**95% CI**	**AHR**	**95% CI**
350 to 499	0.11	(0.10, 0.12)	0.18	(0.17, 0.20)	0.11	(0.10, 0.12)	0.19	(0.17, 0.21)	0.10	(0.86, 0.13)	0.19	(0.15, 0.23)
≥500	0.85	(0.08,0.09)	0.14	(0.13, 0.15)	0.09	(0.08, 0.09)	0.14	(0.13, 0.15)	0.07	(0.06, 0.84)	0.18	(0.11, 0.15)
c. ART mortality												
Sex												
Women	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
Men	1.85	(1.73, 1.98)	1.17	(1.09, 1.25)	1.83	(1.72, 1.95)	1.14	(1.07, 1.21)	1.85	(1.69, 2.02)	1.15	(1.05, 1.26)
Pregnant	0.41	(0.36, 0.47)	0.74	(0.65, 0.85)	0.40	(0.35, 0.46)	0.69	(0.60, 0.79)	0.29	(0.23, 0.34)	0.49	(0.40, 0.61)
Tuberculosis	0.59	(3.35, 3.84)	1.51	(1.40, 1.62)	3.90	(3.66, 4.14)	1.70	(1.59, 1.82)	4.15	(3.80, 4.54)	1.88	(1.70, 2.08)
Age												
15 to 24	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
25 to 34	2.03	(1.80, 2.29)	1.36	(1.20, 1.54)	2.00	(1.77, 2.25)	1.36	(1.21, 1.54)	2.48	(2.05, 3.00)	1.79	(1.48, 2.17)
35 to 44	3.74	(3.31, 4.24)	1.96	(1.73, 2.23)	3.77	(3.34, 4.24)	2.00	(1.77, 2.26)	4.61	(3.81, 5.58)	2.44	(2.01, 2.97)
≥45	6.36	(5.60, 7.23)	3.32	(2.90, 3.79)	6.57	(5.83, 7.41)	3.51	(3.10, 3.97)	9.11	(7.56, 10.97)	4.81	(3.97, 5.82)
First CD4												
0 to 49	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
50 to 99	0.59	(0.54, 0.65)	0.65	((0.58, 0.71)	0.59	(0.54, 0.65)	0.63	(0.57, 0.69)	0.63	(0.55, 0.73)	0.70	(0.60, 0.80)
100 to 199	0.33	(0.30, 0.36)	0.41	(0.38, 0.45)	0.33	(0.30, 0.36)	0.42	(0.39, 0.46)	0.38	(0.34, 0.44)	0.52	(0.46, 0.60)
200 to 349	0.15	(0.13, 0.16)	0.21	(0.19, 0.23)	0.16	(0.14, 0.36)	0.24	(0.22, 0.27)	0.17	(0.15, 0.20)	0.30	(0.26, 0.34)
350 to 499	0.07	(0.06, 0.85)	0.11	(0.10, 0.13)	0.10	(0.09, 0.11)	0.17	(0.15, 0.19)	0.11	(0.09, 0.13)	0.21	(0.18, 0.25)
≥500	0.04	(0.03, 0.05)	0.07	(0.05, 0.08)	0.07	(0.06, 0.08)	0.12	(0.10, 0.14)	0.10	(0.09, 0.12)	0.21	(0.17, 0.25)
d. Overall mortality												
Sex												
Women	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
Men	1.75	(1.68, 1.82)	1.18	(1.13, 1.23)	1.70	(1.63, 1.78)	1.13	(1.08, 1.18)	1.66	(1.55, 1.78)	1.08	(1.01, 1.16)
Pregnant	0.38	(0.35, 0.41)	0.68	(0..62, 0.73)	0.32	(0.29, 0.35)	0.56	(0.50, 0.62)	0.27	(0.23, 0.33)	0.47	(0.40, 0.56)
Tuberculosis	3.34	(3.20, 3.48)	1.46	(1.39, 1.52)	3.74	(3.58, 3.91)	1.55	(1.47, 1.63)	4.20	(3.92, 4.49)	1.74	(1.61, 1.87)
Age												
15 to 24	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
25 to 34	2.03	(21.88, 2.18)	1.45	(1.34, 1.56)	2.07	(1.89, 2.56)	1.48	(1.35, 1.62)	2.57	(2.21, 2.98)	1.88	(1.62, 2.19)
35 to 44	3.64	(3.38, 3.92)	2.07	(1.92, 2.24)	3.91	(3.58, 4.27)	2.20	(2.01, 2.41)	4.93	(4.25, 5.71)	2.71	(2.33, 3.16)
≥45	6.96	(6.45, 7.51)	3.91	(3.61, 4.23)	7.81	(7.15, 8.52)	4.38	(4.01, 4.80)	9.98	(8.63, 11.53)	5.47	(4.71, 6.34)
First CD4												
0 to 49	1	ref	1	ref	1	ref	1	ref	1	ref	1	ref
50 to 99	0.56	(0.53, 0.60)	0.61	(0.57, 0.65)	0.59	(0.55, 0.63)	0.62	(0.57, 0.66)	0.58	(0.52, 0.65)	0.06	(0.57, 0.70)
100 to 199	0.30	(0.28, 0.32)	0.37	(0.35, 0.39)	0.31	(0.29, 0.33	0.39	(0.37, 0.42)	0.32	(0.29, 0.35)	0.04	(0.39, 0.47)

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Table 3. (*Continued*)

	Period 1				Period 2				Period 3			
	HR	95% CI	AHR	95% CI	HR	95% CI	AHR	95% CI	HR	95% CI	AHR	95% CI
200 to 349	0.16	(0.15, 0.17)	0.23	(0.22, 0.25)	0.15	(0.14, 0.16)	0.22	(0.20, 0.24)	0.14	(0.13, 0.16)	0.24	(0.21, 0.27)
350 to 499	0.10	(0.09, 0.11)	0.15	(0.14, 0.16)	0.10	(0.09, 0.11)	0.17	(0.15, 0.18)	0.09	(0.08, 0.10)	0.17	(0.14, 0.19)
≥500	0.07	(0.06, 0.08)	0.11	(0.10, 0.12)	0.09	(0.08, 0.09)	0.14	(0.13, 0.15)	0.09	(0.08, 0.10)	0.16	(0.14, 0.18)

Category; (Period 1) 1 January 2008 to 31 July 2011 [CD4 count eligibility <200 cells/μL]; (Period 2) 1 August 2011 to 31 December 2014 (CD4 count eligibility <350 cells/μL); (Period 3) 1 January 2015 to 31 August 2016 (CD4 count eligibility threshold <500 cells/μL). Sex was split into three mutually exclusive categories, men, women and pregnant women. The analyses covered three years from first CD4 count for a, b and d, and from ART initiation for c. (AHR) Adjusted hazard ratio; ART, antiretroviral therapy; CI, confidence interval; HR, crude Hazard Ratio; ref, reference.

established a working group on the issue, and PEPfAR announced the MenStar public-private collaboration to increase HIV services for men.

4.6 | Strengths and limitations

The population-wide linked dataset with mortality data from vital registration is a strength of this study. The study was restricted to those with vital registry linkage (57% of the cohort), but results were similar in patients with and without available civil identifiers, supporting the generalizability of our findings. A further limitation is that in the early eligibility era, it is unclear whether CD4 cell counts were from first-ever presentation to HIV services. Linked CD4 cell count data were only available from 2007 and some patients would have been in care prior to the first CD4 cell count available for the analysis.

5 | CONCLUSIONS

Exploring a provincial HIV cascade over ten years, men continued to present with more advanced disease, were less likely to attend HIV care services at least annually, were less likely to initiate ART, were less impacted by guideline provisions and had inferior on-ART outcomes. Our findings point to missed opportunities for improving access to and outcomes from interventions for men along the entire HIV cascade.

ART services, offered for free in the public sector, have been rapidly scaled-up in unprecedented magnitude globally, reducing HIV incidence and mortality. However, men have not benefited from these services as much as women due to low uptake. Women and men living with HIV and accessing health care for non-HIV services are more likely to start ART, with pregnant women 38% more likely and non-pregnant women 21% more likely to start ART than men not co-infected with TB. In addition, men co-infected with TB are 5% more likely to start ART than non-pregnant women and more likely to die while on ART. These results highlight a need to improve ways of enrolling and retaining otherwise healthy people living with HIV in antiretroviral care.

COMPETING INTEREST

The authors have no competing interests to declare.

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AUTHORS' CONTRIBUTIONS

MO, AB and MC conceptualized the paper. MO, AB and KH analysed the data. MO, AB, MC, KH, EG and NF wrote the paper. All authors approved the final draft for submission.

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VIEWPOINT

"Khotla Bophelong Bo Botle": a gathering of men for health

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Keywords: primary healthcare; male clinic; chronic disease; differentiated care; HIV care continuum

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Person-centered care through integration of services and engaging clients in their own care is essential to achieving epidemic control of HIV. Verticalization of services along the care continuum contributes to inequities in access to care and leads to stigma and discrimination [1,2]. Our experience implementing an integrated model of primary healthcare (PHC) services at Scott Hospital in Lesotho show that even in a country where one in four adults are living with HIV and substantial national and international resources have been expended over the past 15 years, clients want and expect holistic care.

Men in Lesotho are rarely first in line at health clinics and often do not seek healthcare until their condition becomes severe. PHC, the foundation of service delivery in the country, largely caters to women of reproductive age and children under five years of age; the majority (80%) of healthcare providers are women. While HIV prevalence in Lesotho is substantially higher among women than men 15-49 years of age (28.8% vs. 18.5%), men living with HIV are less likely to know their status than women or be virally suppressed [3-5]. The 2016 Lesotho Population-Based Impact Assessment revealed that men 35-49 years of age had the highest incidence of HIV at 2.7%, higher than among girls 15-24 years of age (1.6%) [5]. The inequities related to health information and care goes beyond HIV services. More than half of men 15-49 years of age who participated in the Demographic Health Survey of 2014 had never had their blood pressure measured (58.5%), and men were less likely to seek treatment when experiencing symptoms associated with tuberculosis, the second leading cause of death in Lesotho [6].

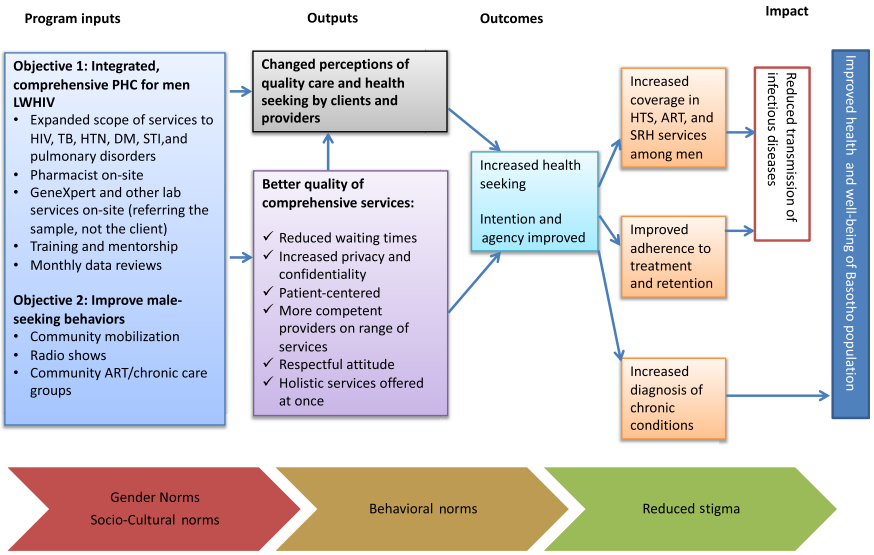

Figure 1. Theory of change for engaging and maintaining men in care.

In June 2016, Jhpiego collaborated with the Ministry of Health and Scott Hospital in Morija to transition an outpatient department (OPD) offering voluntary medical male circumcision into a "male clinic" offering comprehensive outpatient services for men, drawing on Jhpiego's model of continuous engagement of men in defining their own healthcare needs. Prior to the establishment of the male clinic, men living with HIV seeking routine care queued with women and children in the general OPD of the hospital where two rooms are allocated for HIV services; men living with other chronic diseases or seeking acute care services queued in general OPD. In early 2016, the idea of a "male clinic" model was not readily accepted but its success rested on the foundation that it was designed with male clients to define, attract and comprehensively meet the needs of Basotho men, an underserved population in the health sector. The model of care is based upon a Theory of Change that takes into consideration cultural and gender norms and burden of disease in the country (Figure 1). Principles of the clinic are to address client needs holistically, providing comprehensive, integrated, person-centered care, to address stigma and improve health outcomes. Based on continuous feedback by clients, the clinic is a specific space for men and is predominately staffed by male healthcare professionals, expanding services offered to focus on the person; scheduling appointments, and making every effort to have clients seen by the same provider at each visit. It is not a clinic for men living with HIV; it is a clinic where any man can access essential healthcare services – acute or chronic – in an environment that facilitates peer support.

Within the first six months of the clinic opening, evolving insights from men led to the refinement of the model of care, including the branding of the male-centered services as "Khotla" meaning "where men gather," a term that has deep cultural roots in Lesotho, eliciting a sense of confidentiality and importance among men. The longer phrase, "Khotla Bophelong Bo Botle," specifically means "A gathering of men for health" in Sesotho. Today, key differences in care offered at Khotla compared to typical antiretroviral therapy (ART) and PHC clinics across the country include: reserved space and time for services offered to only men; higher male/female provider ratio; flexible routine clinic days (Monday to Saturday); and continuous consultation with clients to redefine services in order to evolve the model of care.

The average age of clients served is 48 years, and men come from all corners of this small, mountainous country. A mapping of clients enrolled in longitudinal care (men living with HIV and/or diabetes, hypertension or other chronic disease) in 2016/2017 revealed that men from all 10 districts travelled to Khotla at Scott Hospital despite decentralized ART and PHC services. Person-centered respectful healthcare services need to be standard of care at the most decentralized level to ensure no one is left behind. In June 2017, the Ministry of Health began the expansion of the male clinic model to additional facilities across the country in collaboration with various partners, and as of September 2019 there were 20 "male clinics," expanding essential care to men.

The Khotla model of care has shown to reach men who perhaps would not otherwise have been reached with essential healthcare services, as evidenced by the broad geographical distribution of clients served. The highest HIV incidence in Lesotho is among this "differentiated population" [7].

Implementation of comprehensive care necessitates expansion of PHC services for the population being served, and has been limited by the inability to address male-specific needs including chronic, non-communicable conditions that are not prioritized in health funding. To close the gender gap in HIV testing and treatment, differentiated care for integrated, quality, male-centered clinical services must be scaled up with fidelity and healthcare needs of men – beyond HIV – have to be considered to keep clients engaged in lifelong healthcare. Context is fundamental to reaching men, as there are different social and cultural barriers and enablers that impact demand for and offering of services.

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COMPETING INTERESTS

Neither author has a conflict of interest.

AUTHORS' CONTRIBUTIONS

SS contributed substantially to the concept and design of the model; AR, Jhpiego/Lesotho Country Director, has overseen project implementation of the model and co-wrote the Viewpoint.

ABBREVIATIONS

ART, antiretroviral therapy; OPD, outpatient department; PHC, primary healthcare.

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The "front-line" clinicians of Khotla are the first to be recognized, as they are the reason why the clinic is a success. Similarly, the clients themselves have designed the model of care they, themselves want and expect to receive. There are a multitude of others who contribute to the past and current success of Khotla, including Polo Matsinyane who oversees day-to-day recording and reporting; Makeneiloe Ramapepe who previously led implementation; Dr. Nestor Ngoy and other members of the Scott Hospital Management Team; clinical staff of Scott Hospital who assist with implementation; Polo Motsoari, Jhpiego Sr. Communications Officer, her team and the media outlets they engaged; and Dr. Limpho Maile of the Ministry of Health who facilitated scale-up of the model.

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DISCLAIMER

None declared.

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RESEARCH ARTICLE

Gendered health institutions: examining the organization of health services and men's use of HIV testing in Malawi

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Abstract

Introduction: Men in sub-Saharan Africa are less likely to use HIV testing services than their female counterparts. Norms of masculinity are frequently cited as the main barrier to men's use of HIV testing services, but very little is known about how health institutions are organized to facilitate or impede men's care. We examined the organization of health institutions in Malawi, and implications for men's use of HIV testing services.

Methods: A mixed methods ethnography was conducted in Malawi between October 2013 and September 2014. National Ministry of Health guidelines from 2012 to 2014 were analysed, counting the frequency of recommended preventative services by sex. In-depth interviews were conducted with 18 healthcare workers and 11 national key informants (29 total). Five rural health facilities participated in direct observation and 52 observational journals were completed to document the structure and implementation of HIV services within local facilities. All data were analysed using the theory of gendered organization. Findings were grouped into one of the three theoretical levels of organization: (1) organizational policy; (2) organizational practice; and (3) structure of gendered expectations.

Results: Health institutions were gendered across three levels. *Organizational policy*: National guidelines omitted young and adult men's health during reproductive years (176-433 recommended visits for women vs. 32 visits for men). Health education strategies focused on reproductive and child health services, with little education strategies targeting men. *Organizational practice*: HIV testing was primarily offered during reproductive and child health services and located near female-focused departments within health facilities. As these departments were women's spaces, others could easily tell that men were using HIV services. *Structure of gendered expectations*: Clients who successfully accessed HIV testing services were perceived as exemplifying characteristics that were traditionally considered feminine: compliance (obeying instructions without explanation); deference (respecting providers regardless of provider behaviour); and patience ("waiting like a woman").

Conclusions: Health institutions in Malawi were organized in ways that created substantial, multilevel barriers to men's HIV testing and reinforced perceptions of absent, difficult men. Future research should prioritize a gendered organization framework to understand and address the complex realities of men's constrained access to HIV services.

Keywords: gender health disparities; health institution; HIV; HIV testing; men; sub-Saharan Africa

Additional Supporting Information may be found online in the Supporting information tab for this article.

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1 | INTRODUCTION

Men in sub-Saharan Africa are less likely than women to test for HIV, initiate treatment and remain in antiretroviral therapy programmes [1]. Men's absence from HIV testing services is particularly concerning given that HIV testing is the entry point for all other HIV services [2]. Across eight countries in sub-Saharan Africa, 22% of men living with HIV remain undiagnosed compared to 10% of women[3]. In recent years, extensive efforts have been made to better engage men [4], however, gender disparities in HIV testing likely still remain [3]. Importantly, men are also underrepresented in other health services, such as tuberculosis [5]. In light of the persistent gender disparities in HIV and other health services, there is an urgent need to identify institutional barriers to men's use of services, and interventions to resolve them.

The structure of health institutions and *how* health services are offered matters. Men are less likely to use HIV testing services when providers are perceived as rude [6-7], testing services are not private [8], services are offered at inconvenient hours [9], or require long travel or wait times [8]. The organization of HIV programmes at the national and international

level may also contribute to men's underrepresentation in care. In an analysis of 146 World Health Organization global or regional HIV guidelines, women were three-times more likely to be mentioned than men (13,882 vs. 4, 302) [10]. Men's representation improved slightly when excluding publications dedicated to children, women and prevention of mother-to-child transmission (PMTCT), however, even in "gender neutral" documents, women were still twice as likely to be mentioned as men (7,719 vs. 3,697 times). Similarly, among 119 policy documents from the President's Emergency Plan for AIDS Relief, men were rarely mentioned, and when they were, men were often portrayed as perpetrators of the epidemic [11]. Men's absence from international guidelines is important because such documents largely shape national policies, and in turn, the structure of HIV services in local health facilities [12,13]. Donor guidelines and priorities are especially influential in countries that rely heavily on donors to fund national programmes. For example, in 2016 only 14% of the Malawi HIV response was funded domestically [14].

To date, extensive work has been done describing barriers to men's access to services both on the supply and demand side, but gaps remain. On the supply side, research has focused on narrow components of health institutions, such as patient–provider interactions or the structure of individual services [9]. There is limited knowledge about *how* health institutions are gendered across multiple levels of health policy, practice and patient–provider interactions. On the demand side, narrow and constraining norms of masculinity, characterized by physical strength, aggression, sexual performance and sexual risk taking, have been shown to limit men's use of HIV and other health services [13, 15]. However, most research has focused on how harmful gender norms influence healthcare seeking behaviour among individual men. Little is known about how these same gender norms are embedded within, and perpetuated through, the organization of health institutions.

Health institutions, like other social organizations, are shaped by dominant social norms and social inequalities [16]. The few studies that have explored how health institutions are organized have found that men in various regions had fewer opportunities than women to engage with health institutions, and with HIV testing services more specifically [17-20]. We build on this work by examining the gendered organization of health institutions across multiple levels in Malawi, and whether institutions are structured to facilitate health services utilization for one gender over the other.

We applied the theory of gendered organization that asserts that organizations are built on and reproduce not only gender norms, but also gender inequalities [16]. The theory has been predominantly applied to women's entry and advancement in traditionally male occupations [21, 22]. The theory posits that organizations shape and reaffirm harmful gender norms across three levels (examples given from literature on women in the workplace): (1) *organizational policy*, including the absence of maternity leave, breastfeeding accommodations and protection against sexual harassment [23]; (2) *organizational practice*, such as impromptu high-level meetings after work hours [24]; and (3) the *structure of gendered expectations*, such as when traditionally male characteristics are required for success within the organization, for example commitment to full-time or intensive careers over family obligations [25, 26].

We examined how Malawi's health institutions are organized, and the implications of gendered health institutions on men's use of HIV testing services.

2 | METHODS

2.1 | Study design

We analysed mixed methods data from an ethnographic study conducted in Malawi between October 2013 and September 2015. The full protocol is described elsewhere [12]. The study included: national health policy documents; in-depth interviews with providers and key informants; and observations of HIV services offered within five health facilities in Zomba District, Malawi. Facilities within Zomba varied in size and location, ranging from a large central hospital to smaller rural facilities. The district had an 11% HIV prevalence at the time of the study [27] and men comprised 35% of all adult HIV testers [28].

2.2 | Data collection

2.2.1 | *National policy*

We analysed national health policy and guideline documents published between 2010 to 2015 from the Malawi Ministry of Health (n=6) [29-34]. We included national guidelines for broader health services (not just HIV services) because these can influence how men and women engage with health institutions, and provide key opportunities for HIV education and provider-initiated HIV testing [13]. National policies and recommendations can inform how local health facilities are organized and how men and women understand their role in the health system [12]. Across all policies, we summarized preventative health services recommended for men and women of reproductive age (15-44 years), capturing the age groups with the highest risk of HIV infection for both men and women [27].

2.2.2 | *In-depth interviews*

Four research assistants conducted 29 in-depth interviews: 18 with healthcare providers (including the chief or "in-charge" for each facility and providers who offered HIV testing services) and 11 with national-level key informants (HIV policy makers within the Ministry, HIV programme managers and local HIV researchers). Interview guides focused on: (1) implementation of HIV testing policies; (2) perception of men as clients; and (3) perception of barriers to men's use of HIV testing services. Oral consent was attained from all respondents. Interviewers and respondents were matched by gender. Interviews lasted approximately 45 minutes and were conducted in either Chichewa or English. All interviews were recorded, transcribed and translated into English (if necessary).

2.2.3 | *Observational journals*

Observational journals were conducted by the same four research assistants at five health facilities in Zomba, Malawi. Observational journals are a form of local ethnography used to examine the social dimensions of HIV in sub-Saharan Africa

[28-30]. Observational journals are well suited to capture practices within a health institution: documenting what people say and how they interact with one another within the health facility, which can be different from what they report in traditional research settings [29]. While observational journals cannot capture all events within one setting, they provide an important overview of common interactions and conversations within routine settings [29].

Research assistants took detailed field notes about observed interactions. At the end of each day, field notes were compiled into detailed observational journals, describing the content and context of interactions. Observational journals documented: (1) location of HIV testing services within the health facility, as well as services offered near HIV testing; (2) times when HIV testing was offered; (3) composition of clients in the waiting spaces near HIV testing services and (4) interactions between clients, and between clients and providers within waiting spaces, including clinic protocols observed. HIV testing consultations were not observed. Research assistants captured general interactions within the facility, and not only barriers for men. Observational journals were conducted over a five-month period, with research assistants spending a consecutive 4 to 8 weeks observing each facility on a full-time basis. Fifty-two observational journals (20-typed pages each) were completed in English. Descriptions of the activities were consistent across research assistants, providing confidence in their accuracy.

2.3 | Data analysis

For national guidelines, we used simple count techniques to count the number of health visits required annually and cumulatively (from 15 to 44 years) for men and women to meet national preventative health service recommendations [38]. For in-depth interviews and observational journals, we developed a codebook using deductive and inductive techniques [39]. Data were first coded by the level of gendered organization: (1) organizational policy; (2) organizational practice; and (3) the structure of gendered expectations. Within each level, we developed deductive codes based on existing literature. Inductive codes were added as transcripts were analysed. The codebook was finalized after reading 10 in-depth interview transcripts and five observational journals. Qualitative data were analysed using Atlas.ti [40] and were triangulated to develop a coherent, holistic description of findings [41].

2.4 | Ethics approvals

Ethical approval was received from the Colorado Multiple Institutional Review Board and Malawi's National Health Sciences Review Committee.

3 | RESULTS

Below we examine the organization of health services across the three levels of the gendered organization (Table 1). We also explore implications of a gendered health institution on men's use of HIV testing services.

Table 1. Summary of the gendered health institution for HIV testing services in Malawi, by level of the gendered organization

Level of gendered organization	Example in Malawi
Organizational policy	
Health service recommendations	Malawi guidelines recommend *176-433* health service during women's reproductive lifespan (15-44 years) versus *32* health service for men in the same period
Health education	Health education services were not provided at locations or health services frequented by men
Organizational practice	
Service availability	HIV testing primarily available during hours of ANC services
Physical environment	HIV testing often located near or in ANC, family planning or under-five services
Structure of gendered expectations	
Successful clients have feminine characteristics	Successful clients exemplify feminine characteristics: patience (waiting); compliance (obeying instructions without explanation); and deference (respecting providers)

ANC, antenatal care.

3.1 | Organizational policy

3.1.1 | National recommendations for health services

Table 2 describes Malawi guidelines for health services and the cumulative number of health visits required across one's reproductive lifetime (15-44 years) to meet recommendations.

Five of the seven recommendations were for women's reproductive health or children under five years of age. Most recommendations required multiple visits each year. High fertility rates in Malawi (4.4 children) [27] meant that women were expected to attend 176-433 reproductive or child health visits during their reproductive lifetime; an average of 6-16 visits/year.

Recommendations for men of the same age range included annual HIV testing and voluntary medical male circumcision (VMMC), resulting in 32 health service visits during men's reproductive lifetime; or an average one visit per year. Estimate justifications and assumptions are provided in Table S1.

Key informants believed that men's absence from national recommendations had several important consequences. Men did not have universal entry points for HIV testing and therefore few opportunities for provider-initiated-testing-and-counselling (PITC), a critical strategy to increase testing coverage at a population level.

> *Clinics do not have favourable conditions for men to go for HIV testing … Men can only come to the clinic for HIV*

Table 2. Malawi Ministry of Health recommended health services and estimated visits required across the reproductive lifespan (15-44 years)

		Estimated number of visits between 15-44 years			
Service	**Target population**	**Women: five-year FP (implant; 9%[a])**	**Women: quarterly FP (injectables; 23%[a])**	**Women: monthly FP (pills; 2%[a])**	**Men**
ANC	Women	18	18	18	–
Delivery	Women	4	4	4	–
Post-natal	Women	4	4	4	–
Family planning	Women	7	88	264	–
Under-five	Women	120	120	120	–
HIV testing	Women and men	23	23	23	29
Circumcision	Men	–	–	–	3
Total		176	257	433	32

ANC, antenatal care; FP, family planning.
[a]DHS 2016[27]

testing. That's all. But women can go [anytime] . . . Women go when the child is born and when the child is sick, the child is tested and the mother as well. And women must also test during pregnancy. But there is no service to encourage men to come to the hospital where they can also be tested. (Male provider, Facility 5)

3.1.2 | *Health education*

Men's limited engagement with health institutions also meant they had little limited exposure to health education. Further, most health education strategies were offered alongside female-focused services, such as antenatal care (ANC), family planning, and underfive services, and in the morning hours. Key informants believed limited exposure to health education contributed to men's poor knowledge and awareness of health services.

Men are certainly unequipped [to use HIV services]. Men are not given skills. Since they were born up they are ignored about health and about taking care of families. They are completely left alone because people assume they already know. So what do we expect from men? They have no knowledge. Men run away from the clinic. . . . We think that shows power? No, men are scared . . . Women are at the clinic multiple times and are given information. Men are not. (Male key informant, local researcher)

In contrast, key informants believed women were frequently exposed to HIV services and educational materials. One female provider suggested that ANC services gave women a "mind for testing" because they learned how to overcome barriers to testing and normalized testing for women at key milestones in their lifetime (Female provider, Facility 4).

Some key informants reported that the lack of recommendations for men's health led men to reject health institutions altogether because they believed they had no place within them.

All programmes are targeting women. They [men] say, "Fine. We will move the other way." And by the time we [health institution] decide that we want to address men, we now have to chase them. It's obvious that we haven't been fair to women as far as rights are concerned. But now to try to solve the problem we are creating another problem. (Male key informant, HIV District Coordinator)

3.2 | Organizational practice

3.2.1 | *Service availability*

In large hospitals (two of five facilities), HIV testing services were available during most facility hours. In small, rural health centres (three of five facilities), HIV testing was primarily offered alongside ANC services, usually in the early morning and on specific days. Testing could be accessed outside these hours, but often required extended wait times before a provider was available. In four of five facilities, the study team observed non-pregnant clients turned away from HIV testing because a qualified provider was not available.

Here there is no one [provider] who is specialized for HIV testing . . . we have someone, but after antenatal [they] are sometimes busy with other things. People wait and get tired so they choose to go. (Male Provider, Facility 2)

Limited service availability may affect both men and non-pregnant women. However, women's universal entry point during ANC services means that most women will be able to access HIV testing throughout their lifetime, regardless of challenges related to service availability during non-ANC health visits.

3.2.2 | *Physical environment*

Testing services were often located near ANC and/or children under-five services (three of five facilities). Providers reported

that the only reason for men to be in these traditionally female-oriented spaces were involvement in ANC (which was rare) or HIV services. Since clients often waited many hours to receive care, providers acknowledged that men faced an increased risk of being identified as accessing HIV services.

> *If a woman walks into this building people can think of those [under-five and antenatal services]. But a man, if a man comes to this building people definitely think, 'Ah, HIV'. (Male provider, Facility 3)*

3.3 | Structure of gendered expectations

Observational journals and interviews with providers revealed three key traits clients needed to successfully access HIV testing services: (1) compliance; (2) deference; and (3) patience, all characteristics traditionally viewed as feminine. Findings from in-depth interviews were similar across both male and female providers.

Clients were expected to *comply* with provider instructions, often without a description of *why* the instructions were given. Nearly all providers mentioned that, in practice, clients were rarely given explicit reasons as to why specific tests, treatments or follow-up appointments were recommended. One provider explained, "You just say, 'HIV testing is important. You should go get tested tomorrow or whenever you can'. That's it." (Female provider, Facility 5).

Clients who were *deferential* were perceived to have better experiences within the facility. Clients were expected to accept rude behaviour from providers. Those who questioned providers' authority were often shouted at or refused services. Clients who were willing to accept rude behaviour from providers may have been more likely to continue attending health facilities, even after negative experiences, and therefore more likely to be exposed to HIV testing services in the future.

Successful clients were viewed as *patient* and waited extended hours to receive services. While facilities had set working hours, the availability of facility staff varied widely, with frequent staff absences. Furthermore, the number of clients seeking care were often extremely high, so that even when providers were present, clients still faced extended wait times of two or more hours. Most providers recognized that men did not like waiting with women. Clients would criticize men who waited in long queues, mocking men for "waiting like a woman." A female research assistant observed:

> *Two young men stood on a line of women. One of the [women] said that "males do not stand in line. They are wasting their time there as if they are females." . . . (Female Research Assistant, Facility 4).*

4 | DISCUSSION

We examined the gendered organization of health institutions and its influence on men's use of HIV testing services in Malawi. Taking an institutional, multi-level approach, we examined holistic barriers within the Malawi health institutions that may deter men's use of not only HIV services, but health services more broadly. We found that the health institutions were organized around children's and women's reproductive health in ways that limited or discouraged men's engagement in care, leading to substantial, multi-level barriers to men's HIV testing within health institutions. While we examined the implications of gendered health institutions on men's use of HIV testing services, these same institutional barriers likely impact men's representation in other health services as well.

Within *organizational policy*, national health guidelines provided few recommendations for men of reproductive years (15-44 years) to access routine care as compared with women of the same age range, resulting in minimal routine health visits for men. Universal entry points for men were limited to HIV testing, VMMC and acute care. Lack of entry points meant there were few natural opportunities to routinely offer PITC to men, a critical strategy for HIV testing [42]. The lack of a universal entry points for men may further perpetuate community-level socialization that health services and health facilities are women's spaces [12]. Routine outpatient services could provide an entry point for men. However, we found that general health education was not common within these services, suggesting a missed opportunity to offer HIV testing and referral for treatment. Men's limited engagement with health institutions contributed to what key informants described as major gaps in men's knowledge and familiarity with health institutions. Other research in the region has previously described limited health literacy and knowledge among men [4].

Within *organizational practice*, HIV testing services were not readily available except during times when ANC, family planning or under-five services were being offered. This resulted in longer than usual wait times for outpatient attendees, and at times, complete unavailability of HIV testing. Furthermore, HIV services were often offered in or near women's reproductive and children's health departments, making it difficult for men to access confidential care. Our findings support previous reports that the feminized environment of facilities may lead to unwanted HIV status disclosure for men [44].

Within the *structure of gendered expectations*, successful clients needed to have characteristics that were considered traditionally "feminine". These included (1) compliance (obeying provider instructions without an explanation as to *why* instructions were given), (2) deference (being respectful and passive to providers, regardless of provider behaviour), and (3) patience (waiting extended hours). Other studies also describe the ideal (or successful) client as self-motivated, compliant, passive and deferential [45-47]. Providers may be more likely to refuse or provide sub-optimal care to men who do not demonstrate these ideal characteristics. In Zimbabwe, for instance, providers were less likely to offer HIV testing to children accompanied by male versus female guardians [48]; and in Uganda, providers excluded some men during antenatal visits, even if men attended as part of a male involvement programme [49].

What can be done to address gendered health institutions in the context of HIV services? One strategy widely implemented across sub-Saharan Africa is outreach services for men. HIV self-testing, community, index and work-based HIV testing strategies generally increase testing among men [9]. However, outreach strategies alone will not alleviate health disparities for men. For HIV-positive men, sustained engagement in health facilities after testing positive is critical for long-term outcomes.

Immediate strategies are needed to address organizational structures that contribute to gendered health institutions and their negative health effects for men. Such changes promise to improve not only men's use of HIV testing services, but men's use of other services in which they have historically been underrepresented. First and foremost, universal entry points for men are essential. Potential entry points include outpatient departments [50], fatherhood and non-communicable disease screening for older men [51]. Male-focused health education services that resonate with men's priorities and concerns have been found effective in some settings [4]. Improved infrastructure to facilitate private HIV testing spaces near outpatient departments, along with innovative strategies to reduce testing wait times such as facility-based HIV self-testing [52] or increased staffing, may be required. Finally, innovative strategies are needed to address negative male stereotypes held by policy makers and health care workers. To date there are few interventions aimed to change negative male stereotypes, and additional research is needed to identify specific strategies that can help to this end.

4.1 | Limitations

This study has several limitations. First, data are from 2013 to 2015 and may not reflect the current situation on the ground. However, recent literature show that men are still absent from national guidelines [53] and continue to comprise the minority of HIV services [1], suggesting that our findings are still relevant. Second, observational journals cannot capture all events within participating health facilities, and may exclude mundane events that research assistants did not notice or deemed unworthy of documentation. Additional limitations of observational journals are discussed in depth elsewhere [36]. Third, social desirability bias is common in in-depth interviews and cannot be excluded as a possibility within the current study. Fourth, this paper does not examine men's interpretation and internalization of gendered organizations or the gendered interactions within health institutions. This deserves further exploration in future research. Finally, findings may not be generalizable outside Malawi, however, similar gendered health institutions likely exist throughout sub-Saharan Africa as national HIV programmes are largely influenced by international donor guidelines and priorities.

5 | CONCLUSIONS

The gendered health institution in Malawi created substantial, multi-level barriers to men's use of HIV testing services that straddle organizational policy, organizational practice and the gendered expectations of how clients should interact with providers. Future research should prioritize a gendered organization framework to address the complex reality of men's engagement with HIV services.

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COMPETING INTERESTS

We declare no competing interests.

AUTHORS' CONTRIBUTIONS

KD conceived the study. KD and SY contributed to study design. KD developed the guideline and training. KD analysed the data. KD, SY and SD developed the theoretical framework. KD, SY, SD, MC and TC provided substantial scientific input into the interpretation of results. KD took the lead in drafting the manuscript. SY, SD, MC and TC provided substantial comments to improve the draft. All authors contributed to the collection or interpretation of data, provided critical revisions to the report and approved the final draft.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Table S1. Justifications and assumptions for estimates described in Table 1: Malawi Ministry of Health recommended health services and estimated visits required across the reproductive lifespan (15-44 years).

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RESEARCH ARTICLE

Creating HIV risk profiles for men in South Africa: a latent class approach using cross-sectional survey data

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Abstract

Introduction: Engaging at-risk men in HIV prevention programs and services is a current priority, yet there are few effective ways to identify which men are at highest risk or how to best reach them. In this study we generated multi-factor profiles of HIV acquisition/transmission risk for men in Durban, South Africa, to help inform targeted programming and service delivery.

Methods: Data come from surveys with 947 men ages 20 to 40 conducted in two informal settlements from May to September 2017. Using latent class analysis (LCA), which detects a small set of underlying groups based on multiple dimensions, we identified classes based on nine HIV risk factors and socio-demographic characteristics. We then compared HIV service use between the classes.

Results: We identified four latent classes, with good model fit statistics. The older high-risk class (20% of the sample; mean age 36) were more likely married/cohabiting and employed, with multiple sexual partners, substantial age-disparity with partners (eight years younger on-average), transactional relationships (including more resource-intensive forms like paying for partner's rent), and hazardous drinking. The younger high-risk class (24%; mean age 27) were likely unmarried and employed, with the highest probability of multiple partners in the last year (including 42% with 5+ partners), transactional relationships (less resource-intensive, e.g., clothes/transportation), hazardous drinking, and inequitable gender views. The younger moderate-risk class (36%; mean age 23) were most likely unmarried, unemployed technical college/university students/graduates. They had a relatively high probability of multiple partners and transactional relationships (less resource-intensive), and moderate hazardous drinking. Finally, the older low-risk class (20%; mean age 29) were more likely married/cohabiting, employed, and highly gender-equitable, with few partners and limited transactional relationships. Circumcision (status) was higher among the younger moderate-risk class than either high-risk class ($p < 0.001$). HIV testing and treatment literacy score were suboptimal and did not differ across classes.

Conclusions: Distinct HIV risk profiles among men were identified. Interventions should focus on reaching the highest-risk profiles who, despite their elevated risk, were less or no more likely than the lower-risk to use HIV services. By enabling a more synergistic understanding of subgroups, LCA has potential to enable more strategic, data-driven programming and evaluation.

Keywords: segmentation; male; multiple sexual partners; transactional sex; alcohol; gender norms; Latent class analysis

Additional Supporting Information may be found online in the Supporting information tab for this article.

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1 | INTRODUCTION

Men—previously a "blind spot" in an HIV response focused primarily on women and children [1,2]—are now its frontier. In sub-Saharan Africa, men experience intractably high HIV incidence, and contribute to high incidence among adolescent girls and young women (AGYW) [3-5]. Men in the region are also less likely than women to test for HIV, initiate antiretroviral treatment (ART), and be virally suppressed, and are more likely to die of AIDS-related illnesses [2]. For these reasons, there has recently been intensified interest in reaching more men with comprehensive social and behavior change programming as well as biomedical prevention and treatment services.

Men are not a monolithic group with respect to HIV risk, even in severe epidemics, and those at highest risk are often "hidden" or "hard to reach" [6]. The goals of understanding and reaching subgroups of men most at risk are currently impeded by few effective tools to figure out how to do so. Increasing age is a clear risk factor for HIV acquisition in South Africa, with prevalence among men rising steeply

between ages 20 to 40 [5,7]. Five-year age bands (e.g., 20 to 24, 25 to 29) are commonly used to establish and monitor HIV prevention and treatment targets, yet this may be insufficiently nuanced since within any age band, there are likely men at both higher and lower risk. Several key behavioral/attitudinal determinants underlie risk for both acquiring and transmitting HIV in high HIV prevalence settings like South Africa. These include having sex without condoms with multiple sexual partners [6,7], alcohol abuse [7,8], and inequitable gender norms and unequal relationship power [9-12]. Age-disparate and transactional sexual relationships further contribute to heightened HIV transmission from men to women, and particularly AGYW [13-15]. Studies examining these factors most commonly use regression-based approaches and yield information about relationships between individual variables. Yet theory suggests that it is, in fact, combinations of factors that synergistically contribute to heightened risk.

Latent Class Analysis (LCA) provides a rigorous, data-driven approach to identifying a set of "hidden" subgroups/classes characterized by multiple dimensions in survey data [16, p. 157,17]. LCA can be thought of as a "person-centered" approach to data analysis, in contrast to the dominant "variable-centered" approach described previously with respect to common regression analyses. The latent classes are identified based on patterns of responses on a selected set of variables, that best represent the data [17]. Originally developed in the 1950's, LCA has been increasingly used in social and behavioral science research over the last decade [16]. Studies employing LCA in the health field have focused on understanding patterns of substance use/abuse, adolescent risk behaviors, mental health, and intimate partner violence [17-19]. Several recent studies have applied LCA to understanding risk for HIV or sexually transmitted infections (STIs). [20-26], as well as patterns of HIV testing [27,28]. One recent study among AGYW in South Africa employed LCA to profile their types of male partners, finding five distinct partner types that were associated with incident HIV infection [29]. However, to our knowledge no studies among men in sub-Saharan Africa have employed LCA to better understand their risk for HIV acquisition/transmission.

In this study we used LCA to identify HIV risk profiles among men in Durban, South Africa. Our goal was to develop an approach for profiling subgroups of men in terms of HIV acquisition/transmission risk that is data-driven, informative for programming, and potentially applicable in other contexts. We conceptualized HIV risk broadly as risk of either acquiring or transmitting HIV, since our intention was to develop profiles that could inform comprehensive programs to prevent both, and most of the behaviors and attitudes we examined underlie both risk of acquisition and transmission. After developing the profiles, we compared use of HIV services between them.

2 | METHODS

2.1 | Study population

From May-September 2017, we administered surveys to 962 men in two peri-urban informal settlements in eThekwini district (Durban), Kwa-Zulu Natal (KZN) province, South Africa. KZN has the highest adult HIV prevalence in the country, at 27% [7]. Informal settlements are characterized by high population density, informal housing structures, and scarcity of social services. South Africa's National Strategic Plan for HIV, TB and STIs 2017 to 2022 identifies people living in informal settlements as a vulnerable population for HIV and STIs, in need of customized and targeted interventions [30].

Eligible participants were between the ages of 20 to 40. Recent population-based research in the region has suggested that it is ages 25 to 40 years at which men are most likely to acquire HIV, as well as transmit HIV to AGYW (ages 15 to 24) [31].

2.2 | Procedures

About two-thirds of men were recruited at "hot spot" venues, and one-third at HIV service sites. This dual recruitment strategy was intended to capture a sample of likely high-risk male partners of AGYW, as well as men already attending HIV prevention and treatment services. Hot spot venues were identified by key informants and included drinking establishments, taxi ranks, and university surrounds (e.g., hang-out spots near university campuses). HIV service sites were both facility-based (government/NGO clinics) and community-based (mobile/home-based/workplace testing). Additional details about recruitment procedures are included in the Data S1.

The survey was administered by a trained interviewer in isiZulu or English and took an average of 45 minutes. The interviewer read out each question to the respondent and then entered his response using a tablet.

2.3 | Measures

We developed hypotheses *a priori* about HIV risk profiles, based on formative research with key informants in Durban (focus group discussions/in-depth interviews with HIV program/service staff and community opinion leaders) and known demographic features of the study area (e.g., concentration of post-secondary institutions and industry/informal labor-related employment; low marital/cohabiting rates [32,33]). We chose not to construct separate LCA models for risk of HIV acquisition versus transmission for several reasons. First, as described above, most of the behavioral/attitudinal determinants we examined confer risk for both acquisition and onward transmission, and we wanted to identify profiles that could inform comprehensive programs to prevent both. In addition, restricting samples by self-reported HIV status was not advisable given likely underreporting of HIV-positive status and low sample size of HIV-positive men (n = 84) (for further detail see Data S1).

We identified ten demographic, attitudinal, and behavioral variables we believed would define and distinguish between the hypothesized profiles, informed by the literature described previously regarding key risk factors for HIV acquisition/transmission. It was not informative to include self-reported HIV-positive status in the model, since prevalence increased with age per known prevalence patterns among men in KZN [5,7]. Table 1 includes detailed descriptions of the measures.

2.4 | Analysis

2.4.1 | *Model definition*

All analyses were conducted using Stata v15 [38]. The LCA followed an iterative process that involved constructing a

Table 1. Measures for variables included in LCA models and postestimation analyses

Variable	Measure description
Socio-demographics	
Age	Continuous; based on the question *"What is your age?"*
Marital/cohabiting status	Binary; defined as married or cohabiting versus not, based on the question *"What is your current relationship status?"*
Highest level of education completed	Ordinal; consolidated from six response options into three categories: some secondary or less, secondary, or technical college/university. Based on the question *"What is the highest level of education you have completed?"*
Occupation	Categorical; seven categories, including unemployed. Based on the questions *"Are you currently working"* (with "No" corresponding to the unemployed category) and *"What do you do for work?"*, with 24 response options. The final occupation variable was consolidated into seven categories (including unemployed as one), based on (a) sufficient sample size in each occupational category, and (b) grouping similar occupation types together. Response options with <10 responses, that could not be meaningfully combined with others to form a category making up >5% of the sample, were categorized as 'other'
HIV risk factors	
Endorsement of inequitable gender norms	Binary; based on mid-point cutoff of a continuous scale score. The continuous variable was measured using an adapted version of the Gender-Equitable Men's (GEM) Scale [34], previously validated in South Africa [35]. The final 19-item scale demonstrated good reliability (ordinal theta = 0.93 [36]). Example items are: *"A man should have the final word about decisions in his home"*; *"Sometimes a woman needs to be put in her place"*; and *"It is a woman's responsibility to avoid getting pregnant."* Response options were agree/partly agree/do not agree. We generated a mean GEM Scale score for each respondent. Then, for clear interpretation (i.e., identifying highly inequitable gender norms), and to reduce the number of continuous variables in the model to improve convergence, we dichotomized scores at the midpoint of the possible range to represent endorsement of more inequitable versus equitable views
Number of sexual partners in the last year	Ordinal; with 3 categories: 0 to 1, 2 to 4, or 5+ sexual partners in the last year. Based on the question *"Over the last 12 months, how many different female sexual partners have you had? If you are not sure of the exact number please give a best guess."* (Of note, <1% of respondents reported ever having had sex with a man.) Categorizing the number of sexual partners into 0 to 1, 2 to 4, or 5 + helped differentiate two aspects of interest: (a) the class' prevalence of no partners/monogamous relationships (i.e., 0 to 1 vs. more), and (b) the proportion with a very high number of sexual partners (i.e., 5+ vs. fewer)
Age disparity of relationships	Continuous; calculated as the mean age difference with up to the respondent's last three non-marital/non-cohabiting partners reported on a partner grid (for each, subtracting the partner's reported current age from the respondent's age). Most partners were younger; 13.5% of non-marital/non-cohabiting partners were older (median of 2 years older; data not shown). Age difference with any marital/ cohabiting partners was not included in the calculation because in KwaZulu-Natal marital/cohabiting partners tend to be closer to men's own age [31], whereas this indicator mainly seeks to capture contribution of age disparity to risk of HIV transmission from men to younger women
Consistent condom use	Binary; with each of up to the last three non-marital/non-cohabiting partners reported in a partner grid, defined as reporting 'always' (vs. 'sometimes' or 'never') in response to the question *"For the last 3 months you were having sexual intercourse with [this partner], how often was a condom used?"*
Engaging in transactional relationships in the last year	Categorical; three categories including: none, less resource-intensive, and more resource-intensive. This categorization was based on reporting giving at least one item or service (the response categories) 'mainly so you could start or stay in a sexual relationship' with a partner [13]. Men who qualified but were married/cohabiting with no other reported partners in the last year, were coded as not having transactional relationships, since transactional sex is commonly defined as involving exchange of sex for material support with non-marital/non-cohabiting partners. "Less resource-intensive" transactional relationships included providing cash/money; drugs, food, cosmetics, clothes, a cell phone, airtime; transportation; or somewhere to sleep for the night. "More resource-intensive" included providing somewhere to live; support or money for their children or family; or money to pay for debt/loans/school or university fees. Since most men who reported "More resource-intensive" forms also reported less resource-intensive forms, to create mutually exclusive categories, "More resource-intensive" included either only providing more-resource intensive, or both more- and less-resource intensive

Table 1. (*Continued*)

Variable	Measure description
Hazardous drinking	Binary; measured using the concise version of the Alcohol Use Disorders Identification Test (AUDIT-C) [37], which asks whether, how much, and how often the participant drinks alcohol, with a total score ranging from 0 to 12. We created a binary variable with a score of 4 or above (standard cutoff) indicating hazardous drinking [37]
HIV service use measures (for postestimation analyses)	
HIV testing in the last 12 months	Binary; based on response of ≥1 to the question *"In the past 12 months, how many times have you been tested for HIV? Please only include tests for which you received the results. If you don't know the exact number give a best guess."* Men who self-reported being HIV-positive and initiating antiretroviral therapy over 12 months ago (suggesting they did not need to test for HIV in the last 12 months), were coded as missing
Circumcision status	Binary; based on answering 'Yes' to the question *"Have you been circumcised?"* (with validity of the response further confirmed/corrected through a series of follow-up questions, e.g., age circumcised, type of circumcision, whether considering getting circumcised in the future)
HIV treatment literacy	Discrete variable with values ranging from 0 to 5, based on the number of correct yes/no responses to five questions about antiretroviral treatment: (1) *"Can antiretroviral therapy (ART) help a person with HIV to stay healthy and live longer?"* (Yes = correct) (2) *"Do you think HIV/AIDS can be cured?"* (Yes = incorrect) (3) *"Are there any special drugs that a doctor can give a pregnant woman infected with HIV/AIDS to reduce the risk of transmission to the baby?"* (Yes = correct) (4) *"Can taking breaks from antiretroviral therapy (ART) make it work better in the long term?"* (Yes = incorrect) (5) *"Can taking antiretroviral therapy (ART) reduce the risk of transmitting the HIV/AIDS virus to another person?"* (Yes = correct)
Current antiretroviral therapy (ART) use (among HIV-positive respondents)	Binary; based on responding 'Yes' to the question *"Are you currently taking antiretroviral therapy (ART)?"*

series of models and refining the variables included. We began by fitting 1- to 5-class models. With each model, we assessed identification, interpretability, overall model fit, and each indicator's ability to differentiate among the classes (e.g., >5% difference between most classes). If an indicator consistently produced similar probabilities across all of the classes, it was excluded from the model.

Final model selection was based on identification and relative-fit statistics (for details see Table 4 and the Data S1), as well as interpretability. For interpretability, we considered whether the latent classes made logical sense and were distinct from each other [17]. The final model yielded probabilities for class membership, and, for each class, item response probabilities for each indicator.

2.4.2 | Postestimation analyses

For postestimation analyses, each respondent was assigned to a class based on their highest posterior latent class probability. We then assessed associations between class membership and four variables (for which measures are described in Table 1): HIV testing in the last year, ever-circumcised, treatment literacy score, and current ART use (among HIV-positive men). Poisson regression was used for treatment literacy (a count variable). For the rest, generalized linear models with a binomial distribution and log link function were used to compute prevalence ratios. This is a recommended approach for binary outcomes characterized by relatively high prevalence [39,40] (a sensitivity analysis using logistic regression yielded nearly identical results). We adjusted models for type of hot spot venue/service site. We did not adjust for demographic characteristics because those characteristics were included in the LCA model.

2.5 | Ethics

This study was approved by the Institutional Review Boards at the Population Council and University of Kwa-Zulu Natal. We obtained written informed consent from all participants.

3 | RESULTS

A total of 962 men participated in the survey. The response rate was 97.3% (18 refusals) at hot spot venues and 99.1% at HIV service sites (3 refusals); this reflects the proportion agreeing to participate after entering the study tent and being read a description of the study. Fifteen respondents were dropped from the analysis since they were missing values for three or more of the ten variables included in the initial LCA models. This resulted in a final sample size of 947, 638 recruited at hot spot venues and 309 at HIV service sites.

Sample characteristics are presented in Table 2. The mean age was 28 years (range 20 to 40). Fifteen percent of participants were married or cohabiting, similar to documented marital/cohabiting rates in urban informal settlements in the

Table 2. Sample characteristics (n = 947)

	n/Mean	%/SD
Socio-demographic		
Age	27.7 years	5.5 years
Married/cohabiting	146	15.4%
Education (highest completed)		
Some secondary or less	215	22.7%
Secondary	529	55.9%
Technical college/University	203	21.4%
Occupation		
Unemployed	370	39.1%
Taxi/bus driver	235	24.8%
Factory/construction worker	72	7.6%
Informal labor	51	5.4%
Service industry	63	6.7%
Small business/entrepreneur	48	5.1%
Other occupation	108	11.4%
Normative gender attitudes		
Inequitable views towards gender norms	235	24.8%
HIV risk behaviors		
Number of sexual partners in last year		
0 to 1	277	29.3%
2 to 4	452	47.7%
5+	218	23.0%
Age difference with last 3 partners (mean years younger)	3.5 years	3.7 years
Transactional relationships		
None	416	43.9%
Less resource-intensive	405	42.8%
More resource-intensive	115	12.1%
Hazardous drinking	486	51.3%

SD, Standard deviation. For each variable, missingness was < 2%. Overall missingness was < 1%. Per Stata v15 standard procedures, missing values were imputed based on equation-wise deletion, which uses valid responses from other variables to estimate missing values [41].

country [33]. Most had completed secondary school (56%), and over one-third (39%) were unemployed. Among employed men, the most common occupation was taxi/bus driver (25%), likely due to having recruited partly at taxi ranks. Other common occupations included being a factory/construction worker, informal laborer, service industry worker, and small business owner/entrepreneur.

3.1 | Latent class solution

Initial variable re-coding (Table 1) was performed for about half of the variables to eliminate collinearity, ensure adequate cell size per response category, and/or condense certain continuous variables to enable model fit. We fit a one-class to a five-class LCA model; each of these solutions was identified except for the five-class. The only variable dropped due to low variability across the latent classes was consistent condom use (with up to last three non-marital/non-cohabiting partners), which was consistently at about 20% for each class (data not shown).

We found four latent HIV risk classes (Table 3). The four-class model was selected because the classes were distinct from each other in terms of item response probabilities and were more interpretable than other class solutions. The model also had good fit statistics (AIC = 21,275; BIC = 22,079; entropy = 0.76) (Table 4). For ease of reference, we labeled the four classes Older high-risk, Younger high-risk, Younger moderate-risk, and Older low-risk. Younger/older age was chosen to include in the label due to the discrepancy in ages between classes (for simplicity classified as below/above the sample mean of 28 years, within the sample's limit of 20 to 40 years). Risk level was chosen to denote which classes may be more important to reach with HIV prevention/care services, and since for each class most or all risk characteristics represented a consistent level of risk for HIV acquisition/transmission.

The **older high-risk** class comprised one-fifth (19.6%) of the sample and had the highest mean age of the sample (35.9 years). This class was the most likely of the classes to be married/cohabiting (37.1%) and least likely to be unemployed (16.8%). The occupation with the highest probability was taxi/bus driver (30.0%). Men in this class had a 26.5% probability of endorsing inequitable gender norms, and 46.7% and 17.6% probabilities, respectively, of having 2 to 4 partners and 5 + sexual partners in the last year. Among the classes, these men's relationships had the greatest age-disparity (on average, 8.0 years younger) and were more resource-intensive transactional in nature (20.5%). Finally, this class had a high probability (58.7%) of reporting hazardous drinking.

The **younger high-risk** class (24.1 % of the sample) were relatively young (mean age 27.2 years) and had a low likelihood of being married/cohabiting (7.8%). They had a 66.2% probability of having completed secondary school and a 20.9% probability of being unemployed and were most likely to be taxi/bus drivers (35.8%) and more likely than other classes to be factory/construction workers (12.4%). Of the four classes, this class was most likely to endorse inequitable gender norms, at 38.8%. They also had the highest probabilities of most risk behaviors, at 54.3% for having 2 to 4 partners in the last year and 41.5% for having 5+; on average their partners were four years younger than themselves. They had the highest likelihood of engaging in transactional relationships, primarily those less resource-intensive in nature (75.9%), as well as hazardous drinking (72.6%).

The **younger moderate-risk** class was the most prevalent class of the sample (36.4%), with an average age of 22.5 years. Among the classes, they were the least likely to be married/cohabiting (3.6%) and the most likely to have completed technical college/university (32.1%). However, they also had the highest probability (73.5%) of being unemployed (although about half of those unemployed were still in school, data not shown). The likelihood of endorsing inequitable gender norms was similar to the older high-risk class, at 25.5%. This class had a high probability of having multiple sex partners (49.8% with 2 to 4; 22.5% with 5+), but the mean age difference with these partners was only one year. They also had a relatively high probability (50.7%) of having transactional relationships, mostly less resource-intensive in nature

Table 3. HIV risk profiles among men (n = 947)

	Class membership (probability)			
	Older high-risk (19.6%)	**Younger high-risk (24.1%)**	**Younger moderate-risk (36.4%)**	**Older low-risk (19.9%)**
	Item response probabilities			
Socio-demographic				
Age	35.9 years	27.2 years	22.5 years	29.4 years
Married/cohabiting	37.1%	7.8%	3.6%	24.8%
Education (highest completed)				
Some secondary or less	35.7%	20.0%	16.9%	23.8%
Secondary	46.5%	66.2%	51.0%	61.5%
Technical college/University	17.8%	13.8%	32.1%	14.7%
Occupation				
Unemployed	16.8%	20.9%	73.5%	20.2%
Taxi/bus driver	30.0%	35.8%	11.5%	30.7%
Factory/construction worker	11.3%	12.4%	2.5%	7.6%
Informal labor	7.3%	5.1%	1.2%	11.4%
Service industry	10.2%	5.3%	3.3%	10.8%
Small business/entrepreneur	8.7%	9.4%	2.0%	2.0%
Other occupation	15.7%	11.1%	6.0%	17.3%
Normative gender attitudes				
Inequitable views towards gender norms	26.5%	38.8%	25.5%	6.4%
HIV risk behaviors				
Number of sexual partners in last year				
0 to 1	35.7%	4.2%	27.7%	56.1%
2 to 4	46.7%	54.3%	49.8%	37.1%
5+	17.6%	41.5%	22.5%	6.8%
Age difference with last 3 partners (mean years younger)	8.0 years	3.6 years	1.1 years	3.6 years
Transactional relationships				
None	49.7%	6.7%	49.3%	76.7%
Less resource-intensive	29.8%	75.7%	44.7%	14.2%
More resource-intensive	20.5%	17.6%	6.0%	9.1%
Hazardous drinking	58.7%	72.6%	41.2%	39.3%

(44.7%), but a lower probability than the high-risk classes of engaging in hazardous drinking (at 41.2%).

Finally, the **older low-risk** class (mean age of 29.4) was about as prevalent in our sample as the older high-risk class, both at about 20%. They had a 24.8% likelihood of being married/cohabiting, and a 20.2% likelihood of being unemployed. Of the four classes, men in this class were least likely to endorse inequitable gender norms (6.4%), have multiple sexual partners (56.1% had 0 to 1 partner), engage in transactional relationships, and report hazardous drinking.

Of note, there were no significant differences between the classes in terms of recruitment strategy (i.e., hot spot venue vs. HIV service site) nor location (i.e., the two informal settlements). We conducted a sensitivity analysis in which we restricted the sample to respondents who did not report being HIV-positive. The resulting LCA model was markedly similar to the full-sample model (see Data S1 for details), therefore we chose the latter as the final model.

Figure 1 is a visual that aims to provide an easily-interpretable snapshot of the four classes, to facilitate translation into programmatic implications.

3.2 | Associations between latent class membership and use of HIV services

For postestimation analyses, each respondent was assigned to a class. Class assignment diagnostics (Table 4) suggested a low chance of misclassification; for example, the average posterior probabilities of class assignment ranged from 0.81 to 0.92.

Three-quarters (74.3%) of men assigned to the younger moderate-risk class reported being circumcised (Table 5), compared with 55.6% among the younger high-risk (aPR 0.75,

Table 4. Model fit statistics and class assignment diagnostics

Goodness-of-fit statistics

Model	Observations	Log likelihood	DF	AIC	BIC	Entropy
1-Class	947	−11363.3	19	22764.6	22856.8	—
2-Class	947	−1002.1	37	22078.2	22257.7	0.79
3-Class	947	−10878.1	55	21866.1	22133.0	0.78
4-Class	947	−10789.2	73	21724.5	22078.8	0.76

Assignment accuracy diagnostics

Classes	Probability of class membership	Proportion assigned to class	AvePP	OCC
Older high-risk	0.196	0.196	0.92	47.17
Younger high-risk	0.241	0.250	0.81	13.43
Younger moderate-risk	0.364	0.360	0.91	17.67
Older low-risk	0.199	0.193	0.82	18.34

AIC, Akaike Information Criteria; AvePP, Average (mean) Posterior Probability of Assignment, ≥0.70 indicates high assignment accuracy [42]; BIC, Bayesian Information Criteria, with lower values signifying a better fit [17]; DF, degrees of freedom; OCC, Odds of Correct Classification, OCC > 5 represents high assignment accuracy [42].
The closer the entropy value is to 1, the stronger the separation between classes [43].
The 4-class model does not meet the conditional independence assumption; however, experts have emphasized that this assumption is more difficult to meet when classifying based on behavioral indicators, and that conditional independence must be balanced with interpretability [44,45].
We did not calculate the Likelihood-Ratio test for each model, since this test is based on the chi-squared statistic which requires observed and expected values and can only be used when all indicators are categorical [41].

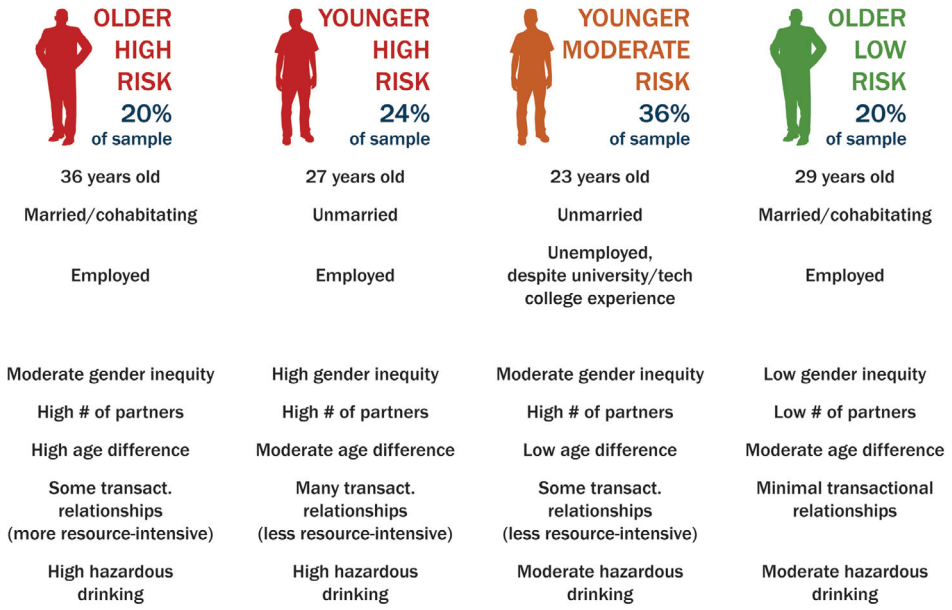

Figure 1. Graphic summarizing men's HIV risk profiles, Durban, South Africa.

95% CI 0.68, 0.84, $p < 0.001$) and 45.1% among the older high-risk (aPR 0.61, 95% CI 0.51, 0.73, $p < 0.001$). There was no association between class membership and levels of HIV testing in the last year (at 64 to 68% across classes) or HIV treatment literacy (at 3.4 to 3.7 on a scale of 0 to 5). Among HIV-positive men, current ART use was similar between classes at 89 to 96%.

4 | DISCUSSION

This study demonstrated the value of applying LCA to advance HIV prevention research in sub-Saharan Africa, by enabling a more synergistic understanding of subgroups of men. We identified four distinct HIV risk profiles among men in Durban, with different socio-demographic characteristics

Table 5. Associations between latent class membership and HIV service use

	Tested for HIV in last 12 months (n = 513)[b]		Circumcised (n = 939)		HIV treatment literacy score (range 0 to 5) (n = 944)		Currently taking antiretroviral therapy (n = 80)[c]	
	n (%)	aPR (95% CI)	n (%)	aPR (95% CI)	Mean ± SD	aIRR (95% CI)	n (%)	aPR (95% CI)
Full sample	337 (65.7%)	–	576 (61.3%)	–	3.55 ± 1.00	–	73 (91.3%)	–
Older high-risk	57 (65.5%)	0.97 (0.79, 1.19)	83 (45.1%)	0.61 (0.51, 0.73)***	3.56 ± 1.00	1.00 (0.96, 1.04)	27 (90.0%)	–[d]
Younger high-risk	89 (64.0%)	0.95 (0.82, 1.10)	130 (55.6%)	0.75 (0.68, 0.84)***	3.38 ± 1.06	0.94 (0.88, 1.01)	16 (88.9%)	–[d]
Younger moderate-risk	138 (67.7%)	ref	252 (74.3%)	ref	3.57 ± 1.03	ref	9 (90.0%)	–[d]
Older low-risk	53 (63.9%)	0.94 (0.78, 1.13)	111 (61.0%)	0.83 (0.71, 0.95)*	3.72 ± 0.81	1.05 (0.98, 1.11)	21 (95.5%)	–[d]
Overall p-value[a]	0.89		<0.001		0.18		0.88	

Analyses adjusted for recruitment site.
[a]Overall *p*-value represents overall statistical significance of difference between groups, based on Pearson's chi-square test; [b]Among venue-based sample only, since service-based sample included many coming for HIV testing. Excluded men who reported initiating ART (i.e., were diagnosed) over 12 months ago; [c]Four of the 84 HIV-positive men did not provide a valid response regarding current ART use; [d]Small sample sizes for each class precluded testing significance of differences between them; $^{*}p < 0.05, ^{**}p < 0.01, ^{***}p < 0.001$; significance of comparisons with the reference category (ref; selected based on youngest mean age of the latent class).
aIRR, adjusted incidence rate ratio; aPR, adjusted prevalence ratio; CI, confidence interval; SD, standard deviation.

and risk factors. Two of the four profiles (one younger, one older) had markedly higher likelihoods of HIV risk factors than the lower-risk groups and, despite this, were less or no more likely to use services.

LCA results clearly distinguished between the classes. There were large differences in most indicators and substantial consistency of risk factor probabilities within each class. Including demographic, attitudinal, and behavioral indicators within the LCA model (as opposed to just risk behaviors) helped develop more interpretable and nuanced profiles, which could prove more useful to intervention planning. Taken together, these findings add to a developing evidence base demonstrating the benefits of a multidimensional approach to modeling HIV acquisition/transmission risk [46], and could help identify subgroups of men we need to prioritize for prevention programs and services. Complementing these findings with qualitative research and consultations with local stakeholders could help funding agencies and implementing partners further translate the profiles into concrete decisions about where and how to reach these groups and with what types of programming/services.

The popular discourse and peer-reviewed literature have focused much attention on older men with financial means having much younger female partners, with relationships motivated by transaction and power imbalances—often called "sugar daddies" or "blessers" [47-50]. Recent evidence from phylogenetic analyses in South Africa suggests it is men of approximate ages 25 to 40, on average 8.7 years older than their non-marital/non-cohabiting partners, who contribute the most incident infections among AGYW [31]. One-fifth of our sample of men ages 20 to 40 generally fit the "sugar daddy" description; thus, this group still requires tailored prevention activities. However, it was in fact younger men—one-quarter of the sample—who were found to reflect the highest levels of risk.

The younger high-risk class should be a particular focus of prevention efforts, as they had the highest probabilities across nearly all risk indicators, as well as suboptimal HIV service uptake. With a mean age of 27, around the peak age for incidence among men and male partners of AGYW [5], strategic HIV testing, with immediate linkage to care, as well as voluntary medical male circumcision (VMMC), are all priorities for this group. Workplaces—such as taxi ranks, factories, and construction sites—could be potential community testing and VMMC promotion sites for younger high-risk men.

The most prevalent profile among our sample was younger moderate-risk men, at 36%, who were commonly university/technical college students/graduates and unemployed. Their predominant risk factor for acquiring/transmitting HIV was their high probability of having multiple sexual partners (including 5 + partners); this was tempered by a lower mean age difference with partners and lower probability of transactional relationships than the younger high-risk class. Finally, the older low-risk profile had markedly low probabilities of risk behaviors compared with the other profiles. Further research with this group could provide insights into protective factors that could aid in designing interventions for the others.

Endorsement of inequitable gender norms was markedly more likely among the younger high-risk group and less likely among the older low-risk group. This is in line with previous research demonstrating causal links between inequitable gender norms/unequal relationship power and HIV risk behaviors/incidence, and suggests that changing gender norms should be prioritized within prevention programming [9-10,12].

It is important to recognize that the sampling strategy was formulated to intentionally locate men at high risk of HIV by focusing on informant-identified hot spot venues. This strategy was effective, as the sample as a whole reported very high levels of risk. Thus, concentrating future prevention activities at such venues could help reach more of the "right" men with HIV prevention interventions. Yet, equally important is that even within this sample, it was possible to identify both higher-risk and lower-risk groups. This suggests that using approaches like LCA can help target limited resources in contexts where much of the population is at risk, as well as identify high-risk subpopulations within large samples.

Another unique approach of our study is comparing HIV service uptake across profiles. With this information, program planners and implementers can create a more nuanced picture – beyond five-year age bands, for example – of who is being reached with each type of service. To maximize prevention of HIV acquisition and/or transmission, it is particularly important to reach those at highest risk with services. Yet among men in our study, the highest risk profiles did not use services any more than the lower risk profiles. And, with the exception of current ART use, HIV service use and consistent condom use were suboptimal for all groups, per the current National Strategic Plan for HIV, TB and STIs [30].

LCA could be a useful tool for future HIV prevention efforts among men in several ways. Using LCA to profile men in terms of their HIV acquisition/transmission risk is an approach that could be replicated in other geographic locations. Applying LCA to existing survey data is also possible. Such surveys, many of which include similar variables to those in the present study, have been conducted in numerous high-prevalence locations that would benefit from a better understanding of at-risk populations. This approach also has potential in terms of monitoring and evaluation. For example, using multiple cross-sectional surveys, one could monitor changes in HIV service use over time by profile or see how an intervention differentially impacted each profile.

This study had several limitations. First, survey responses were based on self-report, potentially introducing social desirability bias. Second, the cross-sectional nature of the data precludes inferences that latent class membership was causally associated with HIV service use. Third, the extent to which the risk profiles are linked to actual HIV acquisition or transmission remains unclear. Fourth, the conditional independence assumption was not met for the final model, although we do not believe this invalidates the model (see note below Table 4). Fifth, by using posterior probability to assign class membership, it is possible that some misclassification occurred. Additionally, for the postestimation analysis for last-year HIV testing, we coded as missing HIV-positive men who initiated ART > 1 year ago as a proxy for diagnosis >1 year ago (not captured on the survey); however this may have missed some ineligible men. Finally, the study was limited to two informal settlements in Durban and to men recruited at hot spot venues and HIV service sites. Therefore findings, including the prevalence of each latent class, may not be generalizable to all men ages 20 to 40 in Durban or other locations in the region. In addition, studies taking a different approach to identifying profiles may find different profiles than those identified in the present study.

5 | CONCLUSIONS

Study findings elucidate a nuanced picture of who the right men are to reach with HIV prevention and treatment programs in Durban, South Africa, and how those programs could be tailored for subgroups representing varying levels of HIV risk. In particular, it is critical to reach both the younger and older high-risk groups with HIV prevention programming and services, grounded in an understanding of the different characteristics of each (e.g., younger high-risk as employed, non-university-affiliated, unmarried, with ubiquitous hazardous drinking and minimally-resource-intensive transactional relationships).

The extent to which the HIV risk profiles we found differ for men in other geographic locations in South Africa and/or other countries remains to be seen, presenting a rich area for future research. It may be that similar patterns of risk, and/or notable differences, will emerge across contexts. Future studies should also explore comparative advantages of having separate models for risk of HIV acquisition versus transmission, particularly if biological endpoints are available, and employ longitudinal designs to track change over time. In sum, LCA is a promising data-driven tool for profiling population subgroups, that could enable more strategic design and evaluation of HIV prevention, care and treatment programs.

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COMPETING INTERESTS

The authors declare no conflicts of interest.

AUTHORS' CONTRIBUTIONS

Study conception: AG JP SM; study design: AG JP SM; protocol development: AG JP SM CC; data collection: CC AG; data analysis and manuscript preparation: CJH AG; manuscript review: all authors. All authors read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Data S1. Additional information regarding study methods.

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RESEARCH ARTICLE

An implementation study of oral and blood-based HIV self-testing and linkage to care among men in rural and peri-urban KwaZulu-Natal, South Africa

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Abstract

Introduction: In South Africa, men living with HIV are less likely than women to test and know their status (the first UNAIDS "90-90-90" target), and men have worse outcomes across the HIV care cascade. HIV self-testing (HIVST) may address this testing disparity but questions remain over the most effective distribution strategy and linkage following a positive test result. We implemented a men-focused HIVST distribution programme to evaluate components contributing to participation and retention.

Methods: We conducted an implementation study of multi-venue HIVST kit distribution in rural and peri-urban KwaZulu-Natal (KZN), South Africa. We distributed HIVST kits at community points, workplaces and social venues for on site or take-home use. Clients could choose blood-based or oral-fluid-based HIVST kits and elect to watch an in-person or video demonstration. We provided a USD2 incentive to facilitate reporting test results by phone or SMS. Persons with reactive HIVST results were provided immediate confirmatory tests (if used HIVST on site) or were referred for confirmatory testing (if took HIVST off site) and linkage to care for antiretroviral therapy (ART) initiation. We describe the testing and linkage cascade in this sample and describe predictors of reactive HIVST results and linkage.

Results: Between July and November 2018, we distributed 4496 HIVST kits in two regions of KZN (96% to men, median age 28 (IQR 23 to 35). Most participants (58%) chose blood-based HIVST and 42% chose oral-swab kits. 11% of men were testing for the first time. A total of 3902 (83%) of testers reported their test result to the study team, with 314 (8%) screening positive for HIV. Among 274 men with reactive HIVST results, 68% linked to ART; no significant predictors of linkage were identified. 10% of kit users reported they would prefer a different type (oral vs. blood) of kit for repeat testing than the type they used.

Conclusions: HIVST is acceptable to men and rapid distribution with optional testing support is feasible in rural and peri-urban settings. HIVST kits successfully reached younger men and identified undetected infections. Both oral and blood-based HIVST were selected. Scaling up HIVST distribution and guidance may increase the number of first-time testers among men and help achieve the first UNAIDS "90" for men in South Africa.

Keywords: HIV infections; male; workplace; South Africa; mass screening; serologic tests

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1 | INTRODUCTION

In sub-Saharan Africa, men access HIV testing and treatment services at lower rates than women [1,2]. Across the UNAIDS 90-90-90 cascade for HIV testing, taking antiretroviral therapy (ART) and virological suppression on ART, men have worse indices than women [1,3]. Following the World Health Organization's (WHO) 2016 recommendation to provide HIV self-test (HIVST) services to improve access to testing, prevention and treatment, South Africa introduced guidelines for HIVST services and support in 2017 [4-6]. In South Africa, the testing gap between men and women has persisted and men have not met any 90-90-90 targets, despite rapid scale-up of ART access and adoption of universal test-and-treat policies [7,8]. Increasing access to HIVST through community-based distribution of kits may overcome some barriers men experience to learning their HIV status, including wanting to avoid female-dominated clinic settings, by providing the convenience to test at home or during hours compatible with a work schedule, overcoming traditional masculine ideals in this population about care-seeking and self-reliance, and reducing initial perceived stigma associated with accessing clinic settings [9-13].

Early, large-scale demonstrations of HIVST kit distribution showed success in increasing HIV testing among men in three sub-Saharan African countries using approaches including community-based, workplace-based and health facility-based distribution [14]. Studies of HIVST distribution to men by female partners have demonstrated moderate linkage to care [15,16], but these studies often relied on secondary reporting about men's behaviour by female partners. Less is known about successful linkage for men after a positive HIVST received in a community programme. We conducted a multi-venue distribution programme of HIVST kits targeting men in the KwaZulu-Natal Province of South Africa. Our aim was to understand whether HIVST distribution is feasible to engage men in testing, to determine the yield of HIV detection and linkage to care for men by providing HIVST in South African communities and to determine predictors of retention along the HIV cascade for men who use HIVST, in order to better optimize engagement for men.

2 | METHODS

We conducted and evaluated a multi-venue distribution programme of HIVST kits in peri-urban and rural districts of KwaZulu-Natal, South Africa, that targeted adult men. In order to understand the impact of HIVST in resource-limited settings with a view towards programmatic scale up, we designed the distribution to be pragmatically implemented, with lay staff providing most services and minimal participation incentives.

2.1 | HIVST kit distribution procedures

Teams of 3-6 lay counsellors set up distribution sites (4-8 events per week during the study period) in community centres, at male-dominated workplaces (farms, agricultural industry, factories, construction sites, taxi ranks), and at venues including sporting events, tuckshops, bottle shops and other public gatherings. Two types of HIVST kits were available at distribution events: a fingerprick blood-based kit (iTest, Atomo, Sydney, Australia) [17] and an oral-fluid-based kit (Oraquick, OraSure, Bethlehem, PA, USA). At each event, counsellors provided a brief informational session on the importance of testing for HIV, what HIVST is, and emphasized key messages about HIVST (Figure 1). Counsellors conducted a live demonstration of how to use and interpret both test kits, and provided cell-phone videos demonstrating kit use, available for watching on site or at home. Men were then invited to select a test kit. They had the option to use the test immediately in a private booth, with or without assistance from a staff person, or take a kit for use after the event. Event duration ranged from one hour workplace sessions to half-day community sessions, with small group information sessions repeated throughout an afternoon.

2.2 | Data collection and ascertaining results

Counsellors obtained informed consent from men interested in participating prior to distributing kits. The only eligibility criterion was being age 18 or older. Participants completed a baseline questionnaire about demographics, HIV testing history, sexual behaviours, alcohol use, test kit preferences and cell phone number. They received a test kit labelled with a study identification number.

Participants were asked to report the results of their HIVST to the study team. All participants received a callback card with their HIVST kit to report the results of their self-test to the study team, as well as a voucher for cellphone airtime (valued at USD2) to be redeemed at the time of reporting results. Participants who tested on site presented to study staff after testing to voluntarily report their results or could elect to leave the site and report results later using the callback card. Participants who were directly assisted by study staff in conducting the HIVST reported their results directly as they received them. Persons taking kits off site reported results by calling or sending an SMS/text message to the number on the callback card for a free callback by a study staff person. Staff then contacted the participant and ask for the HIVST result. Study staff provided post-HIVST counselling including referral for confirmatory testing and ART if the HIVST was reactive, or HIV prevention information and referral for voluntary male medical circumcision if the HIVST was nonreactive.

Participants received a non-identifying reminder text message after 2 weeks if they had not yet reported their result. ("Act now--test for HIV**!** Did the test? Call or send a Please Call Me to XXX."). The reminder was repeated at 1 and 2 months. If no result was reported by 2 months, staff made an outreach call to assess test use and results.

After participants reported their results (either in person or by phone) and received counselling and referrals, staff distributed the airtime incentive and administered a brief questionnaire to assess experience, usability, acceptability and preferences about HIVST.

Distribution events also provided confirmatory HIV testing on site (using standard rapid tests performed by lay counsellors trained in the national Department of Health algorithm) and linkage to ART for persons with positive confirmatory tests. Linkage was offered either through referral to a local clinic of the participant's choice or referral into an ongoing ART delivery study (DO ART study, ClinicalTrials.gov NCT02929992).

2.3 | Ascertaining linkage to care and prevention

All participants who reported their HIVST results received a phone call 2 months after results reporting to assess whether they had linked to confirmatory testing and ART or preventive services. We defined linkage to ART as attending clinic (or enrolling in the DO ART study) and initiating ART. Study staff validated a portion of self-reported ART initiation by confirming registration with ART clinics.

2.4 | Statistical analysis

Percentages were calculated for descriptive statistics. Crude and adjusted relative risks of positive HIVST results were calculated among men with a known HIVST result for selected predictors. Crude and adjusted relative risks of linkage to care were calculated among men with a reactive HIVST. Relative risks were, adjusted for potential sociodemographic confounders: age, study site, testing venue type, testing location,

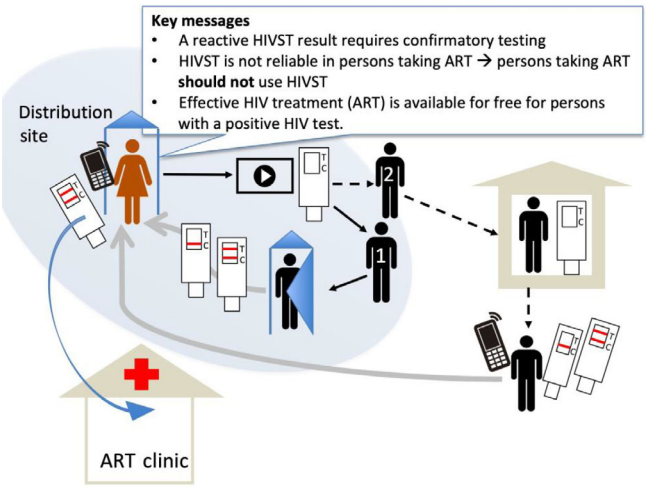

Figure 1. Schematic diagram of HIVST distribution and testing procedures. At the distribution site, study staff provided education, distributed HIVST kits and demonstrated or showed videos of how to use kits. 1) On site testing (solid black arrows): men received a test kit, used the kit in a private booth, then reported their result (solid grey arrow) to study counselling staff. Counselling staff referred to local clinics (blue arrow) for ART initiation if the HIVST was positive and confirmed. 2) Off site testing (dashed arrows): Men collected a kit at the distribution site, watched a demonstration, then took the kit home. After using the kit, they would call or SMS to study staff to report results (solid grey arrow), receive counselling and referral to clinic for confirmatory testing & ART initiation.

HIV testing history, circumcision status, educational status, marital status, employment status and self-reported alcohol use. Adjusted relative risks were calculated in R using modified Poisson regression for binary outcomes with robust variance estimation.

2.5 | Ethics

The study was reviewed and approved by the institutional review boards or ethics committees of the Human Sciences Research Council, University of KwaZulu-Natal, and the University of Washington. All participants provided informed consent.

3 | RESULTS

3.1 | Characteristics of tests distributed and recipients

Between July and November 2018, study teams distributed 4496 HIVST kits (1890 oral fluid kits, 2605 blood-based kits) to South African adults in two districts.

Persons receiving HIVST kits at the distribution sites were overwhelmingly men (96%) by design (Table 1). The median age was 28 years (IQR 23 to 35). Over a third (36%) of participants were unemployed. Eleven percent of participants reported never testing for HIV and 40% of previous testers reported they last tested more than 12 months earlier. Fifty-four percent of men reported being circumcised at baseline. Most (4216, 94%) were unmarried and 37% reported having more than one current sexual partner. More than half of participants reported some alcohol use.

Almost all men (86%) stated that the reason they elected to test using HIVST was that they wanted to know their HIV status. Seven percent stated their reason was HIVST was more convenient than facility-based HIV counselling and testing, and 3% stated they participated to receive the airtime incentive.

3.2 | HIVST results and linkage

Test results were reported for 3486 (81%) of HIVST kits distributed to men. Overall, a total of 8% of reported test results were reactive for HIV antibodies. Among 274 men with reactive HIVST results, linkage outcome was determined for 81% (the remainder could not be reached after multiple attempts, or confirmed remotely); 72% of men with reactive HIVSTs received a confirmatory test (6 confirmatory tests were negative), and 95% of men with a positive confirmatory test linked to care and initiated ART. Overall, 68% of men with reported reactive HIVST results successfully linked to ART.

Retention along the cascade differed between men who tested on site and men who took kits off site to test (Figure 2). Results were ascertained for 100% of tests used by men testing on site; 11% were reactive (Figure 2A). Among men with reactive tests whose linkage status was confirmed (81%), 60% linked to care for confirmatory testing and initiating ART. In comparison, 73% of men who tested off site reported HIVST results, 4% were reactive, linkage was confirmed for 81% and 72% linked to care and started ART (Figure 2B). Participants who did not report HIVST results did not differ significantly from participants with known results with regards to any baseline characteristics assessed, except for the kit type selected. Participants with unknown results were slightly more likely to have chosen a blood-based test (472/745, 63%) compared to participants with known results (2133/3750, 57%).

We evaluated predictors of a reactive HIVST among men whose test results were known (Table 2).

Men who took an HIVST kit off site to test had a lower risk of a reactive HIVST compared to men who tested on site (adjusted risk ratio 0.66, 95% CI 0.49 to 0.88). Factors associated with increased risks of a reactive HIVST included older age, uncircumcised status and unmarried status. Self-reported alcohol use of seven drinks or more per week was associated with 72% higher risk of a reactive HIVST compared to less alcohol use (aRR: 1.72, 95% CI 1.31 to 2.26). Men who reported previously testing for HIV had a decreased risk of a reactive HIVST (aRR 0.70, 95% CI 0.51 to 0.95), compared to men who reported being first-time testers.

Men testing off site were slightly more likely to link to care than men testing on site, (RR 1.24, 95% CI 0.89 to 1.71), but this was not statistically significant. The increased likelihood disappeared after adjusting for demographic features (aRR 1.04, 95% CI 0.75 to 1.63); no statistically significant predictors of linkage to ART were found among men with reactive HIVST results with linkage data available (Table 3). Men with reactive results who had not linked to care at the time of the linkage ascertainment call cited several reasons, including lack of time to go to clinic, having to be at work during the hours that the clinic is open, and being concerned about long wait times at clinic.

Table 1. Characteristics of HIVST kit distribution and recipients

	Total N (%)
Study district	
Peri-urban	1863 (41%)
Rural	2632 (59%)
Distribution setting	
Mobile van	3175 (71%)
Social venue-based	211 (5%)
Workplace	1003 (22%)
Other	107 (2%)
Kit type selected	
Oral fluid	1890 (42%)
Blood-based	2605 (58%)
Age, median (IQR)	28 (23 to 35)
Sex	
Male	4307 (96%)
Female	189 (4%)
Education	
Primary	572 (13%)
Secondary+	3897 (87%)
Unemployed	1626 (36%)
Marital status	
Married	280 (6%)
Unmarried	4216 (94%)
Number of current sex partners	
0	144 (3%)
1	2697 (60%)
>1	1636 (37%)
Ever tested for HIV	
Yes	3982 (89%)
No	505 (11%)
Circumcised (men)	
Yes	2407 (56%)
N	1879 (44%)
Alcohol use (drinks in past week)	
0	1865 (41%)
1 to 6	1943 (43%)
7+	665 (15%)

IQR, inter-quartile range.

3.3 | Experiences and preferences

Men reporting HIVST results (N = 3488) completed a questionnaire about their experience using the kits and learning their HIV status. Most (3389, 97%) reported that using the test kit was "easy" or "very easy." Most men (2334, 67%) reported that they learned to use the kit from the in-person demonstration, and 2937 (84%) reported that they did not require additional help in using the kit. 697 (20%) reported receiving help from a study counsellor using the kit or interpreting results and 26 (1%) requested help from a friend or family member.

Men were asked what type of HIVST kit (blood- or oral-fluid-based) they would prefer to use in the future, based on their experience with the type they used. Over 90% of men reported a preference to use the same type they had used initially: 1428 (90%) of Oraquick users reported preferring to do a repeat test with Oraquick, and 1928 (93%) of the blood-based iTest users stated they would prefer to use the iTest again.

At the two-month outreach call to ascertain HIVST results, 92/3576 (2.6%) men reported they did not use the kit they received. The main reasons cited for not using the HIVST were: being unsure how to use it, not having time to use it, and losing the kit. Five men stated that they attempted to use the blood-based kit and could not obtain blood with the lancet, so could not complete testing. Two men disclosed they were already taking ART (which they did not disclose at the time of receiving the test kit), so did not use the kit.

4 | DISCUSSION

Offering HIVST kits in community-based settings successfully reached men in South Africa for HIV testing, including young men, and resulted in 68% linkage to care among men reporting a reactive HIVST. Small cadres of lay health counsellors distributed over 1000 HIVST kits per month to men, of which nearly 12% were used by first-time testers. Team members were able to provide support for HIVST as needed by clients. These findings support that HIVST strategies found to be efficacious in randomized controlled trials are effective in increasing HIV testing in men in a quasi-programmatic implementation setting [18,19]. Taken with the modelling data of community-based HIVST strategies showing that approaches targeting adult men are among the most cost-effective testing interventions in high-HIV prevalence settings like South Africa, these data suggest that HIVST could and should be scaled up country-wide [20].

In addition to the variety of locations targeted for HIVST distribution, providing men with options for test type (blood- and oral-fluid-based) and support during testing (demonstration of test kits, staff-assisted testing/interpretation or no additional support) was valued. We observed differences in the proportion of first-time HIV testers, prevalence of circumcision and kit type preferences between the two study districts, highlighting the need for options to address preferences in blood versus oral-based HIVST, locations for testing and support needs among the diverse group of men we tried to reach [21,22]. Studies have alternately identified populations with strong preferences for blood-based kits [23] and oral-fluid-based kits [24]; our finding that both types were initially selected and 90% of men would test again with the type they chose supports the importance of providing choice of oral fluid and blood-based HIVST.

First-time testers, men who elected to test on site, and men who used alcohol heavily were more likely to have a reactive HIVST than repeat testers, men who tested off site and men who had lower alcohol use. These findings are encouraging in showing that HIVST can reach men with these risk factors, and also confirms these risk factors for undetected HIV infection. Alcohol use is a known risk factor for HIV transmission, but many men in South Africa who use

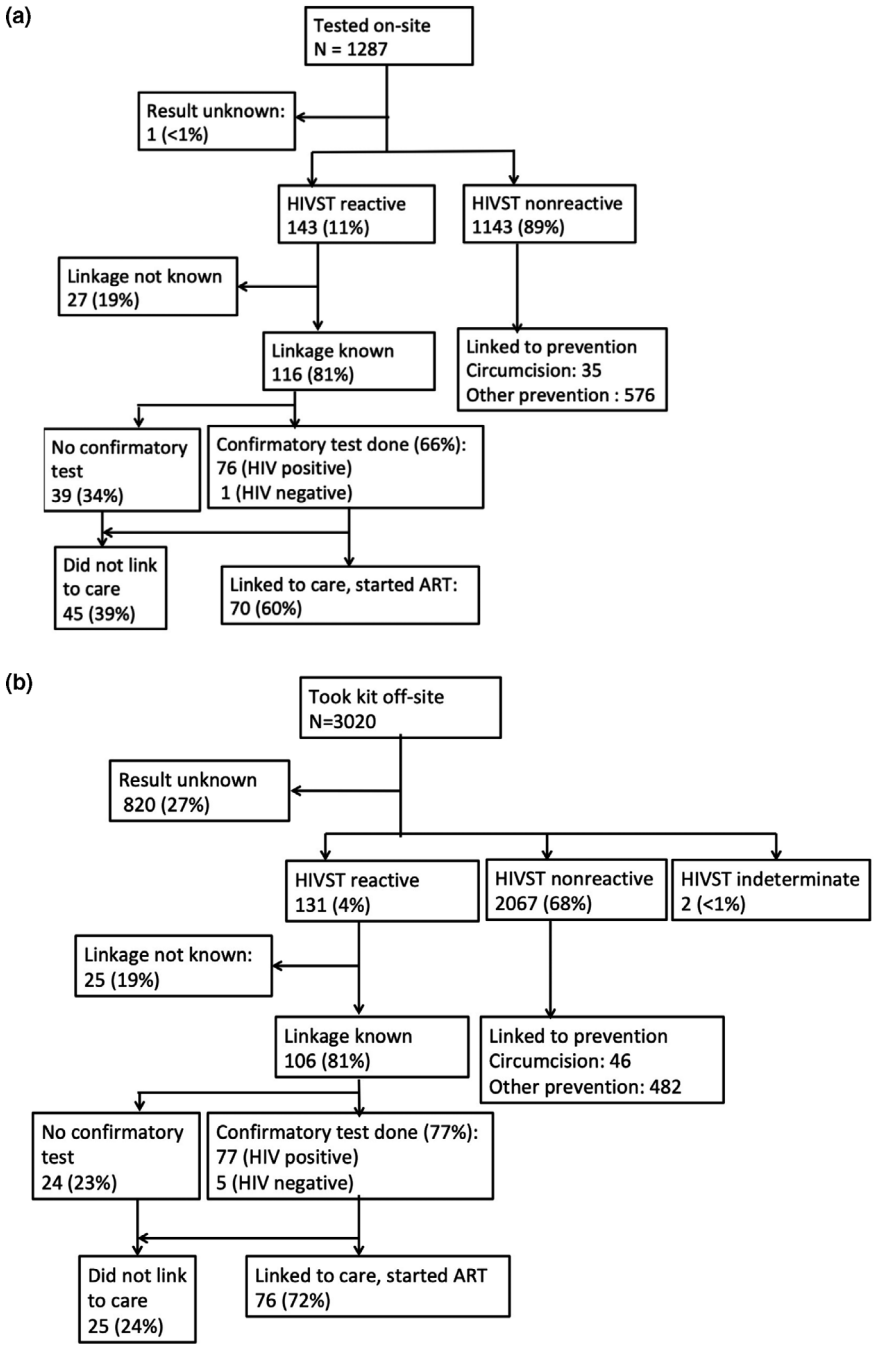

Figure 2. HIVST testing, results and linkage cascade for N = 4307 men in South Africa given an HIVST kit. (a) Men who tested at the distribution site (on site) using HIVST kit; **(b)** Men who took HIVST kit off site. HIVST: HIV self-test.

alcohol heavily report barriers to accessing HIV services, in some cases related to their alcohol use [25,26]. HIVST may be a particularly effective component of strategies to provide HIV testing to men who use alcohol heavily.

In all distribution settings, HIVST distribution was acceptable. A small incentive was adequate to promote reporting of HIVST results for over 80% of participants. Without additional incentives to further engage in care, we observed that 68% of men with reactive tests linked to care and initiated ART. This is encouraging, and consistent with community and household-based HIV testing efforts in the region [27]. We anticipate that a similar rate of linkage could be achieved in a programmatic setting, and thus would not recommend that Departments of Health devote the additional time and resources necessary to ascertain HIVST results. However, this rate of linkage is still well below the target of 90%. HIVST options address some, but not all, barriers men face with HIV testing and linkage. HIVST can be empowering to allow men to test where, when and how they choose, but does not address travel time, costs, lost work and stigma associated with attending public health facilities to initiate treatment, even when ART is free and available.

Table 2. Predictors of reactive HIVST results in men

Predictor	Categories	n/N	Crude Risk Ratio	95% Confidence interval *p*-value	Adjusted Risk Ratio[a]	95% Confidence Interval *p*-value
Age	<30	84/ 1993	-ref-	2.34 to 3.91	-ref-	1.74 to 2.99
	>=30	190/ 1491	3.02	$p < 0.0001$	2.28	$p < 0.0001$
Self-test location	On site	143/ 1286	-ref-	0.42 to 0.68	-ref-	0.49 to 0.88
	Off site	131/ 2198	0.54	$p < 0.0001$	0.66	$p = 0.0044$
Ever tested for HIV before	No	55/ 379	-ref-	0.36 to 0.65	-ref-	0.51 to 0.95
	Yes	219/ 3097	0.49	$p < 0.0001$	0.70	$p = 0.023$
Education level	Primary	55/ 416	-ref-	0.40 to 0.72	-ref-	0.61 to 1.16
	Secondary +	215/ 3049	0.53	$p < 0.0001$	0.84	$p = 0.29$
Employment	Unemployed	108/ 1258	-ref-	0.68 to 1.11	-ref-	0.65 to 1.14
	Employed	166/ 2226	0.87	$p = 0.25$	0.86	$p = 0.29$
Marital Status	Married	17/ 208	-ref-	0.59 to 1.57	-ref-	1.00 to 2.77
	Not married	257/ 3276	0.96	$p = 0.87$	1.67	$p = 0.049$
Alcohol use (drinks/ week)	0 to 6	199/ 2956	-ref-	1.62 to 2.75	-ref-	1.31 to 2.26
	>=7	75/ 528	2.11	$p < 0.0001$	1.72	$p < 0.0001$
Circumcised	No	188/ 1514	-ref-	0.26 to 0.44	-ref-	0.33 to 0.57
	Yes	83/ 1955	0.34	$p < 0.001$	0.43	$p < 0.0001$

[a]Adjusted for: test site, age, self-test location, ever tested for HIV before, education level, employment status, marital status, alcohol use and circumcision status.

Table 3. Predictors of linkage to ART among men with reactive HIVST results

Predictor	Categories	n/N	Crude Risk Ratio	95% Confidence interval *p*-value	Adjusted Risk Ratio[a]	95% Confidence Interval *p*-value
Age	<30	39/57	-ref-	0.68 to 1.42	-ref-	0.75 to 1.63
	>=30	107/159	0.98	$p = 0.93$	1.11	$p = 0.60$
Self-test location	On site	70/115	-ref-	0.89 to 1.71	-ref-	0.72 to 1.52
	Off site	76/101	1.24	$p = 0.2$	1.04	0.83
Ever tested for HIV before	No	32/49	-ref-	0.71 to 1.55	-ref-	0.67 to 1.53
	Yes	114/167	1.05	$p = 0.82$	1.01	$p = 0.96$
Education level	Primary	31/43	-ref-	0.62 to 1.36	-ref-	0.62 to 1.47
	Secondary +	113/171	0.92	$p = 0.67$	0.96	$p = 0.84$
Employment	Unemployed	61/80	-ref-	0.59 to 1.14	-ref-	0.59 to 1.25
	Employed	85/136	0.82	$p = 0.24$	0.86	$p = 0.42$
Marital Status	Married	10/14	-ref-	0.50 to 1.79	-ref-	0.44 to 1.73
	Not married	136/202	0.94	$p = 0.86$	0.87	$p = 0.69$
Alcohol use (drinks/week)	0 to 6	111/161	-ref-	0.63 to 1.35	-ref-	0.64 to 1.40
	>=7	35/55	0.92	$p = 0.68$	0.95	$p = 0.79$
Circumcised	No	105/157	-ref-	0.75 to 1.54	-ref-	0.8 to 1.71
	Yes	41/57	1.08	$p = 0.69$	1.17	$p = 0.42$

[a]Adjusted for: age, self-test location, ever tested for HIV before, education level, employment status, marital status, alcohol use and circumcision status.

In this study, men who elected to test on site (with or without direct assistance from a study team member) were more likely to be HIV-positive, but less likely to link to care compared to men who took HIVST off site to test at home or by themselves. Much of the discrepancy in linkage was explained by important demographic differences in these two groups. However, the discrepancy suggests ways to target interventions to men at higher risk of not linking to care. For example providing on site rapid ART initiation for men with a reactive HIVST and confirmatory test could overcome the initial linkage to care barrier in this population, a service not required for all men needing to link to care, but may benefit this

particular at-risk population. The CASCADE study in Lesotho demonstrated that immediate ART initiation after community-based HIV testing increased linkage to care and viral suppression compared to referral to clinic facilities to initiate treatment, and an early study of linkage after self-testing found that home-based confirmatory testing and ART initiation was associated with greater ART initiation than clinic referral [28,29]. Additional linkage and support tools, such as enhanced or automated post-test follow-up, automated mobile phone-based applications providing linkage reminders and resources, and after-hours, geographically flexible ART initiation approaches, may all have a role in improving retention on the HIV cascade of care for men engaging testing through HIVST [30,31]. Following testing, behavioural economics approaches, such as lottery incentives, can have short-term impact on linkage and decrease time to ART initiation [15,32].

4.1 | Strengths and limitations

Our program had several notable strengths. We conducted HIVST distribution in a pragmatic way designed to be adapted and scaled up to a programmatic setting, where resources for individualized services and follow-up may be limited. Although our project used additional resources to follow up participants beyond what may be feasible in a programmatic setting, these were limited to ascertainment of outcomes: incentives were provided for participants to report results to assess outcomes, and follow-up phone calls to assess HIVST use and linkage to care. Because incentives to report results were not contingent on the result itself, we do not anticipate significant bias was introduced as a result of providing the incentives. In summary, we demonstrated the feasibility of rapid, large-scale distribution of HIVST to reach men, including men who have not yet accessed HIV testing, and high rates of results ascertainment, and linkage-to-care.

Our study had some limitations. HIV testing history, HIVST results and linkage to care data were obtained by self-report, which is subject to responder bias and social desirability bias. For a variety of reasons, people who know their HIV status, including persons on ART, do not always disclose this knowledge in testing settings [33]. There is the possibility that some participants with known HIV-positive status and already on ART participated in HIVST without disclosing their testing and treatment history; this may have overestimated the true proportion of first-time testers. However, education was provided at every test distribution session to discourage HIVST among persons already on treatment. HIVST results from on site testing were visually confirmed by study staff and determined reliable interpretation of HIVST results. Additionally, we were able to validate a subset of self-reports of reactive HIVST results and self-reports of linkage to care with checking clinic registers, and did not find significant inaccuracy in reporting. Our data on linkage may under-represent linkage to care and ART initiation, as HIVST-reactive participants may have initiated ART after the single linkage ascertainment call, which would not have been captured. We were not able to formally assess the cost-effectiveness of the project, which remains a gap in our understanding of the overall impact of HIVST as part of a broader HIV strategy. Finally, due to the pragmatic nature of this implementation, we were unable to ascertain results of all HIVST kits (19% missing data, including 27% missing data among men who took HIVST kits off site to test) and confirm all linkage data among persons with a positive test (19% missing data). This rate of missing data limits the strength of confidence in the predictors to participants who had complete data available, and may not fully extend to the entire population of men in the study sample, particularly the "hardest-to-reach" men whom we were unable to contact. However, we note that less than 20% missing data at each step of the cascade still reflects an overall high rate of retention, from which we can draw important conclusions about the majority of men who we were able to contact, and highlights the real-life challenges of ascertaining outcomes of self-testing in programme settings.

5 | CONCLUSIONS

Men continue to contribute disproportionately to undiagnosed people living with HIV in South Africa. HIVST distribution to men in community settings, including workplaces and social venues, is a feasible strategy to increase the number of men learning their HIV status in South Africa. This strategy can reach thousands of men per month with limited staff and resources, though cost-effectiveness data are lacking and should be urgently pursued as a priority. Essential components of the acceptability of HIVST were access to multiple testing modalities (blood and oral-fluid-based HIVST) and availability of staff support. Although HIVST distribution increased the number of men who learned their positive HIV status ("first 90") and resulted in moderate linkage to ART initiation (approximately 68%), HIVST distribution alone was not sufficient to ensure complete linkage to care. Additional strategies and support are needed to increase engagement of HIV-infected men in linkage to ART after a reactive HIVST result to optimize the HIV cascade; these should be pursued aggressively in combination with continued access to HIVST.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

AES, CLC, HvR and RVB designed the study. MK, AvH, KS, OK and NS conducted the project and collected the data. TTS and AES analysed the data. AES and RVB drafted the manuscript. All authors contributed to revisions and content of the final manuscript.

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RESEARCH ARTICLE

Lottery incentives have short-term impact on ART initiation among men: results from a randomized pilot study

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Abstract

Introduction: Among people living with HIV in South Africa, viral suppression is lower among men than women. The study aim was to test the impact of lottery incentives, which reward positive health choice (e.g. antiretroviral therapy (ART) linkage) with a chance to win a prize, on strengthening the HIV care continuum including ART initiation and viral suppression for men.

Methods: We conducted a randomized, prospective trial of lottery incentives in the context of HIV testing and linkage to ART in rural KwaZulu-Natal, South Africa. Men living with HIV were randomly allocated to: lottery incentives and motivational text messages or motivational text messages only. Lottery prize eligibility was conditional on clinic registration, ART initiation, or viral suppression by one, three and six months respectively. After completing each continuum step, participants in the lottery group were notified whether they had won and were encouraged to continue in care. Lottery prizes were either a mobile phone, data or a gift card (valued at R1000/$100). Kaplan–Meier curves were plotted to determine time to ART initiation by study group. The primary outcome was viral suppression at six months.

Results: Between November 2017 and December 2018, we tested 740 men for HIV and enrolled 131 HIV-positive men who reported not being on ART. At baseline, 100 (76%) participants were 30 years and older, 95 (73%) were unemployed and the median CD4 count was 472 cells/μL. At study exit, 84% (110/131) of participants had visited a clinic and 62% (81/131) were virally suppressed. Compared to motivational text messages, lottery incentives decreased the median time to ART initiation from 126 to 66 days (p = 0.0043, age-adjusted Cox regression) among all participants, and, from 134 days to 20 days (p = 0.0077) among participants who were not virally suppressed at baseline. Lottery incentives had an inconclusive effect on clinic registration (RR = 1.21, 95% CI: 0.83 to 1.76) and on viral suppression at six months (RR = 1.13, 95% CI: 0.73 to 1.75) compared to motivational text messages.

Conclusions: Conditional lottery incentives shortened the time to ART initiation among South African men. Behavioural economics strategies strengthen linkage to ART, but the study power was limited to see an impact on viral suppression.

Clinical Trial Number: NCT03808194.

Keywords: conditional incentives; HIV; men; South Africa; lottery; ART; continuum of care

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1 | INTRODUCTION

Of the 4.5 million South Africans on antiretroviral therapy (ART) only a third are men, despite men making up 45% of people living with HIV nationally [1]. Viral suppression is lower among men (47%) than women (58%) [1]. In addition, men living with HIV are underrepresented throughout the HIV care continuum, being less likely to test, link to care, initiate ART and more likely to be lost to follow-up compared to women living with HIV [2-5]. In a previous study of an optimized testing and linkage to care package of community-based HIV testing, referral, text message reminders and lay-counsellor support, we were only able to achieve 60% linkage to HIV care and ART among men [6]. Men living with HIV who are not virally suppressed are at risk for HIV-associated morbidity and mortality, and their HIV-negative partners are at risk of HIV acquisition. Thus, innovative strategies are needed to motivate HIV-positive men to engage in care, and specifically to initiate and adhere to ART.

Conditional lottery incentives, which reward positive behaviour choices with a chance to win a prize, are a behavioural economics approach to motivate present-day behaviour for future health gains (e.g. engagement in HIV care to increase long-term life expectancy). Men tend to have preferences that are more risk-tolerant, which is described in health economic literature [7]. As a result, men may be willing to take on

greater risks in seeking greater rewards. Also, in the context of accessing healthcare, men face competing risks and may choose the benefit of informal employment over engagement in HIV care. Lottery strategies are hypothesized to benefit men because men tend to have preferences that are more risk-tolerant [7]. Furthermore, lottery incentive strategies have been successfully used to increase uptake of HIV prevention and treatment [8-12]; in one example, lottery incentives, conditioned on being Sexually Transmitted Infection (STI) negative, decreased HIV incidence by 60% among individuals who scored high on risk questionnaires in Lesotho [9,13], demonstrating one of the largest effects to date of a behavioural intervention for HIV prevention.

Given the success of lotteries to engage men and risk-takers in HIV prevention, we hypothesized that lottery incentives have the potential to overcome both structural and behavioural factors for linking HIV-positive men to care, addressing logistical challenges and risk preferences specific to men [4]. Also, while lottery incentives have shown short-term impact, it is not known if the effect is sustained over time and whether lottery incentives would support sustained viral suppression in addition to ART initiation. Therefore, we tested the effectiveness of lottery incentive strategies on time to ART initiation and the proportion of men achieving viral suppression over time in KwaZulu-Natal, South Africa (the Lotto to Link Study). We tested both the short term, ART initiation, and long term, viral suppression, effects of lottery incentives.

2 | METHODS

2.1 | Study design and participants

We conducted an individual randomized study of conditional lottery incentives to link men living with HIV to care, ART initiation and viral suppression over time. The study was conducted from the Human Sciences Research Council's Sweetwaters field office located in the Greater Edendale area, KwaZulu-Natal, South Africa. The Greater Edendale area is characterized by very high HIV prevalence – 30% prevalence – high unemployment and low per capita income (under USD $2 per day) [14]. The study was supported by local department of health staff and conducted at the Sinathing Clinic, which provides HIV prevention and treatment according to national South African guidelines [15]. HIV care and treatment, including ART and laboratory tests, are provided at a nominal cost or free of charge at public clinics. The study staff worked closely with clinic staff to facilitate study recruitment and successful execution of study procedures.

Eligible participants were age 18 years or older, identified as male gender, resident in the study community for the duration of follow-up, able and willing to provide informed consent, had a positive test for HIV using the national rapid HIV antibody testing algorithm, not currently on ART, and had access to confidential text messaging. Men living with HIV were eligible, regardless of whether they were newly diagnosed, if they were not currently taking ART.

All participants provided written informed consent. The University of Washington Institutional Review Board and the Human Sciences Research Council Research Ethics Committee approved this study.

2.2 | Randomization and masking

Participants were randomized 1:1 to either conditional lottery incentives and motivational text message support for linking to care or motivational text messages only (control group). The unit of randomization was the individual. The randomization sequence was predetermined and available through the staff mobile phone app for each participant enrolled. The randomization allocation was not revealed to staff or the participant until all screening procedures were completed and eligibility was confirmed. The randomization code was generated at the University of Washington (UW) International Clinical Research Center (ICRC). The random allocation was programmed into the mobile phone app by Mobenzi Researcher (Durban, South Africa), with UW ICRC oversight. Due to the difficulty of blinding the study team and study participants to the intervention, the study was unblinded; however, all participants receive two-way, supportive motivational text messages. The laboratory staff, who assessed the primary outcome of plasma HIV viral load, were blinded to the allocation of participants as were the study investigators.

2.3 | Procedures

We conducted community sensitization through community events and engaged with local stakeholders including local community leaders and department of health officials. We met with community members and discussed the study rationale and answered questions. Once local community and department of health permissions were obtained, recruitment for the study began.

Participants were recruited for screening through community-based HIV testing and counselling (HTC) at home, through mobile HTC (testing from mobile vans), and by referral of newly identified men living with HIV and not yet on ART from clinics. Men and women were offered HIV testing, but only men were eligible for the intervention. Comprehensive counselling, including disclosure counselling for couples, on HIV treatment and prevention was provided. Persons who tested positive for HIV but who were not eligible for the study, were referred to local clinics for care. Persons who tested HIV negative were referred for prevention services. Additional health services, specifically measurement of blood pressure for hypertension screening, were offered as services to increase HIV testing uptake. Participants were referred for additional clinical services following local guidelines.

Participants completed a demographic questionnaire including their education level attained, employment status, risk behaviour and previous HIV testing and care. Participants completed a hypothetical lottery questionnaire in which they could choose between a fixed sum of money and a prespecified chance of winning another sum of money. The hypothetical gambling questionnaire assessed their willingness to risk a small guaranteed reward for the chance of a large reward [16]. The results of these gambling questions form the basis of assessing the risk-tolerance score [9]. We used a fingerprint biometric, which was translated to a binary code, to identify the participant at subsequent visits.

At baseline we collected dried blood spot (DBS) cards to assess HIV viral load at enrolment. Detectable viral load was

not confirmed prior to study enrolment; participants reported that they were not engaged in care. Thus, this study population likely represents men living with HIV who were re-engaging in care and men initiating ART for the first time. To assess HIV stage and eligibility for opportunistic infection prophylaxis, point-of-care CD4 testing was conducted. Participants were counselled about HIV natural history, the benefits of viral suppression, ART safety and efficacy, and had the opportunity to ask questions. Participants were referred to the Sinathing Clinic for HIV care and treatment, the nearest clinic to the community where testing was conducted. At the end of the screening visit, study staff ensured that questions were answered and participants understood their results.

Eligible participants were enrolled and randomized to either the conditional lottery incentive group plus motivational text messages (SMS + Lottery) or motivational text messages (SMS) only. Participants in both groups received an optimized ART linkage package, including a clinic referral card and two-way text messages to support linkage to ART. At months 1, 2 and 3, participants received a neutral, encouraging text message, for example "Make good decisions for your health today**!**," with a number to text if they needed additional help. Upon arrival at the clinic, participants provided their fingerprint as identification and confirmation of study participation. The study team member, based at the clinic, recorded the purpose of the visit, that is clinic registration, ART initiation, ART refill or Other.

In addition, participants in the lottery group received an immediate text message after visiting the clinic, which indicated that they had been entered into the lottery for completing the next step in the HIV care continuum. One-week later participants received a text message indicating that they had won the lottery or not and encouraging them to continue to link to care for additional opportunities to win the lottery. The lottery winners were predetermined through a random draw prior to the study start, allowing almost real time notification of winners once they completed each conditional step. The minimum probability of winning the lottery was 1 in 56 at each stage (clinic linkage, ART initiation and viral suppression) – this probability was shared with participants at enrolment. If winning participants did not meet the lottery conditions, that is had not linked to care, initiated ART, or achieved viral suppression which we confirmed with the clinic, the incentive was returned to the pool and a new winner selected.

Lottery eligibility was conditional on clinic registration, ART initiation and viral suppression by one, three and six months respectively. Lottery prizes were either a mobile phone, data or a gift card (all valued at R1000/$100). Participants were eligible for the lottery at each of the steps in the HIV continuum, regardless of whether they had won previously. The lottery prize was deemed sufficient to encourage linkage to care through community discussions. Once a lottery prize had been won, general information was provided to participants in the lottery group that someone had won the lottery prize and sharing the details of the prize selected.

At the six-month exit visit all participants completed a questionnaire on uptake of HIV care, clinic visits, ART initiation, ART adherence barriers to care, acceptability and durability of lottery incentive strategies and risk behaviour. Study staff reviewed the clinic records to confirm the medication and dates of visits. We collected plasma for HIV viral load testing, and provided the result to participants to support their HIV care.

2.4 | Outcomes

The prespecified primary outcomes were linkage to the ART clinic, ART initiation and viral suppression [defined as viral load below the assay limit of detection (<20 copies/mL)] at six months among the intention-to-treat population. Linkage to the ART clinic and ART initiation were assessed by study staff recording the reason for the clinic visit and verification in the clinic chart. Prespecified secondary outcomes included time to ART initiation and evaluation of the primary outcomes among individuals who were classified as risk-tolerant using the risk score.

2.5 | Statistical analysis

We estimated that a sample size of 120 eligible participants would be needed to have at least 80% power to see an absolute 25% difference or more in viral suppression in the lottery group vs. the motivational text message group. Based on our previous work, we estimated that viral suppression would be 60% in the control group [6]. With a 5% loss to follow-up, we expected to retain 57 per group.

Relative risks (RR) of viral suppression, ART initiation and clinic registration and 95% robust confidence intervals were calculated comparing randomization groups using a log-linear regression, assuming a working independence Poisson model (i.e. generalized estimating equations). All regressions included adjustment for age (≥30 years). Hypothesis tests for RR $\neq$ 1 were based on two-sided Wald p-values < 0.05. The number and percentage of participants who initiated ART and the median time to ART initiation was plotted using a Kaplan–Meier curve by study group to illustrate the rate at which participants initiated ART, preferentially using the date of dispensation abstracted from the clinic chart if different from the date reported by the participant. Based on previous studies [6] we expected some participants to enrol with a suppressed viral load, despite reporting not currently being on ART. Therefore, we assessed the impact of the lottery incentive among persons who had detectable viral load at baseline to explore the intervention's effect on participants presumably not already on treatment, in a modified-intension-to-treat analysis.

As described by Nyquist and colleagues [9], we constructed an indicator variable "risk-loving"/risk-tolerant on a scale of 0.0 to 1.0, where 1.0 is a risk-tolerant and 0.0 is a risk-averse participant. Participants who chose the lottery even when the fixed amount offered is equal or greater than 500 ZAR (50% chance of winning 1000 ZAR) were assigned a risk-tolerant score of 1.0 and those who consistently chose the fixed amount below the expected value of the lottery (500 ZAR) received a risk-tolerant score of 0.0 (i.e. they are risk-averse). To generate the "risk-tolerance index" (RTI), responses were normalized from 0 (safest) to 100 (riskiest) for the hypothetical lotteries in the questionnaire, and the mean of the lotteries were combined for the RTI. To explore a pragmatic definition of risk, we defined risk as having a detectable viral load as a marker of seeking care late. We used R 3.5 for all the analyses.

2.6 | Laboratory analysis

Community HIV testing was conducted using blood obtained by finger-stick and tested using rapid serologic tests according to national guidelines by ABON HIV Rapid test (Alere, Waltham, MA, USA), and First Response HIV Test (Premier Medical Corporation Ltd, Watchung, NJ, USA) for confirmation, with HIV 1/2 Gold Screening Test (G-Ocean, Singapore) as a tie breaker when needed. Point-of-care CD4 testing (Alere, PIMA™, Waltham, MA, USA) was conducted in the home or mobile van using a finger-stick specimen. Plasma and DBS card were obtained and transported to the reference laboratory for HIV viral load testing by polymerase chain reaction (bioMérieux, Craponne, France) with a limit of detection of 20 copies/mL.

3 | RESULTS

Between November 2017 and December 2018, we tested 740 men for HIV through community HCT and clinic referral and 150 (20%) tested HIV positive. Of the 740 men tested, 609 were excluded; 590 tested HIV negative, 19 did not meet other inclusion criteria. No participants declined study participation. Of the 131 eligible men enrolled in the study, 56 were randomly assigned to the lottery plus text message group and 75 were assigned to the text message only group (Figure 1). The randomization was not blocked and while the group sizes are not even, the difference was not statistically significant and baseline characteristics that could be potential confounders were even by group. No participants were lost-to-follow-up. The primary analysis includes 100% of participants enrolled.

At baseline, 100 (76%) participants were 30 years and older, 113 (86%) attained secondary education level, 95 (73%) were unemployed, 90 (69%) were single, 85 (65%) reported one current sex partner and 102 (78%) reported no condom use at last sex, which was comparable between the study groups (Table 1). Clinical characteristics were also similar between the groups with a median CD4 count of 472 cells/μL. All participants reported that they were currently not taking ART, but surprisingly 73 (56%) percent of participants were suppressed at baseline with a viral load of <20 copies/mL. The median follow-up time was 8.8 months. All three lottery prizes were collected by participants.

In the primary intention-to-treat analyses, at six months, registration at the clinic was high in both groups; 77% in the SMS only group and 93% in the lottery plus SMS group, which were not statistically different (adjusted relative risk [aRR] 1.21, 95% CI 0.83 to 1.76) (Table 2). The proportion of participants initiating ART by six months was high in both groups; 76% in the text message group and 93% in the lottery plus SMS group; which were not statistically different between the groups (aRR 1.23, 95% CI 0.84 to 1.79). There was no difference in viral suppression at six months; 59% of participants in the SMS group and 66% in the lottery group had a viral load of <20 copies/mL (aRR 1.13, 95% CI 0.73 to 1.75).

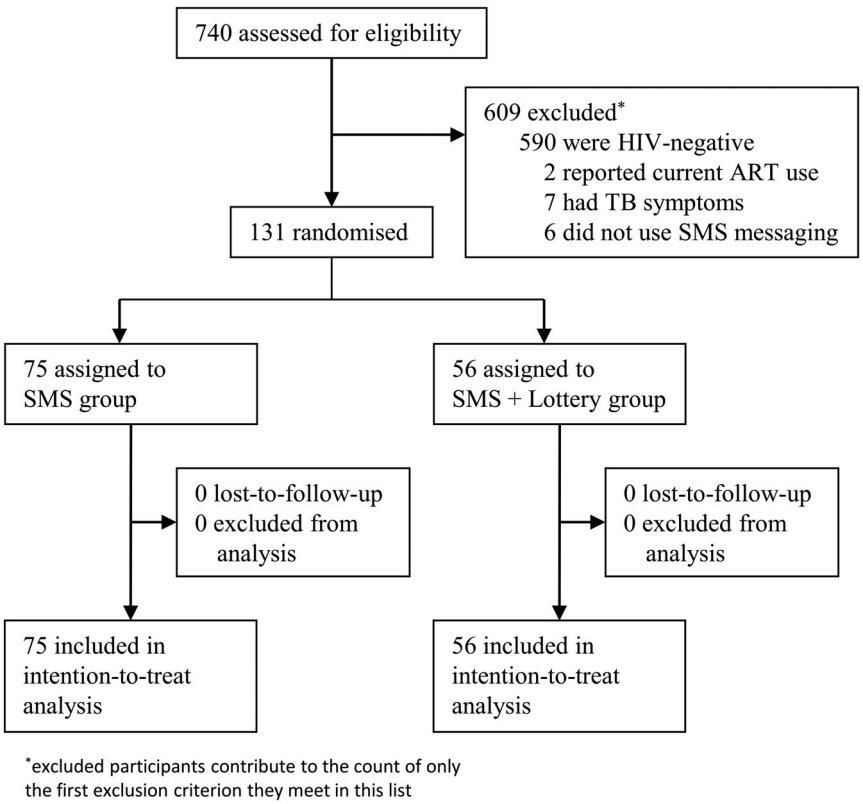

Figure 1. Study profile. ART, antiretroviral therapy; TB, tuberculosis.

Table 1. Baseline characteristics

	Total (n = 131)	SMS (n = 75)	SMS + Lottery (n = 56)
Age			
18 to 24	15 (11%)	8 (11%)	7 (12%)
25 to 29	16 (12%)	9 (12%)	7 (12%)
30 to 49	90 (69%)	50 (67%)	40 (71%)
≥50	10 (8%)	8 (11%)	2 (4%)
Education level			
Primary	18 (14%)	11 (15%)	7 (12%)
Secondary	106 (81%)	58 (77%)	48 (86%)
Tertiary and above	7 (5%)	6 (8%)	1 (2%)
Occupation			
Unemployed	95 (73%)	52 (69%)	43 (77%)
Labourer/semi-skilled/other	29 (22%)	19 (25%)	10 (18%)
Trade/sales	4 (3%)	3 (4%)	1 (2%)
Student	3 (2%)	1 (1%)	2 (4%)
Marital status			
Married	6 (5%)	1 (1%)	5 (9%)
Living together, not married	3 (2%)	2 (3%)	1 (2%)
In a relationship, not married	32 (24%)	24 (32%)	8 (14%)
Single	90 (69%)	48 (64%)	42 (75%)
Number of current sex partners			
0	8/130 (6%)	5/74 (7%)	3 (5%)
1	85/130 (65%)	47/74 (64%)	38 (68%)
≥2	37/130 (28%)	22/74 (30%)	15 (27%)
Condom used at last sex	28/130 (22%)	13/74 (18%)	15 (27%)
Baseline CD4 count[a] (POC, cells/mL)			
<100	2/74 (3%)	2/42 (5%)	0/32 (0%)
100 to 349	24/74 (32%)	10/42 (24%)	14/32 (44%)
350 to 499	14/74 (19%)	7/42 (17%)	7/32 (22%)
≥500	34/74 (46%)	23/42 (55%)	11/32 (34%)
Baseline viral load (DBS, copies/mL)			
<20	73 (56%)	42 (56%)	31 (55%)
20 to 999	15 (11%)	8 (11%)	7 (12%)
1000 to 9999	18 (14%)	10 (13%)	8 (14%)
≥10,000	25 (19%)	15 (20%)	10 (18%)

[a]Functioning point-of-care CD4 count machines were not available for the entire study, thus only 74 CD4 count measures are provided.

Compared to motivational text messages alone, lottery incentives decreased the median time to ART initiation to 66 from 126 days (adjust hazard ratio (aHR) 1.77, 95% CI 1.20 to 2.61, $p = 0.0043$) among all participants (Figure 2a), and to 20 days from 134 days (aHR 2.27, 95% CI 1.24 to 4.14 $p = 0.0077$) among participants who had detectable viral load at baseline (Figure 2b).

Thirty-four participants in the SMS group and 30 in the SMS plus lottery group were assessed as being risk-tolerant based on their responses to hypothetical gambling questionnaires. There was no statistically significant difference in the proportion registering at the clinic, initiating ART, or achieving viral suppression by study group (Table 3). In planned modified intention-to-treat analysis, men with detectable viral load at baseline were about a quarter to a third more likely to register at the clinic (aHR 1.25, 95% 0.71 to 2.22), initiate ART (aHR 1.30, 95% CI 0.73 to 2.32) and become virally suppressed (aHR 1.35, 95% 0.60 to 3.06), although the small sample size did not reach statistical significance (Table 3).

4 | DISCUSSION

In this pilot randomized trial of conditional incentives to strengthen the continuum of HIV care, particularly among men living with HIV, lottery incentives decreased the time to ART initiation overall, particularly among persons with detectable viral load. Clinic registration, ART initiation and viral suppression were higher in the lottery and motivational text message arm, but this did not reach statistical significance in this pilot study. Furthermore, effects were seen early in the continuum of care, that is ART initiation, but were smaller in magnitude later in the continuum, that is viral suppression. The results were not different by risk-tolerance, although men with detectable viral load at enrolment, who were potentially taking greater risks with their health, initiated ART more quickly, half initiating within three weeks in the lottery incentive group compared to 19 weeks in the control group.

While incentives did not have a significant effect on ART uptake, the loss-to-follow-up after six months was notable. While more than 90% of participants in the lottery incentive group registered at the clinic and initiated ART, only two-thirds were virally suppressed – a loss of a third of clients. This suggests that the behavioural economics approach of conditional incentives may have a short-term impact on behaviour and likely requires additional strategies to sustain engagement in care. Well-timed cues for new habit formation, such as lottery incentives, could be added to ART programmes to increase daily ART adherence [17]. The initial "pull" of lottery incentives may increase engagement in care, as manifested by high clinic registration and ART initiation rates, but over time other concerns such as logistics of visiting the clinic and stigma appear to outweigh the incentive effect. Also notable is the proportion of men virally suppressed at baseline (56%), who reported that they were not currently on ART, which may have been motivated by receiving more supportive care through the study. With the remaining sample size of 33 participants in the control group and 25 in the intervention group, our power to see an impact on viral suppression was reduced. Finally, while we did not assess the impact of motivational two-way text messages, this type of intervention has demonstrated utility in other studies [18].

One potential explanation for the findings might be related to the timing of the intervention. We saw success when the intervention occurred after taking the step of engagement – that is fewer days to register at the clinic and initiate ART when patients received a reminder, an immediate text message confirming their lottery entry, and one week later they received the result of the lottery. However, for adherence to and persistence with daily ART pill-taking, additional strategies

Table 2. Effect of conditional lottery incentives on clinic registration, ART initiation and viral suppression at six months

	Registered at clinic		Initiated ART		Viral load <20 copies/mL	
	n (%)	aRR[a] (95% CI)	n (%)	aRR[a] (95% CI)	n (%)	aRR[a] (95% CI)
SMS	58/75 (77%)	Reference	57/75 (76%)	Reference	44/75 (59%)	Reference
SMS + Lottery	52/56 (93%)	1.21 (0.83 to 1.76)	52/56 (93%)	1.23 (0.84 to 1.79)	37/56 (66%)	1.13 (0.73 to 1.75)

[a]aRR, adjusted relative risk. All analyses are adjusted for age.

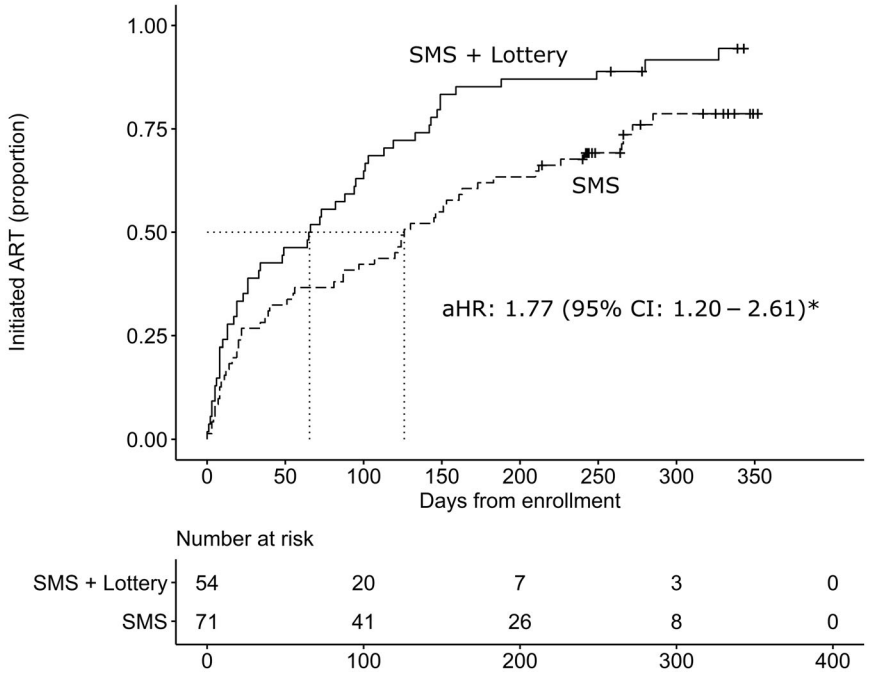

Figure 2. Probability of (a) ART initiation for all participants receiving; **(b)** ART initiation for participants with detectable viral load at baseline receiving (1) SMS + Lottery incentive group or (2) SMS only group. *Adjusted for age less than 30 years.

may be needed. Conditional incentives may be appropriate for a specific, one-time behaviour, but fatigue may prevent the persistence required for daily pill taking.

Among men with detectable viral load, the lottery intervention appeared to increase viral suppression by more than a third, but the small sample size limited the power of this analysis to reach statistical significance. This suggests that a "one-size-fits-all" approach to engagement in the HIV care continuum may not maximize the impact of strategies such as lottery incentives, which could be reserved for persons with detectable viral load as a marker of risk-tolerance but this would need to be tested to ensure that this did not create an incentive to stop taking ART. Behavioural economic approaches require testing among priority populations to increase access to HIV care.

Our findings were consistent with other incentive studies which found a modest or no effect of incentives on sustained viral suppression [12,19-21]; a previous study also had a significant proportion of participants with viral suppression at baseline [20]. However, incentives can work to increase overall viral suppression in specific settings where suppression through usual care is low [11]. An important question is why viral suppression was 62% at the end of six months, below the UNAIDS target of 73% [22]. One explanation is that while lottery incentives provide short-term motivation, barriers to clinic-based care such as transportation, logistics and clinic hours decrease linkage overall [23]. This suggests that other interventions, such as delivery interventions to overcome logistic barriers to clinic access, and simplified regimens such as long-acting injectable ART, which overcome the need for daily adherence, need to be part of a package to engage and retain men in care.

Our study had several limitations. First, although men reported that they were not currently on ART, more than half were virally suppressed at baseline. The impact of viral suppression at baseline is that the study population is likely a combination of men living with HIV engaging in care for the first time, men re-engaging in care and men seeking care through an alternate method. Thus, the impact of lottery incentives for men living with HIV with a detectable viral low (i.e. not engaged in care) was assessed among a subset of 58 men and the analysis was underpowered to show an effect of

Table 3. Effect of conditional lottery incentives on clinic registration, ART initiation and viral suppression at six months among persons with high-risk tolerance scores and persons with detectable viral load at baseline

	Registered at clinic		Initiated ART		Viral load <20 copies/mL	
	n (%)	aRR[a] (95% CI)	n (%)	aRR[a] (95% CI)	n (%)	aRR[a] (95% CI)
Risk-tolerant						
SMS	27/34 (79%)	Reference	26/34 (77%)	Reference	20/34 (59%)	Reference
SMS + Lottery	28/30 (93%)	1.22 (0.72 to 2.09)	28/30 (93%)	1.27 (0.74 to 2.18)	20/30 (67%)	1.16 (0.62 to 2.18)
Detectable baseline viral load						
SMS	25/33 (76%)	Reference	24/33 (73%)	Reference	12/33 (36%)	Reference
SMS + Lottery	23/25 (92%)	1.25 (0.71 to 2.22)	23/25 (92%)	1.30 (0.73 to 2.32)	12/25 (48%)	1.35 (0.60 to 3.06)

[a]aRR, adjusted relative risk. All analyses are adjusted for age less than 30 years.

25% increase in viral suppression. This observation of undisclosed ART use has been described in previous studies [24,25] and may be due to high demand for services among men. To be eligible for the study, participants reported that they were not in care. The higher than expected proportion of participants suppressed at baseline would affect the control and treatment group equally, so the study findings would still be valid even if they might underestimate the potential effects. However, because South African men are a priority group to reach for HIV care, data on the impact of conditional incentives in strengthening linkages to care contributes to a package of services for ART initiation and retention; specifically, the effect among persons with a detectable viral load at baseline. For these persons, while underpowered, the results were encouraging for lottery incentives which could be further investigated. Using point-of-care viral load testing to establish whether persons living with HIV have a detectable viral load may help direct the use of incentive strategies to persons who would benefit from the behavioural "nudge." Second, while we were able to link the clinic registration and ART initiation lottery to those visits, we were not able to do so as easily with the viral load results due to limited access to the laboratory results system. Ideally, being suppressed would trigger a prompt lottery entry message and a detectable viral load would trigger additional support and the prospect of future lottery entry. Lastly, since linkage to care and ART initiation were slow overall, longer windows for linkage, with additional opportunities for incentives, might have increased the proportion achieving viral suppression.

5 | CONCLUSIONS

In summary, lottery incentives for men at each stage of the HIV care continuum decreased time to ART initiation with possible increases in clinic registration and ART initiation compared to the control group of motivational text messages. It is possible that this intervention may be best suited to men with detectable viral loads, for whom the intervention had the biggest impact shortening the time to ART initiation. However, it is likely that men will require additional services to sustain retention in care over time, particularly services aimed at simplifying delivery and increasing adherence.

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COMPETING INTERESTS

We declare that we have no conflicts of interests.

AUTHORS' CONTRIBUTIONS

RVB, AvH, JMB, CC and HvR designed the study. AvH, MK, RBN, PJ and TN oversaw the implementation of the study. RVB wrote the first draft of the paper, which was revised by all authors. All authors contributed to design and execution of the study, as well as to the interpretation of findings. MM provided expertise on behavioural economics. TS did the statistical analysis with input from AAS, RVB, AvH, HvR and CC. All the authors approved the final version of the paper for submission.

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RESEARCH ARTICLE

Index and targeted community-based testing to optimize HIV case finding and ART linkage among men in Zambia

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Abstract

Introduction: Current healthcare systems fail to provide adequate HIV services to men. In Zambia, 25% of adult men living with HIV were unaware of their HIV status in 2018, and 12% of those who knew their status were not receiving antiretroviral therapy (ART) due to pervasive barriers to HIV testing services (HTS) and linkage to ART. To identify men and key and priority populations living with HIV in Zambia, and link them to care and treatment, we implemented the Community Impact to Reach Key and Underserved Individuals for Treatment and Support (CIRKUITS) project. We present HTS and ART linkage results from the first year of CIRKUITS.

Methods: CIRKUITS aimed to reach beneficiaries by training, mentoring, and deploying community health workers to provide index testing services and targeted community HTS. Community leaders and workplace supervisors were engaged to enable workplace HTS for men. To evaluate the effects of these interventions, we collected age- and sex-disaggregated routinely collected programme data for the first 12 months of the project (October 2018 to September 2019) across 37 CIRKUITS-supported facilities in three provinces. We performed descriptive statistics and estimated index cascades for indicators of interest, and used Chi square tests to compare indicators by age, sex, and district strata.

Results: Over 12 months, CIRKUITS tested 38,255 persons for HIV, identifying 10,974 (29%) new people living with HIV, of whom 10,239 (93%) were linked to ART. Among men, CIRKUITS tested 18,336 clients and identified 4458 (24%) as HIV positive, linked 4132 (93%) to ART. Men who tested HIV negative were referred to preventative services. Of the men found HIV positive, and 13.0% were aged 15 to 24 years, 60.3% were aged 25 to 39, 20.9% were aged 40 to 49 and 5.8% were ≥50 years old. Index testing services identified 2186 (49%) of HIV-positive men, with a positivity yield of 40% and linkage of 88%. Targeted community testing modalities accounted for 2272 (51%) of HIV-positive men identified, with positivity yield of 17% and linkage of 97%.

Conclusions: Index testing and targeted community-based HTS are effective strategies to identify men living with HIV in Zambia. Index testing results in higher yield, but lower linkage and fewer absolute men identified compared to targeted community-based HTS.

Keywords: index testing services; finding men; HIV care continuum; linkage to care; HIV testing; sub-Saharan Africa; differentiated care

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1 | INTRODUCTION

Of the 37.9 million people living with HIV (PLHIV) globally, including the 25.6 million residing in sub-Saharan Africa (SSA), 21% remain unaware of their HIV status [1]. To address this gap in SSA, efficient, targeted and evidence-based approaches are urgently needed for HIV case finding programmes, particularly for populations less likely to know their status, such as men [1]. Traditional approaches to HIV testing, such as facility-based testing, while effective for identifying HIV-positive adult women in SSA, have yielded sub-optimal results for reaching men [2].

The HIV epidemic in Zambia is generalized, with HIV prevalence standing at 11.1% among adults aged 15 to 49 [3]. Among men, awareness of HIV status is substantially lower than among women, with 25% of Zambian men having not been tested for HIV and received their results, compared to only 15% of adult women [3]. The problem is most acute among younger men, with 67.1% of HIV-positive males 25 to 29 years old reporting being unaware of their HIV status [4]. Compared to women,

men in Zambia test and obtain their results less frequently and are less likely to link to care [3,4]. Indeed, in the HPTN 071 PopART trial in Zambia, the groups most likely to be missing from the testing and linkage cascade were men and youth [5].

Multiple factors contribute to low testing and linkage rates among men in the HIV care cascade, including cultural notions of masculinity, but also structural factors such as clinic hours and labour requirements [6,7]. Men also cite fears of discovering their HIV status [8] and also often test by proxy and rely on their wives' HIV results [6].

Available facility-based HIV testing modalities in Zambia include voluntary counselling and testing (VCT) and provider-initiated testing and counselling (PITC), which have remained relatively low-yield in SSA [9]. Most HIV programmes in Zambia reported positivity yields in VCT and PITC departments of approximately 4% to 8% [10], with the highest yield reported from facilities in Zambia at 9% [11]. Community-based HIV testing modalities include VCT and mobile/outreach, as well as index testing services (ITS) and partner notification services (PNS) for index clients, which was introduced in Zambia in 2017 to improve HIV case identification.

Community-based HIV testing in SSA has been associated with HIV positivity yields of 6% to 11%, according to a meta-analysis of 126 HIV testing studies in SSA [12]. Targeting community-based testing in venues that feature characteristics associated with a low "number needed to test" to identify a new HIV case, such as where people meet new sex partners, is a promising strategy to improve testing yield [13]. In Zambia, community-based HIV positivity yields in men ranges from 5.2 to 5.7% [14,15] compared to 9.3% among women [14].

By comparison, index testing has consistently been demonstrated to be an effective model for HIV case identification in SSA. Across PEPFAR-supported countries during early ITS roll-out in 2016 to 2018, index testing positivity was 9.8% [9]. Recent literature points to higher yields from index testing in the general population: 10.3% in South Africa [16], 21-29% in Kenya [17], and 32.6% and 38% positivity in similar programs in Zimbabwe [18] and South Africa [19], respectively. At the highest range of programmatic reports, yield in Nigeria [20] and Cameroon [21] reached 51% and 51.8% respectively. ITS has also been shown to increase HIV positivity yield among men in the region [18], as have targeted community HIV testing modalities such as mobile and workplace testing [22].

The Community Impact to Reach Key and Underserved Individuals for Treatment and Support (CIRKUITS) project, implemented by the Center for International Health, Education, and Biosecurity (Ciheb) at the University of Maryland Baltimore (UMB) and the Centre for Infectious Disease Research Zambia (CIDRZ) aimed to enhance HIV case finding, linkage to care and treatment and adherence support at the community level in Zambia. The objective of this paper was to present the CIRKUITS approach to case finding and examine HIV positivity yield and antiretroviral therapy (ART) linkage across index testing and targeted community testing modalities, with sub-analyses by sex, age groups and districts.

2 | METHODS

2.1 | Study design and setting

We conducted a retrospective analysis of programmatic aggregate data collected from 1 October 2018 to 30 September 2019 as part of routine CIRKUITS service delivery. CIRKUITS was implemented across three of Zambia's 10 provinces, Eastern, Western and Lusaka, where estimated HIV prevalence was 7.4%, 10.6%, and 15.1%, respectively (Figure 1) [4]. CIRKUITS was implemented in communities within the catchment areas of 37 participating facilities in these provinces: four urban and five rural facilities in Eastern; three urban and 11 rural facilities in Western and 14 urban facilities in Lusaka. HIV services were delivered to residents in the community by community health workers (CHWs) supervised by community liaison officers (CLOs) working with Ministry of Health (MOH) staff in the corresponding health facilities.

2.2 | Study population

CIRKUITS provided HIV prevention education, testing services and facilitated ART linkage services for all individuals in the community who may be at risk for HIV. In this analysis, we included all individuals 15 years or older that received any community-based HIV testing service as part of the CIRKUITS programme.

2.3 | CIRKUITS intervention

The CIRKUITS approach centred around the work of trained CHWs who were supervised and mentored by CLOs to offer HIV prevention and testing services in the community. CHWs offered different HIV testing services (HTS) modalities to individuals in the community, including voluntary ITS and targeted community testing services. They also provided a combination of HIV preventive services, including health education and referral for voluntary medical male circumcision (VMMC), HIV pre-exposure prophylaxis (PrEP), family planning (FP) and condom distribution. The CLOs and CHWs were supervised by

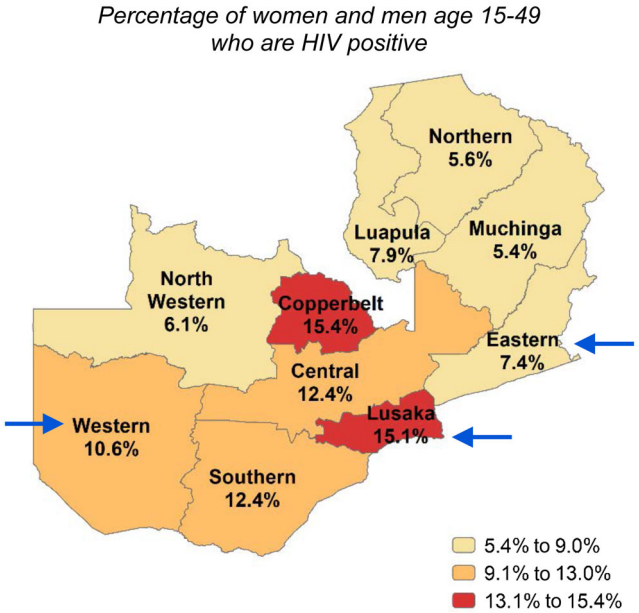

Figure 1. Map of Zambia with HIV prevalence among adults aged 15 to 49 by province. Arrows indicate the provinces in which CIRKUITS was implemented. Data from ZDHS 2018 [3].

Table 1. CIRKUITS staffing across supported provinces and districts

Province	Estimated provincial HIV prevalence[a]	Provincial nurses	District	District CLOs	CIRKUITS-supported facilities	CHWs in district
Eastern	7.4%	1	Chipata	2	6	20
			Petauke	2	3	39
Western	10.6%	1	Mongu	3	7	20
			Limulunga	3	7	15
Lusaka	15.1%	2	Lusaka Urban	12	14	63
Total	Country: 11.1%	4	5	22	37	157

CIRKUITS, Community Impact to Reach Key and Underserved Individuals for Treatment and Support; CLO, community liaison officer; CHW, community health worker.
[a]Prevalence data from ZDHS 2018 [3].

the public health facility staff in their catchment area, were assessed and certified as competent in ITS and PNS by MOH and CIRKUITS technical staff, and reported all community activities to the facility. CIRKUITS had a bidirectional referral system in which either facility staff, or CHWs and CLOs, could direct clients to health services based on their medical conditions and preferences. During the study period, CIRKUITS trained, mentored and deployed 157 CHWs and 22 CLOs to conduct different community-based testing modalities, including ITS (Table 1).

2.4 | CIRKUITS approach to index testing and partner notification services

CIRKUITS employed voluntary and confidential ITS with PNS to increase HIV case identification in the community (see Figure 2). The facility staff, together with CLOs and CHWs, identified individuals as potential index clients eligible for ITS. These included individuals who were diagnosed with HIV in the past six months, had an unsuppressed viral load (>1000 copies/mL), and/or were lost to follow up from ART (>28 days elapsed since last pharmacy pickup). CLOs and CHWs contacted eligible index clients and offered ITS. If the client consented to these services, the CHW then counselled the client on the benefits and importance of their contacts knowing their HIV status, and then proceeded to elicit all sexual contacts in the past year; if the index client was female, they also elicited biological children <15 years. For clients who consented to PNS, the health provider and the client agreed on a referral process for the index contacts following the WHO-recommended approach [23]. CIRKUITS offered three approaches for index client partner notification: (i) for client referral, the index client chose to disclose their HIV status to sexual partners and suggest HIV testing; (ii) for provider referral, CLOs or CHWs obtained consent from the index client to contact sexual partners or biological children to offer HIV testing; (iii) for dual referral, the CHWs or CLOs accompanied the index client to assist with the disclosure of HIV status and offer HTS to their partner(s) or biological children. To minimize gender-based violence (GBV) stemming from partner notification services during index testing, all index cases were screened for risk of GBV via a MOH-approved GBV screening tool. CHWs did not trace any index contact posing a risk of GBV to the index client. Individuals experiencing GBV or at risk for GBV were accompanied to "GBV One Stop Centres," a structured system in Zambia, where clinical, legal and psychosocial counsellors provide comprehensive care to GBV clients [24].

The CHWs then traced all eligible index contacts in the community and offered voluntary and confidential HTS. Sexual partners that tested HIV negative were offered combination HIV prevention services, including FP, VMMC and condoms. High-risk adolescents were linked to youth-friendly spaces established at the health facilities, as well as DREAMS safe spaces in the two DREAMS-supported districts (Lusaka and Chipata). People identified at risk of HIV according to the MOH screening tool were also referred for PrEP. Index contacts identified with HIV were actively accompanied to the facility by the CHW to initiate ART. Any client that deferred same-day ART was followed up in the community for later ART initiation.

2.5 | CIRKUITS targeted community-based testing modalities

In addition to ITS, CIRKUITS provided other community-based testing modalities, including testing in mobile, temporary or other outreach locations (community centres, schools, workplaces, tents) and standalone VCT centres situated outside of affiliated health facilities. The locale of these testing sites was chosen to target priority populations, and often included health education via drama and music. Clients were educated about HIV prevention and the benefits of knowing their HIV status and then offered HTS. HIV-negative persons were offered combination HIV prevention services, including condoms, FP, VMMC and PrEP (if appropriate). HIV-positive persons were offered same-day ART in the community. Alongside testing services, a clinical team was present to initiate ART immediately, including HIV nurse prescribers, pharmacists and psychosocial counsellors. In cases where no facility healthcare workers were available to join the clinical team due to competing facility demands, clients were actively escorted to the facilities by a CLO or CHW for ART initiation, followed by peer health navigation and adherence support to encourage sustained ART.

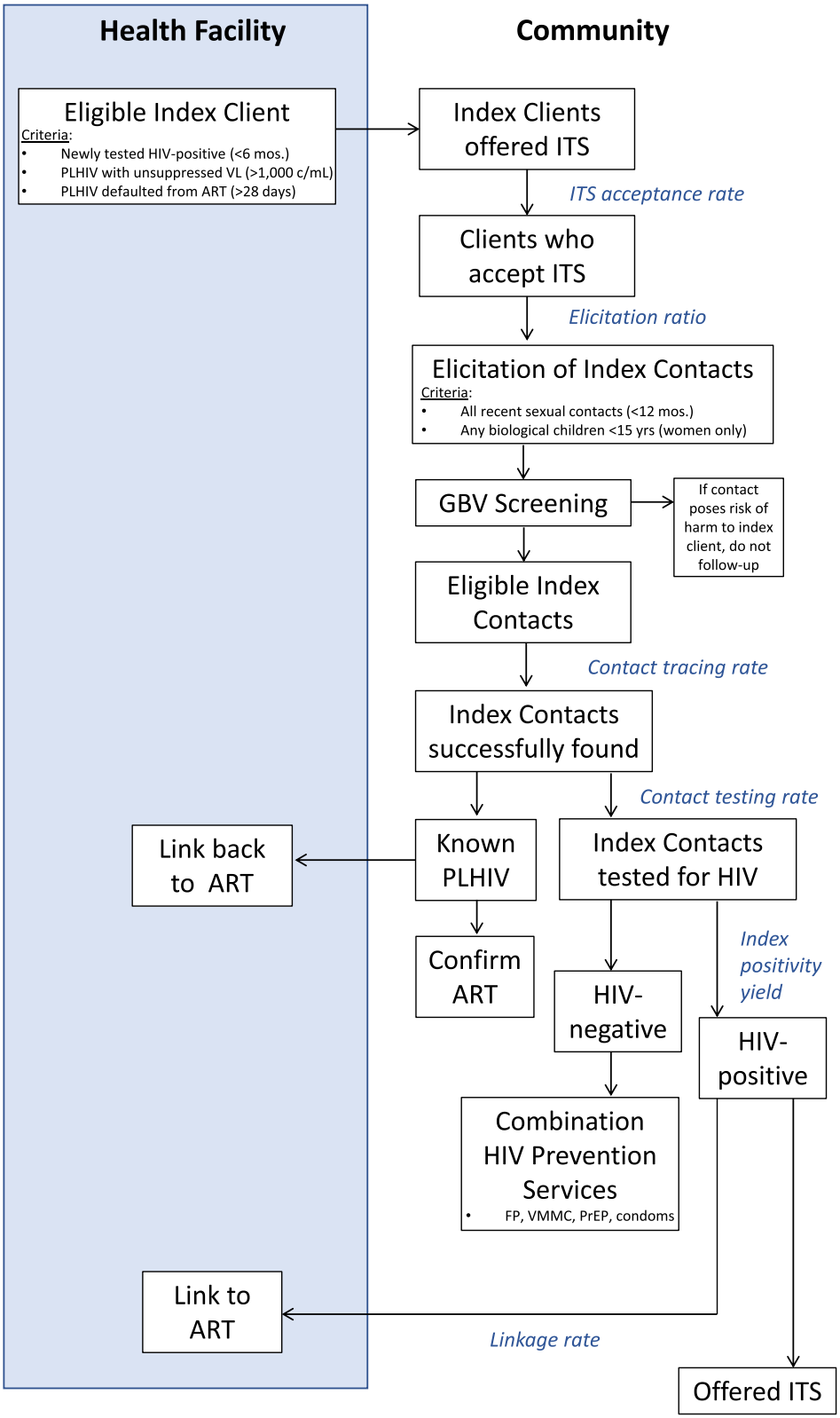

Figure 2. CIRKUITS (Community Impact to Reach Key and Underserved Individuals for Treatment and Support) steps for index testing. Boxes in shaded area represent facility-based activities; other boxes represent activities taking place in the community. Text in blue italics reflects relevant programme metrics. These steps were initially developed by UMB, and then adopted in the National Zambia Consolidated Guidelines for Prevention and Treatment of HIV Infection 2020 [25]. FP, family planning; GBV, gender-based violence; ITS, index testing services; PLHIV, people living with HIV; PrEP, pre-exposure prophylaxis; VMMC, voluntary medical male circumcision.

2.6 | Testing and linkage strategies to find and link men

To optimize the uptake and coverage of HIV testing among men, CIRKUITS trained CLOs and CHWs on specific strategies to reach men with HTS and health promotion and education, such as where to find men, how to provide tailored messaging for men on HIV/AIDS, and how to conduct pre- and post-counselling for men. CIRKUITS conducted HIV prevention and HTS sessions in workplaces that predominantly employ men, such as construction sites, breweries and bottling companies, police departments, and security, electricity and utility companies. This was followed by orientation of human resource managers in the companies on the benefits of HIV prevention and testing services. This initiative resulted in development of workplace policies promoting routine HIV testing that resulted in the CIRKUITS team being invited once a month to provide HIV prevention and testing services. All HTS services were conducted in a confidential manner according to national guidelines [25]. CIRKUITS also worked with local municipal councils and business leaders, such as marketplace chairmen and bus station managers, to deliver HTS services in male-dense areas such as markets, taxi ranks, car washes and bus stations. As a cross-cutting strategy, CIRKUITS partnered with traditional and religious leaders such as chiefs, village headmen and pastors to deliver orientation trainings on HIV/AIDS and encourage community-based HTS. These leaders became instrumental in mobilizing and organizing community HTS activities at sites where men congregate, including *insakas* (meetings of village elders), churches and community sporting events. In addition, CIRKUITS worked with facilities to expand male-focused services, including provision of male-oriented sexual reproductive health services such as prostate cancer screening, sexually transmitted infection screening and treatment and condom pick-up points, as well as extension of clinic hours during weekdays and weekends to offer more flexibility and convenience for male clients.

2.7 | Outcomes and variables

Outcomes of interest included: (1) positivity yield, defined as the number of individuals identified HIV positive divided by the total number of individuals who received HTS and received their test results; and (2) linkage rate, defined as the total number of individuals newly enrolled on ART divided by the number of individuals identified as HIV positive. We also developed an index testing cascade comprised of the following variables: (1) number of index cases offered ITS; (2) number of index cases that accepted ITS; (3) number of contacts elicited; (4) number of contacts tested; (5) number of contacts identified HIV positive and (6) number of HIV-positive clients linked to ART, defined as number of individuals newly enrolled on ART during the evaluation period. We also calculated the elicitation ratio, defined as the number of contacts elicited per index patient.

For testing modalities, we compared community index testing to other targeted community testing modalities, which included mobile and community-based testing locations (community centres, schools, workplaces, tents) and standalone VCT. For outcomes, testing modalities and age groups disaggregation, we used definitions and guidance from the PEPFAR Monitoring, Evaluation and Reporting Indicator Reference Sheet (MER) version 2.3 [26].

2.8 | Data sources and collections

Aggregated data were abstracted from routine Zambian MOH HTS, index testing and linkage registers. At community level, each CHW collected patient-level information onto individual community HTS and index elicitation forms. At facility level, CLOs then merged these data and entered them into facility registers. Community data was also manually entered into the UMB electronic Community Information Management System (eCOMMIS), a customized web-based District Health Information Software 2 (DHIS2) data platform. DHIS2 is a health management information system (HMIS) platform commonly used in low and middle-income countries [27]. eCOMMIS ensured data quality relevant to several programmatic elements, included training, supervision, weekly data reviews and validation.

2.9 | Statistical analysis

Proportions were calculated for outcomes of interest, and the index testing cascade analysed using descriptive statistics. Chi-square tests were used to compare overall positivity yield and ART linkage by age, sex and district strata, as well as differences between HIV positivity yield by testing modalities across sex and age strata. Chi-square tests were also used to compare the proportion of index testing acceptance, contact tracing, positivity and ART linkage along the index cascade by sex. All analyses were performed using SAS 9.4 (Cary, NC).

2.10 | Ethical approval

Ethical approval for this retrospective analysis of aggregate routine programme data was covered by the routine PEPFAR MER data protocol approved by the ERES Converge Zambian Institutional Review Board (IRB), the Zambian National Health Research Authority, the CDC, and the UMB IRB.

3 | RESULTS

3.1 | CIRKUITS HIV testing and linkage services (all community modalities)

A total of 38,255 individuals 15 years or older were tested for HIV from 1 October 2018 to 30 September 2019 (Table 2). Among these, 18,336 (47.9%) were male and 19,919 (52.1%) female. Forty-five percent of HIV testing was performed among individuals aged 20 to 29 years and 51.9% occurred in Lusaka District.

Among those tested, 10,974 were identified as HIV positive, corresponding to an overall positivity yield of 28.7% (Table 2). Both the absolute numbers of individuals tested positive (4458 vs. 6516) and the positivity yield (24.3% vs. 32.7%) were higher among women than men ($p < 0.001$). Across age groups, positivity yield ranged between 13.0% and 36.8% ($p < 0.001$), peaking among people aged from 35 to 39. Positivity yield ranged between 21.8% and 32.1% across districts ($p < 0.001$), with the highest yield in Lusaka.

Table 2. Overall CIRKUITS HIV testing performance from October 2018 to September 2019

	HIV testing services (n)	Persons tested HIV positive (n)	Positivity yield (%)	*p* value	Persons linked to ART (n)	ART linkage[a] (%)	*p* value
Sex				<0.001			0.033
Male	18336	4458	24.3		4132	92.7	
Female	19919	6516	32.7		6107	93.7	
Age bands, years				<0.001			<0.001
15 to 19	3968	516	13.0		476	92.2	
20 to 24	8686	2049	23.6		1850	90.3	
25 to 29	8361	2413	28.9		2286	94.7	
30 to 34	6334	2206	34.8		2076	94.1	
35 to 39	4737	1741	36.8		1645	94.5	
40 to 44	3153	1022	32.4		943	92.3	
45 to 49	1628	587	36.1		550	93.7	
50+	1388	440	31.7		413	93.9	
Districts				<0.001			<0.001
Chipata	6037	1354	22.4		1289	95.2	
Limulunga	2882	629	21.8		606	96.3	
Lusaka	19857	6374	32.1		5868	92.1	
Mongu	5311	1586	29.9		1495	94.3	
Petauke	4168	1031	24.7		981	95.2	
Total	38255	10974	28.7		10239	93.3	

ART, antiretroviral therapy; CIRKUITS, Community Impact to Reach Key and Underserved Individuals for Treatment and Support.
[a]This corresponds to the TX_NEW proxy measure.

Of the 10,974 identified PLHIV, 10,239 (93.3%) were linked to ART (Table 2). Linkage to ART differed significantly by gender ($p = 0.033$). Linkage to ART ranged between 90.3% and 94.7% across age groups and between 92.1% and 96.3% across districts ($p < 0.001$).

3.2 | CIRKUITS HIV positivity yields and contributions by testing modality

A total of 11,762 contacts of index clients were tested through index testing, of whom 5260 were HIV positive, for a positivity yield of 44.7% (Table 3). Both the absolute numbers of people tested (6277 for women and 5485 for men) and the positivity yield were higher among women (49.0%) compared to men (39.9%). Across age groups, positivity yields ranged from 29.3% to 50.9%, peaking across people aged 35 to 39 years. Among the 10,974 individuals diagnosed with HIV in the CIRKUITS project, 5260 were identified via index testing, for a contribution to overall HIV positives identified of 47.9%.

Through the other targeted community-based testing modalities combined, a total of 26,493 individuals were tested, of whom 5714 were HIV positive, for a positivity yield of 21.6% (Table 3). Both the absolute numbers tested (12,851 vs. 13,642) and positivity yield (17.7% vs. 25.2%) were higher for females than males. Across age groups, positivity yields ranged between 9.7% and 28.4%, peaking across people aged 30-34 and 45-49. Non-index community testing modalities contributed 52.1% of overall HIV-positive clients identified by CIRKUITS.

The overall positivity yield between the two categories of testing modalities was significantly different ($p < 0.001$), where index testing had a higher positivity yield than the other community testing modalities. These differences remain when compared by age and sex strata (Table 3).

3.3 | Index testing cascade

CIRKUITS offered ITS to 12,391 HIV-positive clients, including the 10,974 newly identified HIV-positive clients from community HTS modalities and 1417 PLHIV found to have an unsuppressed viral load. Among the 12,391 HIV-positive clients, 11,480 individuals accepted index testing services, for an overall 92.6% index testing acceptance. Acceptance rate did not significantly differ by sex (88.4% for females vs. 89.2% for males, $p = 0.159$). A total of 20,130 contacts were elicited from 11,480 individuals who accepted index testing services, for an elicitation ratio of 1:1.8. A total of 15,661 of the elicited contacts were traced, for a contact tracing rate of 77.8%. Contact tracing rate was higher among females (81.8%) than males (73.7%) ($p < 0.001$). Among the 15,661 traced contacts, 160 (1.0%) were known HIV-positive clients who were not on ART, 3739 (23.9%) were known HIV-positive clients who were on ART, and 11,762 (75.1%) were contacts with unknown HIV status. All traced contacts with unknown status were tested for HIV; of these, 5260 were newly diagnosed as HIV positive, representing 44.7% positivity yield (Figure 3). Among the individuals diagnosed with HIV, 2244 (42.7%) were women 25 years or older, 1962 (37.3%) were men 25 years or older, 830 (15.8%) were AGYW ages

Table 3. HIV positivity yields by testing modality from October 2018 to September 2019

	Index testing			Other community testing			
	No. tested	No. positives	Yield (%)	No. tested	No. positives	Yield (%)	Difference[a]
Sex							
Male	5485	2186	39.9	12851	2272	17.7	22.2
Female	6277	3074	49.0	13642	3442	25.2	23.7
Age bands, years							
15 to 19	669	196	29.3	3299	320	9.7	19.6
20 to 24	2030	858	42.3	6656	1191	17.9	24.4
25 to 29	2723	1174	43.1	5638	1239	22.0	21.1
30 to 34	2305	1063	46.1	4029	1143	28.4	17.7
35 to 39	1826	929	50.9	2911	812	27.9	23.0
40 to 44	1150	539	46.9	2003	483	24.1	22.8
45 to 49	595	294	49.4	1033	293	28.4	21.0
50+	464	207	44.6	924	233	25.2	19.4
Overall	11762	5260	44.7	26493	5714	21.6	23.2

[a]All differences were statistically significant at $p < 0.001$.

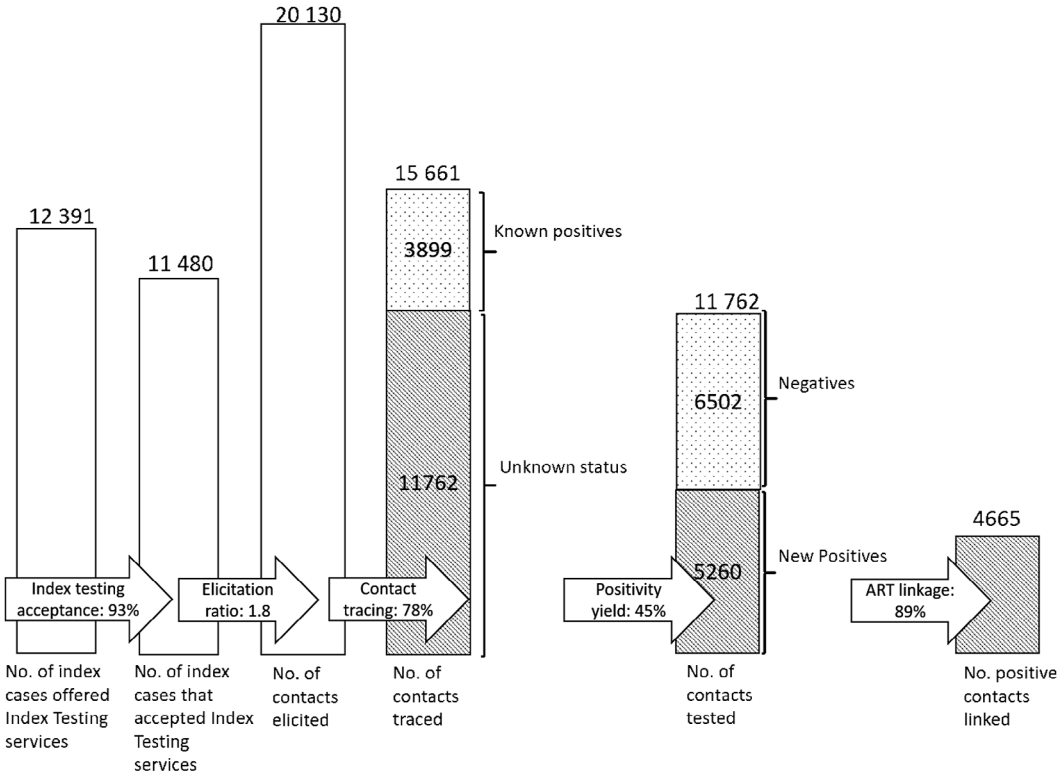

Figure 3. Overall index testing cascade.

15 to 24 and 224 (4.2%) were adolescent males ages 15 to 24. Positivity yield was higher among females (49.0%) than males (39.9%) ($p < 0.001$). Among the 5260 newly diagnosed HIV-positive clients, 4665 were linked to ART for an overall ART linkage rate of 88.7%. Females had an ART linkage rate of 89.2% and males had an ART linkage of 87.9% ($p = 0.140$).

3.4 | Male HTS

Over a 12-month period, a total of 18,336 males were tested and 4458 were identified as HIV positive for an overall positivity yield of 24.3%. Of men identified as HIV positive, 13.0% were aged 15 to 24, 60.3% were aged 25 to 39, 20.9% were

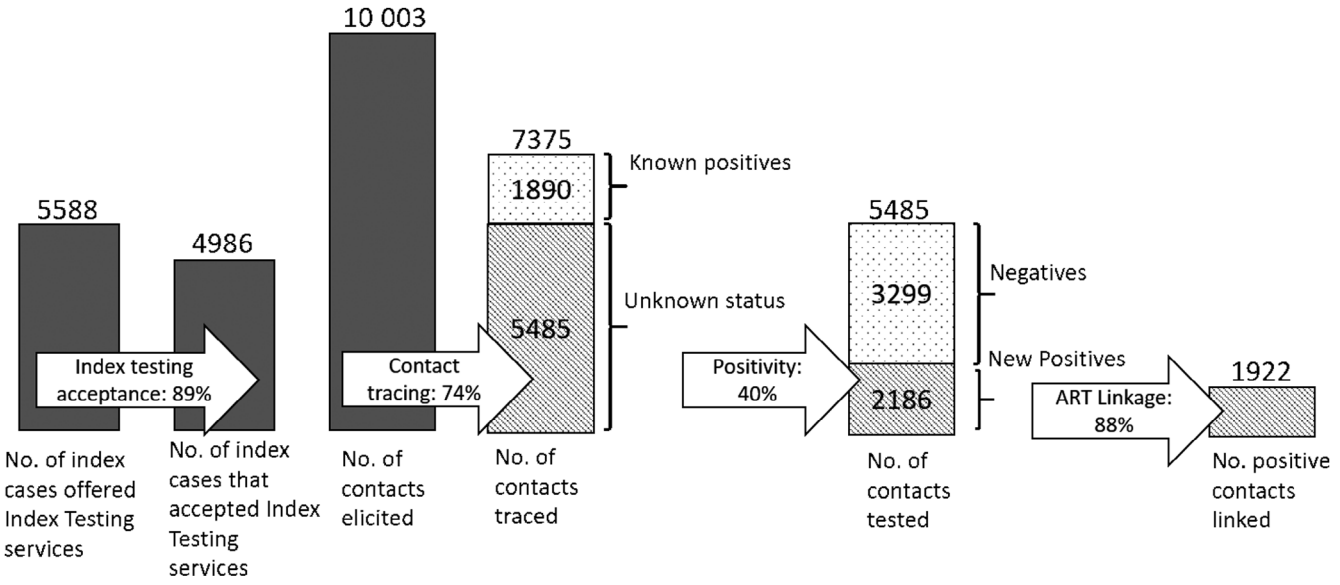

Figure 4. Index cascade for men.

aged 40 to 49 and 5.8% were 50 or older. Among these 4458 HIV-positive males, 4132 were linked to ART (92.7%).

ITS led to a higher positivity yield (39.9%) in comparison to other community-based testing (17.7%). In terms of absolute numbers, ITS resulted in a smaller number of men who were newly identified with HIV (n = 2186) in comparison to other testing modalities (n = 2272). Other community testing modalities accounted for 51.0% of HIV-positive men identified, with ART linkage of 97.3%.

Index testing was offered to 5588 male clients, 89% of whom accepted services. From 10,003 male contacts elicited through index testing, 74% (n = 7375) were traced and all with unknown HIV status (n = 5485) were tested. The positivity yield for men through this modality was 39.9%. Among the 2186 newly identified HIV-positive clients, 1922 were linked to ART (87.9%) (Figure 4).

4 | DISCUSSION

We report first year results from CIRKUITS, an innovative community-based project that effectively engaged men and other key and priority populations with HIV services through a combination of index and targeted community-based testing coupled with facilitated linkage to HIV prevention and treatment provided by trained CHWs and CLOs. This approach resulted in consistently high numbers of HIV cases identified and high overall testing yield (29%) with robust linkage to ART surpassing 93% among new positives identified. Positivity yield exceeded 20% for both men and women across all districts and age bands, with the exception of 15 to 19-year-olds (13%). We found index testing to be a high yield strategy for men, with among the highest positivity yield reported thus far in the literature [20,21], with a large proportion of cases among young men aged 25 to 39. Targeted community outreach HTS such as mobile and standalone VCT centres were also effective strategies to identify HIV-positive men in Zambia, resulting in 18% yield, 98% ART linkage and contributing over 50% of all male PLHIV identified, suggesting that a combination of traditional HTS, targeted community and ITS may be needed to reach men. Such high-yield approaches are critical in light of recent test and treat trials showing that high HIV incidence persisted in SSA communities due to a failure to reach men and key populations with HTS and other HIV services [28-30].

Despite high overall testing yield across modalities using the CIRKUITS approach, not all community-based strategies yielded the same results. This observation has been born out elsewhere in the region as detailed in a systematic review examining community and facility-based HTS in SSA [31]. However, few studies have specifically described results from ITS in SSA, and relatively few reports describe facilitated ART linkage approaches relying on CHWs [31].

We found a high level of acceptance of index testing services. More than 93% of individuals provided information about their sexual partners to enable contact tracing, which we attribute to intensive and continuous mentorship and competency assessment of providers on essential elements of PNS. CHWs were able to elicit nearly two sexual contacts per client. More than three-quarters of traced contacts were unaware of their HIV status. The ITS modality led to high testing positivity at 45% and ART linkage at 89%, representing a high-yield entry point into the HIV care cascade.

Other studies from SSA have corroborated findings that index testing is associated with higher HIV positivity yield compared to other testing modalities. Shamu et al. conducted a comparison of index testing to community HTS in South Africa, and found index testing resulted in a positivity yield of 10.3% versus 7.3% [16] for other testing modalities. The ZHCT project in Zimbabwe achieved 32.6% index positivity yield, which was significantly higher than the 4.1% positivity yield observed with facility-based testing [18].

We found community index testing to be effective at finding HIV-positive men among elicited sexual contacts. This is

consistent with Kenyan data showing that index testing that began with female indexes resulted in significantly higher case-identification than starting with male indexes [17]. Studies that have focused on HIV-positive pregnant and breastfeeding women indexes also have reported similarly high positivity yield [32].

In CIRKUITS, we achieved high testing positivity among men primarily by engaging them where they were found, rather than expecting them to come to the facility. Men often perceive health facilities as geared towards women's and paediatric health, and clinic hours are not favourable to men who often have jobs that prevent them from accessing the clinic [33]. CIRKUITS addressed these barriers by going into the community and providing HIV prevention and testing services in work places, particularly with companies that engage a primarily male workforce, such as construction, security and utility companies. This approach may explain the high absolute number of men who were newly diagnosed with HIV, specifically in workplace and outreach testing settings.

For men, the difference in testing yield was particularly pronounced between community-based testing (18%) and ITS (40%). Several key elements likely contributed to the higher positivity yield of our index testing approach among men. First, index testing coverage was high as we offered partner elicitation to all clients who tested positive. Second, the elicitation ratio during index testing in the general population was equally high, with a mean of nearly two sexual contacts disclosed per index client. Finally, we maintained high rates of contact tracing, ensuring that nearly all index contacts were followed up and tested.

Interestingly, while index testing resulted in higher yield than other community-based testing modalities, clients identified via index testing had lower linkage to ART. This result contrasts with other studies which found that linkage was higher among index testing modality versus other approaches [34,35]. Our finding could be due to facility healthcare workers being present onsite at mobile and community standalone VCT to initiate ART, whereas index contacts in the community were escorted to the facility by CHWs, potentially allowing for greater client attrition before ART start. This finding may also reflect less engagement on the part of the client identified via index testing. Persons reached through workplace testing must still actively present themselves for testing, which may reflect either underlying concerns about their HIV status or their health in general. Clients identified via index testing, however, play a less active role, and thus may be less motivated to engage in ongoing health care. Once a CIRKUITS client was identified as HIV positive, they were accompanied in person to the nearest facility for same-day ART initiation. If the client declined, they were repeatedly followed up by the CHW until they began treatment. This close follow-up and longitudinal engagement with a CHW or other peer provider was thought to facilitate effective linkage to care across settings [36].

As we move towards achieving epidemic control, there is ever-greater need to find, in a targeted and cost-effective manner, those PLHIV unaware of their status and being left behind by prevailing HTS approaches. High-yield approaches such as index testing and targeted community-based testing are strategies to better reach men and other hidden populations; indeed it is why we have highlighted positivity yields as a measure of success. However, to close the gap to the first 95 such modalities must be part of a comprehensive approach to HIV case finding that bridges communities and facilities, and includes the high absolute number of PLHIV found through traditional facility-based approaches. As noted by De Cock et al., the majority of new PLHIV are still identified via facility-based approaches, though their positivity yield is often lower. While ITS and targeted community approaches are high yield approaches, they are also costlier and more labour-intensive, and the absolute numbers of PLHIV found are typically less. Reaching the first 90 will require more testing overall and scale up of *both* facility- and community-based approaches to ensure that all PLHIV are reached and know their status [37].

4.1 | LIMITATIONS

Our study was limited by the use of routine programme data collected and analysed in aggregate. Therefore, some analyses were not possible, including individual-level evaluation of testing and clinical outcomes and examination of the association between testing modality and long-term HIV outcomes, such as retention in care or VL suppression. Aggregate data also limited our ability to examine individual socio-demographic factors associated with uptake of the HTS modalities studied. We were not able to examine male testing outcomes by CHW gender, which would have been interesting, as prior studies have shown better uptake of HTS by men when offered by male CHWs and HCWs. [38-40] Due to the aggregate nature of our data, we were unable to perform further analyses to adjust for other potential confounders and clustering by site.

CIRKUITS focused on community-based HIV testing, and, therefore, we could not compare our results to facility-based HIV testing. Finally, while CHWs screened for GBV prior to offering ITS, they did not collect data on the number of individuals either declining index testing due to concerns related to GBV, or screening positive for risk of GBV and thus excluded, and as such we cannot make inferences about the effects of GBV on the results observed. Nor were we able to assess negative social outcomes stemming from partner notification, though reassuringly other studies have shown low rates of partner harm following partner notification [41-43]. Despite these limitations, our evaluation highlights the programmatic relevance of offering ITS and targeted community-based testing to men. Further research is needed on potential adverse effects of ITS, as well as new strategies to reach men with differentiated HTS modalities.

5 | CONCLUSIONS

Index testing and targeted community-based HTS are effective strategies to identify men living with HIV in Zambia. Index testing results in higher yield, but lower linkage and fewer absolute men identified compared to targeted community-based HTS. In Zambia, there may be up to 400,000 individuals who are currently unaware of their HIV status [4]. Expansion of effective HIV testing modalities such as those we have implemented in CIRKUITS could accelerate the timeline for achieving near-universal testing coverage and the first 95 of HIV epidemic control.

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COMPETING INTERESTS

The authors declare that they have no conflicts of interest.

AUTHORS' CONTRIBUTIONS

All authors contributed to writing, reviewing and editing the manuscript. LM, KS, MM, MH, MCL and CC designed the study; LM, MM, NN, HS, JC, BP, CN, SM, KN, AS, AM, MH and CC designed project concept and implementation; LM, MM, KT, NN, HS, JC, BP, CN, SM, MH and CC contributed to data collection; and KS, NB, MM, KT, MCL, MH and CC contributed to data analysis. All authors have read and approved the final manuscript.

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RESEARCH ARTICLE

Male partner testing and sexual behaviour following provision of multiple HIV self-tests to Kenyan women at higher risk of HIV infection in a cluster randomized trial

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Abstract

Introduction: Without significant increases in uptake of HIV testing among men, it will be difficult to reduce HIV incidence to disease elimination levels. Secondary distribution of HIV self-tests by women to their male partners is a promising approach for increasing male testing that is being implemented in several countries. Here, we examine male partner and couples testing outcomes and sexual decision making associated with this approach in a cluster randomized trial.

Methods: We examined data from women at higher risk of HIV participating in the intervention arm of an ongoing pair-matched cluster randomized trial in Kenya. HIV-negative women ≥18 years who self-reported ≥2 partners in the past month were eligible. Participants received self-tests at enrolment and three-monthly intervals. They were encouraged to offer tests to sexual partners with whom they anticipated condomless sex. At six months, we collected data on self-test distribution, male partner and couples testing, and testing and sexual behaviour in the three most recent transactional sex encounters. We used descriptive analyses and generalized estimating equation models to understand how sexual behaviour was influenced by self-test distribution.

Results: From January 2018 to April 2019, 921/1057 (87%) participants completed six-month follow-up. Average age was 28 years, 65% were married, and 72% reported income through sex work. Participants received 7283 self-tests over six months, a median of eight per participant. Participants offered a median three self-tests to sexual partners. Of participants with a primary partner, 94% offered them a self-test. Of these, 97% accepted the test. When accepted, couples testing was reported among 91% of participants. Among 1954 transactional sex encounters, 64% included an offer to self-test. When offered self-tests were accepted by 93% of partners, and 84% who accepted conducted couples testing. Compared to partners with an HIV-negative result, condom use was higher when men had a reactive result (56.3% vs. 89.7%, $p < 0.01$), were not offered a self-test (56.3% vs. 62.0%, $p = 0.02$), or refused to self-test (56.3% vs. 78.3, $p < 0.01$).

Conclusions: Providing women with multiple self-tests facilitated male partner and couples testing, and led to safer sexual behaviour. These findings suggest secondary distribution is a promising approach for reaching men and has HIV prevention potential.

Clinical Trial Number: NCT03135067.

Keywords: HIV self-testing; women at higher risk; male partner testing; couples testing; secondary distribution

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1 | INTRODUCTION

In much of eastern and southern Africa, HIV incidence remains high despite the scale-up of promising biomedical and behavioural prevention interventions [1]. The UNAIDS 95-95-95 fast track goals to end the AIDS epidemic by 2030 provide tangible targets for testing and treatment that can substantially reduce HIV incidence in the region [2]. However, these goals may be compromised by disparities in engagement in HIV services among certain subpopulations. Men in sub-Saharan Africa in particular continue to be less engaged in services [3-5]. Despite impressive increases in knowledge of HIV status across the region, uptake of HIV testing remains low among men. Of the 21 countries in eastern and southern Africa region, as designated by UNAIDS, all but one report more women than men testing in the past 12 months [6]. This differential engagement in HIV services represents a public health inequity, and contributes to high risks of HIV infection among adolescent girls and young women. Without significant increases in uptake of HIV testing among men, it will be difficult to achieve the 95-95-95 goals and reduce HIV incidence to disease elimination levels [1].

The privacy, convenience and autonomy that oral fluid-based HIV self-testing provides has the potential to overcome many of the barriers to HIV testing, including those cited by men. This strategy has high acceptability among men; and in community-based distribution of self-testing, uptake by men has often been roughly equal to that of women [7-9]. The World Health Organization has recommended the scale-up of HIV self-testing as an alternative testing strategy, and a number of countries have begun to make self-tests available [10]. Models for delivering self-tests to men, and others less likely to use standard HIV testing services (HTS), are being considered and a promising strategy is the provision of multiple self-tests to women at higher risk so they can voluntarily initiate partner or couples testing [11]. This strategy of "secondary distribution" has the potential to generate multiple HIV prevention benefits, including promotion of male partner testing, results disclosure and facilitation of safer sexual behaviours. This has been included as a potential distribution strategy in Kenya's 2017 operational manual for HIV self-testing [12]. Research in Kenya and elsewhere has demonstrated that secondary distribution is acceptable and feasible, and that women from different settings, including antenatal clinics and sex workers, are able to distribute self-test kits to their sexual partners [11,13,14]. While this approach is being implemented in several countries, data from large-scale studies on partner and couples testing outcomes are lacking, and there are few data on changes in sexual decision making following secondary distribution [11,13,15].

To assess the HIV prevention potential of this approach, we are conducting a cluster randomized trial (cRCT) of secondary distribution of self-tests by women at higher risk in Kenya (NCT03135067). The study is being conducted in beach, peri-urban and urban communities in Siaya County, Kenya [16,17]. HIV prevalence in Siaya is among the highest in Kenya, at 21% [18]. Despite progress in reducing the spread of HIV in the region overall, HIV incidence remains persistently high in these communities [19-21]. The prominence of multiple partnerships and transactional sex in this region has been widely documented [21-24]. Here we describe outcomes for women in the intervention arm only of the pair-matched cRCT following six months of self-test provision. We explored self-test kit distribution patterns and male partner testing uptake, results disclosure, couples testing, as well as testing and sexual behaviour data from the three most recent transactional sex encounters.

2 | METHODS

2.1 | Study design and participants

The study is being conducted in a total of 66 geographic clusters in Siaya County, Kenya. Each cluster consists of one or more nearby beach communities along Lake Victoria where fishing drives the local economy as well as market centres containing hotspots (bars and hotels) where transactional sex is common. Clusters were defined after a comprehensive mapping of beach communities and hotspots in the study region. Nearby beach communities were consolidated into a single cluster, as were hotspots that were located near each other. Clusters were matched on the basis of spatial proximity, population size and type (hotspot or beach community) and pairs of clusters were randomized in a 1:1 ratio to an intervention arm in which participants received multiple self-tests or to a comparison arm in which participants were given referral cards for clinic-based HIV testing and counselling to distribute to their male sexual partners. Computer-generated randomization was used to determine study arm assignment of clusters. After randomization, the study team conducted household surveys to prepare a list of adult women in each cluster who were potentially eligible. Women were then selected from the list at random for recruitment into the study. Based on power calculations for the primary cRCT outcome of HIV incidence, we sought to enrol about 30 participants in each cluster.

Upon recruitment from each cluster women were screened for eligibility. Eligibility criteria were as follows: age ≥18 years, residing in the study area and intending to stay there for at least 24 months, ownership of a mobile phone, HIV-negative and self-reporting ≥2 male partners in the past four weeks. Eligible participants were enrolled after providing written informed consent in their preferred language (English, Swahili or Dholuo). Prior to enrolment, participants underwent standard HIV testing according to national algorithms to determine HIV status [25]. Participants completed an interviewer-administered questionnaire at baseline that collected information on a range of topics including demographics, sexual behaviour and HIV testing history. Screening and follow-up visits were conducted at study sites established within the study communities, and data collection instruments were administered in the preferred language of the participant.

Participants in the intervention arm were trained on the use of oral fluid-based rapid HIV self-tests (OraQuick Rapid HIV-1/2 antibody tests; OraSure Technologies, Bethlehem, PA, USA). They were counselled on how to discuss HIV self-testing with male sexual partners and on the importance of using their own discretion and assessing the risk of intimate partner violence (IPV) when deciding whether to offer a self-test to a sexual partner. Participants were encouraged to offer tests to their male primary partner and to any other male sexual partners with whom unprotected sex was likely. They received five self-tests at enrolment. Self-test kits included written and pictorial instructions for use, including information on results interpretation and a list of clinics in the area where they could confirm their test result and seek post-test services. Research assistants contacted participants at three-monthly intervals and provided them additional self-tests, as needed. Participants were also able to receive self-tests in-between three-monthly intervals by contacting research assistants. At six months, we collected follow-up data via interviewer-administered questionnaire on self-test distribution, partner uptake, results disclosure and couples testing – defined as testing by the participant and her partner testing together at the same time – and sexual behaviour. We also obtained testing and sexual behaviour information on participants' three most recent transactional sex encounters. Transactional sex was defined as sex in exchange for money, goods or services, in line with the Joint United Nations Programme on HIV/AIDS definition [26]. The study is ongoing, with participants completing follow-up assessments and HIV testing every six months for a duration of up to 24 months. All questionnaires and study materials were in English, Kiswahili or Dholuo, based on participant preference.

2.2 | Outcomes and measures

Key outcomes assessed in this analysis were the self-reported number of self-tests distributed by participants and the proportion distributed to a male sexual partner. We evaluated, through participant self-report, the proportion of male partners who accepted self-tests when offered, and who disclosed their results to the participant. Test results were categorized as HIV-positive, HIV-negative, indeterminate or unknown. We also evaluated couples testing, as indicated by participant report that they tested together with a sexual partner. Sexual decision making among women who reported transactional sex was another key outcome. Using the data obtained on the three most recent transactional sex encounters, we examined the association between self-testing outcomes and whether or not participants had sex with the transaction sex partner as well as whether a condom was used in the encounter. We explored these outcomes by four categories of transactional sex partners: clients who had a reactive self-test, clients who tested HIV-negative, clients who refused the self-test and clients who were not offered a self-test.

2.3 | Statistical analyses

We conducted descriptive analyses for all outcomes among intervention arm participants at the six-month visit. We focused on self-test distribution to sexual partners, partner testing and result, and sexual behaviour change. To understand how sexual behaviour was influenced by distribution of self-tests to sexual partners we used unadjusted generalized estimating equation models. We clustered encounters by participant to compare participant reporting of condom use with sexual partners by use of HIV self-tests, HIV-negative result, or reactive result. All data were analysed using Stata 15.1 (StataCorp, College Station, TX, USA).

2.4 | Ethical considerations

The study received ethics approval from the institutional review boards at the University of Pennsylvania and the University of North Carolina at Chapel Hill as well as the Maseno University Ethics Review Committee. Eligible women who wished to participate provided written informed consent in their preferred language (English, Swahili or Dholuo) prior to initiation of any study procedures.

3 | RESULTS

A total of 1057 participants from 33 clusters were enrolled in the intervention arm of the study between June 2017 and August 2018. A total of 265 women were enrolled in eight beach community clusters and 792 from 25 hotspots. Between January 2018 and April 2019, 921 (87%) participants completed the six-month follow-up visit and were included in this analysis. Participants' average age was 28 years, with the majority (65%) being married and 63% having at least a primary school education (Table 1). Sex work was the primary source of income for 14% of participants, and an additional 58% reported earning some income through sex work.

Table 1. Baseline characteristics of participants randomized to the intervention arm who completed the six-month follow-up (N = 919[a])

Variable	N (%)
Demographics	
Age, mean (SD)	27.6 (6.9)
Education	
Some primary or less	303 (33.0)
Primary	276 (30.0)
Some secondary	168 (18.3)
Secondary/high school or more	172 (18.7)
Marital status	
Married and/or cohabitating	597 (65.0)
In a relationship, but not married or living together	91 (9.9)
Single	155 (16.8)
Divorced or widowed	76 (8.3)
Primary source of income	
Sales and service	309 (33.6)
Sex work	129 (14.0)
Unskilled manual	128 (13.9)
Fishing/fish trade	98 (10.7)
Agriculture	50 (5.4)
Unemployed	53 (5.8)
Other	151 (16.4)
Refused	1 (0.1)
Sex work is another source of income	531 (57.8)
Typical one-month income in U.S. $, median (IQR)	30 (20, 60)
Household size, median (IQR)	5 (4, 6)
Male sexual partners and sexual behaviour	
Number of sexual partners in the past month, median (IQR)	2 (2, 3)
Used condom during last sexual encounter	335 (36.5)
Ever engaged in transactional sex[b]	869 (94.6)
Number of transactional sex partners in the past month, median (IQR)[c]	2 (1, 2)
Used condom with most recent transactional sex partner during vaginal or anal sex[d]	440 (51.3)
Experienced any type of intimate partner violence in the past 12 months	475 (51.6)

[a]921 women in the intervention arm completed the six-month follow-up questionnaire, however baseline questionnaire data for two of those individuals was lost; [b]Transactional sex defined as sex in exchange for money, goods, food, housing, or services; [c]Among 868 participants reporting transactional sex in the past month; [d]Among 858 encounters involving vaginal or anal sex. IQR, inter-quartile range

3.1 | HIV self-test distribution

Over the six months of follow-up, participants received a total of 7283 self-test kits for distribution, a mean (IQR) of eight self-tests per person (7,9). Figure 1 shows self-test kit distribution by participants. All sexual partners in this study, including primary and transactional sex partners, were male. Participants distributed a total of 3327 (46%) of self-tests to

sexual partners, a mean (IQR) of 3 (2,5) per person. Participants reported that 153 partners disclosed reactive results, equalling 4.6% (153/3327) of all tests distributed which could be confirmed as reactive, and an average of 0.17 HIV-positive partners being identified per participant. There were 253 (3%) self-tests distributed to other individuals, that is non-sexual partners, and 2862 (39%) self-tests were used by participants themselves. The remaining 841 (12%) self-tests were unused.

3.2 | Self-testing with primary partners

Of 890 participants with a primary partner, 838 (94%) offered their primary partner a self-test (Table 2). A total of 813 (97%) accepted the self-test. Among primary partners who accepted a self-test, 800 (98%) shared their test results with the participant, with 15 (2%) reporting a reactive result. Couples testing was reported by 740 (91%) participants whose primary partner accepted a self-test, and in all 83% of all participants with a primary partner conducted couples testing with them (Figure 2).

3.3 | Self-testing with transactional sex partners

A total of 870 (94%) participants reported having transactional sex during the study period, and we asked these participants about their three most recent transactional sex encounters. Participants reported on a total of 1954 transactional sex encounters involving vaginal and/or anal sex in the past six months (Table 3). Of those, 1256 (64%) encounters included an offer of a self-test to the partner and 1173 (93%) partners accepted the self-test. Among all encounters in which a self-test was accepted, the partner disclosed their test result in 1133 (97%) encounters, and 29 (3%) results were reactive. In 987 (84%) encounters the participant and their partner tested together.

Table 2. HIV self-test use reported by participants among their male primary partners (N = 890)

Variable	N (%)
Age difference, primary partner age – participant age, median (IQR)[a]	5 (2, 7)
Offered HIV self-test to primary partner	838 (94.2)
Primary partner accepted the self-test[b]	813 (96.9)
Participant didn't know if primary partner used self-test	7 (0.9)
Primary partner used self-test, but participant didn't learn result	6 (0.7)
Primary partner test was reactive	15 (1.8)
Primary partner test was HIV-negative	785 (96.6)
Participant conducted couples testing with primary partner[c]	740 (91.0)

[a]N = 851. 39 participants did not report primary partner age; [b]Among 839 participants who offered a HIV self-test to their primary partner; [c]Among 813 participants whose partner accepted the self-test. Couples testing is defined as participant-reported testing together with a sexual partner. IQR, inter-quartile range

3.4 | Sexual behaviour with transactional sex partners

Figure 3 shows condom use based on transactional sex partner uptake, utilization and self-test result. Condom use was significantly higher with transactional sex partners who obtained a reactive versus HIV-negative result (89.7% vs. 56.3%, $p < 0.01$). Condom use was also significantly higher with transactional sex partners who were not offered a self-

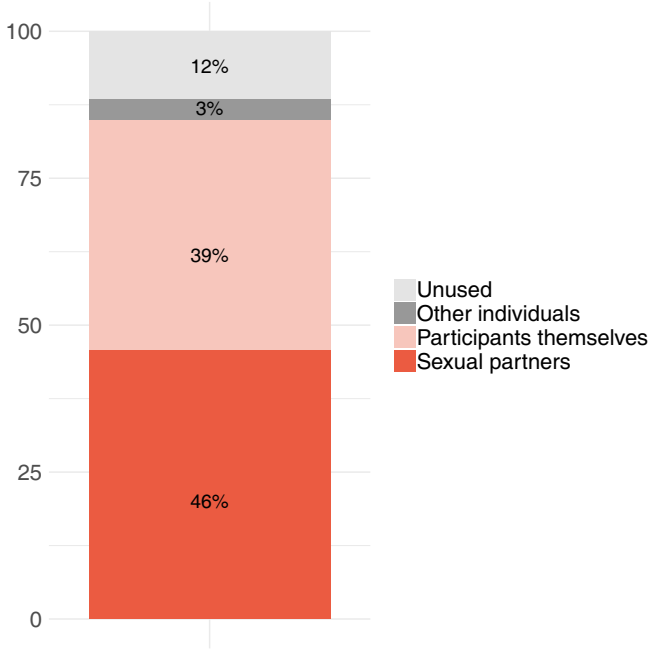

Figure 1. Use of 7,283 HIV self-test kits by 921 participants.

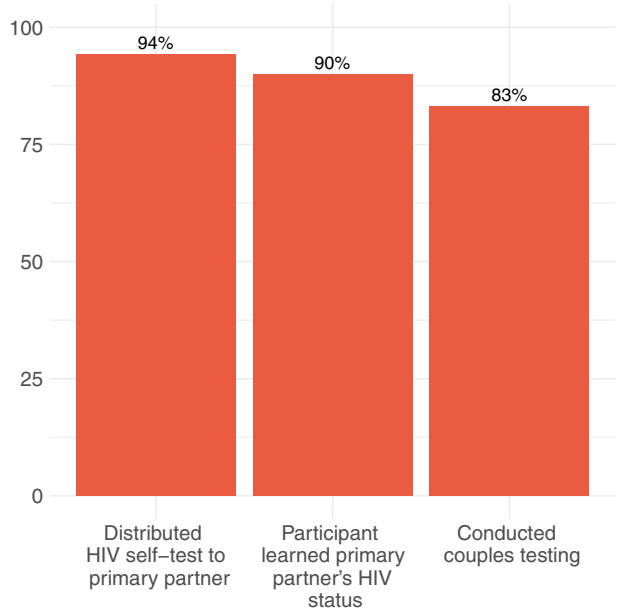

Figure 2. Primary partner and couples testing (N = 891).

Table 3. Use of HIV self-tests during transactional sex encounters with male partners involving vaginal and/or anal sex (N = 1954)

Variable	N (%)
Offered HIV-self test to transactional sex partner	1256 (64.3)
Among those offered HIV self-test, transactional sex partner accepted the self-test[a]	1173 (93.4)
Participant did not learn result	21 (1.8)
Partner test was reactive	29 (2.5)
Partner test was HIV-negative	1101 (93.9)
Partner test was indeterminate	3 (0.3)
Among those offered HIV self-test, participant conducted couples testing with transactional sex partner[b]	987 (84.1)

[a]Among 1256 participants who offered a self-test to their partner. HIV test results were missing for 19 (1.5%) partners; [b]Among 1173 transactional sex encounters where a self-test was offered.

test as compared to those with a HIV-negative result (62.0% vs. 56.3%, $p = 0.02$), or who refused to self-test versus those with a HIV-negative result (78.3 vs. 56.3%, $p < 0.01$).

3.5 | Sexual behaviour with all male partners

In terms of overall sexual behaviour among study participants at six months, participants reported that the mean number of sexual partners in the past month was 2.8 at baseline and 2.2 at the six-month follow-up visit (Table 4). The proportion of participants who reported using a condom during their last sexual encounter was 37% at baseline and 44% at the six-month follow-up. A total of 131 (14%) participants reported refusing to have sex with 158 potential sexual partners because they either refused to accept a self-test or had a reactive test result. Additionally, 107 (12%) women reported that they decided to use a condom with 141 sexual partners because they either refused the self-test or had a reactive result.

4 | DISCUSSION

This is the first large-scale study to evaluate self-reported self-test distribution patterns and partner testing outcomes in the context of secondary distribution by women at higher risk of HIV infection. The study also examines changes in sexual decision making with transactional sex partners enabled by self-testing. Among women receiving multiple self-tests in Kenya, nearly 50% of self-tests provided were offered to male sexual partners and high rates of partner and couples testing were observed. This confirms findings from other research demonstrating that women can readily and capably distribute self-tests to both their regular and transactional sex partners, and that men are willing to accept and use tests distributed by their sexual partners [11,13,27]. This finding is of particular relevance for women at higher risk in the study setting, as they are likely to be in contact with and distribute test kits to men who are also at high risk of HIV transmission. We found that when a test kit was offered, uptake by men was high and results disclosure between both regular and transactional sex partners was common. Furthermore, couples testing was very common, with a large proportion of the test kits provided being used by women to test together with their partner.

One of the most compelling findings in this study relates to sexual decision making with self-tests. We found significantly higher condom utilization with transactional sex partners when a self-test was refused and when the result was reactive, as compared with transactional sex partners who had a negative result. At the same time, we found moderately higher condom use when a self-test was not offered as compared to a negative result as well (62% vs. 56%). While the latter finding implies less condom use with known HIV-negative partners and therefore a potential shift in risk perception, women were encouraged to offer a self-test to partners when they did not intend to use a condom. Furthermore, we have no information about the relative risk profiles of those men who were and were not offered self-tests. Therefore, these data should be interpreted with caution. Among participants overall, 14% reported refusing sex, and 12% reported using a condom, with one or more partners if they were not offered or refused a self-test. These sexual decision-making data suggest there is substantial potential for this strategy to have HIV prevention benefits for both women and their male sexual partners.

The data available to us did not permit an accurate estimate of male HIV-positive case identification per test kit distributed – an important consideration for programme implementation. While we know the overall number of test kits distributed to male partners, we cannot discern whether a single partner used multiple test kits. Likewise, not all men who self-tested disclosed their test result to the participant, and there may be biases in male disclosure of a positive result to participants. Of the 3327 test kits distributed to sexual partners, a total of 153 men disclosed a reactive result to a participant. It is important to note, however, that not all partners disclosed their result and some sexual partners may have used more than one self-test during the six-month follow up period. We can assume that at a minimum, 4.6% of all tests distributed were confirmed reactive and that 0.17 HIV-positive partners were identified per participant. As we cannot accurately estimate overall case identification (i.e. yield), it remains unclear how case identification among men in this intervention compares to other HTS strategies, another useful data point for self-test programming. Subsequent analyses will compare the case identification in the intervention arm to the comparison arm in which only HTS referral cards were provided. Due to the nature of our study design and inherent confidentiality of self-testing, we do not have an accurate sense of the demographic and behavioural characteristics of the men we are reaching. As men are targeted based on their contact with women at higher risk, it is likely that the men in this research are at high risk of HIV transmission as well. Therefore, secondary distribution by women at higher risk may be a compelling strategy to engage men in HIV testing, and potentially other HIV services.

A primary limitation of this research is the reliance on self-reported self-test distribution and sexual behaviour data, which has the potential for bias. A study of secondary distribution among antenatal care clients and their male partners in Kenya compared male and female reporting of couples testing and found strong agreement between partners, and therefore

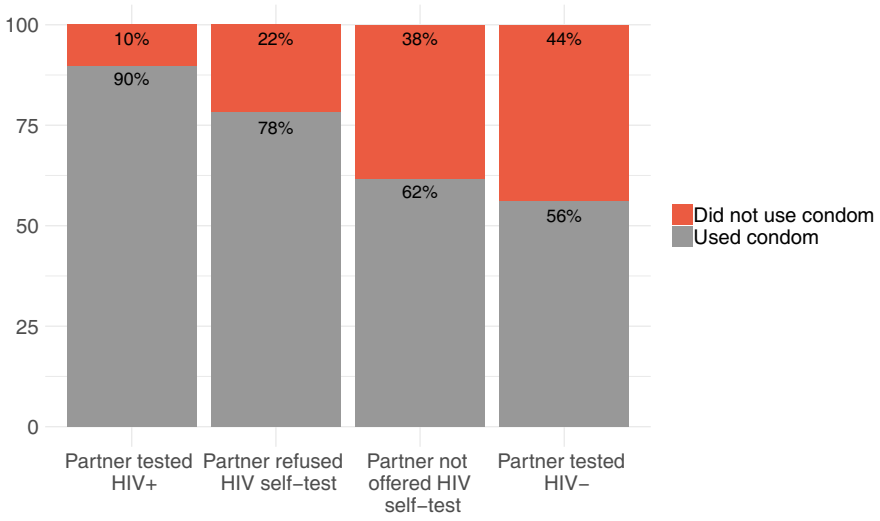

Figure 3. Condom use during recent transactional sex encounters (N = 1957).

Table 4. Overall sexual behaviour among study participants (N = 921)

Variable	N (%)
Number of sexual partners in the past month, median (IQR)	2 (1, 3)
Used condom during last sexual encounter	403 (43.8)
In past six months, participant declined to have sex with one or more partners because they refused to accept a HIV self-test, or had a reactive self-test	131 (14.2)
Total number of partners	158
In past six months, participant used a condom with one or more partners because they refused to accept a HIV self-test, or had a reactive self-test	107 (11.6)
Total number of partners	141

minimal reporting bias [28]. To explore this potential bias in the current study subsequent analyses will compare these self-reported outcomes on partner testing and sexual behaviour to those from the comparison group that did not receive self-tests. We will also examine the effect of the intervention on HIV incidence, which is being assessed over an average 18-month period. Another limitation is that we did not collect data around men's use of post-test services, another important consideration for future programming. While women were instructed to consider offering their partner a self-test when they anticipated having condomless sex, we cannot determine overall how many sexual encounters which were "at risk" of HIV transmission included the offer of a self-test. However, we did ask detailed questions about self-test use in the past three transactional sex encounters and determined that 64% of these encounters included the offer of a self-test.

Data on the cost-effectiveness of secondary distribution by women at higher risk as an additional HTS strategy, both for the outcome of HIV prevention among women and case identification among men, will be important to explore. These data will be collected and analysed in the context of the current study and will provide an important contribution to future research and programming. Modelling studies from Zimbabwe suggest that distribution of self-tests to women engaged in transactional sex is an efficient strategy to avert new HIV infections and is potentially cost-effective [29]. Additional modelling suggests that secondary distribution of self-tests by female sex workers in Zimbabwe to their male partners also has the potential to be highly cost-effective at identifying HIV-positive men [30].

Other important next steps for research would be to explore from men directly their views and testing outcomes related to secondary distribution of self-tests by female partners, particularly high-risk female partners and in the context of transactional sex. Currently all our data on acceptability and uptake among men is derived from the female partner. The in-depth interviews we are presently conducting among male partners of study participants will provide a necessary and complementary perspective to the findings presented here. Exploring social harms associated with secondary distribution, such as IPV, is another important area of research. This is particularly relevant given the high baseline level of IPV, with 52% of participants experiencing IPV in the previous 12 months. Programming for men, particularly in the context of secondary distribution, needs to incorporate a holistic approach to men's health. This includes addressing unhealthy masculine ideals and IPV. We are collecting and monitoring IPV data on an ongoing basis and will be presenting comparisons of IPV in the two study arms at study completion. Likewise, assessing linkage to post-test prevention and care by men in this context would be helpful in considering how best to implement and support secondary distribution strategies. The nature of self-testing, and secondary distribution of self-test kits among women at higher risk in particular, make acquiring these type of data challenging. Most strategies employed in other studies, such as encouraging reporting of self-testing upon attending post-test services, telephone follow-up, or centralized database tracking, have proved imperfect measures of linkage [31]. In a study of secondary distribution among antenatal care clients in Kenya 28% of men reported going for confirmatory testing after their

self-test [28]. There is no gold standard for how to support linkage, and optimal strategies will likely be context specific, but a range of approaches have been employed such as counselling, phone reminders, hotlines, incentives, referrals slips, vouchers and home initiation of HIV care [10,31,32]. For men, strategies that accommodate their work or lifestyle may be particularly appropriate.

Based on the willingness of participants in this study to distribute self-tests to their primary and transactional sex partners, the high uptake of self-testing by male partners, high levels of results disclosure, frequent couples testing, as well as evidence of safer sexual behaviour in this context, we anticipate that secondary distribution of self-tests by women at higher risk to male sexual partners represents a promising strategy for increasing knowledge of HIV status among men, and potentially for reduction of HIV transmission. Secondary distribution by women at higher risk could be an important addition to regional and country wide HTS strategies. Operationalizing secondary distribution of self-tests could be an important way to ensure that men have higher access to HIV testing, and could increase couples testing and promotion of risk-reducing behaviours. Future analyses from this ongoing study will use the randomized trial design to determine the effect of the secondary distribution intervention on male partner testing outcomes on HIV incidence among women.

5 | CONCLUSIONS

Data obtained over a period of six months indicate that women at higher risk are willing and capable of distributing HIV self-tests to regular and transactional male partners. Providing women at higher risk with multiple self-tests facilitated male partner testing, and couples testing. We also demonstrated positive sexual behaviour change, based on whether a self-test was accepted by the male partner, and what the result was. Further research is required to evaluate male partner access to post self-test services. This includes confirmatory testing for all reactive results, and linkage across the cascade of prevention and treatment services. Also important will be consideration of what type of programming can best support men's linkage to these services. These findings suggest that secondary distribution of self-tests is a feasible way to reach men at high risk, who may not be aware of their HIV status, and also has considerable HIV prevention potential.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHORS' CONTRIBUTIONS

SN, HT, KA and SM contributed to study design. EB, SN and HT were involved in analysis. SN, HT, KA, SM, EB, NM and PO were involved in interpretation of results. SN, HT, KA, SM, EB, NM and PO were involved in manuscript writing.

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VIEWPOINT

Reframing the approach to heterosexual men in the HIV epidemic in sub-Saharan Africa

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Despite the body of evidence on heterosexual men's inequitable access to HIV prevention, testing and antiretroviral therapy (ART) [1,2], and poorer viral suppression in sub-Saharan Africa (SSA), public health responses to address this gap remain surprisingly sparse [3]. Gender stereotypes prevail, implicitly blaming men for infecting women with HIV, and for their own health outcomes due to "poorer health-seeking behaviour" [4]. These generalizations about men come at a cost, as neither men nor women benefit when men are portrayed largely as vectors of disease, and when the health needs of women and men are seen as competing rather than complementary. Recent evidence suggests that men care about their health and will participate in HIV prevention, testing and treatment programmes when these are appropriately targeted [5]. This viewpoint argues for a reframing of the approach to heterosexual men in the HIV epidemic in SSA.

The gendered nature of health services in SSA has been well described [1,3-4,6,7]. Given women's biological and social vulnerability to HIV infection, research, programmes and policies have primarily focused on the needs of women [8]. When programmes have included heterosexual men, whether intentional or not, they have frequently been depicted as the *problem* (i.e. transmitting HIV), and the health outcomes of women and children have been prioritized [9]. Consequently, the health needs of men in SSA and generally across the world have been largely ignored [1,3,10]. There are two compelling reasons why the health and HIV risks of heterosexual men should be addressed urgently: like women, men have the right to health; and to reach the ambitious UNAIDS targets of 90:90:90, we need a response that is based on public health and gender inclusiveness rather than gender bias. Given men's higher AIDS-related morbidity and mortality in the context of a limited focus on men, HIV-positive men represent a new vulnerable population in the AIDS epidemics of sub-Saharan Africa [3]. The exclusion of heterosexual men from targeted HIV prevention, testing and treatment strategies constrains the ability of HIV-positive men to manage the risks associated with their health and increases the gender gap in HIV survival [1,4].

A successful HIV response requires a shift from portraying men as the "problem" to acknowledging that, like women, men are vulnerable to HIV infection due to individual, social and structural drivers. We recently undertook a study in a peri-urban region of KwaZulu-Natal province of South Africa, an area where high levels of poverty, unemployment and alcohol consumption co-exist alongside high HIV prevalence rates. A total of 6993 men participated in male-focused community-based HIV and non-communicable diseases screening from August 2017 to June 2019. In contrast to widely cited generalizations about men's poorer health-seeking behaviour, we found that men were concerned about their own and their families' health. Out of 6988 men who consented to HIV screening, 6740 (97%) gave consent for an HIV test [4]. Notably, 80% of the men felt blamed for the HIV epidemic, and unsupported when they did access healthcare services [4]. This study also highlighted the inadequacy of HIV prevention for men which focuses solely on HIV, outside of the broader contexts which shape HIV risk and vulnerability.

Our work confirms that men, like women, are not a homogenous group. The 2017 South African National HIV Prevalence, Incidence, Behaviour and Communication Survey found that age, race, education, employment and locality type were all significant predictors of new HIV infection among men aged 15 years and older [11]. Thus, like women, men are vulnerable to HIV infection due to individual, social and structural drivers, which function in tandem with risky sexual behaviours to increase their risk of HIV infection. Despite these challenges, these men belong to families; they are partners and they are fathers. They can survive and thrive when they live in families and communities that are supportive, caring, loving and resilient.

The news is not all bleak, however. Recently, there is some sense that the narrative has shifted. International agencies such as UNAIDS, the World Health Organization and PEPFAR

have an increased focus on men and HIV. Some countries have developed, or are formulating, national strategic plans on men and HIV [12]. Using Demographic and Health Surveys data, researchers recently characterized the "missing men" in six African countries, highlighting the particular need to reach poor single men without children in rural areas [2]. Others are researching the preferences of men, to inform the development of effective programmes. These are important steps towards ensuring that men are part of the HIV response.

The landmark IAS Forum on Men and HIV prior to the 10th IAS Conference in Mexico represented a turning point in challenging the prevailing discourse on men. Building on the momentum created by the Forum, it is time to reframe the approach to heterosexual men in the HIV epidemic. Men and women should not be seen as competing populations. Like women, men have the right to health, HIV care and treatment, and their poorer access to HIV care cannot be reduced to individual behaviour. HIV interventions for both men and women must be guided by evidence. We need to watch our language: no more "men as a problem" or "men as the vectors". HIV interventions should improve heterosexual men's health for their own sake, not only to improve outcomes for women and children. Future HIV/AIDS conferences must include heterosexual men as a vulnerable population. In getting the frame right in the way we view men, we have the chance to address the biggest gap in the response to HIV in SSA.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

TM conceptualized and drafted the paper, HvR provided comments and edits, MC provided guidance on the key messages and edited drafts. All authors approved the final version.

ABBREVIATIONS

AIDS, Acquired immunodeficiency syndrome; ART, Antiretroviral therapy; HIV, Human immunodeficiency virus; SSA, sub-Saharan Africa.

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RESEARCH ARTICLE

HIV prevalence, testing and treatment among men who have sex with men through engagement in virtual sexual networks in Kenya: a cross-sectional bio-behavioural study

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Abstract

Introduction: In Kenya, men who have sex with men (MSM) are increasingly using virtual sites, including web-based apps, to meet sex partners. We examined HIV testing, HIV prevalence, awareness of HIV-positive status and linkage to antiretroviral therapy (ART), for HIV-positive MSM who solely met partners via physical sites (PMSM), compared with those who did so in virtual sites (either solely via virtual sites (VMSM), or via both virtual and physical sites (DMSM)).

Methods: We conducted a cross-sectional bio-behavioural survey of 1200 MSM, 15 years and above, in three counties in Kenya between May and July 2019, using random sampling of physical and virtual sites. We classified participants as PMSM, DMSM and VMSM, based on where they met sex partners, and compared the following between groups using chi-square tests: (i) proportion tested; (ii) HIV prevalence and (iii) HIV care continuum among MSM living with HIV. We then performed multivariable logistic regression to measure independent associations between network engagement and HIV status.

Results: 177 (14.7%), 768 (64.0%) and 255 (21.2%), of participants were classified as PMSM, DMSM and VMSM respectively. 68.4%, 70.4% and 78.5% of PMSM, DMSM and VMSM, respectively, reported an HIV test in the previous six months. HIV prevalence was 8.5% (PMSM), 15.4% (DMSM) and 26.7% (VMSM), $p < 0.001$. Among those living with HIV, 46.7% (PMSM), 41.5% (DMSM) and 29.4% (VMSM) were diagnosed and aware of their status; and 40.0%, 35.6% and 26.5% were on antiretroviral treatment. After adjustment for other predictors, MSM engaged in virtual networks remained at a two to three-fold higher risk of prevalent HIV: VMSM versus PMSM (adjusted odds ratio 3.88 (95% confidence interval (CI) 1.84 to 8.17) $p < 0.001$); DMSM versus PMSM (2.00 (95% CI 1.03 to 3.87), $p = 0.040$).

Conclusions: Engagement in virtual networks is associated with elevated HIV risk, irrespective of individual-level risk factors. Understanding the difference in characteristics among MSM-seeking partners in different sites will help HIV programmes to develop subpopulation-specific interventions.

Keywords: HIV prevalence; HIV testing; men who have sex with men; virtual networks; Kenya; HIV care continuum

Additional Supporting Information may be found online in the Supporting information tab for this article.

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1 | INTRODUCTION

Globally, men who have sex with men (MSM) shoulder a high burden of HIV [1], with HIV acquisition risk 28 times higher than among men who only have sex with women [2]. In Kenya, bio-behavioural surveillance studies among MSM in 2010 (the most recent national data available) documented an HIV prevalence of 18.9% [3], whereas the HIV prevalence among men in the general population in Kenya, in 2018, was 3.1% [4]. Thus, MSM comprise a priority population in Kenya's national HIV response, despite the criminalization of same sex relationships [5].

There are more than 30 MSM-focused HIV service providers (non-governmental and community-based organizations) in 33 of the 47 counties in Kenya [6]. They work in partnership with the National AIDS and STI Control Programme (NASCOP) and the National AIDS Control Council under the Ministry of Health. Services related to HIV care include HIV

prevention, testing and linkage to HIV treatment, provided by MSM-focused clinics or government clinics, as preferred by the client [7]. In 2012, geographical "hotspot" mapping and population size estimation of MSM in Kenya found that MSM primarily met male sex partners in physical spaces such as venues (bars, clubs), streets, homes and sex dens [8]. Accordingly, MSM-focused HIV services were largely designed around outreach at these physical sites [7].

In Kenya, as elsewhere in sub-Saharan Africa, and in other low and middle income settings, MSM are increasingly using virtual, web-based apps and social network sites to meet male sex partners [9-13]. Studies conducted in Malawi, Namibia and Botswana in 2008 showed that in a pooled analysis, 44.7% of MSM had used the Internet to find male sexual partners in the last six months [14]. Similar studies conducted in 2011 in Eswatini, 2014 in Lesotho and 2015 in Nigeria, respectively, reported that 39%, 44% and 62% of MSM met new male sex partners online [10,15]. In Kenya, Internet-based mapping conducted by NASCOP in 2018 found that 25% of MSM sought male sexual partners solely in virtual sites, and thus would be missed in mapping and estimation that only included physical sites [16].

As indicated earlier, studies from sub-Saharan Africa suggest that HIV prevalence is higher among MSM who seek partners in virtual sites than in physical sites, and that a large proportion are unaware of their HIV-positive status [14,15]. There are no data from Kenya comparing HIV risk or engagement in HIV services by MSM who met their partners in virtual as opposed to physical networks. There is also a concern that men who solely engage in virtual networks to meet sex partners may be less visible to existing MSM-focused service providers, because services generally rely on outreach to physical sites [17]. At present in Kenya, MSM-focused service providers do not systematically leverage online platforms to reach MSM at scale, although a few pilot projects have tested specific online platforms to reach MSM who use virtual sites [18].

Thus, to adapt MSM-focused HIV prevention and care services in response to the changing landscape of how men meet other men for sex, it is important to understand whether and how MSM who meet other male sex partners solely in physical spaces (PMSM), may differ from those who meet partners in both physical and virtual spaces (dual network, DMSM), and MSM who solely meet sex partners in virtual spaces (VMSM), with respect to socio-demographic characteristics, sexual behaviour and HIV prevention and care related practices. Our aims were to compare the following parameters between the three groups: (i) engagement in HIV services, including HIV testing; (ii) HIV prevalence and (iii) engagement in the HIV care continuum (awareness of HIV-positive status and linkage to antiretroviral therapy (ART) for people living with HIV (PLHIV). We then sought to estimate the independent risk of HIV by network type, after accounting for individual-level predictors of prevalent HIV infection among MSM in Kenya [19-22].

2 | METHODS

2.1 | Study setting

This community-based study was conducted in three counties in Kenya: Kisumu, Mombasa and Kiambu, representing the western, coastal and central regions of Kenya respectively.

2.2 | Study design and participants

We used data from a cross-sectional bio-behavioural survey conducted among 1200 MSM recruited from virtual and physical sites in the three counties, from May to July 2019, as part of the baseline for an evaluation of HIV self-testing implementation strategies among MSM [23]. Participants were included if they: (a) identified as male; (b) reported engaging in anal or oral sex with another male in the previous 12 months; and (c) were of 15 years of age or above. The study was co-designed with community researchers and community-based organizations in each of the three counties [23]. A multi-stage cluster sampling approach involving physical and virtual sites was used to recruit 1200 participants. Programmatic mapping and enumeration was conducted in physical sites and in virtual sites where MSM met other male sex partners, to generate the sampling frame [16,24]. A sample size of 1200 (400 in each county) was calculated to observe, with 80% power, a 10% to 15% absolute difference in the proportion of MSM living with HIV who are diagnosed and aware of their HIV status, between a baseline and a post-intervention survey. After stratifying by county, we separately sampled sites to recruit 200 MSM from physical sites and 200 MSM from virtual sites in each county. Recruitment via physical sites involved random sampling of sites, within which two participants were randomly selected for recruitment. Each eligible participant who consented to participate then provided a list of all known contacts that identify as MSM, from which a random sample of one contact was selected for peer-recruitment into the study. Recruitment via virtual site sampling was based on the estimated number of MSM who met sex partners using each virtual site within each county. Virtual sites were selected via random sampling, and peer researchers used each randomly selected virtual site to further randomly recruit the pre-defined number of potential participants who were online when the peer researcher logged into the site. As with physical sites, each consented participant from the virtual sites provided a list of all known contacts that identify as MSM, from which a random sample of one contact was selected for peer-recruitment into the study. The methodology is described in detail elsewhere [23].

2.3 | Data collection

Data collection took place in private spaces (e.g. community-based organizations, offices, drop in centres and clinics), at a time and location that was convenient to the participant. Individuals who met eligibility criteria were requested to visit a specified data collection site, where they were invited to provide informed, written consent, and they could choose to participate in all or some elements of the baseline bio-behavioural survey. Trained researchers administered a face-to-face structured questionnaire (Appendix S1) in Kiswahili or English, as preferred by the respondent. All participants were offered HIV testing and counselling with a rapid two-test algorithm as per Kenya national guidelines, with onsite reporting of results. If their HIV test was positive or inconclusive, participants were also offered accompanied referral to an MSM-focused clinic, or to a government testing and treatment clinic. All participants were provided with condoms and lubricants, and given information on HIV self-testing. Those who were

seronegative were also offered referral for HIV pre-exposure prophylaxis through local MSM-focused clinics. Participants were also asked to provide a dried blood spot for HIV confirmatory serology, performed at the HIV National Laboratory in Nairobi, using the Bioelisa HIV test kit for screening and if positive, the Murex HIV1-2-O test for confirmation. Completed questionnaires were transferred to Nairobi and data were entered into a database developed using Census and Survey Processing System software (CSPro, US Census Bureau and ICF International). The data collection process is detailed further in the study protocol paper [22].

2.4 | Measurement and data analysis

To define our three groups of interest, we used the following question (Appendix S1): "which are the different places/locations through which you have met other male sexual partners? (more than one option possible)" (question 17). If responses included "other," researchers asked the respondent to specify, and places/locations were classified as virtual or physical sites during the analysis. Locations such as Internet/web app, Facebook, WhatsApp, mobile were categorized as virtual sites; and street, home, bus/taxi stand/lodge/markets/social gatherings were categorized as physical sites. Participants who reported using only physical sites as locations through which they met other male sexual partners were defined as physical site MSM (PMSM). Participants who reported using dual sites, that is both physical sites and virtual sites as locations through which they met male sexual partners, were defined as dual site MSM (DMSM). Participants who self-reported only virtual sites as locations through which they met other male sex partners were defined as virtual site MSM (VMSM).

Socio-demographic characteristics included current age, highest level of educational attainment and monthly income. Variables related to sexual behaviour included: preferred sexual position/role; age at first anal/oral sex with a man; duration in years since first anal/oral sex with a man; number of different male partners in the past one month; receipt of money or gifts in exchange for sex with a man and condom use at last sex with a male partner. The two measures of engagement with MSM-focused HIV services were as follows: contact by a peer educator in the prior three months; and visit to an MSM-focused clinic/drop-in centre in the previous three months. HIV testing was measured via self-reported "ever" tested for HIV, and self-reported HIV test in the previous twelve, six and three months.

We compared available HIV "cascade/care continuum" indicators among those living with HIV: the proportion diagnosed and aware of their results at the time of the survey; the proportion registered in an HIV care and treatment programme; those ever on ART; those currently on ART; and among those currently on ART, the proportion who missed taking ART last month. Among participants living with HIV, those who reported their HIV status as HIV-negative, or did not know, or did not want to disclose, were classified as undiagnosed and unaware. We used chi-square tests for comparison of proportions, and the Kruskal–Wallis H non-parametric test to compare medians.

To determine if engagement in a particular sex network was independently associated with prevalent HIV infection, we performed multivariate logistic regression using HIV infection (based on the dried blood spot serology result) as the outcome variable. Our main exposure variable of interest was sole engagement in physical sites, dual site engagement or sole engagement in virtual sites. We adjusted for county and for potential individual-level confounders for prevalent HIV infection based on prior literature [19-22]: socio-demographic characteristics (age, educational attainment); and sexual behaviour and partnership characteristics. The unadjusted and adjusted analyses excluded 11 participants who responded "other" or "no answer" to the question related to preference with respect to sexual position/role. We have presented the crude and adjusted odds ratios (ORs) of prevalent HIV infection among VMSM and for DMSM compared to PMSM; and the corresponding 95% confidence intervals (CIs). Data were analysed using SPSS 25 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

2.5 | Ethics approval

The study received ethics approval from the institutional review boards of the Kenyatta National Hospital – University of Nairobi, Kenya (P557/08/2018) and the University of Manitoba – Health Research Ethics Board, Winnipeg, Canada (HS22205).

3 | RESULTS

3.1 | Comparison of socio-demographic and sexual behaviour

The non-response rate from sampling of physical sites was 13%, but was not documented from the sampling of virtual sites (Table 1). Overall, 177/1200 (14.7%) of participants reporting solely using physical sites (PMSM), 768/1200 (64.0%) reported using dual sites (DMSM) and 255/1200 (21.2%) reported solely using virtual sites (VMSM). The socio-demographic and sexual behaviour characteristics by network engagement are depicted in Table 1.

Although the age distribution across groups was similar, VMSM were more likely to report higher educational attainment (42.4% reported post-secondary as their highest level of education, compared with 22.6% of PMSM and 28.8% of DMSM, $p < 0.001$); and to report zero monthly income (52.2% of VMSM vs. 19.8% of PMSM and vs. 24.0% of DMSM, $p < 0.001$). There was notable variability in preferred sexual position or role, as a higher (29.4%) of VMSM preferred a predominant receptive anal sex role, compared with 18.1% of PMSM and 20.1% of DMSM, $p = 0.002$. The median age at first anal/oral sex with a man was similar across groups, but the age distribution was different, with a slightly higher proportion (63.1%) of VMSM reporting first sex after age 18 years, as compared with PMSM (59.3%) and DMSM (51.6%), $p = 0.003$. Accordingly, and given a similar distribution in current age, VMSM reported a shorter duration since first sex with another man. The median number of male sex partners in the past month was similar across groups, but a higher proportion of VMSM (60.8%) and DMSM (62.4%) reported more than two sex partners, as compared with

Table 1. Comparison of socio-demographic and sexual behaviour among MSM by network type in Kenya, May to July 2019

	Total N = 1200 (%)	PMSM[a] N = 177 (%)	DMSM[a] N = 768 (%)	VMSM[a] N = 255 (%)	*p* value
Age (years)					
Median (IQR)	23 (21.0 to 27.0)	23.0 (21.0 to 27.0)	24.0 (21.0 to 27.0)	23.0 (21.0 to 27.0)	0.022
<25 years	61.1%	59.3%	60.2%	65.1%	0.327
25 + years	38.9%	40.7%	39.8%	34.9%	
Highest level of educational attainment					
Up to primary	19.8%	27.1%	21.9%	8.6%	0.000
Secondary	49.4%	50.3%	49.3%	49.0%	
Post – secondary[b]	30.8%	22.6%	28.8%	42.4%	
Monthly income					
Median (IQR)	8000 (0 to 15000)	8000 (4000 to 15000)	9000 (2000 to 15000)	0.0 (0 to 16000)	0.004
No income	29.3%	19.8%	24.0%	52.2%	0.000
<10000 Shilling/<100 USD	24.3%	36.2%	27.0%	7.8%	
10000 + Shilling/100 + USD	46.4%	44.1%	49.1%	40.0%	
Preference with respect to sexual position/role					
Predominantly receptive (bottom)	21.8%	18.1%	20.1%	29.4%	0.002
Predominantly insertive (top)	45.8%	56.5%	45.2%	40.0%	
Both receptive and penetrative	31.6%	24.9%	33.6%	30.2%	
Others/non-answer	0.9%	0.6%	1.2%	0.4%	
Age at first anal/oral sex with a man (years)					
Median (IQR)	18.0 (16.0 to 20.0)	18.0 (16.0 to 22.0)	18.0 (16.0 to 20.0)	18.0 (17.0 to 20.0)	0.025
<15 years	10.3%	7.3%	12.4%	6.3%	0.003
15 to 17 years	34.5%	33.3%	36.1%	30.6%	
18 + years	55.2%	59.3%	51.6%	63.1%	
Duration since first had anal/oral sex with another man (years)					
Median (IQR)	5.0 (3.0 to 8.0)	4.0 (2.0 to 7.0)	5.0 (3.0 to 9.0)	4.0 (2.0 to 7.0)	0.020
<5 years	46.0%	53.7%	42.0%	52.8%	0.001
5 to 9 years	34.2%	30.5%	35.1%	34.3%	
10 + years	19.8%	15.8%	22.9%	13.0%	
Number of different male sexual partners in the past one month					
Median (IQR)	2.0 (1.0 to 3.0)	1.0 (1.0 to 3.0)	2.0 (1.0 to 3.0)	2.0 (1.0 to 3.0)	0.832
<2	41.1%	58.9%	37.6%	39.2%	0.000
2+	58.9%	41.1%	62.4%	60.8%	
Received money/gift in exchange of sex with man	59.9%	64.4%	66.0%	38.4%	0.000
Condom use with last male sexual partner	71.8%	67.0%	73.1%	71.1%	0.260

IQR, inter-quartile range; MSM, men who have sex with men.
[a]PMSM (physical-space only network); DMSM (dual network); VMSM (virtual-space only network). Participants who self-reported only virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met other male sex partners were defined as MSM who met sex partners solely using virtual sites (VMSM). Participants who reported using only physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) as locations through which they met other male sexual partners were defined as MSM who met sex partners solely using physical sites (PVSM). Participants who reported using both physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) and virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met male sexual partners were defined as MSM who met sex partners using dual sites (DMSM); [b]post-secondary (tertiary/college/university).

PMSM (41.1%, $p < 0.001$). Fewer (38.4%) of VMSM reported receiving money/gifts in exchange for sex with men, as compared with 64.4% of PMSM and 66.0% of DMSM ($p < 0.001$). The proportion of men who reported condom use with last male sex partner was similar across groups.

3.2 | Comparison of engagement in MSM-focused HIV services and HIV testing

Half of VMSM (50.2%) and DMSM (51.3%) had been contacted by a peer educator or outreach worker from an MSM-

focused HIV service in the previous three months, as compared with only 36.0% of PMSM ($p < 0.001$) (Table 2). Similarly, half of VMSM (48.6%) and DMSM (49.0%) had visited an MSM-focused HIV clinic or drop-in centre in the previous three months, compared with only 31.1% of PMSM ($p < 0.001$). Nearly all respondents reported a prior HIV test (97.0%), and HIV testing in the past 12 months was also high (85.1%), and similar across groups. However, the likelihood of recent testing was highest in VMSM, followed by DMSM, and lowest in PMSM: 78.5%, 70.4% and 68.4% were tested in the previous six months, $p = 0.03$; and 68.7%, 58.2% and 57.3 were tested in the previous three months, $p = 0.01$. With respect to their most recent HIV test, 20.0%, 29.63% and 40.2% of PMSM, DMSM and VMSM had been tested in an MSM-focused clinic ($p < 0.001$, Table S1).

3.3 | Comparison of the HIV cascade/care continuum

HIV prevalence was highest in VMSM (26.7%, 95% CI: 21.2 to 32.1), followed by DMSM (15.4% 95%, CI: 12.8 to 17.9) and lowest in PMSM (8.5%, 95% CI: 4.3 to 12.6; $p < 0.001$) (Table 3). Among those living with HIV, 46.7% (PMSM), 41.5% (DMSM) and 29.4% (VMSM) were diagnosed and aware of their HIV status ($p = 0.220$). Of the 201 participants living with HIV, 32.8% were registered at an HIV treatment and care centre, all of whom had "ever initiated on ART" and 32.3% were currently on ART (40.0% in PMSM, 35.6% in DMSM and 25.0% of VMSM, $p = 0.270$). However, of those on ART, 50.0% of PMSM, 60.5% of DMSM and 88.2% of VMSM never missed taking their antiretroviral (ARV) drugs in the past one month, $p = 0.08$).

3.4 | Association between network engagement and prevalent HIV infection

Compared with PMSM, DMSM were at a twofold (unadjusted OR 1.96, 95% CI: 1.12 to 3.45) higher risk of a prevalent HIV infection; and VMSM were at a fourfold higher risk (unadjusted OR 3.93, 95% CI: 2.16 to 7.14) (Table 4). The association between network type and HIV persisted in direction and magnitude after adjusting for county and for potential individual-level confounders: VMSM versus PMSM (adjusted OR 3.88, 95% CI: 1.84 to 8.17) and DMSM versus PMSM (adjusted OR 2.00, 95% CI: 1.03 to 3.87).

4 | DISCUSSION

Our cross-sectional study identified a large subset of MSM in Kenya who use both virtual and physical sites to meet sex partners; and smaller, but important subsets who only use virtual sites or only physical sites. A surprising finding was that recent engagement with MSM-focused HIV services and recent HIV testing was more commonly reported by men engaged in virtual networks (either solely or as part of a dual network). However, engagement in virtual networks was associated with a two to fourfold higher risk of prevalent HIV

Table 2. Engagement in MSM-focused HIV services and HIV testing among MSM by network type in Kenya, May to July 2019

	Total	PMSM[a]	DMSM[a]	VMSM[a]	*p* value
Contacts with MSM-focused HIV programme					
Contacted by a peer educator or outreach worker in the past three months (N = 1194)	48.8%	36.0%	51.3%	50.2%	0.001
Visited an MSM-focused HIV programme clinic or drop-in centre in the past three months (N = 1199)	46.3%	31.1%	49.0%	48.6%	0.001
HIV testing					
Ever tested for HIV (N = 1200)	97.0%	95.5%	97.4%	96.9%	0.400
Tested for HIV in the past 12 months (N = 1184)	85.1%	82.2%[b]	84.5%[c]	89.1%[d]	0.104
Tested for HIV in the past six months (N = 1170)	71.8%	68.4%[b]	70.4%[c]	78.5%[d]	0.029
Tested for HIV in the past three months (N = 1153)	60.3%	57.3%[b]	58.2%[c]	68.7%[d]	0.010

MSM, men who have sex with men.
[a]PMSM (physical-space only network); DMSM (dual network); VMSM (virtual-space only network). Participants who self-reported only virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met other male sex partners were defined as MSM who met sex partners solely using virtual sites (VMSM). Participants who reported using only physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) as locations through which they met other male sexual partners were defined as MSM who met sex partners solely using physical sites (PVSM). Participants who reported using both physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) and virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met male sexual partners were defined as MSM who met sex partners using dual sites (DMSM); [b]among PMSM, the denominator was N = 174, N = 171 and N = 171, for individuals tested in the past twelve, six and three months respectively. Individuals reported that in their most recent HIV test at >12, >6 months ago as positives were removed from the numerator and denominator of the analysis of >6 and >3 months respectively; [c]among DMSM, the denominator was N = 762, N = 753 and N = 739, for individuals tested in the past twelve, six and three months respectively. Individuals reported that in their most recent HIV test at >12, >6 months ago as positives were removed from the numerator and denominator of the analysis of >6 and >3 months respectively;[d]among VMSM, the denominator was N = 248, N = 246 and N = 243, for individuals tested in the past twelve, six and three months respectively. Individuals reported that in their most recent HIV test at >12, >6 months ago as positives were removed from the numerator and denominator of the analysis of >6 and >3 months respectively.

Table 3. HIV prevalence and HIV cascade among MSM living with HIV by network type in Kenya, May to July 2019

	Total (N = 1200) % [95% CI]	PMSM[a] (N = 177) % [95% CI]	DMSM[a] (N = 768) % [95% CI]	VMSM[a] (N = 255) % [95% CI]	*p* value
HIV prevalence[b]	16.8 [14.6 to 18.9]	8.5 [4.3 to 12.6]	15.4 [12.8 to 19.9]	26.7 [21.2 to 32.1]	0.000
	Total MSM living with HIV[b] (N = 201)	**PMSM[a] (N = 15)**	**DMSM[a] (N = 118)**	**VMSM[a] (N = 68)**	***p* value**
MSM living with HIV aware of HIV-positive status[c]	37.8%	46.7%	41.5%	29.4%	0.220
Registered in HIV treatment and care centre	32.8%	40.0%	35.6%	26.5%	0.367
Ever on ART	32.8%	40.0%	35.6%	26.5%	0.367
Currently on ART	32.3%	40.0%	35.6%	25.0%	0.266
Never missed taking ARV in the past one month (of those currently on ART) (N = 66)	66.7%	50.0%	60.5%	88.2%	0.080

ART, antiretroviral treatment; MSM, men who have sex with men
[a]PMSM (physical-space only network); DMSM (dual network); VMSM (virtual-space only network). Participants who self-reported only virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met other male sex partners were defined as MSM who met sex partners solely using virtual sites (VMSM). Participants who reported using only physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) as locations through which they met other male sexual partners were defined as MSM who met sex partners solely using physical sites (PVSM). Participants who reported using both physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) and virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met male sexual partners were defined as MSM who met sex partners using dual sites (DMSM);[b]HIV serology based on the dried blood test; [c]aware of HIV status based on self-reported positive status as per the last test HIV prior to the study and the test was HIV positive. Individuals who had "never tested for HIV" were categorized as not aware. All respondents who had "ever tested for HIV" and disclosed their last HIV test result to the interviewer were considered as aware of HIV status.

infection compared with sole engagement in physical sites, which could not be explained by geography nor by individual-level risk factors examined in the study.

The use of virtual sites to meet partners was more commonly reported in our study (85% of MSM overall, including those who exclusively used virtual sites and those who used physical sites as well) than in other studies across sub-Saharan Africa [10,14,15]. This may reflect differences in socio-political and Internet availability, but also temporal differences, as suggested from other high income settings, where the use of virtual spaces has increased over time [25].

There were notable differences between the three networks. Chief among them was higher educational attainment, yet higher levels of zero income among VMSM. We hypothesize that this may be because VMSM include a large proportion of (unemployed) college or other students; however, we did not ask about current educational enrolment in the survey. The educational profile of VMSM in our study is similar to the educational profile of MSM engaged in virtual networks in Lesotho, Eswatini and Nigeria [10,15]. The sexual behaviour of VMSM and of DMSM included factors known to be associated with both higher and lower HIV risk. Our findings show that MSM who seek sexual partners in virtual sites (either solely or along with physical sites) preferred receptive anal sex role and had more sexual partners. Studies from Asia and United States have shown that MSM who seek sexual partners on the Internet had more homosexual partners, similar to our study [12].

Our finding of an elevated risk of HIV in MSM who meet sex partners online is similar to findings from China [12], Malawi [14] and Nigeria [15]. Importantly, the individual-level risk factors that we explored could not explain the difference between the two groups. One possible explanation for this could be that there are unexplained confounders such as the experience of violence or condomless anal sex, which can lead to increased individual-level risk of HIV acquisition [18,26]. Another reason could be that the structure of the sexual network itself increases the likelihood of acquiring HIV, even if all other individual-level or partner-level factors remain the same [27]. If a subset of MSM meet sex partners via virtual sites, then the likelihood that their sex partner is living with HIV is already two to three times that of MSM in other networks. Sexual network characteristics such as network structure, density, homophily and a person's centrality within a sexual network play important roles in understanding HIV transmission among MSM [27-29].

The overall high proportion of undiagnosed HIV is consistent with findings from several countries in sub-Saharan Africa [14], and is cause for concern when the proportion recently tested is moderately high. The reasons for low awareness could include acquisition of HIV after the last test or having tested during the window period and received a negative test result [30]. Some participants living with HIV may have been aware of their HIV diagnosis but did not wish to disclose in a face-to-face interview due to fear of stigma or discrimination [31] or social desirability bias. If VMSM and DMSM

Table 4. Independent association between network type and HIV after adjusting for county and individual – level risk factors for HIV among MSM in Kenya, May to July 2019

	Prevalence of HIV infection (N = 197/1200)[a]			
	Unadjusted		Adjusted	
	Odds ratio [95% CI]	*p* value	Odds ratio [95% CI]	*p* value
Network[b]				
PMSM	1	Ref	1	Ref
VMSM	3.93 [2.16 to 7.14]	0.000	3.26 [1.60 to 6.67]	0.001
DMSM	1.96 [1.12 to 3.45]	0.019	1.79 [0.95 to 3.36]	0.072
County				
Kisumu	1	Ref	1	Ref
Mombasa	2.57 [1.66 to 3.97]	0.000	1.46 [0.88 to 2.43]	0.141
Kiambu	3.37 [2.20 to 5.15]	0.000	2.11 [1.26 to 3.51]	0.004
Age (years)[c]	1.10 [1.07 to 1.13]	0.000	1.13 [1.09 to 1.17]	0.000
Highest level of Education attainment				
Up to primary	1	Ref	1	Ref
Secondary	0.63 [0.42 to 0.93]	0.020	0.85 [0.53 to 1.37]	0.509
Post – secondary[d]	0.96 [0.64 to 1.44]	0.843	1.24 [0.74 to 2.06]	0.412
Monthly income[c]	1.00 [1.00 to 1.00]	0.085	1.00 [1.00 to 1.00]	0.905
Preference with respect to sexual position				
Insertive (top)	1	Ref	1	Ref
Receptive (bottom)	2.73 [1.82 to 4.11]	0.000	2.59 [1.67 to 4.02]	0.000
Both	2.85 [1.96 to 4.13]	0.000	2.26 [1.51 to 3.37]	0.000
Age at first anal/oral sex with a man (years)[c]	0.98 [0.94 to 1.02]	0.351	0.94 [0.90 to 0.98]	0.003
Number of male sexual partners in the past one month[c]	1.08 [1.03 to 1.14]	0.002	1.04 [0.98 to 1.10]	0.192
Receive money/gift in exchange of sex with another man[e]				
No	1	Ref	1	Ref
Yes	0.97 [0.71 to 1.32]	0.843	1.03 [0.70 to 1.51]	0.889

CI, confidence interval; MSM, men who have sex with men.
[a]HIV serology based on the dried blood test. Analyses excludes N = 11 respondents who responded as "other" or "no answer" to question related to preference with respect to sexual position; [b]PMSM (physical-space only network); DMSM (dual network); VMSM (virtual-space only network). Participants who self-reported only virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met other male sex partners were defined as MSM who met sex partners solely using virtual sites (VMSM). Participants who reported using only physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) as locations through which they met other male sexual partners were defined as MSM who met sex partners solely using physical sites (PVSM). Participants who reported using both physical sites (street, home, bus/taxi stand/lodge/markets/social gatherings) and virtual sites (Internet/web app, Facebook, WhatsApp, mobile) as locations through which they met male sexual partners were defined as MSM who met sex partners using dual sites (DMSM); [c]included as continuous variable; [d]post-secondary (tertiary/college/university); [e]asked as "do you receive money/gifts in exchange for sex with another man?"

experience a higher incidence of HIV compared to PMSM (as the prevalence data would suggest), then HIV testing frequency among MSM in virtual networks should be further enhanced. Stanford et al. found that increased frequency of HIV testing was related to awareness of the HIV diagnosis [32]. Our findings also suggest that once MSM living with HIV are diagnosed, then initiation into ART, and adherence to ART programme, is good. Of note, VMSM were more likely to adhere to their ARVs, a finding that warrants further exploration [33]. Our findings also suggest that with new strong evidence around undetectable equals untransmittable [34], reducing the undiagnosed fraction among men engaged in virtual networks, along with their initiation and retention on ART, could be an important strategy for reducing onward transmission of infection.

These findings have several implications for HIV prevention and care programming for MSM. First, moving from individual-level risk factors to considering networks – and thus, types of networks – could better identify subsets of MSM who remain most vulnerable to HIV acquisition and transmission. Network types, therefore, could be prioritized for HIV prevention and treatment, and MSM-focused services could harness virtual sites to reach MSM [35-42]. A systematic review of HIV intervention delivery among MSM in sub-Saharan Africa identified pilot projects to reach MSM through the Internet in Ghana and the Democratic Republic of Congo [43]. Sexual networks

are dynamic, and our findings signal the importance of leveraging how MSM connect with each other and the information platforms they use, to deliver rights-based and effective HIV prevention and treatment interventions.

To date, few studies from low and middle income countries have compared MSM across such networks to characterize their profiles and their HIV risks and HIV prevalence [12,44,45]; to our knowledge, our study is one of the first from East Africa to do so. However, our study has important limitations. First, the data were collected via face-to-face interviews and thus are subject to social desirability bias, with the possibility of underreporting of higher risk practices or HIV status [46]. Second, our definitions of VMSM, PMSM and DMSM did not include a time-frame, and so we could not distinguish men who used virtual sites for a short period of time from those who used them for several years. Third, we combined data from three counties, and although we adjusted for county when exploring the association between network engagement and HIV, further work is needed to characterize the sexual networks within each county. Fourth, the sampling method included multi-stage sampling of physical sites and of virtual sites, which means that there could be some within-site homogeneity in estimates because we recruited two seeds and two peers, we could not appropriately account for within-cluster homogeneity in our analysis and thus may have overestimated differences between groups. The 2018 mapping and enumeration of MSM in Kenya signalled the importance of recruiting MSM from virtual sites (as 25% of MSM sought male sexual partners solely in the virtual sites), and thus it was critical to include virtual-site sampling. However, there are no established approaches to doing so, and our approach (like those of others) might lead to selection bias. For example, participants from the virtual sites who are online at the same time might belong to the same subnetwork, and may therefore have similar characteristics. Our approach to virtual-site sampling made it challenging to document a non-response rate, which further limits our ability to judge selection bias. Fifth, we did not include sexual identity in our list of variables because we erroneously merged the categorical responses in the study tool. Sixth, we did not ask questions about current or recent schooling level, which may be important in understanding participants in virtual networks. Finally, we did not measure exposure to ART via biological sampling, and thus are limited to self-reported ART status.

Further research is needed to understand the reasons for the high proportion of MSM who indicated that they were undiagnosed, even after moderately frequent testing. This could help us to understand the optimal frequency of HIV testing. Our findings also call for investigation into the structure and characteristics of virtual and dual networks, and how structures of networks might help to explain observed HIV prevalences. Studies in Kenya have shown that MSM also have female partners and engage in sex work [47]. Further research is needed to understand heterosexual sexual relationships among MSM engaged in virtual sites and their sex work-related partnerships. Finally, we need implementation and programme science to assess how, when and under what contexts innovative network-based interventions could be effectively delivered within virtual sites for MSM in Kenya, and across sub-Saharan Africa.

5 | CONCLUSIONS

Virtual spaces have become common ways to meet sex partners among MSM in Kenya, and are associated with a two to threefold greater risk of HIV compared to those using only physical sites. Hence, tailoring HIV-related prevention, testing and treatment programmes to MSM using virtual sites should be an important focus for HIV prevention and care programmes.

Programmes need to better understand the heterogeneity in the MSM population and develop different service delivery models to enable: (a) effective reach of prevention interventions such as PrEP and condoms, (b) frequent testing and early diagnosis and (c) entry and retention in care and treatment.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

PB, SI, FE, SMi and HM conceptualized the paper. PB, SI and SMi designed the plan of analysis. PB, SI and SMi wrote the first draft of the paper with edits from SI, RL, MB, MP, JB and SM. All authors contributed to questionnaire design, and interpretation of data and results; and all reviewed the manuscript and provided edits and suggestions. JB and PB conceptualized the larger study method. HM and PB generated the data, and JM, SK, JK, MM, MN and JO managed the data collection process. KO, SM, MOK, MM and JW supported the design of the study and on site data collection process. SI led questionnaire development and sampling design, and conducted the data analyses with input from PB and SMi. SM did the final edit of the manuscript. All authors have read and approved the final manuscript.

ABBREVIATIONS

CBO, community-based organization; CI, confidence interval; DMSM dual site MSM; MSM, men who have sex with men; NASCOP, National AIDS and STI Control Programme; OR, odds ratio; PMSM, physical site MSM; VMSM, virtual site MSM.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Survey questionnaire for baseline and end line survey.

Table S1. Consumption of drugs (oral or injecting) and place of most recent test among MSM who meet sex partners solely via virtual sites versus solely via physical sites versus via both physical and virtual sites in Kenya, May to July 2019

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