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Results of the *Sukuma Ndoda* ("Stand up, Man") HIV Self-Screening and Assisted Linkage to Care Project in Johannesburg: A Quasi-Experimental Pre–Post Evaluation

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Background: HIV testing rates among South African men lag behind rates for women and national targets. Community-based HIV self-screening (HIVSS) distribution and follow-up by community health workers (CHWs) is a scalable option to increase testing coverage, diagnosis, and treatment initiation. We provided HIVSS and assisted linkage to care to men not recently tested (within the past 12 months) residing in high-HIV-burden areas of Johannesburg.

Methods: CHWs distributed HIVSS in 6 clinic catchment areas. Follow-up to encourage confirmatory testing and antiretroviral therapy initiation was conducted through personal support (PS) or an automated short message service (SMS) follow-up and linkage system in 3 clinic areas each. Using a quasi-experimental pre–post design, we compared differences in the proportion of men testing in the clinic catchment areas during the HIVSS campaign (June–August 2019) to the 3 months prior (March–May 2019) and compared treatment initiations by assisted linkage strategy.

Results: Among 4793 participants accepting HIVSS, 62% had never tested. Among 3993 participants with follow-up data, 90.6% reported using their HIVSS kit. Testing coverage among men increased by 156%, from under 4% when only clinic-based HIV testing services were available to 9.5% when HIVSS and HIV testing services were available ($z = -11.6$; $P < 0.01$). Reported test use was higher for men followed through PS (99% vs. 68% in SMS); however, significantly more men reported reactive self-test results in the SMS group compared with PS (6.4% vs. 2.0%), resulting in more antiretroviral therapy initiations in the SMS group compared with PS (23 vs. 9; $P < 0.01$).

Conclusions: CHW HIVSS distribution significantly increases testing among men. While PS enabled personalized follow-up, reporting differences indicate SMS is more acceptable and better aligned with expectations of privacy associated with HIVSS.

Key Words: HIV self-screening (HIVSS), HIV self-testing (HIVST), linkage to care, men, South Africa

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INTRODUCTION

In South Africa, which has the most persons living with HIV globally,[1] HIV testing remains far below the levels necessary to impact the epidemic, particularly among men, who test significantly less than women. National data indicate that 70.9% of men have ever tested vs. 79.3% of women.[2,3] While 66% of men (aged 15+) reported testing for HIV within the past year in the 2017 national survey[2] studies have also documented substantial overreporting of HIV testing, particularly among men.[4] Estimates of the proportion of men living with HIV who know their status in South Africa vary widely, from as low as 45%[2,5] to modeled estimates as high as 82%.[6] Despite national HIV testing campaigns, male clinic attendance remains low, leading to disparities in HIV-related care and wellbeing[7,8] and continued transmission to partners.[9–11] Barriers to testing are numerous, including difficulty accessing HIV testing services (HTSs) for men who may be working, traveling for work, or whose livelihoods make clinic attendance difficult.[12–14] Logistical barriers can be heightened by norms of masculinity[12,15–17] and by stigma associated with clinic attendance.[14,18,19] Evidence-based strategies to reach men with HTS and to facilitate linkage to care following a positive test are critical.[20–24]

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HIV self-testing, referred to in South Africa and in this article as HIV self-screening (HIVSS), offers an alternative to clinic and provider-based testing that can be conducted alone or with others and can occur at any time or place.[25–29] HIVSS has been demonstrated to increase testing uptake and frequency and could facilitate early HIV detection and treatment.[30–32] Among HIVSS distribution strategies for men in sub-Saharan Africa, peer or health worker–based distribution through workplaces, transport hubs, community venues, and homes have shown promise,[33–37] as have strategies distributing HIVSS to men through female partners.[24,38,39] Community-based distribution has also proven successful: in a population-based study in Blantyre, Malawi, men preferred HIVSS 2:1 over home-based HTS.[33] In that study, first-time testers made up over a third of the self-testing population,[33] suggesting that HIVSS can engage men unlikely to access testing elsewhere. Despite its promise, few community-based HIVSS distribution programs have been evaluated or integrated into public programming. Questions also remain about the best strategies to ensure linkage to care, including confirmatory testing and antiretroviral therapy (ART) initiation, following a positive self-test.[40,41]

To address the need for feasible, impactful, and scalable HIVSS distribution and linkage to care strategies that could inform implementation in the real world, we implemented a demonstration project called *Sukuma Ndoda* ("Stand up, Man"). *Sukuma Ndoda* used a quasi-experimental pre–post design to assess the feasibility and efficacy of community-based HIVSS distribution and assisted linkage to care by integrating HIVSS kit distribution into the work of Department of Health contracted community health teams performing community outreach from government clinics. Our primary aim was to determine whether the program would increase the number of men who received testing services. We also sought to assess differences in rates of linkage to care and treatment initiations using 2 assisted linkage strategies—1 based on an automated short message service (SMS) system and 1 based on personal support (PS).

METHODS

Setting

The project was implemented in the City of Johannesburg, Gauteng Province, South Africa, and integrated into the community health services delivered by 6 clinics with active Ward-based Primary Health Care Outreach Teams (WBPHCOTs). WBPHCOTs are the cornerstone of the South African Government's strategy to strengthen community-based health models and are composed of community health workers (CHWs) and a limited number of more specialized providers responsible for community-based care in the geographic area covered by the clinic, also known as the clinic's catchment area.[42] Study clinics were selected purposefully in consultation with the District and Sub-District WBPHCOT managers to include HIV hotspots, prioritizing areas where WBPHCOTs were reaching households in informal settlements, which include mobile populations and undocumented migrants, a population less likely to engage in healthcare services.[43–46] Six facilities were selected: 3 in Region A and 3 in Region G. Region A is the northern region of Johannesburg, encompassing industrial business areas, growing residential areas, and the densely populated informal settlements of Diepsloot and Ivory Park. Region G is the southernmost and second most populated region of the city with several middle-income townships and one of the largest informal settlements in South Africa, Orange Farm.

Between the 6 clinics, a total of 178 WBPHCOT CHWs and outreach team leads were trained to distribute HIVSS and provide assisted linkage within their clinic catchment area—specifically focusing their efforts on men in informal settlements. Each clinic's WBPHCOT team was assigned to a single linkage protocol (described below), either registering participants in automated SMS reminders or providing personal support (PS); teams were trained in only 1 linkage protocol to ensure the outreach team leads needed to only manage a single protocol. Clinic assignments to SMS or PN linkage were designated by District and Sub-District Health Management Teams based on proximity (eg, 1 informal settlement in Region A was too distant to ask CHWs to return multiple times in a short period on foot). Both assisted linkage strategies have demonstrated promise in linking patients to care and promoting early ART initiation in our previous linkage and retention trial in North West Province[47–50] and elsewhere.[51–53]

Materials

HIVSS consisted of the OraQuick HIV 1/2 Rapid Antibody Test (OraSure Technologies, Bethlehem, PA), an oral fluid HIV antibody screening tool approved by the FDA for clinical use in 2004 and for over-the-counter sales in 2012. The OraQuick has 99.3% sensitivity and 99.80% specificity in a laboratory setting and 93.0% sensitivity and 99.98% specificity in self-testing studies.[54–56] The self-test is approved for use and sale in South Africa since it received WHO Pre-Qualification in 2017. The OraQuick self-test includes Instructions for Use (IFU) with pictorial and written instructions designed for low-literacy populations in 3 South African languages (English, Setswana, and isiZulu). HIVSS kits are available in South Africa through PEPFAR and Global Fund programming, for sale in the private sector (pharmacies and online), and through limited government procurement in the public sector. The South African government supports HIVSS as an extension of national HIV testing.[29]

Procedures

CHWs recruited participants and distributed HIVSS kits from June to August 2019, setting out on foot during regular work hours to visit current patients, contact those out of care, and recruit men for this study in and around their homes. Participant inclusion criteria included being 18 years and older, male (or identifying as male), having not tested for HIV in the past 12 months, not known to be HIV positive, residing in the area (to facilitate follow-up), and having access to a cell phone to receive messages and follow-up. The goal was to distribute a minimum of 4500 kits; each CHW was tasked with providing approximately 25–40 HIVSS kits to men in their catchment areas.

Upon contact with a potential participant, CHWs introduced themselves and the study and described the HIVSS kit. If interested, participants underwent a brief eligibility screener, reviewed and signed the informed consent form with the enrolling CHW, and provided a cell phone number and a location where they could be found for follow-up. The CHW then demonstrated the use of the oral fluid self-test, explaining each component and order of procedures, including a review of the IFU. Any CHW with access to a smartphone could opt to show the client the manufacturer's 3-minute instructional video on HIVSS use. CHWs then assisted men to register their individual kit ID numbers into a secure database and automated 2-way messaging service; this process included texting a registration code to a local number and then entering the kit ID number. All participants received 1 HIVSS kit, including the IFU with visual aids for correct use and interpretation, a "care card" to take to local clinics for follow-up services, and pre- and post-test information. Participants were encouraged to make a self-screening plan with an agreed time and place to use the HIVSS kit. Finally, participants who requested them were also provided with HIVSS kits for their primary partner.

The CHW then introduced the follow-up protocol assigned to their clinic team. Participants in clinic catchment areas assigned to SMS, continued to engage with the 2-way communication system, responding to weekly prompts until the HIVSS kit was used and results were reported. If the HIVSS kit was not used or no response was received, the system provided a message encouraging use and offering further assistance or information. If the HIVSS kit was used, the system requested a result [eg, reply 1 if negative, reply 2 if positive (self-test reactive), 3 if unknown]. Each response option generated a different, tailored message from the system. For example, if the participant selected "1" [negative (nonreactive)], the system advised repeat testing in 3–6 months. If the participant selected "2" (positive) or "3" (unknown), the system asked if confirmatory testing was sought and if the participant would like to receive a call from the study team. Following receipt of results, SMS texts decreased to monthly check-ins on the use of care (if reactive) or prevention services (if nonreactive) for up to 3 months. Prevention services messaging centered on repeat HIV testing, testing with partners, and medical male circumcision. All participants received a "thank you and farewell" message at the end of the follow-up. All replies to SMS prompts were free to the participants and were automatically captured into the study database.

Those in clinic catchment areas assigned to PS received weekly follow-up contact through calls, texts, or in-person visits, per participant preference, until they confirmed using the HIVSS kit. Once results were reported, the CHW contacted the participant monthly thereafter to encourage confirmatory testing and either ART initiation (if positive) or uptake of prevention services (if negative). CHWs were trained to work with participants to determine a prevention or care linkage plan following the use of HIVSS. In addition, those in the PS arm could arrange in-person support, including help with self-testing or accompaniment to a clinic for confirmatory testing. The PS program was designed to have standard communications but also to be flexible to support the participants as needed, as not all participants require the same amount of support. All PS contacts were reported on participant follow-up registers (paper) and entered in the study database.

The protocol was reviewed and approved by the South Africa Human Sciences Research Council, the Institutional Review Boards at the University of California San Francisco and the University of Washington, and by the Associate Director for Sciences (ADS) at CDC. All procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 2000.

Data Analysis and Measures

Data on kit distribution, kit use, self-screening results, confirmatory testing, and ART initiation were collected through study distribution logs, the SMS system, and follow-up registers for the 3 months of study activities (June–August 2019). To evaluate the program's impact on HIV testing and treatment uptake among men in the clinic catchment areas, we utilized concurrent data on HIV testing and treatment initiations collected at each partnering clinic; these data are extracted from clinic treatment records as part of the TIER.Net data system[57] and from paper-based HIV testing registers. These data are routinely summarized by each Department of Health public health facility and prepared for inclusion in the national District Health Information System. For this study, we utilized monthly TIER.Net data dispatches provided by each facility to Anova, the implementing partner supporting facility-based data collection and monitoring activities and service delivery. The facility data were used to establish rates of clinic-based HIV testing and treatment initiation in the partnering clinics for the 3 months before and during the HIVSS distribution campaign. Indicators extracted included HIV tests performed monthly for all men 15 years or older by age group; number of positive tests for men by age group; and the number of ART initiations from March through September. The HIVSS data include only those who were 18 years or older, so there is a slightly wider age range in the clinic data.

For our primary analysis, we utilized a time-based control, comparing the number of men reached with testing in the catchment population (total testing coverage) in the 3 months before program initiation (March–May) and during the HIVSS programming (June–August) to estimate the impact of HIVSS distribution on total testing among men. We used time (before vs. during the program) as a binary exposure with HIV testing as the binary outcome, using a χ^2 to test for the significance of the change in the proportion of men testing over time. We estimated the overall number of men in the clinic catchment areas using subdistrict reports of clinic population size, estimating the number of men 18 and over from the closest census areas, and then subtracting 10% to account for men who are HIV positive (approximately

20%[2]) and know their status (approximately half), and would not be eligible for testing. This study was powered based on clinics reporting approximately 200 tests monthly per facility; a proposed study period of 10 months (which was reduced to 6 months due to delays in establishing local agreements); and an estimated 70% increase in testing volume among men by distributing 4500 test kits across the area. Even if only half of the men receiving HIVSS were to utilize their test kit, we had over 90% power to detect a difference in overall testing due to the addition of HIVSS programming.

To evaluate the performance of SMS linkage to PS linkage, we compared the proportion of reported positive cases, reported confirmatory testing, and reported ART initiations among study participants by linkage arm using a 2-sample test for proportions. As with the HIV testing outcome, we also assessed differences in the proportion of men who initiated ART before and during the HIVSS program using time as the exposure. For this later analysis, we utilize both TIER.Net data on test positive cases and new initiations and participant responses in the SMS system and in CHWs' follow-up for the PS arm. We compare ART initiation among positive tests captured among men in TIER.Net for the comparison time period (March–May) to initiations among positive tests captured in TIER.Net and reported in the HIVSS study cohort for the intervention time period (June–August). We also ran descriptive statistics to assess the characteristics of participants in the HIVSS program and the results of testing as compared with men accessing clinic-based HTS.

RESULTS

Program staff distributed 4793 HIVSS kits to eligible men in the 6 clinic catchment areas, with almost every eligible man accepting HIVSS. Only 58 men (1.2% of those approached) declined participation due to disinterest in HIV or self-screening, preferring to not know their HIV status, and having no time. During the 6-month period of study, there were 8636 HIV tests recorded in TIER.Net among men at the 6 study clinics. Generally, men accepting HIVSS were slightly younger, but not significantly so, than those receiving HTS (Table 1). Because HIVSS distribution was focused on informal settlements and low-income areas as well as men who had never tested, only 55% of the study population had

TABLE 1. Characteristics of Men Accepting HIVSS and Those Presenting for HIV Testing During Study Period, as Reported in TIER.Net (March–August), 2019

Characteristics	Accepted HIVSS–6 Clinic Catchments		Men Receiving HTS at 6 Clinics (TIER.Net Data)	
	4793	100	8636	100
Total Population With Confirmed HIVSS Kit Distributed	n	%	N	%
Age*				
18–24 (15–24 in clinics)	1106	23.17	1766	20.45
25–29	1091	22.86	2077	24.05
30–34	953	19.97	1744	20.19
35–39	648	13.58	1191	13.79
40–44	444	9.30	735	8.51
45–49	224	4.69	432	5.00
50+	307	6.43	691	8.00
Paid work in the past 6 months?*				
Yes	2635	55.65	—	—
No	2100	44.35	—	—
HIV testing history*				
Never tested	2909	61.72	—	—
Tested in past 1–2 yrs	947	20.09	—	—
Tested >2 yrs ago	857	18.18	—	—
Partnership status*				
Married	712	14.98	—	—
In relationship/cohabitating	1219	25.64	—	—
Single	2765	58.16	—	—
Separated/Divorced	45	0.95	—	—
Single (widowed)	13	0.27	—	—
Test results* (n = 3619)			—	—
Positive	137	3.79†	1196	13.85‡
Negative	3219	88.95	7440	86.15‡
Indeterminate	66	1.82	—	—
Declined to provide result	197	5.44	—	—

*Kit use and thus results were not reported for the remaining participants.
†Positive among reported test results = 4%.
‡Differences in characteristics by those accepting HIVSS and those receiving HTS at clinics ($P \leq 0.05$).

recent paid work (compared with over 70% nationally[58]) and just over 60% reported never having tested for HIV (compared with 30% nationally[2]). Data on work history and testing history were not available in TIER.Net for direct comparison with the HIVSS study population.

Of HIVSS kit recipients, a total of 3993 (83.3%) had any follow-up data, with 800 participants either unable to register in the data capture system (SMS linkage arm) or not found/unable to be contacted (PS linkage arm) following distribution (Fig. 1). Among participants with follow-up information, 3619 (90.6%) reported using the HIVSS kit and 374 participants reported they had not used the kit when contacted, though some still planned to do so. Of 3619 participants who reported HIVSS kit use, 197 (5.4%) chose not to share test results; 3219 (88.9%) reported negative (nonreactive) results; 137 (3.8%) reported positive (reactive) results, and 66 (1.8%) reported indeterminant results. Reported self-test kit reactivity was approximately 4% among those reporting results in the HIVSS study population, which is lower than HIV test positivity noted in TIER.Net, where positivity was almost 14%.

Total testing coverage in the clinic catchment areas in the pre-HIVSS distribution period ranged from 1.3% (Clinic D) to 7.2% (Clinic F) of area men undergoing testing, for an overall testing coverage of 3.77% over 3 months (Table 2). During the HIVSS distribution period, coverage increased by 156% overall, with the 6 clinic areas seeing significant increases that ranged from a 70% increase (Clinic E) to over a 10-fold increase in testing (Clinic D) (Table 2).

HIVSS distribution resulted in 137 reported positive (reactive) HIVSS results (Fig. 1). There were significantly more reactive HIVSS results reported through the SMS system (93 positive reports or 6.44% of tests used) as compared with the PS follow-up (44 positive reports or 2.02% of tests used; $P < 0.001$) (Table 3). Similarly, significantly more participants in the SMS arm reported linking to a clinic for confirmatory testing (n = 76; 5.27% of tests used) as compared with the PS arm (26; 1.19% of tests used; $P < 0.001$). This study resulted in a total of 32 reported ART initiations, with significantly more initiations documented following SMS as compared with PS.

Total ART initiations and the percent of initiations per test positive among men varied widely by clinic between the pre-HIVSS distribution period and the HIVSS distribution period, demonstrating a decrease in initiations in 3 clinics and an increase in 2 clinics (Table 4). Despite the initiations that were likely due to the HIVSS program, the fluctuations in ART initiations month by month and the lack of a known denominator (the confirmed number of newly diagnosed men initiating ART) make it difficult to draw any conclusions about the impact of this study on treatment uptake.

DISCUSSION

Our findings confirm that adding HIVSS distribution through WBPHCOT teams increased the portion of men testing for HIV and that men in extremely resource-poor areas, including informal settlements, are eager to use HIVSS. WBPHCOT-based distribution was highly feasible and reached a large number of men who had never accessed testing. We found less evidence to support our hypothesis that HIVSS distribution and assisted linkage would increase the number of men initiating ART. That said, we did find significantly more men who reported reactive HIVSS results and accessed care in the SMS arm as compared with the PS arm, which may signal increased acceptability of the automated SMS format for anonymous reporting as compared with the PS approach.

Our findings that community-based HIVSS distribution can improve testing uptake are well supported in the literature. In our HIVSS work with young women in a low-income rural area of South Africa, we found that male peers and partners of

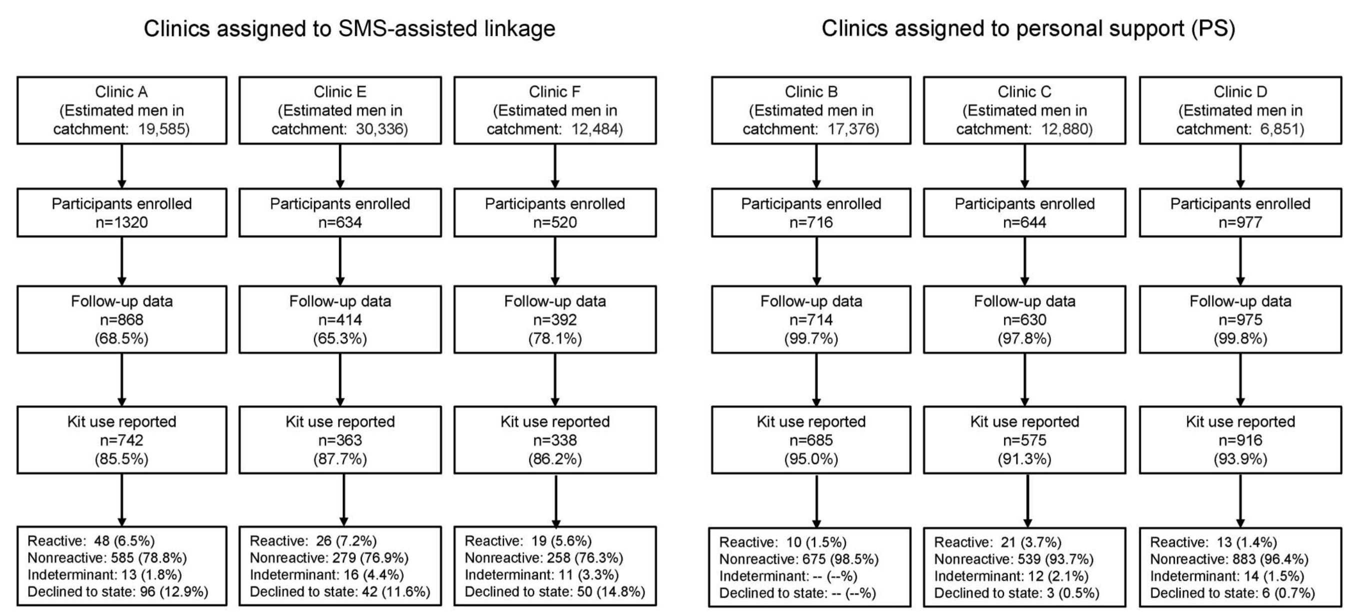

FIGURE 1. Study population, enrollment, follow-up, and HIVSS reporting.

TABLE 2. Overall Uptake of HIV Testing Among Participating Facilities in the Three Months Before and the Three Months During Distribution of HIVSS Among Men, by Facility

	HIV Testing Before HIVSS Program (March–May)		HIV Testing During HIVSS Distribution (June–Aug)		Changes in HIV Testing Uptake	
	N	% Coverage*	N	% Coverage*	Difference	% Increased
Facility						
Clinic A	1232	6.29	2583	13.19	1267	110†
Clinic B	390	2.24	1185	6.82	751	204†
Clinic C	218	1.69	925	7.18	662	324†
Clinic D	90	1.31	1041	15.20	834	1057†
Clinic E	916	3.02	1561	5.15	574	70‡
Clinic F	901	7.22	2285	18.30	1413	154†
Overall (across facilities)	3747	3.77	9580	9.51	5833	156†

*Testing coverage estimated using district catchment populations of men over 18 and not known to be HIV positive in the area.
†$P \leq 0.01$ and ‡$P \leq 0.05$ in differences in uptake before and after HIVSS introduction using a 2-sample test for proportions.

young women were 3 times more likely to test when offered HIVSS vs. an invitation for clinic testing.[59] Research with men across sub-Saharan Africa has found community-based strategies outperform clinic-based HTS for men[35,60] and these approaches are highly feasible and acceptable.[36,37] Accordingly, the South African HTS policy recommends community-based testing approaches for men.[61] However, while community-based HIVSS has been implemented by PEPFAR and Global Fund partners, it is yet to be implemented through the National DOH WBPHCOTs. Of note, we purposively targeted nontesting men and successfully reached those who are not accessing HTS: over 60% reported never testing for HIV before enrolling in the HIVSS program compared with approximately 30% in a nationally representative sample.[2] As South Africa moves closer to the target of 95% of the population knowing their status, CHW-provided HIVSS in regions with a high density of informal settlements seems a valuable approach. Most importantly, it is an approach that could be replicated and scaled through national programming.

Despite high uptake and reported use of HIVSS (over 90% among those with follow-up information), reported self-test reactivity was quite low: only 4% of participants reported reactive results, though 5.4% chose not to share self-test results and could represent additional reactive results. The TIER.Net dispatch data from catchment clinics suggested HIV positivity among adult men at 13.85%. The unexpected higher proportion of positives in TIER.Net is likely due to suboptimal reporting of HIV-negative tests in the public sector, where clinic staff might be less rigorous about registering tests and results for nonreactive tests, as follow-up is less urgent. Our team documented some large differences in the TIER.Net data and data we captured directly from HTS registers, with negative tests being severely underreported in TIER.Net. Discrepancies may also be due to reluctance to report positive results among participants in our study, as found elsewhere in South Africa.[4] Informal project staff discussions with CHW in the PS arm confirmed that many CHW felt participants were choosing not to report positive results. The likely underreporting is evidenced in the

TABLE 3. Rates of Reported Reactive Self-Tests, Confirmatory Testing, and ART Initiation Among Participants Confirming HIVSS Kit Use, by Facility-Assisted Linkage Assignment

	Reactive (Positive) Self-Test/HIVSS Kits Used		Confirmatory Tests (Linkage)/HIVSS Kits Used		ART Initiations/HIVSS Kits Used	
	N	(%)	N*	(%)	N	(%)
SMS Facilities						
Clinic A	48	6.47	39	5.26	10	1.35
Clinic E	26	7.16	15	4.13	7	1.93
Clinic F	19	5.62	22	6.51	6	1.76
Overall (SMS)	93	6.44†	76	5.27†	23	1.59†
Personal support facilities						
Clinic B	10	1.46	4	0.58	3	0.44
Clinic C	21	3.65	4	0.70	4	0.70
Clinic D	13	1.42	18	1.97	2	0.22
Overall (PS)	44	2.02	26	1.19	9	0.41

*Confirmatory testing may be higher than positive diagnoses; 14 participants in the SMS arm reported confirmatory testing following an undisclosed test result and 12 participants in the PS arm reported confirmatory testing following a negative test result.
†$P \leq 0.01$ and ‡$P \leq 0.05$ based on a 2-sample test for proportions comparing SMS and PS arms.

TABLE 4. Overall Initiation of ART Among Participating Facilities in the Three Months Before and the Three Months During the Distribution of HIVSS Kits to Men, by Facility and Facility-Assisted Linkage Assignment

	ART Initiation Before HIVSS (March–May)		ART Initiation During HIVSS (June–August)		Initiations Likely Due to HIVSS		Difference in Proportion ART Initiated
	n	% Initiated*	n	% Initiated†	n	%	% Change
SMS facilities							
Clinic A	218	97.3	122	83.0	10	7.56	−14.7§
Clinic E	133	99.3	124	95.4	7	5.34	−3.9‖
Clinic F	97	90.7	99	100‡	6	5.71	10.3§
Overall (SMS)	448	96.3	345	93.2	23	6.25	−3.2‖
PS facilities							
Clinic B	103	93.6	82	100‡	3	3.53	6.8‖
Clinic C	60	98.4	76	84.4	4	5.00	−14.2§
Clinic D	36	100‡	46	100‡	2	4.17	0
Overall (PS)	199	97.1	204	100‡	9	4.22	3.0‖

*Among positive tests captured among men in TIER.Net for the March–May time period.
†Among positive tests captured in TIER.Net and reported in the HIVSS study cohort, excluding HIVSS participants reporting confirmatory testing already that would already be captured in TIER.Net, for the June–August time period.
‡More initiations reported than positive tests reported, likely due to people reinitiating ART who do not undergo testing with a positive test history or ART use on file.
§$P \leq 0.01$ and ‖$P \leq 0.05$ in differences in ART initiation before and after HIVSS introduction using a 2-sample test for proportions.

data: only 2% of participants reported reactive results in the PS arm, vs. 6.44% of participants reporting reactive results utilizing the anonymous SMS service.

We found notable differences between assisted linkage arms in post-HIVSS follow-up. Not only did a higher proportion of men report reactive tests in the SMS arm, but among those who reported reactive HIVSS results, 81.7% in the SMS arm reported presenting at a clinic for confirmatory HIV testing as compared with 59% in the PS arm. Coupled with reports from the CHW teams that the SMS approach was both more efficient and more confidential in a context where stigma remains a major concern, the higher rate of follow-up in the SMS arm implies that it is likely the optimal approach for future distribution programs. Government use of SMS programming for health is already in use in South Africa.[29,59] Furthermore, 98% of households in Gauteng Province have access to mobile phones, and 89% of households exclusively use mobile phones.[62] Notably, we did encounter challenges with cell phones, including lack of electricity in some informal settlements, interrupted network availability, lack of cellular coverage in different areas, and some plans not allowing 2-way messaging. We did find people without access to a cell phone (n = 33, or 0.7% with eligibility screening data) and, overall, we never heard back from approximately 25% of those registered in the SMS group; we cannot distinguish purposeful nonresponse from inability to respond.

Finally, we found little evidence to support our hypothesis that HIVSS distribution with assisted linkage would increase the number of men initiating ART. Total ART initiations and the percent of initiations per reactive self-test varied widely, decreasing in some clinics and increasing in others. Furthermore, reported ART initiations were higher than the number of reported positive tests in some clinics, which could indicate data capture errors or a push to link people to care who were on the "waiting on ART" list (those who had tested HIV positive but never initiated ART). In March 2019, PEPFAR-funding partners, including Anova, implemented a large linkage and reinitiation campaign called "Siyenza!" ("We are doing it!"). The campaign, which targeted people who had defaulted from treatment at high-volume facilities, could have impacted our findings. We also had to close out the study, including the SMS reporting system, just 1 month after HIVSS distribution ended; it is possible that some participants waited to test or initiate ART until after the study closed out or initiated at a clinic in a different geographic area where people were less likely to know them, and thus there could be initiations missing in our data. Our lack of findings demonstrating improved ART uptake following test distribution is consistent with past literature, in which HIVSS distribution has resulted in similar or lower rates of linkage to care when compared with HTS offered at facilities.[31,32] Continued efforts to innovate in this area and improve linkage to care following HIVSS are critically needed.

This study has limitations. The study was designed to evaluate HIVSS distribution and linkage to care within a real-world implementation scenario—relying on government workers and integrated into the CHW tasks—to best understand the potential impact of this approach at scale when implemented directly by National DOH WBPHCOTs. This was not a clinical trial with separate staffing to ensure strict compliance with the completion of study forms or follow-up. As a result, though the project was negotiated with DOH and approved by district, subdistrict, and clinic managers, the CHW teams varied in terms of their comfort and compliance with kit distribution, follow-up, and documentation. In informal discussions with CHWs, we learned that the addition of HIVSS as a tool was welcome, particularly when follow-up could be conducted by phone/SMS. However, some CHWs were unhappy about the additional work of enrolling participants and felt it should be compensated separately. In the future, new programming should be introduced and integrated directly by district teams; our project was introduced by external staff, which caused tension for some CHWs who felt it was not a district program. Furthermore, although different regions of South Africa have varying degrees of WBPHCOT coverage and different contracting practices, we believe that with proper planning, local adaptation, training, and support, this is an intervention that could feasibly be scaled up by DOH within existing resources. Participants are not representative of all nontesting men in the areas; those who were not in the area during the day and those without cell phone access are not included. However, cell phone use is ubiquitous in South Africa, with 98.8% of households in Gauteng Province reporting cell phone ownership in 2019.[62] Therefore, while the most impoverished men may have been excluded from this sample, we expect that this number was very small. Finally, this analysis relies on clinic data capture of HIV testing and on participant self-report of HIVSS utilization.

Achievement of targets for HIV testing and linkage to care are the weakest areas of South Africa's HIV response,[63] with men trailing behind women.[64] Men's HTS uptake is critical to turn the tide of the HIV epidemic. Our data demonstrate that the provision of HIVSS through the CHW teams anchored to clinics near informal settlements was both feasible to implement and acceptable to men, including nontesting men, with extremely high uptake and a demonstrated increase in HIV testing coverage. Data indicate that SMS follow-up may be more acceptable for men than PS follow-up, likely because it better aligns with expectations of privacy associated with HIVSS. SMS was also more acceptable for CHWs, as it requires less time for follow-up. As a result, the establishment of an SMS reminder system, commencing with WBPHCOTs with mHealth system devices, could prove the most efficient way to ensure both confidentiality and facilitate linkage to care.

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