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Supervised oral HIV self-testing is accurate in rural KwaZulu-Natal, South Africa

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Abstract

OBJECTIVES To achieve UNAIDS 90-90-90 targets, alternatives to conventional HIV testing models are necessary in South Africa to increase population awareness of their HIV status. One of the alternatives is oral mucosal transudates-based HIV self-testing (OralST). This study describes implementation of counsellor-introduced supervised OralST in a high HIV prevalent rural area.
METHODS Cross-sectional study conducted in two government-run primary healthcare clinics and three Médecins Sans Frontières-run fixed-testing sites in uMlalazi municipality, KwaZulu-Natal. Lay counsellors sampled and recruited eligible participants, sought informed consent and demonstrated the use of the OraQuick™ OralST. The participants used the OraQuick™ in front of the counsellor and underwent a blood-based Determine™ and a Unigold™ rapid diagnostic test as gold standard for comparison. Primary outcomes were user error rates, inter-rater agreement, sensitivity, specificity and predictive values.
RESULTS A total of 2198 participants used the OraQuick™, of which 1005 were recruited at the primary healthcare clinics. Of the total, 1457 (66.3%) were women. Only two participants had to repeat their OraQuick™. Inter-rater agreement was 99.8% (Kappa 0.9925). Sensitivity for the OralST was 98.7% (95% CI 96.8–99.6), and specificity was 100% (95% CI 99.8–100).
CONCLUSION This study demonstrates high inter-rater agreement, and high accuracy of supervised OralST. OralST has the potential to increase uptake of HIV testing and could be offered at clinics and community testing sites in rural South Africa. Further research is necessary on the potential of unsupervised OralST to increase HIV status awareness and linkage to care.

keywords HIV/AIDS, HIV testing, oral HIV self-testing, sensitivity and specificity, South Africa

Introduction

Availability of and access to free, confidential and accurate testing services is the first stage in achieving the UNAIDS 2020 targets of having 90% of the HIV-infected population aware of their status, 90% of these started on antiretroviral and 90% of those treated with a suppressed viral load [1]. Current HIV counselling and testing (HCT) strategies are insufficient to achieve universal HIV status awareness [1, 2]. Innovative alternatives to provider and client-initiated HCT models which increase HCT uptake are a public health imperative [1].

South Africa's HIV prevalence, estimated at 12.2% in 2012, is among the highest in the world [3]. According to the 2012 National HIV Prevalence Survey, only 65.5% of the adult population had ever tested for HIV [3]. Among the 28 997 participants in this survey, 62.2% of HIV-positive males and 45.0% of HIV-positive females were not aware of their status [3]. To achieve the 90-90-90 objectives, the Department of Health of South Africa aimed to increase efforts to expand HCT strategies both at public healthcare facilities and at the community level [4]. However, there are barriers to overcome (e.g. ensuring that HCT services are safe and confidential; the financial and time investment required by patients) which cannot be completely eliminated in the context of HCT. Current HCT models have facilitated access to HIV care to a large number of people [5], however, some populations, including both men and women, may benefit from new models which enable them to test in private at their own convenience [6].

HIV self-testing involves the self-administration of an HIV test in any private and convenient place with or without the guidance of a third party such as a healthcare

worker. Unsupervised or 'home' self-testing (HomeST) has been shown to be an acceptable innovation in a variety of settings for individuals to overcome barriers to HCT [7–9]. Easy access to HomeST might increase testing uptake among key populations such as men who have sex with men and commercial sex workers who fear stigma, discrimination and breaches in confidentiality [7].

Among the HIV self-testing modalities, oral mucosal transudates-based self-testing kits (OralST) are less invasive than blood-based kits and are more easily self-administered [2, 9]. An O-HIVST device available in South Africa is the OraQuick ADVANCE HIV 1/2 Rapid Antibody Test (™Orasure Technologies Inc., Bethlehem, PA, USA). Accuracy studies have been conducted in Zambia and Malawi, where OraQuick™ showed a sensitivity of 98.7% (95% CI: 97.5–99.4) and 93.6% (95% CI: 88.2–97.0), with specificity of 99.8% (95% CI: 99.6–99.9) and 99.9% (95% CI: 99.6–100), respectively [10, 11]. A meta-analysis identified, in high-prevalence settings, a pooled sensitivity 2% lower in oral-based specimens than in blood-based specimens alongside similar specificity and positive predictive values [12].

In South Africa, self-testing devices are not prohibited by current legislation. While the Department of Health of South Africa does not recommend their use [13], the Pharmacy Council of South Africa has recently removed the ban on pharmacists' sales of self-testing kits [14]. The main concerns around self-testing include user errors, incorrect interpretation of results, potential self-harm following a positive self-test result, potentially increased risks of coercion and missed opportunities for confirmatory testing and linkage to care [2, 7–9, 15].

In a recent cross-sectional study in South Africa, 22.3% of participants reported that they would prefer HomeST over provider and client-initiated HCT (n = 466) [16]. A study in KwaZulu-Natal reported high accuracy in reading results and high compliance with blood-based self-testing procedures in a supervised environment [17]. Another usability study reported higher acceptability of home OralST compared with home blood-based self-testing [18]. Health personnel using home OralST reported high acceptability and potential for linkage to care in another study in Cape Town [19].

More evidence on the implementation of self-testing under field conditions is crucial. The purpose of this study was to describe implementation of supervised OralST in a high HIV prevalence rural area. The specific aim of this article was to determine whether it is feasible for participants to correctly perform, read and interpret an OralST under counsellor supervision and the diagnostic accuracy of OralST.

Methods

This study was prospective cross-sectional, and its conduct was preceded by a formative assessment using qualitative methodologies [20]. OralST was offered at two Department of Health-run primary healthcare clinics (PHCs), between June and December 2014. OralST was then offered at three Médecins Sans Frontières (MSF)-run fixed HIV testing sites (FTSs) in Eshowe town between November 2014 and April 2015. The FTSs are standalone health posts staffed by lay HIV counsellors where any community member can receive HCT, point-of-care CD4 testing, and STI, TB and pregnancy screening. All study sites were in the rural uMlalazi municipality (population 231 601), in KwaZulu-Natal province. The overall HIV prevalence in the study area was 15.9% in men and 30.9% in women according to a cross-sectional survey conducted in 2012 (n = 5649) [21]. According to this survey, HIV prevalence peaked at 56% among women aged 30–35 years [21].

Sampling and recruitment

All PHC and FTS clients who were at least 18 years of age and willing to give written informed consent were eligible to participate. Clients with dentures, who had eaten or drunk anything or who had brushed their teeth, used mouthwash or flossed within 30 min of conducting the OralST were excluded. Clients could wait and enrol once they were eligible to do so. Individuals who were known to be HIV infected were eligible.

Recruitment strategies were designed to suit the context of the two types of study site. At the FTSs, community mobilisers announced the study to street passers-by to attract potential participants. At the PHCs, research counsellors announced the study in the waiting area and invited all clinic users to participate. In both FTSs and PHCs, individuals who expressed interest in the study were screened for eligibility and enrolled in the private spaces used to conduct HCT. Across all sites, the research counsellors obtained informed consent, demonstrated and supervised the use of the OralST to consenting participants and provided pre- and post-test counselling.

Testing algorithm

The counsellors explained the OralST procedure to each participant individually and demonstrated how to conduct the OraQuick™ test (™Orasure Technologies Inc.) according to the manufacturer's package instructions. Following the demonstration, the participants

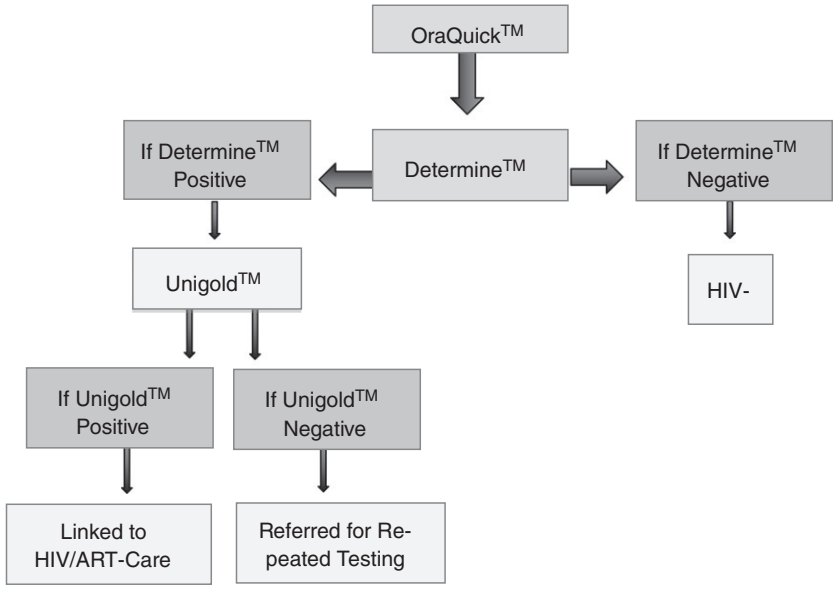

Figure 1 Testing algorithm used in this study.

first self-tested in front of the counsellor, and immediately afterwards, they received a blood-based Determine rapid test (™Alere, Scarborough, ME, USA) (Figure 1). As per OraQuick™ procedures, participants could read the result in the period 20–40 min after the test. The participant's reading was then verified by the counsellor, and agreement or disagreement between the two was noted.

All participants who had an HIV-positive Determine™ result received confirmatory testing using a blood-based Unigold rapid test (™Trinity Biotech, Bray, Co., Wicklow, Ireland). If the HIV infection diagnosis was confirmed, the participants were linked to HIV care at their preferred clinic. If the HIV testing result was indeterminate, the participants were referred for repeated testing.

Sample size

We calculated the sample size required to demonstrate with 95% confidence the true sensitivity, to a precision of ±5%, to be 1000 people at the PHCs and 1000 at the FTSs.

Data management

Information that related to the participants' demographics and to the OralST and confirmatory test results was manually collected onsite in a paper register. All documents – consent forms and registers – were returned daily by the counsellors to the MSF office in Eshowe.

The data from the registers were captured into an EpiData database (™Epidata Foreningen, Odense, Denmark). Univariable and bivariable descriptive analyses were conducted using STATA 11 (™StataCorp, College Station, TX, USA).

Measurement and analysis

The ability of participants to correctly perform, read and interpret the results of OralST was assessed by determining the user error rate (number of tests repeated as a result of user error/total number of tests) and the inter-rater agreement (participant *vs.* counsellor) of OralST result. The Kappa statistic was used to establish statistical significance in inter-rater agreement of reading OralST results.

The diagnostic accuracy of OralST was assessed by calculating sensitivity, specificity and positive and negative predictive values using the Determine™ and the Unigold™ results as the gold standard. Sensitivity and specificity were reported with 95% CIs. X^2 tests were used to assess statistical differences in categorical outcomes such as uptake of the OralST between groups stratified by sex, site and recent HIV testing.

Uptake of OralST in the framework of this study was approximated by assessing the proportion of those who participated among those who were eligible. Uptake was calculated by determining the proportion of participants out of (i) the clinic users' headcount in the waiting room at the PHCs and (ii) the daily attendance registers (i.e. the numbers tested under the routine client-initiated counselling and testing) at the FTSs.

Ethics

At point of recruitment, written informed consent was sought for each participant in the same private place where all research procedures were conducted. A signed copy of the information sheet and informed consent was handed to each participant. This study received ethical approval from the Human Research Ethical Committee of the University of Cape Town (Cape Town, South Africa) and from the KwaZulu-Natal Department of Health (Pietermaritzburg, South Africa).

Results

Uptake

A total of 2205 participants completed the OraQuick™. Seven participants were excluded from the analysis as they did not receive a Determine™ test (Figure 2). In total, 1457 (66.3%) women and 741 (33.7%) men were included in the analysis (Table 1).

At the FTSs, 1193 participants (54.1%) were recruited. At the PHCs, 1005 participants (45.7%) were recruited. With regard to the FTSs, 29.6% of men and 35.9% of the women approached consented to participate. Compared to the headcount, uptake of OralST was 25.4% for the two PHCs (headcount at the PHCs did not differentiate between men and women).

The ages of male and female participants were similar. The median age of men was 27 years (IQR 22–34) and of women 28 years (IQR 22–36). Overall, 1397 female participants (95.8% of total women) and 671 male (83.2% of total men) had tested for HIV before, and 74 women (5.1%) and 29 men (3.9%) had heard about OralST before the study (Table 2). Among the 70 men and 60 women who had never tested before but who used the OraQuick™, 30 men (42.8%) and 29 women (48.3%) were in the 18–25 years age group.

Feasibility: inter-rater agreement and user error rate

As an indicator of feasibility of supervised OralST, inter-rater agreement between counsellor's and participant's reading of the OraQuick™ was calculated excluding 11 women and six men who were known HIV infected (Table 3). Of 2181 participants who were unaware of their status, there was disagreement on four tests; three women and one man read their OraQuick™ result as negative while the counsellor read the result as positive. Thus, overall inter-rater agreement was 99.8% (Kappa 0.9925).

Another measurement of feasibility was the rate of user errors. The OraQuick™ was correctly performed by 2196 users (user error rate 0.09%). Only two participants – a woman and a man – had to repeat their self-test because, accidentally, they spilled the developer solution vial.

Accuracy

Specificity and sensitivity were calculated using the results of all OraQuick™ as read by the participants and the Determine™ and Unigold™ test results (Table 4). Eleven indeterminate results were excluded from the accuracy analysis. In this study, the sensitivity and specificity of the OralST test were high at both PHCs and FTSs (data not shown). Overall sensitivity for the OraQuick™ was

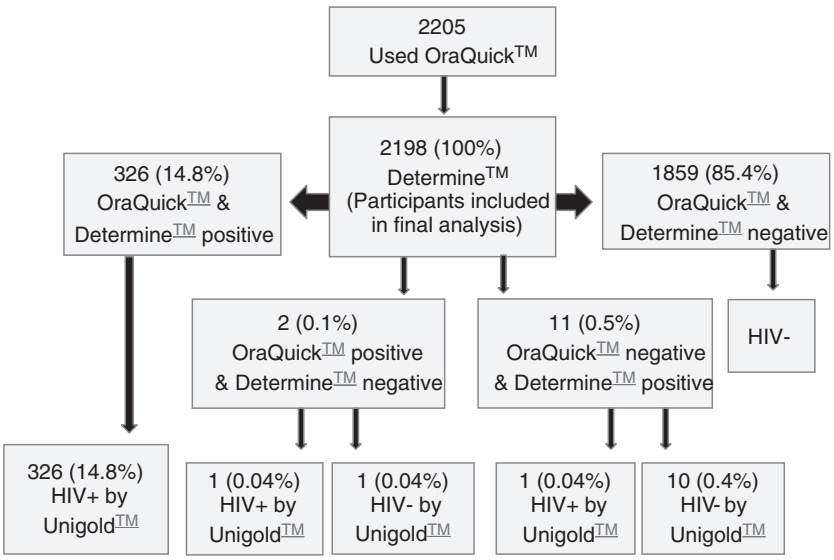

Figure 2 Testing flow in the study.

Table 1 Uptake of OraQuick™ at the study sites

Site	PHCs			FTSs			
Sex	Men	Women	Subtotal	Men	Women	Subtotal	Total
Participants	260	745	1005	481	712	1193	2198
Total clients offered OralST in the study period*	3955		3955	1623	1979	3602	7557
Uptake	25.4%		25.4%	29.6%	35.9%	33.1%	29.1%

*Based on the headcount in the clinic waiting areas, and on the number of clients registered at the FTSs. Headcount at the PHCs did not differentiate between men and women.

Table 2 History of HIV testing and knowledge of OralST stratified by age and sex

	Ever tested for HIV (n = 2068/2198)			Ever heard of OralST (n = 103/2198)		
Age	Women†	Men†	P-value*	Women‡	Men‡	P-value*
18–25	784 (56.1%)	302 (45.0%)	<0.001	49 (66.2%)	10 (34.5%)	0.049
26–35	338 (24.2%)	211 (31.4%)		19 (25.7%)	16 (55.2%)	
36–45	134 (9.6%)	75 (11.2%)		3 (4.0%)	1 (3.4%)	
46–55	75 (5.4%)	41 (6.1%)		2 (2.7%)	1 (3.4%)	
56+	66 (4.7%)	42 (6.2%)		1 (1.3%)	1 (3.4%)	
Total	1397 (100%)	671 (100%)		74 (100%)	29 (100%)	

*Chi-squared test ($P < 0.05$).
†Denominator: Total number of participants who had ever tested for HIV by sex.
‡Denominator: Total number of participants who had ever heard of self-testing by sex.

Table 3 Inter-rater agreement at both FTSs and PHCs

	Agreement			
	Participant Negative	Participant Positive	Subtotal	
Counsellor Negative	1870 (85.7%)	0 (0.0%)	1870 (85.7%)	99.8% Agreement
Counsellor Positive	4 (0.2%)	307 (14.1%)	311 (14.2%)	0.9925 Kappa
Subtotal	1874 (85.9%)	307 (14.1%)	2181 (100%)	

98.7% (95% CI 96.8–99.6) and specificity was 100.0% (95% CI 99.8–100). Positive and negative predictive values were also high with values set at 100.0% (95% CI 98.2–99.9) and 99.7% (95% CI 99.4–99.9), respectively.

HIV prevalence

Fifteen (6.2%) of the 248 HIV-infected women and two (0.6%) of the 89 HIV-infected men in this study were known HIV positive. Excluding these 17 participants, the HIV prevalence in this study was 14.7% (95% CI; 13.2–16.2): 10.6% (95% CI; 13.1–16.1) were women and 3.9% (95% CI: 3.1–4.8) were men.

Eighty women and 34 men received their first HIV diagnosis at the FTSs (Table 5). Forty (50%) of these 80 women were in the age group 18–25 years, and 21 (61.7%) of these 34 men were in the age group 26–35 years. Another 153 women and 53 men received their first HIV diagnosis at the PHCs. Seventy-eight (50.9%) of these 153 women were in the age group 18–25 years,

Table 4 Accuracy: sensitivity, specificity, negative predictive value and positive predictive values

	Overall accuracy*				
	Determine™ & Unigold™ Positive	Determine™ & Unigold™ Negative	Subtotal	Indeterminate†	Total
OralST Positive	323	0	323	1	324
OralST Negative	4	1860	1864	10	1874
Subtotal	327	1860	2187	11	2198
Accuracy	Sensitivity 98.7% (95% CI 96.8–99.6) Specificity 100.0% (95% CI 99.8–100) PPV 100.0% (95% CI 98.2–99.9) NPV 99.7 (95% CI 99.4–99.9)				

*This analysis considers the OraQuick™ results as read by the participants.
†In this sensitivity and specificity analysis, eleven (11) indeterminate and unconfirmed results are excluded.
NPV, Negative predictive value; PPV, Positive predictive value.

Table 5 First HIV+ diagnosis per site

	Fixed-testing sites				Primary healthcare clinics			
Age	Women	Men	Subtotal	*P*-value*	Women	Men	Subtotal	*P*-value*
18–25	40	6	46 (40.3%)	0.015	78	8	86 (41.7%)	<0.001
26–35	31	21	52 (45.6%)		49	24	73 (35.4%)	
36–45	5	4	9 (7.9%)		16	13	29 (14.1%)	
46–55	4	3	7 (6.1%)		7	6	13 (6.3%)	
56+	0	0	–		3	2	5 (2.4%)	
Total	80 (70.2%)	34 (29.8%)	114 (100.0%)		153 (74.3%)	53 (25.7%)	206 (100%)	

Note: excludes 17 participants who were known HIV+.
*Chi-squared test ($P < 0.05$).

and 24 (45.2%) of these 53 men were in the age group 26–35 years.

Discussion

This cross-sectional study demonstrates high inter-rater agreement (99.8%) and high accuracy (sensitivity 98.7%; specificity 100.0%) of counsellor-introduced, supervised OralST in rural South Africa. User error rate (0.09%) was negligible as only two self-tests were repeated.

This study contributes to evidence provided by previous research in the Southern Africa region on the feasibility, under field conditions, of oral-based self-testing [19]. This study is consistent with previous research on the accuracy of counsellor-introduced and supervised OraQuick™ in Zambia and in Malawi that reported sensitivities of 98.7 (95% CI 97.5–99.4) and 97.7 (95% CI 87.9–100) with specificities of 99.8 (95% CI, 99.6–99.9) and 100 (95% CI 97.8–100), respectively [10, 11].

Building on this and provided that instructions are in local languages and adapted for cultural appropriateness [17], it is reasonable to hypothesise that accuracy of OralST for unsupervised use could also be high in rural KwaZulu-Natal. Although the user error rates in our study were low, we did not explore the types of errors that clients might make if they conducted the OraQuick™ OralST in the absence of a counsellor. Therefore, the generalisability of these results to home based or unsupervised OralST needs to be further explored.

In spite of high accuracy, it must be noted that fourteen of our 2198 study participants read their OraQuick™ as negative but had a positive Determine™ test. There are several different oral rapid diagnostics devices currently available commercially; however, many of them have not yet been pre-qualified by WHO for self-testing [22]. It must be noted that most research on accuracy of OralST devices carried out in Southern Africa used an OraQuick™ and, hence, further research on other

available OralST devices in necessary [10–12, 23]. It is important to understand available devices, particularly with respect to a shorter window period. Ideally a device which detects p24 protein to establish acute HIV infection is desirable. The importance of receiving a confirmatory HIV test will need be emphasised to all users of an OralST in an unsupervised environment.

The strength of this study is its large sample size, which allowed assessing accuracy with high precision. Data on socio-demographics and other variables of interest such as engagement in risky sexual behaviours, uptake of HIV prevention technologies, frequency of retesting and most recent date of testing were not collected. In this regard, a more detailed description of the participants and a comparison of the characteristics of the participants with other studies on self-testing in the region are not possible.

A limitation of this study might be the uptake rates of OralST at the MSF-run FTSs (33.1%) and at the Department of Health-run PHCs (26%). Although these uptake rates seem low, we consider them acceptable due to the sampling and recruitment methods used. It needs to be noted that the OralST was offered on weekdays at healthcare posts where many users had arrived to demand services others than HIV testing.

Future prospects

This study was preceded by a formative assessment using qualitative methodologies [20]. Female and male PHCs clients were interviewed, many of whom claimed that men and youth could benefit from the privacy and confidentiality of using a home OralST. These findings coincided with other qualitative research on acceptability of home OralST conducted among community members and healthcare workers in a MSF-run health post in the informal settlement of Khayelitsha, Cape Town [24].

Our study was not powered to allow a gendered analysis, and therefore, we cannot corroborate findings from previous qualitative research in South Africa. Nevertheless, our results suggest that both women and men might access and demand OralST. In our study, 35.9% and 29.6% of approached women and men, respectively, used an OralST at the FTSs in Eshowe. Half of the participants comprised young adults in age group 18–25 years and among these, one-third (33.7%) were men. Women who face time constraints and social and financial barriers to demand clinic-based HCT services may benefit from easy access to OralST devices.

Our findings support previous research on men using self-tests when available to them. In a cross-sectional study in Ethiopia (n = 307), 67% of male healthcare workers reported having ever used a self-test that they accessed in their workplaces [25]. In multiple countries, men who have sex with men report the use of OralST purchased over the counter, on Internet sites or in electronic vending machines [7, 26]. Future research on mens' and young adults' access to self-testing will need to focus on monitoring uptake of post-test counselling services and linkage to care.

To influence policy in South Africa, more evidence is necessary on the impact of unsupervised HIVST among key populations such as men who have sex with men, commercial sex workers, migrants and prisoners. In South Africa, men are less aware of their HIV status than women: a cross-sectional survey conducted in 2005 in rural KwaZulu-Natal reported that only 18% of sexually active men 18–32 years old had ever tested [27]. A population-based survey conducted by MSF in Eshowe and Mbongolwane areas in 2013 (n = 5649) identified men and young people as populations that require targeted and novel testing strategies, as HIV status awareness was much lower among them than among women [21]. In high HIV prevalence contexts such as KwaZulu-Natal, it is imperative that efforts are pooled to increase testing among men and youth – and, in general, among key populations – as an increase in the proportion of people who are aware of their HIV status will allow earlier initiation of ART and may facilitate behaviour change and ultimately decrease HIV transmission.

A sex and gender research approach [28] will be helpful to ascertain the validity of the hypothesis that unsupervised HIVST would contribute to an increase in HIV status awareness. Southern African men might be aware of mainstream public health recommendations to demand HCT services but research suggests that they see clinics as gendered spaces in which they feel unwelcome and which they avoid because they do not want to be attended to by female healthcare workers [29]. According to most recent research on the impact of hegemonic masculinities, gender scripts such as imperviousness, fearlessness or invulnerability prevent men from accepting HCT. Client-initiated HCT therefore contradicts how they act out their masculinity through toughness, independence and self-confidence as gendered, condoned characteristics of men [6, 30]. More research on whether unsupervised HIVST could be a feasible male-centred model to increase testing of men is necessary.

Conclusion

In July 2015, WHO released new consolidated guidelines on HIV testing services and included HIVST as one of the approaches that could potentially extend HIV testing

services to people who are reluctant to attend existing HCT services and to people who frequently retest [31]. The WHO and UNAIDS had previously emphasised the need to develop a larger evidence base on HIVST to better inform national policies and implementation of HIVST services [32]. This study responds to this need.

This study shows good user compliance with OralST procedures, inter-rater agreement and accuracy of supervised OralST in clinic and community-level testing sites in rural South Africa. The data suggest that OralST could be offered at clinics and community testing sites in rural KwaZulu-Natal. The use of OralST in an unsupervised environment could be feasible and accurate; however, instructions should be adapted to the literacy levels of the population, and users must be encouraged to receive a confirmatory test. Although further research is needed on the potential of unsupervised OralST to increase HIV status awareness and linkage to care for key populations that do not access conventional HCT, this study supports WHO consideration of OralST as an approach to be implemented alongside other conventional HCT services.

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