RESEARCH ARTICLE



REVISED Trends and predictors of HIV positivity and time since

last test at voluntary counselling and testing encounters

among adults in Kilifi, Kenya, 2006-2017 [version 3; peer

review: 2 approved]

Previously titled: Trends and predictors of new HIV diagnosis and time since last test at testing encounters among adults in Kilifi, Kenya, 2006-2017

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 V3 First published: 23 Aug 2019, 4:127 https://doi.org/10.12688/wellcomeopenres.15401.1
 Second version: 18 Feb 2021, 4:127 https://doi.org/10.12688/wellcomeopenres.15401.2
 Latest published: 04 Jun 2021, 4:127 https://doi.org/10.12688/wellcomeopenres.15401.3

Open Peer Review

Reviewer Status 🗹 🗸

Abstract

Background: Little is known about HIV retesting uptake among key populations (KP) and general populations (GP) in Kenya. We assessed trends and predictors of first-time testing (FTT), late retesting (previous test more than one year ago for GP or three months for KP), and test positivity at three voluntary counselling and testing (VCT) centres in coastal Kenya.

Methods: Routine VCT data covering 2006-2017 was collected from three VCT centres in Kilifi County. We analysed HIV testing history and test results from encounters among adults 18-39 years, categorized as GP men, GP women, men who have sex with men (MSM), and female sex workers (FSW).

Results: Based on 24,728 test encounters (32% FTT), we observed declines in HIV positivity (proportion of encounters where the result



was positive) among GP men, GP women, first-time testers and MSM but not among FSW. The proportion of encounters for FTT and late retesting decreased for both GP and KP but remained much higher in KP than GP. HIV positivity was higher at FTT and late retesting encounters; at FSW and MSM encounters; and at encounters with clients reporting lower educational attainment and sexually transmitted infection (STI) symptoms. HIV positivity was lower in GP men, never married clients and those less than 35 years of age. FTT was associated with town, risk group, age 18-24 years, never-married status, low educational attainment, and STI symptoms. Late retesting was less common among encounters with GP individuals who were never married, had Muslim or no religious affiliation, had lower educational attainment, or reported STI symptoms.

Conclusions: HIV positive test results were most common at encounters with first-time testers and late re-testers. While the proportion of encounters at which late retesting was reported decreased steadily over the period reviewed, efforts are needed to increase retesting among the most at-risk populations.

Keywords

Voluntary counselling and testing, HIV retesting, HIV diagnosis, Kilifi County, Kenya

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Competing interests: No competing interests were disclosed.

Grant information: We thank the International AIDS Vaccine Initiative (IAVI) for funding this study. IAVI's work is made possible by generous support from many donors, www.iavi.org. The KWTRP at the Centre for Geographical Medicine Research-Kilifi is supported by core funding from the Wellcome Trust (#077092). This study is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The views expressed in this publication are those of the authors and not necessarily those of USAID, the NIH, or the United States Government. This work was also supported through the Sub-Saharan African Network for TB/HIV Research Excellence (SANTHE), a DELTAS Africa Initiative [grant # DEL-15-006]. The DELTAS Africa Initiative is an independent funding scheme of the African Academy of Sciences (AAS)'s Alliance for Accelerating Excellence in Science in Africa (AESA) and supported by the New Partnership for Africa's Development Planning and Coordinating Agency (NEPAD Agency) with funding from the Wellcome Trust [grant # 107752/Z/15/Z] and the UK government. The views expressed in this publication are those of the authors and not necessarily those of AAS, NEPAD Agency, Wellcome Trust or the UK government. SMG was supported by the Robert W. Anderson Endowed Professorship in Medicine.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Mugo PM, Agutu CA, Wahome E *et al*. Trends and predictors of HIV positivity and time since last test at voluntary counselling and testing encounters among adults in Kilifi, Kenya, 2006-2017 [version 3; peer review: 2 approved] Wellcome Open Research 2021, 4:127 https://doi.org/10.12688/wellcomeopenres.15401.3

First published: 23 Aug 2019, 4:127 https://doi.org/10.12688/wellcomeopenres.15401.1

REVISED Amendments from Version 2

Figure 2 and Figure 3 were updated to include 24 participants that had been excluded erroneously. In the limitations section of discussion, two references were added: Soni *et al.*, 2020 to support the statement on potential bias caused by misreporting of HIV status; and Ellison *et al.*, 2014 to support the new statement on the potential bias caused by the use of p-value cut-offs in model building. Also, a number of typographical errors were corrected.

Any further responses from the reviewers can be found at the end of the article

Introduction

Kenya has the fifth-largest human immunodeficiency virus (HIV) epidemic in the world¹, with 1.3 million adults living with HIV in 2018². Data from sentinel surveillance and national population-based surveys indicate that national HIV prevalence peaked at 10%-11% in the mid-1990s and declined to about 6% in 2006^{1,3,4}. Prevalence has remained relatively stable at that level for several years with a modest decline observed from 2010 to 2017⁵. In 2018, national prevalence was estimated at 4.9%, higher in women (6.6%) than men $(4.5\%)^2$. The epidemic is geographically diverse, with prevalence ranging from 19.6% in Homa Bay county in the west to <0.1% in Garissa county in the north-east². There were approximately 36,000 new infections in 2018², with more than a third occurring among young women 15-24 years^{5,6}. Key populations, including men who have sex with men (MSM) and female sex workers (FSW) remain disproportionately affected by HIV. In 2017, prevalence was estimated at 18% among MSM and 29% among FSW6. County-level prevalence estimates for key populations are not available.

The proportion of Kenyan adults 15–64 years who have ever tested for HIV increased from 37% in 2007 to 70% in 2012^{4,7}, and to 80% in 2014⁸. This tremendous increase in testing coverage is the result of an expanded testing program, including voluntary counselling and testing (VCT), routine (opt-out) provider-initiated testing in health facilities, routine testing in prevention of mother-to-child transmission programs, home-based (door-to-door) testing, mobile testing, and annual testing campaigns. However, knowledge of HIV status remains low. In 2018, it was estimated that 79.5% of people living with HIV knew their status². This falls short of the UNAIDS target of 90% and plays a major role in ongoing transmission⁹. It is estimated that 54–90% of new transmission events arise from persons with undiagnosed infection^{10–13}.

Low knowledge of HIV status may be attributable in large part to infrequent testing. Current national HIV testing guidelines recommend retesting quarterly for key populations (KP) and annually for the general population (GP)¹⁴. In 2012, a population survey estimated national retesting uptake at 55% among all adults 15–64 years⁷. A more up-to-date estimate is not available, but a repeat survey was underway in 2018. Little is known about retesting uptake at the sub-national level or the factors that predict adherence to recommended retesting frequency. To address such information gaps, data collected at VCT centres can supplement population-based surveys^{15,16}, if regularly and rigorously analysed. Currently, test data collected at various testing facilities are reported to county and national headquarters only in summary form, combining VCT and other testing points, and not disaggregated by risk groups.

Kilifi county, one of the six counties in the coastal region of Kenya, is among the poorest counties in Kenya¹⁷, with low literacy levels and high rates of school dropout affecting both girls and boys^{18,19}. In 2017, 30,597 adults were living with HIV in the county, for an estimated HIV prevalence of $3.8\%^5$. In the same year, the county experienced 1,380 new infections, with a third occurring among adolescents and young people in the age-group 15–24 years⁵.

In the present study, we used routine data collected over a period of 12 years at three VCT centres located in three neighbouring towns in Kilifi county, to assess trends in HIV positivity (proportion of test encounters where the result was positive), and the proportion of encounters at which clients reported first-time testing (never tested before) or late retesting (previous test more than one year ago for GP or three months for KP). Information on these outcomes in different sub-groups who utilize VCT services can support the targeting of HIV prevention efforts.

Methods

Study setting and population

Data were collected at three VCT centres operated by the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme (KWTRP) in Kilifi county (Figure 1, population 1.4 million²⁰). The three centres followed the serial testing strategy recommended in national guidelines^{14,21}. The centres served clients seeking testing out of their own initiative (walk-in clients) and clients mobilized during periodic campaigns by KWTRP outreach workers (mobilized clients).

The oldest of these centres started operating in 2006 and is situated within the KWTRP main campus in Kilifi town, 60 kilometres (km) north of Mombasa (the second largest town in Kenya), and approximately 500 meters from the Kilifi County Hospital. The estimated catchment population for the county hospital is 125,500^{22,23}. HIV testing for the general population at the hospital started in 2004, and a large comprehensive HIV care centre was set up in 2005.

The second centre started operating in 2010 and is situated on the premises of the KWTRP clinic in Mtwapa town, 20 km north of Mombasa. Its estimated catchment population is 116,000^{22,23}. The town has a busy nightlife, with a large number of bars, nightclubs and hotels among other businesses, including many private health facilities and pharmacies²⁴. Since 2005, the KWTRP clinic has conducted cohort studies among KP, including MSM and FSW²⁵. The centre was set up following a request by community leaders who wanted clinic services to be accessible to the general population in the area.



Figure 1. Map of study area.

The third centre also started operating in 2010 and is situated at a KWTRP-supported drop-in centre within the sub-county hospital in Malindi town, 120 km north of Mombasa. Its estimated catchment population is 128,000^{22,23}. This centre initially targeted MSM and FSW, but increasingly served the general population. During the period 2014–2015, KWTRP collaborated with community-based organizations to mobilize KP for testing.

Data collection procedures

For each test encounter during the study period, a data collection form was completed by VCT staff capturing type of client (walk-in or mobilised in an outreach campaign), test location (Kilifi, Mtwapa, or Malindi), test date, gender, date of birth, highest level of education, religious affiliation, marital status, reason for testing, HIV test results, whether the client had ever tested before, and date of previous test (whether at our VCT or any other testing site). Starting in 2010, data were collected on self-reported HIV risk behaviour in the past six months, including: gender of sex partners, receipt of payment for sex, and current symptoms of sexually transmitted infections (STI). STI symptoms included: for men, urethral discharge and dysuria; for women, excessive or foul-smelling vaginal discharge; and for both men and women, genital sores and history of rectal discharge for those who reported anal sex. VCT records were extracted in early 2018, cleaned, and prepared for analysis.

Sample selection

Our sample selection was guided by our goal to assess trends in adult walk-in VCT clients (i.e., clients seeking testing out of their own initiative). We therefore excluded data from mobilized clients who were tested during outreach campaigns and may have felt social pressure to test, even if previously diagnosed. In addition, the frequency and intensity of outreach campaigns varied over time, making it difficult to evaluate time trends. We also excluded VCT clients seeking confirmatory testing after a positive test done elsewhere, partners of HIV-positive index clients, Malindi clients from 2010-2011 (a period when testing exclusively targeted MSM), and clients outside the age group 18-39 years, where HIV incidence is highest in Kenva. We included 24,728 (52%) of all 47,893 test encounters in the original dataset (Extended data: Supplementary Table 1). The dataset analysed included tests conducted at the Kilifi VCT centre in the period 2006-2017, Mtwapa VCT in 2010–2017, and Malindi VCT in 2012–2017.

Data analysis

Data cleaning, recoding and analysis was conducted using Stata[®] version 15 (StataCorp, USA). Based on sex, sex of sex partners, and report of transactional sex (collected since 2010), we categorized clients into four risk groups: GP men, MSM, GP women, and FSW. As sexual behaviour data was not collected before 2010, test encounters from that period (all Kilifi-based) were categorized as GP.

The three main outcomes were HIV positivity (proportion of test encounters where the result was positive), proportion of encounters at which clients reported first-time testing (FTT), and proportion of encounters at which clients reported late retesting (previous test more than one year ago for GP or three months for KP). One year was defined as 365 calendar days, and three months as 90 days. We assessed change in outcomes over calendar year using locally weighted regression (²⁶, Stata package "lowess").

Using multivariable log binominal regression ("binreg") and data from the period when information on sexual behaviour was complete (2012–2017, n=19,298), we assessed factors associated with the three outcomes. Given the difference in definitions of late retesting for GP and KP, we fit separate GP and KP models for this outcome. Age and sex were included a priori in all models; all other variables for which p<0.10 in bivariable analyses were carried forward in multivariable models. Factors with p<0.05 in the multivariable model were considered to have statistically significant associations with the outcome in question. For the FTT model, we assessed interactions between study area and risk group.

Ethical statement

The study received ethical approval from the KEMRI Scientific and Ethical Review Unit (KEMRI/SERU/CGMR-C/188/4014).

Results

Characteristics of testing encounters

Of 24,728 tests conducted in the period 2006–2017, 50% were conducted in Mtwapa, 33% in Kilifi, and 16% in Malindi (Table 1). Overall, 56% of encounters were among men, 68% among never-married individuals, 73% among Christians, and 41% among those with secondary education; 92% were among GP and 9% among KP; 32% were FTT encounters and 22% involved clients who were late retesters, that is, had a previous test more than a year ago for GP or three months for KP.

Time trends in the proportion of encounters with first-time testers

For GP, we observed a decline in the proportion of encounters where the client was testing for the first time among men overall, women overall, and women aged 18–24 years (Figure 2). Slopes were similar for all three sub-groups. For KP, the proportion of encounters that involved FTT declined less steadily, with the lowest percentage-point decline per year observed in MSM.

For the final year assessed (2017), the proportion of encounters involving FTT was 15% for GP clients: 16% for men, 13% for women, and 20% for women aged 18–24 years. The proportion of encounters involving FTT was 29% for KP: 42% for MSM and 9% for FSW.

Time trends in the proportion of encounters with late retesters

We observed declines in the proportion of encounters involving late retesting for both GP (previous test more than one year ago) and KP (previous test more than three months ago) (Figure 3). Throughout the period assessed, the proportion of encounters involving late retesting among the KP remained

Characteristic	All centres combined		Mtwapa		Kilifi		Malindi	
	Ν	%	Ν	%	N	%	N	%
Number of test encounters	24,728	100	12,420	100	8,234	100	4,074	100
Gender								
Male	13,949	56	6,731	54	4,837	59	2,381	58
Female	10,779	44	5,689	46	3,397	41	1,693	42
Age group								
18–24 years	8,848	36	4,307	35	3,215	39	1,326	33
25–34 years	12,857	52	6,637	53	3,997	49	2,223	55
35–39 years	3,023	12	1,476	12	1,022	12	525	13

 Table 1. Characteristics of HIV testing encounters among clients attending three voluntary counselling and testing centres in Kilifi County, Kenya, 2006–2017.

Characteristic	All cent combin	tres ned	Mtwa	ара	Kili	ifi	Malii	ndi
	N	%	N	%	N	%	N	%
Marital status ¹								
Never married	16,771	68	9,124	73	4,933	60	2,714	67
Married	6,594	27	2,810	23	2,766	34	1,018	25
Separated/ Divorced/ Widowed	1,361	6	486	4	533	6	342	8
Religion								
None	1,908	8	727	6	852	10	329	8
Christian	18,156	73	9,453	76	5,929	72	2,774	68
Muslim	4,664	19	2,240	18	1,453	18	971	24
Education level								
Primary or none	9,863	40	3,832	31	3,379	41	2,652	65
Secondary	10,064	41	5,934	48	3,061	37	1,069	26
Higher education	4,801	19	2,654	21	1,794	22	353	9
Test period								
2006-2009	2,357	10	0	0	2,357	29	0	0
2010-2011	3,636	15	1,781	14	1,855	23	0	0
2012-2014	8,219	33	4,741	38	2,063	25	1,415	35
2015-2017	10,516	42	5,898	48	1,959	24	2,659	65
HIV testing history ²								
On-time testing	11,291	46	7,140	57	2,956	36	1,195	29
Late retesting	5,563	22	3,127	25	1,513	18	923	23
First-time test	7,874	32	2,153	17	3,765	46	1,956	48
Risk group ³								
GP Men	12,502	51	6,268	50	4,729	57	1,505	37
MSM	1,447	6	463	4	108	1	876	22
GP Women	10,026	41	5,202	42	3,373	41	1,451	36
FSW	753	3	487	4	24	0	242	6
Current STI symptoms ⁴								
No	21,456	96	11,687	94	5,796	99	3,973	98
Yes	915	4	733	6	81	1	101	2

¹ Data were missing for marital status (n=2) and risk group (n=1). ² Late retesting was defined as previous test more than one year ago for GP or three months for key population. ³ Derived from gender of sex partners and report of transactional sex in past six months. These two variables were collected from 2010 onwards. All test encounters before 2010 (all Kilifi-based) were categorized as GP. ⁴ Any report of urethritis, dysuria, vaginal discharge, genital sore, or proctitis. As these variables were only collected from 2010 onwards, data were missing for 2,603 test encounters. *GP: General population; MSM: Men who have Sex with Men; FSW: Female Sex Workers; STI: Sexually Transmitted Infection*



Figure 2. Time trends in the proportion of encounters involving first-time testers among clients attending voluntary counselling

and testing centres in Kilifi County, Kenya. Plots drawn using locally weighted scatterplot smoothing (LOWESS). Slope is percentage-point change per year. Data points on which the plots are based are included in the supplemental materials (Extended data: Supplementary Table 2 and 3). MSM: Men who have Sex with Men; FSW: Female Sex Workers.



Figure 3. Time trends in the proportion of encounters involving late retesting among clients attending voluntary counselling and testing centers in Kilifi County, Kenya. Plots drawn using locally weighted scatterplot smoothing (LOWESS). Slope is percentage-point change per year. (Extended data: Supplementary Table 4 and 5). MSM: men who have sex with men; FSW: female sex workers.

much higher than that in GP. The percentage-point changes per year were similar for all sub-groups assessed.

For the final year assessed (2017), the proportion of encounters involving late-retesting was 28% for GP: 29% for encounters with men, 28% for encounters with women, and 25% for encounters with women aged 18–24 years. The proportion of encounters involving late retesting was 83% for KP: 81% for MSM encounters and 85% for FSW encounters.

Time trends in HIV positivity

For GP, there was a decline in overall HIV positivity at encounters with both men and women, as well as with the sub-group of those testing for the first time, but not among female late re-testers (Figure 4). For encounters among MSM, HIV positivity was steady among encounters involving late re-testing (Figure 5). For encounters among FSW, there was an increase in HIV positivity over time. This was also true for encounters with FSW involving first-time testing (large increase at +4.9 percentage points per year) and late re-testing, but not for encounters with FSW involving on-time re-testing.

For the final year assessed (2017), overall HIV positivity for GP encounters was 2.3%: 1.1% for encounters with men, 3.9% for encounters with women, and 2.8% for encounters with women aged 18-24 years. Overall HIV positivity in KP encounters was 7.8%: 6.0% for MSM encounters and 10.7% for FSW encounters.



Figure 4. Time trends in HIV positivity at testing encounters among general population clients attending voluntary counselling and testing centres in Kilifi County, Kenya. *Plots drawn using locally weighted scatterplot smoothing (LOWESS). (Extended data: Supplementary Table 6 and 7).*



Figure 5. Time trends in HIV positivity at testing encounters among key population clients attending voluntary counselling and testing centres in Kilifi County, Kenya. *Plots drawn using locally weighted scatterplot smoothing (LOWESS). Slope is percentage-point change per year. (Extended data: Supplementary Table 8 and 9).*

Factors associated with first-time testing encounters

As presented in Table 2, factors associated with increased probability of FTT at VCT encounters included: test location (Kilifi and Malindi), age 18–24 years, never-married status, lower educational attainment. Compared to GP women encounters, MSM and GP men encounters were more likely to involve FTT, while FSW encounters were less likely to involve FTT. First-time testing encounters were less likely during earlier testing periods and among clients with current STI symptoms. No interactions between study area and risk group were identified (data not shown).

Factors associated with late retesting encounters

The GP model is presented in Table 3, and the KP model in *Extended data:* Supplementary Table 10. The KP model did

not identify any predictors of late retesting (previous test more than three months ago).

In the GP model, encounters involving late retesting (previous test more than one year ago) were less likely among never-married clients, clients professing Muslim or no religious affiliation, those with secondary education, and those with current STI symptoms. Encounters involving late retesting were more likely during 2012–2014 and among clients served in Kilifi compared to Mtwapa.

Factors associated with HIV positivity

Table 4 presents factors associated with HIV positivity at testing encounters. Encounters with a positive test result were more likely to involve Malindi clients, clients with less than

 Table 2. Factors associated with first-time testing encounters among adult clients attending voluntary counselling and testing centres in Kilifi, Kenya, 2012-2017.

Factor	Number of test encounters ¹	Number (%) first- time testing	Bivariable an	alysis	Multivariable analysis (Full model)			
		encounters	Risk ratio [95% Confidence interval]	P value	Adjusted risk ratio [95% Confidence interval]	P value		
Testing location								
Kilifi	4,022	1,355 (27.2)	2.2 [2.0-2.3]	<0.001	2.1 [1.9-2.2]	<0.001		
Malindi	4,074	1,956 (39.3)	3.1 [2.9-3.2]	<0.001	2.7 [2.5-2.9]	<0.001		
Mtwapa	10,639	1,666 (33.5)	Ref	Ref	Ref	Ref		
Age group								
18–24 years	6,440	2,031 (40.8)	1.4 [1.3-1.5]	<0.001	1.3 [1.2-1.4]	<0.001		
25–34 years	9,969	2,415 (48.5)	1.1 [1.0-1.2]	0.158	1.0 [0.9-1.1]	0.509		
35–39 years	2,326	531 (10.7)	Ref	Ref	Ref	Ref		
Marital status ²								
Never married	13,026	3,622 (72.8)	1.2 [1.1-1.2]	<0.001	1.2 [1.1-1.3]	<0.001		
Separated/ Divorced/ Widowed	937	218 (4.4)	1.0 [0.9-1.1]	0.708	0.9 [0.8-1.1]	0.236		
Married	4,770	1,137 (22.8)	Ref	Ref	Ref	Ref		
Religion								
None	1,308	364 (7.3)	1.1 [1.0-1.2]	0.078	1.0 [0.9-1.1]	0.959		
Muslim	3,560	1,060 (21.3)	1.2 [1.1-1.2]	<0.001	1.0 [0.9-1.1]	0.707		
Christian	13,867	3,553 (71.4)	Ref	Ref	Ref	Ref		
Education level								
Primary or none	7,271	2,480 (49.8)	1.8 [1.7-2.0]	<0.001	1.6 [1.4-1.7]	<0.001		
Secondary	7,727	1,794 (36.0)	1.2 [1.1-1.3]	<0.001	1.3 [1.2-1.4]	<0.001		
Higher Education	3,737	703 (14.1)	Ref	Ref	Ref	Ref		
Testing period								
2015-2017	10,516	2,428 (48.8)	0.7 [0.7-0.8]	< 0.001	0.7 [0.7-0.7]	<0.001		
2012-2014	8,219	2,549 (51.2)	Ref	Ref	Ref	Ref		
Risk group ³								
GP men	9,262	2,515 (50.5)	1.2 [1.1-1.3]	<0.001	1.3 [1.2-1.4]	<0.001		
MSM	1,256	640 (12.9)	2.2 [2.1-2.4]	<0.001	1.4 [1.3-1.6]	<0.001		
FSW	751	112 (2.3)	0.7 [0.5-0.8]	<0.001	0.6 [0.5-0.7]	<0.001		
GP women	7,466	1,710 (34.4)	Ref	Ref	Ref	Ref		
Current STI symptoms								
Yes	848	146 (2.9)	0.6 [0.5-0.7]	<0.001	0.7 [0.6-0.9]	<0.001		
No	17,887	4,831 (97.1)	Ref	Ref	Ref	Ref		

¹ For Mtwapa and Kilifi, numbers are less than in Table 1 since the time periods are different. ² Data were missing for marital status (n=2). ³ Gender and transactional sex were excluded from the model due to collinearity with the risk group variable. *GP: General population; MSM: Men who have sex with men; FSW: Female sex workers; STI: Sexually transmitted infection.*

Table 3. Factors associated with late retesting encounters among general population clientsattending voluntary counselling and testing centres in Kilifi, Kenya, 2012-2017.

Factor	Number of test encounters ¹	Number (%) of late- retesting	Bivariable a	analysis	Multivariable analysis (Full model)	
		encounters	Risk ratio [95% Confidence interval]	P value	Adjusted risk ratio [95% Confidence interval]	P value
Testing location						
Kilifi	2,612	753 (22.7)	1.1 [1.1-1.2]	0.001	1.1 [1.0-1.2]	0.039
Malindi	1,603	456 (13.7)	1.1 [1.0-1.2]	0.012	1.1 [1.0-1.2]	0.079
Mtwapa	8,288	2,112 (63.6)	Ref	Ref	Ref	Ref
Age group						
18–24 years	3,906	971 (29.2)	0.8 [0.7-0.9]	<0.001	0.9 [0.8-1.0]	0.065
25–34 years	6,897	1,831 (55.1)	0.9 [0.8-0.9]	0.001	0.9 [0.8-1.0]	0.081
35–39 years	1,700	519 (15.6)	Ref	Ref	Ref	Ref
Marital status						
Never married	8,367	2,105 (63.4)	0.9 [0.8-0.9]	< 0.001	0.9 [0.8-1.0]	0.009
Separated/ Divorced/ Widowed	626	202 (6.1)	1.1 [1.0-1.3]	0.084	1.1 [1.0-1.3]	0.157
Married	3,508	1,014 (30.5)	Ref	Ref	Ref	Ref
Religion						
None	849	195 (5.9)	0.8 [0.7-1.0]	0.007	0.8 [0.7-1.0]	0.012
Muslim	2,189	532 (16.0)	0.9 [0.8-1.0]	0.004	0.9 [0.8-1.0]	0.010
Christian	9,465	2,594 (78.1)	Ref	Ref	Ref	Ref
Education level						
Primary or none	4,196	1,147 (34.5)	1.0 [0.9-1.0]	0.363	1.0 [0.9-1.1]	0.487
Secondary	5,390	1,348 (40.6)	0.9 [0.8-1.0]	0.001	0.9 [0.8-1.0]	0.024
Higher Education	2,917	826 (24.9)	Ref	Ref	Ref	Ref
Testing period						
2015-2017	7,390	1,891 (56.9)	0.9 [0.9-1.0]	0.003	0.9 [0.8-1.0]	0.006
2012-2014	5,113	1,430 (43.1)	Ref	Ref	Ref	Ref
Risk group						
GP men	6,747	1,841 (55.4)	1.1 [1.0-1.1]	0.047	1.1 [1.0-1.1]	0.069
GP women	5,756	1,480 (44.6)	Ref	Ref	Ref	Ref
Current STI symptoms						
Yes	508	105 (3.2)	0.8 [0.6-0.9]	0.003	0.8 [0.7-1.0]	0.019
No	11,995	3,216 (96.8)	Ref	Ref	Ref	Ref

¹ For Mtwapa and Kilifi, numbers are less than in Table 1 since the time periods are different. *GP: General population; STI: Sexually transmitted infection.*

Number Factor Number **Bivariable analysis** Multivariable tested analysis (%) positive (Full model) **Risk ratio** P value Adjusted P value [95% risk ratio [95% -Confidence interval] Confidence interval] **Testing location** Kilifi 4,022 122 (16.8) 0.9 [0.8-1.2] 0.576 0.9 [0.7-1.1] 0.223 Malindi 4,074 262 (36.1) 2.0 [1.7-2.3] < 0.001 1.3 [1.1-1.5] 0.011 Mtwapa 10,639 342 (47.1) Ref Ref Ref Ref Age group 18-24 years 6,440 168 (23.1) 0.4 [0.4-0.5] < 0.001 0.5 [0.4-0.6] < 0.001 25-34 years 9,969 420 (57.9) 0.7 [0.6-0.9] < 0.001 0.8 [0.6-0.9] 0.008 35-39 years 2,326 138 (19.0) Ref Ref Ref Ref **Marital status** Never married 13,026 382 (52.6) 0.6 [0.5-0.6] < 0.001 0.6 [0.5-0.7] < 0.001 Separated/ 937 92 (12.7) 1.9 [1.5-2.3] < 0.001 1.2 [1.0-1.5] 0.081 Divorced/ Widowed Married 4,770 252 (34.7) Ref Ref Ref Ref Religion None 1,308 63 (8.7) 1.3 [1.0-1.6] 0.062 1.3 [1.0-1.6] 0.067 Muslim 3,560 139 (19.1) 1.0 [0.9-1.2] 0.726 0.9 [0.8-1.1] 0.578 Christian 13,867 524 (72.2) Ref Ref Ref Ref **Education level** Primary/none 7,271 382 (52.6) 2.7 [2.1-3.5] < 0.001 1.6 [1.3-2.1] < 0.001 Secondary 7,727 272 (37.5) 1.8 [1.4-2.4] < 0.001 1.5 [1.2-1.9] 0.002 Higher Ref 3,737 72 (9.9) Ref Ref Ref Education **Testing period** 2015-2017 10,516 371 (51.1) 0.8 [0.7-0.9] 0.005 0.8 [0.7-0.9] 0.007 2012-2014 8,219 355 (48.9) Ref Ref Ref Ref HIV testing history¹ On-time testing 9,375 212 (29.2) Ref Ref Ref Ref Late retesting 4,383 260 (35.8) 2.6 [2.2-3.1] < 0.001 2.0 [1.6-2.4] < 0.001 First-time testing 4,977 254 (35.0) 2.3 [1.9-2.7] < 0.001 2.0 [1.7-2.5] < 0.001 Risk group² MSM 1,256 99 (13.6) 1.6 [1.3-2.0] < 0.001 1.1 [0.9-1.4] 0.341 FSW 751 90 (12.4) < 0.001 < 0.001 2.5 [2.0-3.1] 1.8 [1.4-2.3]

 Table 4. Factors associated with HIV positivity at testing encounters among adult clients attending voluntary counselling and testing centres in Kilifi, Kenya, 2012–2017.

Factor	Number tested	Number (%) positive	Bivariable a	inalysis	Multivariable analysis (Full model)				
			Risk ratio [95% Confidence interval]	P value	Adjusted risk ratio [95% Confidence interval]	P value			
GP men	9,262	176 (24.2)	0.4 [0.3-0.5]	< 0.001	0.4 [0.3-0.5]	< 0.001			
GP Women	7,466	361 (49.7)	Ref	Ref	Ref	Ref			
Current STI symptoms									
Yes	848	59 (8.1)	1.9 [1.4-2.4]	< 0.001	1.6 [1.2-2.0]	0.001			
No	17,887	667 (91.9)	Ref	Ref	Ref	Ref			

¹Late retesting was defined as previous test more than one year ago for GP or three months for key population.

²Gender and transactional sex were excluded from the model due to collinearity with the risk group variable. *GP: General population; MSM: Men who have sex with men; FSW: Female sex workers; STI: Sexually transmitted infection.*

higher education, first-time testers and late re-testers, MSM and FSW, and clients with current STI symptoms. Of note, encounters involving FTT and late retesting were about twice as likely to result in a positive test compared to on-time retesting encounters. Encounters among clients with primary or no education were 1.6 times more likely to result in a positive HIV test, compared to those among clients with higher education, while those among clients with secondary education were 1.5 times more likely.

Encounters where a positive HIV result was less likely were among clients under 35 years, those who were never married, and GP men.

Discussion

Analysis of 12-year data from three VCT centres in Kilifi county, Kenya, revealed a decline in the proportion of encounters involving first-time testing (those who had never tested before) among GP men, GP women, GP women aged 18-24 years, and FSW; suggesting increasing coverage of HIV testing in the county, in line with national trends⁶. However, the proportion of encounters involving FTT among MSM was relatively constant, and the prevalence of FTT encounters among MSM in the final year assessed (2017) was relatively high at 42% (compared to 15% in GP and 9% in FSW). We also found an overall decline - albeit more modest - in the proportion of encounters involving late retesting, but this remained, in absolute terms, much higher among KP, for whom more frequent testing is recommended, compared to GP. While the proportion of encounters involving late retesting (i.e. previous test more than a year ago) was 28% for GP in 2017, 83% of encounters for KP in the current study involved late retesting (previous test more than 3 months ago).

FTT encounters were more common among men (both GP men and MSM), among younger (18-24 years) or single persons,

and among persons with lower educational attainment. Such persons may perceive themselves to be at higher risk. Among GP, late retesting encounters were less common among single persons, those with secondary education, those professing Muslim or no religious affiliation and those who had current STI symptoms. While the association with religious affiliation is less clear, the other associations may indicate increased awareness of risk for HIV. These findings are of interest given that encounters involving first-time and late re-testing were more likely to yield a positive test result, compared to on-time re-testers. Increased education and a mobilization strategy targeting sub-groups with these attributes could potentially contribute significantly to achieving the 90% UNAIDS HIV diagnosis target in Kilifi county and other similar settings. Because current STI symptoms were associated with a near doubling of HIV positivity at encounters, such approaches should incorporate integrated sexual reproductive health services that include screening, diagnosis and treatment for STI²⁷.

Encounters in which HIV test results were positive declined among GP men and women, and among MSM, but increased among FSW. The increase in positivity among FSW may have been due to a high proportion of encounters involving FTT among FSW in one location (Malindi, data not shown) as a result of increased knowledge or risk perception after cumulative outreach efforts in recent years. While MSM-focused community-based organizations were active in the three areas from the beginning of the study period, there were initially limited services targeting FSW²⁸. At the KWTRP VCT centre in Malindi, specifically, the initial focus was on MSM and did not expand to include FSW until 2015²⁹.

The low uptake of quarterly retesting (implied by the low proportion of on-time retesting encounters among KP in our study) and consequent continuing transmission among MSM and FSW may be due to stigmatizing attitudes of healthcare workers, discrimination, and concerns about confidentiality; factors that have been shown to decrease access to health In our study, low educational attainment was associated not only with encounters for FTT but also with HIV positivity. Testing encounters among clients with primary or no education were 1.6 times more likely to result in a positive HIV test, compared to those among clients with higher education, while those among clients with secondary education had 1.5 times the likelihood. Kilifi County is amongst the poorest counties in the country¹⁷, and has low literacy levels^{18,19}. Specifically, in Kilifi county, educational outreach and targeted HIV testing programs tailored to the needs of low-literacy, rural populations might improve HIV testing services. For instance, HIV knowledge and literacy could be assessed among patients seeking healthcare, and patients with no or low level of education could be offered brief education sessions with visual aids and confidential HIV testing with clear and simple messages. Community outreach could also help to dispel myths about HIV and increase awareness and uptake of services.

In Kenya and other similar settings, adolescents and young women 15–24 years are disproportionately affected by HIV³⁸. In 2017, this sub-population accounted for more than a third of all new adult HIV infections in Kenya^{5,6}; HIV prevalence in this group was estimated at $2.6\%^{5.6}$. In the present study, HIV positivity at VCT encounters by young women 18–24 years was 2.8% in 2017. Initiatives that tackle social determinants of HIV risk in this vulnerable group, such as poverty, gender inequality, and sexual violence are needed^{39–41}. However, resources to implement such initiatives may be limited, since Kilifi is categorized as a medium priority county for HIV prevention and care. Less donor-dependent interventions, such as sex education at primary and secondary schools, will be crucial and could be rolled out in tandem with HIV education aimed at improving health literacy.

Our findings suggest unequal delivery of HIV prevention services across the county. Testing history and HIV positivity at VCT encounters varied by town, with Malindi having the lowest testing prevalence and highest HIV positivity. Malindi is more geographically isolated, being furthest from Mombasa – Kenya's second largest city, main seaport and former administrative headquarters for the coast province. On the other hand, the town has a vibrant tourism sector which attracts large numbers of KP. Clearly, greater coverage of HIV testing and prevention services is needed in this area, with a strong focus on KP.

This study demonstrates the utility of rigorous analysis of routinely collected data to evaluate trends in first-time testing, late retesting, and HIV positivity at VCT encounters at a county level⁴². Currently, test data collected at various testing facilities are reported to county headquarters only in summary form,

combining data from VCT centres and other testing points such as provider-initiated testing in outpatient and antenatal clinics; the data is also not disaggregated by risk groups. Our findings also show that additional socio-demographic, sexual behaviour, and testing history data can be useful in identifying subpopulations in need of additional education and outreach, as well as targeted HIV prevention and care services.

Our study had a number of limitations. First, we cannot be sure that encounters with a positive test result documented were new diagnoses of HIV infection, as stigma and social desirability bias may lead some clients to report their previous test result as negative even if it was positive43,44. Second, social desirability bias may also have resulted in over-reporting of previous HIV test uptake. Third, stigma and discrimination towards MSM may have resulted in under-reporting of same-sex behavior practices among men and sex work stigma may have resulted in under-reporting of transactional sex among women. Additionally, our dataset lacked information on sexual behaviour prior to 2010, limiting our ability to describe trends by risk group in that period. Fourth, the data capture system we used did not track individual testers longitudinally, precluding our ability to analyse individual testing practices over time. As one individual's multiple retesting episodes were counted as individual encounters, this may have biased our modelling. Fifth, cross-site comparisons of time trends may have been biased by changes in covered populations in the different VCT centers over time. Sixth, although we excluded clients mobilized through outreach activities, some of the clients registered as walk-in may have been influenced indirectly by outreach activities, hence the sample used may not be wholly representative of the walk-in VCT clientele. Seventh, our data do not enable us to hypothesize about mechanisms underlying some findings, such as associations with religion, and some findings may be due to chance or residual confounding. In particular, the use of p values to select variables for model building can be misleading⁴⁵. Finally, the three VCT centres included in the study are close to KWTRP research clinics, hence clients may not be representative of the whole VCT clientele in the county.

Conclusions

Our study showed that in Kilifi county, HIV positivity at encounters in the three VCT centres studied was most common when encounters involved first-time testing, testing less than annually, key populations, and persons with lower educational attainment. While encounters involving first-time testing and late retesting decreased over time, potentially reflecting increased testing coverage, there is an urgent need to evaluate actual HIV test coverage in different sub-populations and to implement non-stigmatizing HIV testing programs accessible to all in order to achieve the 90% diagnosis target set for the county.

Data availability

Underlying data

Harvard Dataverse: Underlying dataset for: Trends and predictors of HIV positivity and time since last test at voluntary testing and counseling encounters among adults in Kilifi, Kenya, 2006–2017, https://doi.org/10.7910/DVN/43DAWU⁴⁶.

This project contains the following underlying data:

- Underlying data
- Codebook

Extended data

Harvard Dataverse: Supplementary tables for: Trends and predictors of HIV positivity and time since last test at voluntary testing and counseling encounters among adults in Kilifi, Kenya, 2006–2017, https://doi.org/10.7910/DVN/TVQJZP⁴⁷.

This project contains the following extended data:

- Supplementary Table 1. Number of test encounters excluded from the analysis and HIV positivity for each exclusion category.
- Supplementary Table 2. Time trends in the proportion of encounters involving first-time testers among general population attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 22,528
- Supplementary Table 3 Time trends in the proportion of encounters involving first-time testers among key population attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 2,200
- Supplementary Table 4. Time trends in the proportion of encounters involving late retesting among general population attending voluntary counselling and testing centers in Kilifi County, Kenya, N = 15,488
- Supplementary Table 5. Time trends in the proportion of encounters involving late retesting among key population attending voluntary counselling and testing centers in Kilifi County, Kenya, N = 1,366
- Supplementary Table 6. Time trends in HIV positivity at testing encounters among general population men

attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 12,502

- Supplementary Table 7. Time trends in HIV positivity at testing encounters among general population women attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 10,026
- Supplementary Table 8. Time trends in HIV positivity at testing encounters among MSM attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 1,447
- Supplementary Table 9. Time trends in HIV positivity at testing encounters among FSW attending voluntary counselling and testing centres in Kilifi County, Kenya, N = 729
- Supplementary Table 10. Factors associated with testing less than quarterly (> 3 months ago) among episodes with Key Populations, voluntary counselling and testing centres in Kilifi County, Kenya, 2012–2017

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 Public domain dedication).

Acknowledgements

We acknowledge the KWTRP counsellors who provided testing and counselling services at the three VCTs during the period under study, data entry staff, and Christopher Nyundo for the map of study area.

This manuscript was submitted for publication with permission from the Director of the Kenya Medical Research Institute (KEMRI).

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- Mugo P: Supplementary tables for: Trends and predictors of new HIV diagnosis and time since last test at testing encounters among adults in Kilifi, Kenya, 2006-2017. Harvard Dataverse, V1. 2019. http://www.doi.org/10.7910/DVN/TVQJZP

Open Peer Review

Current Peer Review Status:

Version 2

Reviewer Report 12 April 2021

https://doi.org/10.21956/wellcomeopenres.17809.r42696

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Mathieu Maheu-Giroux 匝

Department of Epidemiology, Biostatistics, and Occupational Health, School of Global and Population Health, McGill University, Montreal, Canada

Comments

- 1. Within Figure 2 and 3 captions, it is written: "Due to the small number of FSW clients from Kilifi location, data for 24 FSW were not included in the figure." It is unclear to us why those participants were excluded from those figures since a small number of participants is not a sufficient reason for exclusion. Those participants must be included in the analyses and if not possible, exact and relevant reasons for exclusion should be explained in the Data analysis section of the manuscript.
- 2. In their answer to our previous comment saying that inclusion of variables based on their statistical significance could be misleading, we don't understand why the authors said: "The issue of variables being excluded because of p>0.1 in bivariable analysis that could have had P<0.1 in adjusted analysis does not arise for our study since, as explained here above, all variables were included in the multivariable model. [Pages 8, (data analysis)]". Indeed, in the Data analysis section of the manuscript, it is rather clearly said that "Variables with p<0.10 from bivariable analyses were included in the multivariable model", which suggest that variables with p>0.1 in bivariable analyses were excluded from multivariable models and thus that not all variables were included in the multivariable model.
- 3. Figures 4 and 5: the Y axis title should be "HIV positivity" and not "Proportion newly diagnosed".
- 4. To support the following statement in the Discussion section: "First, we cannot be sure that encounters with a positive test result documented were new diagnoses of HIV infection, as stigma and social desirability bias may lead some clients to report their previous test result as negative even if it was positive." we suggest to reference a meta-analysis of misreporting of known HIV status (Soni et al. 2020¹. Under-reporting of known HIV-positive status among people living with HIV: a systematic review and meta-analysis) that can be found here as a

preprint.

5. Please correct the following typo: "literacacy" Page 9.

References

1. Soni N, Giguère K, Boily M, Fogel J, et al.: Under-Reporting of Known HIV-Positive Status Among People Living with HIV: A Systematic Review and Meta-Analysis. *SSRN Electronic Journal*. 2020. Publisher Full Text

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Infectious disease epidemiology; HIV and other sexually transmitted and blood-borne infections; Impact Evaluation; Mathematical modeling; Population health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 03 May 2021

Peter Mugo, Kenya Medical Research Institute (KEMRI) -Wellcome Trust Research Programme, Kilifi, Kenya

Within Figure 2 and 3 captions, it is written: "Due to the small number of FSW clients from Kilifi location, data for 24 FSW were not included in the figure." It is unclear to us why those participants were excluded from those figures since a small number of participants is not a sufficient reason for exclusion. Those participants must be included in the analyses and if not possible, exact and relevant reasons for exclusion should be explained in the Data analysis section of the manuscript.

We thank the reviewer for pointing this out. This exclusion was a carry-over from a previous version of the graphs that included site-specific panels by population group: the small number of FSWs in Kilifi was causing wild ups and downs. We have revised the graph to include them and removed the relevant text from the figure captions.

In their answer to our previous comment saying that inclusion of variables based on their statistical significance could be misleading, we don't understand why the authors said: "The issue of variables being excluded because of p>0.1 in bivariable analysis that could have had P<0.1 in adjusted analysis does not arise for our study since, as explained here above, all variables were included in the multivariable model. [Pages 8, (data analysis)]". Indeed, in the Data analysis section of the manuscript, it is rather clearly said that "Variables with p<0.10 from bivariable analyses were included in the multivariable model", which suggest that variables with p>0.1 in bivariable analyses were excluded from multivariable models and thus that not all variables were included in the multivariable model.

Age and sex were included a priori, and other variables were indeed carried forward if the p value from bivariable analysis was <-10. We have clarified this in our revised manuscript. We agree with the reviewer that inclusion of variables based on their statistical significance alone can lead to

misleading conclusions, and have added this as a limitation of our study.

Figures 4 and 5: the Y axis title should be "HIV positivity" and not "Proportion newly diagnosed".

We have corrected this error.

To support the following statement in the Discussion section: "First, we cannot be sure that encounters with a positive test result documented were new diagnoses of HIV infection, as stigma and social desirability bias may lead some clients to report their previous test result as negative even if it was positive." we suggest to reference a meta-analysis of misreporting of known HIV status (Soni et al. 20201. Under-reporting of known HIV-positive status among people living with HIV: a systematic review and meta-analysis) that can be found here as a preprint.

We thank the reviewer for bringing this to our attention. We have added the suggested reference.

Please correct the following typo: "literacacy" Page 9. *We have corrected the typo. Thanks.*

Competing Interests: No competing interests were disclosed.

Version 1

Reviewer Report 15 July 2020

https://doi.org/10.21956/wellcomeopenres.16834.r39379

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Parinita Bhattacharjee 回

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The subject of the paper is very important. As the country is debating the need for retesting or frequent testing, this paper would be an important resource.

The paper is being reviewed and possibly published in 2020. The national data on the epidemic and testing used in the introduction is 3 years old. In the meantime the country did a population based survey in 2018 (KENPHIA) and the preliminary report is available now. I think the paper should use the updated data and cite current literature.

The definition of resting is different for GF and KP. Though it is explained clearly in the method section, in other sections of the paper only one definition is used. This needs to be consistent.

One of the limitations could be access to HIV testing services for populations in multiple sites. It could be possible that clients retested in other sites. How was that captured?

The other limitation could be that KPs did not identify themselves as KPs in the testing sites due to stigma and discrimination and hence some of the KPs may have been categorised as GF in a public facility.

Is the work clearly and accurately presented and does it cite the current literature? Partly

Is the study design appropriate and is the work technically sound? Yes

Are sufficient details of methods and analysis provided to allow replication by others? $\ensuremath{\mathsf{Yes}}$

If applicable, is the statistical analysis and its interpretation appropriate? I cannot comment. A gualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility? Yes

Are the conclusions drawn adequately supported by the results? $\ensuremath{\mathsf{Yes}}$

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: HIV prevention among key populations

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 26 Jan 2021

Peter Mugo, Kenya Medical Research Institute (KEMRI) -Wellcome Trust Research Programme, Kilifi, Kenya

The paper is being reviewed and possibly published in 2020. The national data on the epidemic and testing used in the introduction is 3 years old. In the meantime the country did a population based survey in 2018 (KENPHIA) and the preliminary report is available now. I think the paper should use the updated data and cite current literature.

We thank the reviewer for pointing this out. The introduction has been updated with findings from the 2018 KENPHIA survey, also in response to a comment by reviewer 1. [Pages 5,6 (intro)]

One of the limitations could be access to HIV testing services for populations in multiple

sites. It could be possible that clients retested in other sites. How was that captured?

In the revised manuscript, we have clarified that clients were asked to report the date of their last HIV test, whether conducted at the same VCT or elsewhere. [Page 7 (data collection procedures)]

The other limitation could be that KPs did not identify themselves as KPs in the testing sites due to stigma and discrimination and hence some of the KPs may have been categorised as GF in a public facility.

We have added this limitation, also in response to a comment by reviewer 1. [Page 23 (discussion; limitations)]

Competing Interests: No competing interests were disclosed.

Reviewer Report 28 October 2019

https://doi.org/10.21956/wellcomeopenres.16834.r36589

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In their research article, Dr. Peter M Mugo and colleagues used program data from HIV testing services to examine 2006-2007 trends in self-reported new diagnoses, first time testing, and time since last test in Kilifi county, Kenya. Importantly, the authors examined these trends among self-reported key population status of attendees.

Overall, we found that the paper was innovative and well written. We congratulate the authors for leveraging the available wealth of testing data to gain a better understanding of longitudinal HIV testing trends. However, we have some concerns regarding limitations of these data and feel that some conclusions are not supported by the paper's results.

Please find our comments, suggestions, and questions below.

<u>Methods</u>

• The most important limitation of the study is the use of self-reported information, especially with regards to new diagnoses. Several studies have found considerable under-reporting of

knowledge of HIV status (see list at the end of review). We would recommend that the authors use extreme caution when interpreting these self-reported "new diagnoses". Indeed, if one examines HIV national testing program data from several countries, it is difficult to reconcile the national total annual number of HIV positive tests performed with the estimated size of the population living with HIV without allowing for considerable retesting of already diagnosed individuals. For example, in many countries the annual numbers of positive tests reported can represent up to 25 – 30% of the whole estimated PLHIV population, which is inconsistent with survey data on the proportion of PLHIV ever tested. For more details on these issues, the authors can consult this preprint (Maheu-Giroux et al. 2019¹) (also in press at AIDS).

- A total of 47,893 tests encounters were recorded. Yet, the authors exclude almost half of these to obtain an "homogenous sample". It is unclear to us why this is warranted and how this achieves a sample that is more representative of the "at-risk adult population in the area ". By definition, the authors' data constitute a convenience sample (i.e., health-care seekers) that is probably not representative of the underlying "at-risk population". Could the authors confirm that excluding 46% of observations does not change their main conclusion (qualitatively)?
- *"HIV positivity"* is usually defined as the number of positive tests over the total number of HIV tests performed. Can the authors consider replacing what they call *"HIV positivity"* with *" % of self-reported new diagnosis"*? We understand this is a verbose change but it is also more accurate.
- It is said that risk behaviors were collected from 2010 onward. However, figures showing trends among key populations show estimates from 2009. Were risk behaviors rather collected from 2009?
- Why are the authors smoothing the time trends using LOWESS? Why is that warranted? Since their data do not constitute a sample – but rather contains all testing encounters in Kilifi county (akin to a census) – we are also wondering why the authors are using statistical test of significance to measure trends. If the proportion of self-reported first-time testers was 60% in the general population in 2006 and that it decreases to 20% ish in 2017 in Kilifi County, why perform statistical tests? The decrease was 40% point over that period: there are no random errors. Instead, it could be more appropriate for the authors to look at meaningful changes in testing metrics and disregard p-values to assess if changes are important.
- In the multivariable regression models, the inclusion of variables based on their statistical significance could be misleading. For example, a variable with a p-value>0.1 could become important after adjustments for other potential confounders. Could the authors include variables (and confounders, if any) that were determined *a priori* to plausibly be associated with the outcomes? The authors should, at the very least, recognized the limitations of their model-building process. (That being said, we appreciate the use of log-binomial models over logistic regressions.)
- Ethical approval was not sought because the data was de-identified. De-identification of individual-level observations that contains potentially sensitive information is usually not a

sufficient reason for not obtaining ethics approval. Can the authors clarify?

<u>Results</u>

- Figure 5: the authors conclude that there was no change over time for most of the outcomes presented in this figure. Actually, we see that some of the presented curves tend to be quadratic. It could be there was a (quadratic) change over time for some of these outcomes, but that the authors could not detect it because they tested a linear trend.
- It is written that, in 2017: "Overall FFT prevalence in KP was 28%" and "Overall late-retesting prevalence in KP was 83%". How could the sum of these two estimates be over 100%? Especially considering that we would expect that at least some of the tests in KP were ontime testing.
- <u>Discussion</u>
 - In the discussion section, it is written: "Annual retesting coverage in GP was 72% in 2017, which signals a population-level increase from the 2012 estimate of 55%. On the other hand, less than 20% of KP in the current study were retesting quarterly." Both estimates (72% and 20%) were not provided in the results section. Please make sure that discussed results are also presented in the results section.
 - Some parts of the discussion are disconnected from the authors' analyses. For example, the authors' second paragraph of page 8 that discussed low educational attainment seems out of place. Why are the authors making statement such as "this suggests that HIV prevention programmes are insufficiently reaching those with low educational attainment"? The authors only looked at HIV testing program data and HIV prevention programs are way broader than this. In fact, the whole paragraph is not supported by data presented in their article. The same applies for the discussion of the likely impact of "underage sex", "early childhood marriage", and "sex tourism". Could the authors avoid such wide extrapolations of their findings?
 - The same applies for other sections of the discussion. For example, the authors conclude that PrEP users will likely need intense engagement and tailored support services in order to adhere to the recommended retesting frequency. This conclusion is surprising since the authors did not assess HIV testing among PrEP users. Please consider re-wording that section.
 - It is written: "Testing coverage and HIV positivity varied by town [...]" Testing coverage was not assessed in this study. The only metric the authors are able to calculate are the % of first-time tester but this is not testing coverage per se. You could well have a region where only 10% of the population has ever been tested for HIV but where repeat testing is very high among this 10% of "testers". Even though the program data would show a very low proportion of first-time testers, testing coverage would still be <10%. Please refrain from making conclusions about testing coverage when examining program data only.
 - A similar argument applies to the interpretation of the regression models of the factors associated with first-time testing. The fact that a certain variable (i.e., religion) is associated with self-reported first-time testing is not necessarily evidence that testing coverage is lower among this group.
 - Among limitations of the study, please discuss also potential selection bias in assessment of

trends due to the changes in covered populations in the different VCT centres over time. We also suggest discussing potential information bias from self-report "*new diagnosis*" and, importantly, key population status. It is highly likely that a potential high proportion of MSM do not disclose same-sex activity to their health-care providers. The same applies for FSW.

Minor comments

- Introduction: The 2019 AIDS report published by UNAIDS has the updated figure for knowledge of HIV status in Kenya. Consider updating it.
- In the results section, it is written: "The percentage-point changes were similar for all subgroups assessed." We think that it would worth mentioning "The percentage-point changes per year were similar..."
- The conclusions regarding on-time testing would benefit from mentioning potential limitations associated with these self-reports. In particular, *"telescoping bias"* is likely to occur if respondents inadvertently recall testing that occurred beyond the last 3 (KP) or 12 (GP) months. This would not necessarily affect the conclusion regarding trends but would affect the absolute proportion testing on time.
- Figure 4. There is a "T" missing at the beginning of the title.

References

1. Maheu-Giroux M, Marsh K, Doyle C, Godin A, et al.: National HIV testing and diagnosis coverage in sub-Saharan Africa: a new modeling tool for estimating the "first 90" from program and survey data. *bioRxiv*. 2019. Publisher Full Text

2. Rohr J, Xavier Gómez-Olivé F, Rosenberg M, Manne-Goehler J, et al.: Performance of selfreported HIV status in determining true HIV status among older adults in rural South Africa: a validation study. *Journal of the International AIDS Society*. 2017; **20** (1). Publisher Full Text 3. Fuente-Soro L, Lopez-Varela E, Augusto O, Sacoor C, et al.: Monitoring progress towards the first UNAIDS target: understanding the impact of people living with HIV who re-test during HIV-testing campaigns in rural Mozambique.*J Int AIDS Soc.* **21** (4): e25095 PubMed Abstract | Publisher Full

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Is the work clearly and accurately presented and does it cite the current literature? Partly

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others? Partly

If applicable, is the statistical analysis and its interpretation appropriate? $\ensuremath{\mathbb{No}}$

Are all the source data underlying the results available to ensure full reproducibility? $\ensuremath{\mathsf{Yes}}$

Are the conclusions drawn adequately supported by the results?

No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Infectious disease epidemiology; HIV and other sexually transmitted and blood-borne infections; Impact Evaluation; Mathematical modeling; Population health.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to state that we do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 26 Jan 2021

Peter Mugo, Kenya Medical Research Institute (KEMRI) -Wellcome Trust Research Programme, Kilifi, Kenya

The most important limitation of the study is the use of self-reported information, especially with regards to new diagnoses. Several studies have found considerable underreporting of knowledge of HIV status (see list at the end of review). We would recommend that the authors use extreme caution when interpreting these self-reported "new diagnoses". Indeed, if one examines HIV national testing program data from several countries, it is difficult to reconcile the national total annual number of HIV positive tests performed with the estimated size of the population living with HIV without allowing for considerable re-testing of already diagnosed individuals. For example, in many countries the annual numbers of positive tests reported can represent up to 25 – 30% of the whole estimated PLHIV population, which is inconsistent with survey data on the proportion of PLHIV ever tested. For more details on these issues, the authors can consult this preprint (Maheu-Giroux et al. 2019) (also in press at AIDS).

We agree with the reviewer that not all positive tests at the VCT may be new diagnoses. We excluded from our analysis clients seeking confirmatory testing, after testing positive elsewhere. We have revised the title and the manuscript to use the term "HIV positivity" and speak of positive test results and not new diagnosis. We have also added this limitation and referenced the study that the reviewer kindly pointed us to in the discussion. [Page 1 (title), 5 (abstract), 6 (intro), 18 (factors associated with HIV positivity), 21-23 (discussion)]

A total of 47,893 tests encounters were recorded. Yet, the authors exclude almost half of these to obtain an "homogenous sample". It is unclear to us why this is warranted and how this achieves a sample that is more representative of the "at-risk adult population in the area". By definition, the authors' data constitute a convenience sample (i.e., health-care seekers) that is probably not representative of the underlying "at-risk population". Could the authors confirm that excluding 46% of observations does not change their main conclusion (qualitatively)?

Our sample selection was guided by our goal to assess trends in "adult walk-in VCT clients", i.e., clients seeking testing out of their own initiative and not those testing as a result of outreach activities. Clients mobilized during outreach activities may be more open to social pressure to test or retest, and differences in the frequency and intensity of outreach activities over the years would make time trends difficult to assess.

In response to this comment, we have added supplementary table 1 with data on the numbers of encounters and HIV positivity of the categories excluded. [Pages 7, 8 (Data collection procedures and sample selection)]

"HIV positivity" is usually defined as the number of positive tests over the total number of HIV tests performed. Can the authors consider replacing what they call "HIV positivity" with "% of self-reported new diagnosis"? We understand this is a verbose change but it is also more accurate.

Our calculation of positivity was as per the reviewer's definition, i.e., "number of positive tests divided by total number of HIV tests performed". We have changed the definition to reflect this, viz: "proportion of test encounters where the result was positive". In the revised manuscript, we have avoided referring to "new diagnosis," in response to this reviewer's earlier comment. [Pages 1 (title), 5 (abstract), 6 (intro), 8 (data analysis), 18 (factors associated with HIV positivity), 21-23 (discussion).}

Why are the authors smoothing the time trends using LOWESS? Why is that warranted?

We smoothed the plots to improve visibility of the trends, especially for graphs where we have plots that cross each other. We have added in the supplementary materials the actual data points on which the plots are based. [Pages 11 (figure 2),12 (figure 3 and 4) and 13 (figure 5). Supplementary tables 2- 9.]

Since their data do not constitute a sample – but rather contains all testing encounters in Kilifi county (akin to a census) – we are also wondering why the authors are using statistical test of significance to measure trends. If the proportion of self-reported firsttime testers was 60% in the general population in 2006 and that it decreases to 20% ish in 2017 in Kilifi County, why perform statistical tests? The decrease was 40% point over that period: there are no random errors. Instead, it could be more appropriate for the authors to look at meaningful changes in testing metrics and disregard p-values to assess if changes are important. In response to this comment, we have omitted the test for trend. As our goal was to describe the change over the years and not simply the start and end points, we now focus, as suggested by the reviewer, on the slope (percentage-point change per year). [Pages 5 (abstract), 8 (data analysis), 11, 12, 13 (time trends in FTT, late retesting and positivity), 21, 22 (discussion)]

In the multivariable regression models, the inclusion of variables based on their statistical significance could be misleading. For example, a variable with a p-value>0.1 could become important after adjustments for other potential confounders. Could the authors include variables (and confounders, if any) that were determined a priori to plausibly be associated with the outcomes? The authors should, at the very least, recognized the limitations of their model-building process. (That being said, we appreciate the use of log-binomial models over logistic regressions.)

We thank the reviewer for commending our use of log-binomial regression which gives estimates that are more intuitive.

We did not initially highlight our a priori variables since these variables met criteria of p<0.1 in bivariable analysis and so were included in the full multivariate model. However, sex and age were considered confounders a priori; this is now clarified in the manuscript.

The issue of variables being excluded because of p>0.1 in bivariable analysis that could have had P<0.1 in adjusted analysis does not arise for our study since, as explained here above, all variables were included in the multivariable model. [Pages 8, (data analysis)]

Ethical approval was not sought because the data was de-identified. De-identification of individual-level observations that contains potentially sensitive information is usually not a sufficient reason for not obtaining ethics approval. Can the authors clarify?

Ethical approval for the analysis has since been granted by the KEMRI Scientific and Ethical Review Unit (SERU). We have amended the ethical statement to reflect the same. [Page 8 (ethical statement)]

Figure 5: the authors conclude that there was no change over time for most of the outcomes presented in this figure. Actually, we see that some of the presented curves tend to be quadratic. It could be there was a (quadratic) change over time for some of these outcomes, but that the authors could not detect it because they tested a linear trend.

We have omitted the statistical test for trend and now focus on the estimated slope (percentage-point change per year), also in response to another comment above. [Pages 11 (figure 2),12 (figure 3 and 4) and 13 (figure 5).]

It is written that, in 2017: "Overall FFT prevalence in KP was 28%" and "Overall lateretesting prevalence in KP was 83%". How could the sum of these two estimates be over 100%? Especially considering that we would expect that at least some of the tests in KP were on-time testing. FTT is based on data from clients who reported never testing before, while late retesting is from clients who ever tested before, so the numerators and denominators for these two metrics are different. We have edited the text for clarity, as these statistics refer to the proportion of all encounters that involved first-time testing or late-retesting *within subgroups*. [Page 8 (data analysis)]

In the discussion section, it is written: "Annual retesting coverage in GP was 72% in 2017, which signals a population-level increase from the 2012 estimate of 55%. On the other hand, less than 20% of KP in the current study were retesting quarterly." Both estimates (72% and 20%) were not provided in the results section. Please make sure that discussed results are also presented in the results section.

We thank the reviewer for pointing out this problem. We edited the discussion to ensure that it only includes results that were presented in the results section. [Page 21 (discussion)]

Some parts of the discussion are disconnected from the authors' analyses. For example, the authors' second paragraph of page 8 that discussed low educational attainment seems out of place. Why are the authors making statement such as "this suggests that HIV prevention programmes are insufficiently reaching those with low educational attainment"? The authors only looked at HIV testing program data and HIV prevention programs are way broader than this. In fact, the whole paragraph is not supported by data presented in their article. The same applies for the discussion of the likely impact of "underage sex", "early childhood marriage", and "sex tourism". Could the authors avoid such wide extrapolations of their findings?

We thank the reviewer for the comment and critical review of our discussion points. The discussion section has been amended to reflect potential strategies based on literature to tackle the socioeconomic inequalities such as poverty and education and their impact on HIV. [Pages 21-23 (discussion)]

It is written: "Testing coverage and HIV positivity varied by town [...]" Testing coverage was not assessed in this study. The only metric the authors are able to calculate are the % of first-time tester – but this is not testing coverage per se. You could well have a region where only 10% of the population has ever been tested for HIV but where repeat testing is very high among this 10% of "testers". Even though the program data would show a very low proportion of first-time testers, testing coverage would still be <10%. Please refrain from making conclusions about testing coverage when examining program data only.

We thank the reviewer for pointing this out. In the revised manuscript, we have avoided the use of "coverage" and "prevalence" when referring to the testing encounters were studied. [Page 23 (discussion)]

Among limitations of the study, please discuss also potential selection bias in assessment of trends due to the changes in covered populations in the different VCT centres over time. We also suggest discussing potential information bias from self-report "new diagnosis" and, importantly, key population status. It is highly likely that a potential high proportion of MSM do not disclose same-sex activity to their health-care providers. The same applies

for FSW.

We thank the reviewer for the comment and critical review of limitations. We edited the limitations to discuss potential social desirability bias that may lead some clients to report their previous test as negative even if it was positive. In addition, we have commented on the effects of stigma and discrimination towards MSM which may result in under-reporting of same-sex behavior practices among men, and under-reporting of transactional sex among women. We have also discussed the limitation of cross-site comparisons of time trends that may have been biased by changes in covered populations in the different VCTs over time. [Page 25 para 2]

Competing Interests: No competing interests were disclosed.