**Journal:** Journal of the International AIDS Society

**Title:** ”The impact and cost-effectiveness of community-based HIV self-testing in sub-Saharan Africa. A health economic and modelling analysis“

**Authors:** Working Group on Cost Effectiveness of HIV self-testing in Southern Africa [Valentina Cambiano1§, Cheryl Johnson2, Karin Hatzold3, Fern Terris-Prestholt4, Hendy Maheswaran5, Harsha Thirumurthy 6, Carmen Figueroa2, Frances Cowan7,8, Euphemia L Sibanda7,8, Getrude Ncube9, Paul Revill10, Rachel Clare Baggaley2, Liz Corbett11,12, Andrew Phillips1]

1. Institute for Global Health, University College London, UK
2. World Health Organization, Geneva, Switzerland
3. Population Services International, Washington D.C., USA
4. Department of Global Health and Development, London School of Hygiene and Tropical Medicine, London, UK
5. Institute of Psychology, Health and Society, University of Liverpool, Liverpool, UK
6. Department of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
7. Centre for Sexual Health and HIV AIDS Research (CeSHHAR), Harare, Zimbabwe
8. Liverpool School of Tropical Medicine, Liverpool, UK
9. Zimbabwe Ministry of Health and Child Care, Harare, Zimbabwe
10. Centre for Health Economics, University of York, York, UK
11. Malawi–Liverpool–Wellcome Trust Clinical Research Programme, Blantyre, Malawi,
12. Department of Clinical Research, London School of Hygiene & Tropical Medicine, London, UK

**Corresponding author:** Valentina Cambiano, Institute for Global Health, University College London, Rowland Hill Street, London NW3 2PF; Tel: +44(0)2077940500 (ext. 34570); v.cambiano@ucl.ac.uk

**Email addresses of authors:**

CJ: johnsonc@who.int;

KH: khatzold@psi.org;

FTP: Fern.Terris-Prestholt@lshtm.ac.uk;

HM: H.Maheswaran2@liverpool.ac.uk;

TH: hthirumu@pennmedicine.upenn.edu;

CF: karrleen@hotmail.com;

FC: Frances.Cowan@lstmed.ac.uk;

ES: euphemia@ceshhar.co.zw;

GN: getrudencube@yahoo.co.uk;

PR: paul.revill@york.ac.uk;

RCB: baggaleyr@who.int;

LC: Liz.Corbett@lshtm.ac.uk;

AP: andrew.phillips@ucl.ac.uk;

**Keywords:** HIV testing, community-based HIV self-testing; cost-effectiveness; mathematical modelling; HIV; benefits and cost;

**Abstract (318 words; max 350)**

**Introduction:** Prevalence of undiagnosed HIV is declining in Africa, and various HIV testing approaches are finding lower positivity rates. In this context, the epidemiological impact and cost-effectiveness of community-based HIV self-testing (CB-HIVST) is unclear. We aimed to assess this in different sub-populations and across scenarios characterised by different adult HIV prevalence and antiretroviral treatment programmes in sub-Saharan Africa.

**Methods:** The Synthesis model was used to address this aim. Three sub-populations were considered for CB-HIVST: (i) women having transactional sex (WTS), (ii) young people (15-24 years), and (iii) adult men (25-49 years)

We assumed uptake of CB-HIVST similar to that reported in epidemiological studies (base case), or assumed people use CB-HIVST only if exposed to risk (condomless sex) since last HIV test. We also considered a five-year time-limited CB-HIVST programme. Cost-effectiveness was defined by an incremental cost-effectiveness ratio (ICER; cost-per-disability-adjusted life-year [DALY] averted) below US$500 over a time-horizon of 50 years. Efficiency of targeted CB-HIVST was evaluated using the number of additional tests per infection or death averted.

**Results:** In the base case, targeting adult men with CB-HIVST offered the greatest impact, averting 1500 HIV infections and 520 deaths per year in the context of a simulated country with 9 million adults, and impact could be enhanced by linkage to voluntary medical male circumcision (VMMC). However, the approach was only cost effective if the programme was limited to 5 years or the undiagnosed prevalence was above 3%. CB-HIVST to WTS was the most cost effective. Main drivers of cost-effectiveness were the cost of CB-HIVST and the prevalence of undiagnosed HIV. All other CB-HIVST scenarios had an ICER above US$500 per DALY averted.

**Conclusions:** CB-HIVST showed an important epidemiological impact. In order to maximise population health within a fixed budget, CB-HIVST needs to be targeted on the basis of the prevalence of undiagnosed HIV, sub-population, and the overall costs of delivering this testing modality. Linkage to VMMC enhances its cost-effectiveness.

**Introduction**

The ambitious UNAIDS targets, set in 2014, of diagnosing 90% of people living with HIV, having 90% of those diagnosed on antiretroviral treatment (ART), and having virological suppression in 90% of those on treatment by 2020 has prompted concerted programmatic efforts and review of progress around these three indicators [1]. The annual volume of HIV tests performed in sub-Saharan Africa (SSA) has more than doubled over ten years.

Based on UNAIDS estimates, awareness of HIV status amongst people living with HIV (PLHIV) continues to increase rapidly, from 45% in 2014 [1] to 75% in 2017 [5]. Recent population-based surveys (2015-17) in Eastern and Southern African countries found that between 52% and 85% of PLHIV were aware of their status [6-11]. These may, indeed, be underestimates, as people tend to under-report HIV diagnosis [12]. Of concern though, despite increases in HIV testing, challenges remain, as men, adolescents (10-19 years) and key populations remain underserved by current testing strategies [13, 14] with lower proportions diagnosed than in the general population [5]. To reach the first 90 target, and possibly the even more ambitious future goals, it will be necessary to implement approaches that reach those in need of HIV testing and who are being missed.

Community-based HIV self-testing (CB-HIVST), defined as the distribution of HIVST by approaches such as home distribution, mobile outreach campaigns, distribution of HIVST at workplaces, bars or educational establishments, is highly acceptable, even to populations otherwise resistant to testing [15]. It provides complementary coverage to other approaches, including reaching people who have never tested before, and is reasonably accurate [16]. CB-HIVST in urban Malawi reached 68% of men aged ≥16 years and 89% of young people (16-29 years) within the first year of implementation [17]. Similar levels of uptake were seen amongst men and young people through CB-HIVST in rural Zimbabwe [18] and slightly lower in a subsequent cluster randomized controlled trial: 46.5% of men and 46.2% of people aged less than 25 [19]. In both Malawi and Zimbabwe approximately a third of those who accessed CB-HIVST reported never testing before [17, 19].

A measure of relevance for all HIV testing models is the proportion of people tested in whom the test result is positive (referred to here as the test positivity rate). CB-HIVST models report test positivity rates of approximately 8% [19] (excluding retesting while taking ART and studies that used late-read, given the issues with the stability of the test results when re-read after 72 hours), whilst facility-based HIVST distribution (excluding studies that used late-read) have found test positivity rates as high as 11% [20] and even higher rates with distribution of HIVST among female sex workers (FSW): 27% in Malawi [20], 30% in Zimbabwe [21]. However, the positivity rate may not correspond to the proportion of tests that actually result in a first diagnosis because re-testing among those previously diagnosed is common in all these studies, albeit that this occurs also with standard HIV testing services (HTS) [22]. The proportion of tests resulting in a first diagnosis has been shown to be an important driver of whether HIVST distribution is cost-effective [24]. As countries get closer to reaching the first “90”, the prevalence of undiagnosed HIV will decline further and test positivity rates of HIV testing models will fall, potentially impacting on whether different HIV testing approaches remain cost-effective.

The HIV Self-Test AfRica (STAR) project recently estimated the unit cost per individual tested across health facilities testing services [25] and CB-HIVST sites in Zimbabwe, Malawi and Zambia (see details in [26]). Using a mathematical model previously used to evaluate the potential cost-effectiveness of HIVST [24], we aimed to identify which HIV epidemic and programmatic attributes and in which populations in SSA CB-HIVST would have the greatest epidemiological impact, and whether CB-HIVST could be cost-effective, using the costs per individual tested estimated in STAR. This builds on another piece of work using the same mathematical model aimed at estimating the cost of HIV testing per diagnosis at which HIV testing programs are cost-effective [27].

**Methods**

*Synthesis Model*

We used an individual-based stochastic model of HIV transmission, progression and the effect of ART in adult populations in SSA. More detailed description of the model can be found in previous papers [24, 27, 28] and in the Supplementary Material. Each time the model program is run, it samples values of variables including the number of short term condomless sex partners, whether they have a long term condomless sex partner, HIV testing, HIV acquisition and additionally, for people with HIV, viral load, CD4 count, use of specific ART drugs, adherence to ART, resistance to specific drugs and risk of HIV-related death, each updated in 3 month time steps from 1989.

The model provides means by which we can quantify the health effects of testing which occur via increases in the proportion of PLHIV on ART, with the consequent beneficial effects on both individual health and onward transmission. This allows estimation of the overall number of disability adjusted life years (DALYs) averted in the whole adult population as a result of these effects. Possible linkage to pre-exposure prophylaxis for people tested negative is not included.

Parameters intrinsic to biological properties of HIV transmission and progression and effects of ART have been informed by data from European cohorts and confirmed by data from Africa, where available, and are kept fixed. We sampled parameter (see distributions in the Supplementary Table 1) values relating to sexual behaviour, HIV transmission, HIV testing (including proportion of the population who is willing to test only if symptomatic or if HIVST is available), linkage to care and retention in care and on ART in order to generate a range of scenarios applicable to different settings in SSA (hereafter referred to as setting-scenarios) in terms of HIV epidemic, HIV testing and ART programme characteristics.

We track a population ) of approximately 20,000 living adults (15-64 years old; increasing over time) which is then scaled up to obtain estimates relevant for a population of around 9 million (in 2018 Zimbabwe 7.8m [29], Malawi 9.8m [30], Zambia 8.2m [31]). We excluded simulations where in 2004 there was an HIV prevalence among women below 5% or above 30% and in 2016 a number of women having condomless transactional sex (defined as having had more than 3 condomless sex partners in a 3 month period in the last year) below 1,460 or above 146,000. These were deemed implausible given the estimates from sentinel antenatal clinics [32] and on the percentage of women who are women having transactional sex (WTS) in SSA [33]. 150 setting-scenarios were obtained. The characteristics of the 150 setting-scenarios in 2017 are presented in Table 1, along with examples of observed data. Details of the model are given in the Supplementary Material.

*Implementation options under consideration*

For each setting-scenario, we projected forward for 50 years from 2018-2068 under seven possible CB-HIVST implementation options (see Table 2). The reference option assumed that the current pattern and level of testing continues, including in WTS, in pregnant women (twice per pregnancy), in people presenting with potential HIV symptoms, and in men presenting for voluntary medical male circumcision (VMMC), but that no CB-HIVST is available. In the other six implementation options, HIVST is introduced through community-based distributors in addition to the current testing in one of the following subpopulations: young people (15-24 years), WTS and adult men (25-49 years). In these implementation options HIVST is assumed to partially replace standard HTS (See Table 2). In our base case, CB-HIVST implementation options involve continuous CB-HIVST availability for the entire timeframe (50 years). We based assumptions on accuracy of CB-HIVST on the overall results for oral fluid HIVST in a systematic review and meta-analysis of HIV self-test performance in field settings, including low- and middle-income countries (sensitivity of 93.9% and specificity of 99.2%) [16]. However, we made the conservative assumption that neither standard HTS nor the CB-HIVST in SSA can detect HIV within three months of infection (the time step in the model). In addition, we assumed that a positive result using a CB-HIVST is not sufficient to make an HIV diagnosis but that a confirmatory test performed by a trained health care worker is required for the person to be diagnosed with HIV and be able to be linked to care and treatment. The main assumptions related to HIVST are summarized in Table 3 (and Supplementary Table 2).

In addition, we considered several sensitivity analyses around the implementation option of CB-HIVST being available for adult men aged 25-49 years: (i) five-year time-limited CB-HIVST programme; (ii) assuming that the increase in the number of tests obtained by introducing CB-HIVST is instead introduced with standard HTS (this was to understand, in case CB-HIVST was not cost-effective, whether this was due to characteristics intrinsic to CB-HIVST or whether any increase in testing is not cost-effective regardless of mode of testing); (iii) assuming that 10% of men with negative CB-HIVST and aged 25-50 link to VMMC and (iv) assuming a discount rate of 10% for both costs and health benefits. In the base case we considered the conventional discounting rate of 3.0% per annum [34].

To reduce stochastic variability, we performed two repetitions of the projections of the population from 2018 for each implementation option in each simulation, except for the options involving WTS, where four repetitions were performed due to the small sample size of this sub-group, or in the 5-year CB-HIVST distribution implementation option, and we calculated the mean across these repetitions.

We assume that all people are eligible for ART at diagnosis from 2017 and that viral load monitoring was used from mid-2016 (at six, twelve months and then annually).

Disability weights to calculate DALYs were derived from a comprehensive study (Conditions included are: TB, WHO 4 and WHO 3) [35].

*Costs and cost-effectiveness approach*

We used the fully loaded average recurrent cost per CB-HIVST estimated in STAR in Zimbabwe and Malawi, respectively US$10.18 and US$5.61 [26] (see further details in the Supplementary Material),

and a cost per person tested for HIV testing performed by a health care worker (except for community-based) ,derived from [37], of respectively US$8.66 for Zimbabwe (US$9.37 if positive), US$4.82 for Malawi (US$5.82 if positive). Other unit costs are provided in the Supplementary Table 3 but, in brief, the annual cost, (including 20% of supply chain costs) of the first-line regimen of efavirenz, lamivudine, tenofovir is US$98 per person [38], programme costs for clinic visits (not including drug or viral load or CD4 count tests) are US$20 per 3 months [39, 40] with an assumed reduction to US$10 per 3 months when viral load is measured to be < 1000 copies/mL [25].

The cost-effectiveness analysis was undertaken from the health provider perspective. Costs were estimated in 2016 US dollars. Health outcomes were quantified in DALYs averted and, as mentioned above, a discount rate of 3% was applied to both costs and health outcomes [34]. We calculated incremental costs and DALYs averted for the CB-HIVST implementation options compared with the reference over a 50-year time horizon, in order to capture all costs and effects relevant to this decision problem. The CB-HIVST implementation option was deemed cost-effective if the incremental cost-effectiveness ratio (ICER) was below US$500 per DALY averted, or if it is resulted in both cost savings and DALYs averted. This use of the cost-effectiveness threshold reflects the health foregone (opportunity costs) due to resources committed to HIV testing consequentially being unavailable to provide other interventions (i.e. so that US$500 reflects the cost-per-DALY-averted of these foregone activities [41, 42]). Severe constraints on overall healthcare spending in low income countries in the region, notably for Malawi [43] mean that this cost-effectiveness threshold is only likely to be relevant for resource allocation within the HIV programme, which is overwhelmingly reliant on donor funds.

**Results**

The characteristics of the 150 setting-scenarios in 2017, before the introduction of the different CB-HIVST implementation policies, are presented in Table 1. Overall, the median (90% range) HIV prevalence across setting-scenarios in 2017 is estimated to be 12.8% (4.7%-27.5%), the prevalence of undiagnosed HIV (ratio between the number of PLHIV who are undiagnosed and the entire population) is 2.1% (0.7% - 4.8%) and the test positivity rate (which in our model corresponds to the proportion of tests resulting in a first diagnosis) is 3.2% (1.1% – 8.3%). As expected, the test positivity is higher for women having condomless transactional sex (18.0%), adult men 15-49 (5.1%) and symptomatic individuals (9.4%). We modelled CB-HIVST introduction in three independent sub-populations: young people (aged 15-24 years) amounting to 3.2 million people in 2017 (35% of people aged 15-64 years), adult men (aged 25-49 years) amounting to 2.3 million men (2.0 – 2.6; 25% of people aged 15-64 years) and WTS (160,000 women; 70,000 – 250,000; 1.8% of people aged 15-64 years).

Table 4 illustrates the scope of implementation and the epidemiological impact of the considered implementation options; with the highest average number of tests required when CB-HIVST is available continuously in the future, people self-test even if not exposed to risk of HIV acquisition (no sex without condom) since last test, and CB-HIVST is available for young people (3,744,000 additional test/year compared to the reference option, +97%). Targeting adult men entails 2,631,300 additional tests/year (+68%) and targeting WTS results in 222,400 additional test/year (+6%). Of note, we assume that similar uptake of CB-HIVST can be achieved nationally as reported for the STAR subnational demonstration projects and cluster randomized trials: respectively 87% in young people, 73% in WTS and 71% in adult men.

In terms of epidemiological impact, in the base case for the implementation options, offering CB-HIVST to adult men has the highest impact, with an average (across setting-scenarios) of 1,500 HIV infections averted per year, followed by targeting of young people (1,490 HIV infections averted per year) and WTS (1,430 HIV infections averted per year). Similarly, deaths averted (in PLHIV and without HIV) are highest when CB-HIVST is targeted at adult men (520 death averted/year), followed by young people (360 death averted/year) and WTS (330 death averted/year). Health benefits from CB-HIVST for adult men are enhanced if 10% of men with negative HIVST in the 25-50-year age-group link to VMMC (1,720 HIV infections averted per year vs 1,500; 580 deaths averted/year vs 520). However, in terms of numbers-needed-to-test to avert one new HIV infection, targeting WTS is by far the most efficient strategy requiring 160 additional tests per HIV infection averted, compared to 2,500 for young people and 1,750 for adult men. For deaths, the equivalent numbers of additional tests are 670 per death averted for strategies targeting WTS, compared to 10,460 for young people and 5,060 for adult men. Numbers of additional tests needed are almost halved for young people if CB-HIVST is taken up only if they have had condomless sex since their last test. Similarly, five-year time-limited CB-HIVST programme only reduces the number of additional tests per HIV infection averted and per death averted to 180 and 710, respectively.

Figure 1 shows the cost per DALY averted (compared to the reference option) using a 50- year timeframe and two sets of costs for CB-HIVST and HTS for the base case scenarios (assuming a maximum of one standards HTS annually, but regardless of sexual risk-taking) and for several sensitivity analyses. The cost per DALY averted using a 20-year timeframe is illustrated in Supplementary Figure 1. In addition, variation in CB-HIVST cost-effectiveness in different settings is considered by stratifying simulations by prevalence of undiagnosed HIV (quartiles). The timeframe considered has a crucial impact on cost-effectiveness: under the 50-year timeframe introduction of CB-HIVST is cost-effective if introduced among WTS (whether the use is limited to when having condomless sex or not), for five-year programme among adult men (unless the prevalence of undiagnosed HIV is below ~1% and cost per CB-HIVST is US$10.18) and among adult men provided that the prevalence of undiagnosed HIV is relatively high (> 3% if cost per CB-HIVST is US$5.61, > 5.5% if US$10.18). However, when considering a 20-year time horizon, it is cost-effective only when offered to WTS in setting with a prevalence of undiagnosed HIV above 3.7% and if the cost of CB-HIVST is relatively low ($5.61). The cost of delivering CB-HIVST, not surprisingly, plays a crucial role in determining the ICER. Applying higher discounting rates of 10% to additional costs and health benefits rendered CB-HIVST among adult men not cost-effective regardless of the prevalence of undiagnosed HIV.

**Discussion**

CB-HIVST offers the opportunity to reduce the “testing gap” in men, young people and WTS: sub-groups that are hard to reach with standard HIV testing services. Here we show that, when health benefits and costs are considered over a relatively long time horizon, targeted CB-HIVST can be cost-effective using strategies that vary by the prevalence of undiagnosed HIV. The most efficient approaches are targeted to WTS, which remain cost-effective at all levels of prevalence of undiagnosed HIV in our setting scenarios (~1% to 5.6%). A five-year time-limited CB-HIVST programme can also be cost-effective for adult men, at all levels when using cost for the CB-HIVST of US$5.61 and at levels of prevalence of undiagnosed HIV above 1% when using CB-HIVST cost of US$10.18. This is due to the fact that by considering an intervention that lasts for only 5 years, the cost is reduced substantially and the HIV testing earlier in time is more beneficial as the undiagnosed prevalence is declining over time. Indefinite introduction of CB-HIVST for adult men is cost-effective only at relatively high initial prevalence of undiagnosed HIV, depending on the cost of CB-HIVST. When considering CB-HIVST in WTS, it is important to note that we have assumed the same cost per person tested as in the other populations in which implementation was considered. Data on these costs have been collected as part of the STAR project but final estimates are not available yet.

Current estimates of the prevalence of undiagnosed HIV from national surveys range from 0.3% in Rwanda [44] to 4% in Zimbabwe [10] and Zambia [9] with considerable variation also within countries. For example, in Zimbabwe estimates range from 2.9% in Manicaland to 5.8% in Matabeleland South [10] and in Zambia from 1.9% in Muchinga to 5.3% in Lusaka [9]. Thus, health benefits from investments at national level can be maximised through implementation of different HIVST strategies in different geographical regions [45, 46]. The corollary of this argument is that implementers may need to limit CB-HIVST efforts, potentially through periodic campaign style implementation, in settings with very low HIV awareness, as the benefits of testing people with very low probability of being infected will be limited. Community-based distribution of HIVST kits can take place in different ways and this partly drives the differences in costs seen in Zimbabwe compared to Malawi. The costs of government implementation CB-HIVST may be lower than estimated in the STAR project [26] and we anticipate that delivery costs will continue to fall due to economies of scale and efficiencies from increasing familiarity with this concept. This would increase the likelihood of HIVST programmes being cost-effective. However, the issue of “diminishing returns” will reduce the cost-effectiveness of all HIV testing strategies as the prevalence of undiagnosed HIV falls. In the context of declining undiagnosed prevalence, programme metrics such as the cost-of-testing-per-new-HIV-diagnosis have potential use for monitoring programme cost-effectiveness and in other work we have described approaches to link this metric to programme cost-effectiveness [27].

Secondary distribution models, where HIVST kits are distributed to sexual partners of WTS or pregnant women, which have high positivity rates and similar delivery costs [47, 48], are likely to offer cost-effective approaches to distributing HIVST [49]. Additionally, improving linkage of those who test HIV-negative to HIV prevention services may improve cost-effectiveness. In our sensitivity analysis, we explored the possibility that 10% of men with a negative CB-HIVST result are linked into VMMC and show that this would improve the benefits and cost-effectiveness of CB-HIVST targeted to men (considering the additional cost of VMMC). While not included in the scenarios modelled, the addition of linkage to pre-exposure prophylaxis could also enhance impact of HIVST.

Previous cost-effectiveness analysis of adding CB-HIVST to existing testing services are available from urban Blantyre, Malawi [50] and for secondary distribution models delivering self-testing kits to sexual partners of antenatal clinic attendees in South Africa [49]. The Blantyre study was in a setting of high HIV prevalence and high levels of undiagnosed and untreated PLHIV and assumed constant HIV incidence. That analysis concluded that over a 20-year time horizon adding CB-HIVST to facility-based testing was cost-effective and was suited to early ART initiation strategies. In the South African study, secondary distribution of self-testing kits to partners of pregnant women became cost-saving when considering the total cost of the HIV programme, although expenditure by the testing-programme was increased. These findings concur with our current analysis, that community-based strategies targeting a large group of the population, such as young people and adult men, achieve the greatest population level-impact in terms of proportion diagnosed, but are not very cost-effective, unless the prevalence of undiagnosed HIV is relatively high.

This work has limitations. As for any economic evaluation which takes an appropriately long-time horizon we rely on a mathematical model to give predictions of the long-term impact of the alternative implementation options. We consider the implementation in three specific groups, which are either underserved by current testing approaches or characterized by a high incidence, but we could have considered slightly different groups.

**Conclusions**

CB-HIVST provides a new option for reaching relatively underserved sub-populations and can provide health benefits cost-effectively if targeted to WTS, as well as adult men for a limited time. The prevalence of undiagnosed HIV, assumptions relating to linkage to prevention post-HIVST and the cost of CB-HIVST are then critical in determining whether or not wider intervention strategies, which have higher potential benefits but also much higher costs, should be introduced.

**Table 1.** Characteristics of the HIV epidemic / ART programme setting-scenarios in 2017 in SSA countries with an adult population age 15-64 y approximately 9 million.

|  |  |  |
| --- | --- | --- |
| **Indicator** | **Median (90% range) across**  **Setting-scenarios (n = 150)** | **Examples of observed data** |
| Population size (in million)  Overall 15-64 y  Women 15-49 y  Men 15-49 y  Young (15-24 y)  Adult men (25-49 y)  WTS 15-64 y | 9.1 (8.2 – 9.9)  4.1 (3.8 – 4.3)  3.9 (3.6 – 4.1)  3.2 (3.1 – 3.2)  2.3 (2.0 – 2.6)  0.16 (0.07 – 0.25) | Zimbabwe 15-64 (2018): 7.8m [29]  Malawi 15-64 (2018): 9.8m [30]  Zambia 15-64 (2018): 8.2m [31]  Lesotho 15-64 (2018): 1.2m [51] |
| HIV prevalence  Overall 15-49 y  Women 15-49 y  Men 15-49 y | 12.8% (4.7% – 27.5%)  13.0% (4.5% – 29.4%)  12.6% (5.0% – 23.3%) | Zimbabwe DHS 2015 [14]:14%  Tanzania DHS 2011 [52]: 5%  Uganda DHS 2011 [53]: 9%  Lesotho DHS 2014 [54]: 25% |
| Prevalence of undiagnosed HIV  Overall 15-64 y  Women 15-49 y  Men 15-49 y | 2.1% (0.7% - 4.8%)  1.2% (0.4% - 3.5%)  3.3% (1.0% - 7.0%) | Malawi PHIA 2016 [7]: 2.9%  Zimbabwe PHIA 2016 [10]: 3.8%  Zambia PHIA 2016 [9]: 4.0%  Rwanda [44]: ~ 0.3%  (Survey estimates could be over-estimates due to undisclosed diagnosed HIV [12]) |
| HIV incidence (age 15-49 y) per 100 person years | 0.91 (0.23 – 2.19) | Malawi PHIA 2016 [7]: 0.37%  Zimbabwe PHIA 2016 [10]: 0.45%  Zambia PHIA 2016 [9]: 0.66%  Swaziland [11]: 2.4%  Lesotho [6]: 1.5%  Mbongolwane and Eshowe published in 2014 (KZN) [55]: 1.2% |
| Number of HIV tests in year  Overall 15-64 y  Women 15-49 y  Men 15-49 y  ANC services  WTS 15-64  Symptomatic (PLHIV)†  Symptomatic (HIV-)  VMMC services | 2,300,000 (1,293,000 – 3,327,000)  1,485,000 ( 708,000 – 2,271,000)  796,000 ( 461,000 – 1,072,000)  721,000 ( 96,000 – 1,595,000)  78,000 ( 30,000 – 142,000)  22,000 ( 8,000 – 47,000)  181,000 ( 160,000 – 200,000)  150,000 ( 114,000 – 189,000) | Zimbabwe 2.2m (2015) [2], Malawi 1.9m (2014) [4] |
| Percentage of tests resulting in new HIV diagnosis‡  Overall 15-64 y  Women 15-49 y  Men 15-49 y  Young (15-24 y)  ANC services  WTS 15-64 y  Symptomatic  VMMC services | 3.2% (1.1% - 8.3%)  2.4% (0.7% - 6.3%)  5.1% (1.6% - 11.3%)  2.2% (0.4% - 5.7%)  2.9% (0.6% - 17.5%)  18.0% (3.3% - 35.1%)  9.4% (3.5% - 18.2%)  3.2% (0.6% - 6.9%) | Observed data Estimates are susceptible to bias due to re-diagnosis of people who do not report previous diagnosis. 6%-55% depending on group [56]  Malawi 1st quarter 2016 [57]: 5% |
| Proportion tested in past year  Women 15-49 y  Men 15-49 y  Women 15-24 y  Men 15-24 y  When Symptomatic (PLHIV) §, †  In pregnancy 15-49 y  WTS 15-64 y | 29% (15% - 41%)  19% (12% - 27%)  25% (11% - 38%)  17% (11% - 23%)  16% ( 9% - 24%)  93% (30% - 98%)  39% (22% - 52%) | Zimbabwe DHS 2015 [14]: 49% women, 36% men (age 15-49 y)  Namibia DHS 2013 [58]: 49% women, 38% men (age 15-49 y)  Nigeria DHS 2013 [59]: 10% women, 10% men x |
| Proportion of HIV positive people diagnosed  Overall 15-64 y  Women 15-49 y  Men 15-49 y  Women 15-24 y  Men 15-24 y  WTS 15-64 y | 83% (73% - 90%)  90% (79% - 95%)  74% (61% - 85%)  79% (56% - 88%)  43% (26% - 57%)  75% (58% - 87%) | Malawi PHIA 2016 [7]: 73%; 76% in women, 67% in men  Zimbabwe PHIA 2016 [10]: 74%  Zambia PHIA 2016 [9]: 67%  Mbongolwane and Eshowe [KZN] published in 2014 [55]: 75%  District of Chiradzulu (rural Malawi) 2013 [60]: 77%  Botswana 2013-2015 [61]: 78%, higher in women than men  Survey estimates likely to be over-estimates due to undisclosed diagnosed HIV [12] |
| Proportion of diagnosed people on ART  Overall 15-64 y  Women 15-49 y  Men 15-49 y  Women 15-24 y  Men 15-24 y  WTS 15-64 y | 88% (59% - 92%)  89% (59% - 92%)  87% (56% - 91%)  89% (42% - 93%)  79% (33% - 91%)  90% (50% - 94%) | Malawi PHIA 2016 [7]: 89%  Zimbabwe PHIA 2016 [10]: 87%  Zambia PHIA 2016 [9]: 85%  Botswana 2013-15 [61]: 85% |
| Proportion of people on ART with VL < 1000 cps/mL  Overall 15-64 y | 85% (81% - 89%) | World Bank South Africa [62]: 60%-88% over districts  Malawi PHIA 2016 [7]: 91%  Zimbabwe PHIA 2016 [10]: 87%  Zambia PHIA 2016 [9]: 89%  District of Chiradzulu (rural Malawi) 2013 [60]: 91%  Mbongolwane and Eshowe (KZN) published in 2014 [55]: 90%  Rural Uganda and Kenya [63]: 90%  Botswana 2013-15 [61]: 94% (among citizens of Botswana) |

† symptoms of a WHO stage 3 or 4 condition; ‡This is also referred to as yield. In our model this is the same as test positivity rate as within the Synthesis model people who received a diagnosis of HIV cannot test again, so this is the ratio between the number of new diagnoses and the number of tests performed; §in this case is not in the past year but of those symptomatic/pregnant in a specific time period;

# ANC: antenatal care; ART: antiretroviral therapy; DHS: Demographic and Health Surveys; KZN: KwaZulu-Natal; PHIA: Population-based HIV Impact Assessment; PLHIV: people living with HIV; VMMC: voluntary male medical circumcision; WTS: women having transactional sex.

**Table 2. Implementation options**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Core testing** | **Population in which CB-HIVST is available** | **Possibility of using CB-HIVST if no CLS since last test** | **Replacement of HTS with CB-HIVST** |
| Ref | Current level of testing continues, in particular testing in:   * general population (including WTS) * in pregnant women (twice per pregnancy) * in people presenting with potential HIV symptoms * in men presenting for VMMC | None | Not applicable | Not applicable |
| 1 | young people (15-24 years) | Yes† | 30%§ |
| 2 | adult men (25-49 years) | 30%§ |
| 3 | WTS (15-64 years) | 50%¶ |
| 4 | young people (15-24 years) | No‡ | 30%§ |
| 5 | adult men (25-49 years) | 30%§ |
| 6 | WTS (15-64 years) | 50%¶ |

CB-HIVST: community-based HIV self-testing; CLS: condomless sex; HTS: HIV testing services; PLHIV: people living with HIV; VMMC: voluntary medical male circumcision; WTS: women reporting transactional sex;

†^ They can HIVST only once per year, but they can HIVST even if they had HTS in the last year (% self-tested per year indicated in Table 4); ‡^^They can use HIVST only if they had condomless sex since last test (HTS or CB-HIVST) but they can test more than once per year if having CLS.

§Study offered standard HTS or HIVST and 30.9% men opted for HIVST [64]

¶54% of women who attended a FSW clinic where provider initiated testing and counselling was available (n=604) and were offered HIVST opted for it [21]. Higher rate of substitution has been reported as well [65, 66]

**Table 3. Assumptions on CB-HIVST**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value assumed for base case** | **Source** |
| Sensitivity of CB-HIVST | 93.9% | [16] |
| Specificity of CB-HIVST | 99.2% | [16] |
| Sensitivity of HTS† | 98% | [67] |
| Specificity of HTS† | 99.2% | [68] |
| Confirmatory HTS following positive CB-HIVST | 50% by 3 months,  78% by 1 year from positive CB-HIVST. ‡ | At 6 weeks: 50% in the arm without incentive after excluding those re-testing on ART [19]  Evidence on disclosure from [17] and % self-reported linking to care in STAR |
| Proportion initiated on ART of those who had a positive (not previously diagnosed) CB-HIVST | 36% by 3 months§ | At 6 week: 30% in the arm without incentive after excluding those re-testing on ART [19] |
| Change in condomless sex in those who are tested HIV+ by HTS | with long-term partner: none,  with short-term partner: -17% in the first 6 months, -9% after | [69, 70] |
| Change in condomless sex in those tested HIV- by HTS | No change | [71]  Among FSW no difference in condom use, but reduction in number of partners following HIVST at 4 months  [72] |
| Change in condomless sex after CB-HIVST (and before any confirmation with HTS) | No change | Among FSW no difference in condom use, but reduction in number of partners following HIVST at 4 months [72] |

ART: antiretroviral therapy; CB-HIVST: community-based HIV self-testing; HTS: HIV testing services;

†assumed as facility based rapid diagnostic test; ‡ It is assumed that people can have a confirmatory test as a consequence of a positive CB-HIVST only within 1 year of the positive CB-HIVST. § This is the median proportion initiated on ART at 3 months; the probability of initiating ART in people engaged to care is 0.8 per 3 months; for people diagnosed with HIV not linked to care by 3 months since diagnosis there is a probability of linkage to care (or re-engaging into care if lost) per 3 months which is sampled from a distribution 0.1 (90% range: 0.03-0.32).

**Table 4.** Mean over 50 years (2018-2068) of intermediate measures describing the implementation and the epidemiological impact of the options considered (across 150 setting-scenarios).

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Implementation option** | **Sub-population receiving HIVST** | **Number of HIV tests (HTS or HIVST) / year - age 15-64 y(additional test compared to no intervention, relative increase)** | **Number of new diagnoses per year (age 15-49 y)** | **Number of new diagnoses per year in the subpopulation of interest** | **% tested in the past year (HTS or HIVST; age 15-49 y)** | **% tested in the past year in the subpopulation of interest** | **% self-tested in the past year (age 15-49 y)** | **% self-tested in the past year in the subpopulation of interest** | **% ever tested (HTS or HIVST; age 15-49 y)** | **% ever tested (HTS or HIVST) in the sub-population of interest** |
| No Intervention  HIVST is available – no requirement for CLS - base case  HIVST is available – requirement for CLS  HIVST is available, next 5 years  HIVST is available - as good as HTS  HIVST is available – linkage to VMMC | NA  Young people  WTS  Adult men  Young people  WTS  Adult men  Adult men  Adult men  Adult men | 3,860,300 (-)  7,604,300 (3,744,000,+97%)  4,082,800 ( 222,400, +6%)  6,481,600 (2,621,300,+68%)  5,947,900 (2,087,600,+54%)  4,088,400 ( 228,100, +6%)  6,150,400 (2,290,000,+59%)  4,082,800 ( 222,400, +6%)  6,457,200 (2,596,900,+67%)  6,485,800 (2,625,500,+68%) | 58,500  55,500  55,000  57,800  55,300  54,700  57,100  55,700  58,200  57,100 | Young: 16,500  WTS: 15,400  Adult men: 22,900  18,900  16,300  24,700  17,900  15,900  23,800  21,800  25,200  24,200 | 25%  51%  26%  42%  30%  26%  33%  27%  42%  42% | Young: 21%  WTS: 39%  Adult men: 21%  91%  86%  76%  35%  58%  47%  27%  75%  76% | 0%  35%  2%  24%  10%  1%  12%  3%  24%  24% | Young: 0%  WTS: 0%  Adult men: 0%  87%  73%  71%  24%  39%  35%  7%  70%  71% | 74%  98%  79%  81%  78%  78%  78%  79%  81%  81% | Young: 50%  WTS: 85%  Adult men: 82%  99%  99%  99.6%  54%  86%  90%  93%  99.6%  99.6% |

# CB-HIVST: community-based HIV self-test; CLS: condomless sex; HTS: HIV testing services; NA: not applicable; VL: viral load; VMMC: voluntary medical male circumcision; WTS: women having transactional sex;

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Implementation option** | **Sub-population receiving HIVST** | **% who never tested before, out of those who use HIVST for the 1st time** | **% of HIVST resulting in a diagnosis (referred to as positivity rate; age 15-49 y)** | **% of HIV positive people diagnosed (age 15-49 y)** | **% of HIV positive people diagnosed in the sub-population of interest** | **% of people with HIV and VL > 1000 (out of the entire population; age 15-64 y)** | **Number of condomless (short term and long term) infectious partnership** | **Number of people living with HIV with VL > 1000 copies/mL.** | **Number of deaths per year (averted compared to the no intervention)** | **Number of HIV infections per year (averted compared to the no intervention)** | **Number of additional tests per HIV infection averted (per death averted)** |
| No Intervention  HIVST is available – no requirement for CLS – base case  HIVST is available – requirement for CLS  HIVST is available, next 5 years  HIVST is available - as good as HTS  HIVST is available – linkage to VMMC | NA  Young people  WTS  Adult men  Young people  WTS  Adult men  Adult men  Adult men  Adult men | NA  97%  34%  21%  20%  6%  3%  25%  21%  21% | NA  0.28%  2.92%  0.80%  0.61%  3.42%  1.03%  1.31%  0.92%  0.78% | 86%  89%  88%  91%  88%  88%  90%  88%  93%  92% | Young: 67%  WTS: 74%  Adult men: 80%  84%  81%  94%  77%  81%  91%  84%  96%  94% | 3.2%  2.8%  2.9%  2.7%  2.9%  2.9%  2.8%  2.9%  2.7%  2.7% | 944,500  871,800  875,900  876,800  882,700  866,700  884,200  907,700  874,400  879,300 | 416,900  367,900  380,700  351,700  376,800  380,500  361,000  384,000  346,900  348,700 | 43,300 (-)  43,000 (360)  43,000 (330)  42,800 (520)  43,000 (340)  43,000 (340)  42,900 (460)  43,000 (310)  42,800 (550)  42,800 (580) | 17,560 (-)  16,060 (1,500)  16,130 (1,430)  16,060 (1,500)  16,160 (1,400)  16,040 (1,520)  16,100 (1,460)  16,340 (1,220)  15,970 (1,590)  15,830 (1,730) | - (-)  2,500 (10,460)  160 ( 670)  1,750 ( 5,060)  1,490 ( 6,070)  150 ( 660)  1,570 ( 4,960)  180 ( 710)  1,640 ( 4,760)  1,520 ( 4,530) |

# CB-HIVST: community-based HIV self-test; CLS: condomless sex; HTS: HIV testing services; NA: not applicable; VL: viral load; VMMC: voluntary medical male circumcision; WTS: women having transactional sex;

**Figure 1. Cost per DALY averted of community-based HIVST by implementation option, prevalence of undiagnosed HIV (quartile) and cost of testing in the sub-population indicated - 2018-2068**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **ICER, Mean Cost per DALY averted (Additional cost in US$ million /DALYs averted in 1,000s)** | | | | | | | | | |
|  | | **High cost of CB-HIVST (US$10.18) and HTS**  **(US$8.66 if negative; US$9.37 if positive)** | | | | | **Low Cost of CB-HIVST (US$5.61) and HTS**†  **(US$4.82 if negative; US$5.82 if positive)** | | | | |
| **Overall** | **Prevalence of undiagnosed HIV** | | | | **Overall** | **Prevalence of undiagnosed HIV** | | | |
| **0.3 - 1.6%** | **1.6 – 2.4%** | **2.4 – 3.7%** | **3.7 – 7.4%** | **0.3 - 1.6%** | **1.6 – 2.4%** | **2.4 – 3.7%** | **3.7 – 7.4%** |
| **HIVST is available – no requirement for CLS (base case)** | **Young** | 2,000 (943/483) | 5,400  (965/177) | 2,800  (947/339) | 1,700  (950/574) | 1,100  (913/837) | 1,100 (528) | 3,100  (545) | 1,600  (529) | 930  (535) | 600  (504) | |
| **WTS** | 120  (51/412) | 380  (75/201) | 220  (64/290) | 100  (53/517) | 20  (12/638) | 60  (27) | 260  (53) | 140  (40) | 50  (28) | -20  (-13) | |
| **Adult men** | 880  (693/786) | 2,700  (732/267) | 1,200  (700/605) | 770  (700/908) | 470  (642/1,352) | 520  (410) | 1,600  (421) | 670  (405) | 470  (426) | 290  (388) | |
| **Sensitivity analyses** | | | | | | | | | | | | |
| **HIVST is available – requirement for CLS** | **Young** | 1,200  (515/419) | 3,000  (488/161) | 1,700  (492/282) | 980  (487/498) | 810  (590/730) | 680  (286) | 1,700  (282) | 970  (274) | 560  (277) | 430  (311) | |
| **WTS** | 110  (45/410) | 370  (72/196) | 210  (62/293) | 70  (36/525) | 20  (10/622) | 50  (20) | 260  (51) | 130  (38) | 20  (13) | -30  (-20) | |
| **Adult men** | 930  (591/636) | 2,500  (568/226) | 1,100  (580/540) | 750  (549/729) | 640  (665/1,039) | 550  (347) | 1,500  (330) | 620  (336) | 450  (331) | 370  (389) | |
| **HIVST is available for the next 5 years** | **Adult men** | 230  (115/502) | 690  (142/205) | 310  (121/388) | 220  (122/559) | 90  (77/851) | 150  (74) | 470  (95) | 200  (78) | 150  (83) | 50  (40) | |
| **HIVST is available - as good as HTS** | 680  (594/869) | 1,800  (612/335) | 970  (602/621) | 560  (605/1,091) | 390  (560/1,420) | 410  (359) | 1,100  (354) | 580  (358) | 350  (379) | 240  (346) | |
| **HIVST is available – linkage to VMMC**‡ | 780  (693/887) | 2,000  (739/367) | 1,100  (705/665) | 660  (693/1,052) | 440  (634/1,455) | 460  (410) | 1,200  (427) | 620  (411) | 400  (419) | 260  (379) | |
| **Base case – 10% discounting rate** | 1,600  (250/154) | 4,400  (257/59) | 2,200  (250/116) | 1,400  (251/181) | 940  (243/259) | 1,000  (159) | 2,600  (155) | 1,300  (154) | 900  (163) | 630  (162) | |

•Cost-saving; •ICER $0-$249 per DALY; •ICER $250-$499 per DALY; •ICER $500-$999 per DALY; •ICER $1,000-$2,499 per DALY; •ICER ≥$2,500 per DALY;

†DALYs averted not reported when showing the ICERs using the cost of CB-HIVST of $5.61 and HTS of $4.82, as the same regardless of the costs assumed; ‡10% of men with negative HIVST and aged 25-50 link to circumcision;

CB-HIVST: community-based HIVST; DALY: disability-adjusted life years; HIVST: HIV self-test; HTS: HIV testing services; ICER: incremental cost-effectiveness ratio; VMMC: voluntary medical male circumcision; WTS: women having transactional sex;

**Recommendations**

* Targeting adult men with community-based HIV self-testing (CB-HIVST) tends to allow aversion of a large number of infections as this is a large group which is currently under tested.

• Linkage to voluntary medical male circumcision (VMMC) following a negative HIVST should be considered as this can enhance the impact.

• Providing CB-HIVST to women having transactional sex (WTS) offers the best value for money and should be implemented.

• The introduction of CB-HIVST among adult men is cost-effective, provided that the undiagnosed HIV prevalence is above 3% or the distribution programme is limited to 5 years duration. Shortening the intervention period improves the cost-effectiveness because as we continue testing at the same rate the test positivity rate declines while the cost (except for discounting) remains the same.

• At its current cost, introduction of CB-HIVST among young people does not offer value for money.

• When deciding whether to implement CB-HIVST the overall cost of CB-HIVST (not only the kit cost) should be considered as well as the current prevalence of undiagnosed HIV.

**Conflict of Interest Statement**The authors declare that they have no competing interests.

**Authorship**

VC, CJ, KH, FTP, FC, PR, LC, AP made substantial contributions to formulation of the research question and conception of the study. VC and AP worked on development and programming of the HIV synthesis model. VC did the modelling analysis. VC and AP analysed the simulations. VC, CJ, KH, FTP, HM, TH, CF, FC, ES, GN, PR, RCB, LC, AP have been involved in drafting the manuscript or revising it critically for important intellectual content. All authors have given final approval of the version to be published.

**Acknowledgments**

The STAR Initiative is funded by Unitaid.

We thank the UCL Legion High Performance Computing Facility (Legion@UCL);

1. The Joint United Nations Programme on HIV/AIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic. Geneva; 2014.

2. Republic of Zimbabwe. Global AIDS Response progress report 2016. Zimbabwe Country Report - Reporting Period: January 2015 ‐December 2015. Harare, Zimbabwe; 2016.

3. [Malawi] Ministry of Health. Annual Report from HIV/AIDS Clinical Unit, MOH: January – December, 2004.

4. Government of Malawi. Malawi AIDS Response Progress Report 2015. 2015.

5. The Joint United Nations Programme on HIV/AIDS. Miles to go: closing gaps, breaking barriers, righting injustices. Geneva; 2018.

6. ICAP at Columbia University. Lesotho population-based HIV impact assessment LePhia 2016–2017. 2017.

7. ICAP at Columbia University. Malawi population-based HIV impact assessment MPHIA 2015–2016. 2016.

8. ICAP at Columbia University. PHIA Project [Available from: <http://phia.icap.columbia.edu/resources/>.

9. ICAP at Columbia University. Zambia population-based HIV impact assessment ZAMPHIA 2015–2016. 2016.

10. ICAP at Columbia University. Zimbabwe population-based HIV impact assessment ZIMPHIA 2015–2016. 2016.

11. Justman J, Reed JB, Bicego G, Donnell D, Li K, Bock N, et al. Swaziland HIV Incidence Measurement Survey (SHIMS): a prospective national cohort study. Lancet HIV. 2017;4(2):e83-e92.

12. Kim AA, Mukui I, Young PW, Mirjahangir J, Mwanyumba S, Wamicwe J, et al. Undisclosed HIV infection and antiretroviral therapy use in the Kenya AIDS indicator survey 2012: relevance to national targets for HIV diagnosis and treatment. AIDS. 2016;30(17):2685-95.

13. National Statistical Office (NSO) [Malawi] and ICF. Malawi Demographic and Health Survey 2015-16. Zomba, Malawi, and Rockville, Maryland, USA; 2017.

14. Zimbabwe National Statistics Agency and ICF International. Zimbabwe Demographic and Health Survey 2015: Final Report. Rockville, Maryland, USA: Zimbabwe National Statistics Agency (ZIMSTAT) and ICF International; 2016.

15. Figueroa C, Johnson C, Verster A, Baggaley R. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav,. 2015;19(11):1949-65.

16. Figueroa C, Johnson C, Ford N, Sands A, Dalal S, Meurant R, et al. Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis. Lancet HIV. 2018.

17. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. Plos Med. 2015;12(9):e1001873.

18. Sibanda EL, Mutseta M, Hatzold K, Gudukeya S, Dhliwayo A, Lopez C, et al. Community-based distribution of HIV self-test kits: results from a pilot of door-to-door distribution of HIV self-test kits in one rural Zimbabwean community. 21st International AIDS Conference; 2016 Jul 18–22; Durban, South Africa.

19. Sibanda E, Neuman M, Tumushime M, Hatzold K, Watadzaushe C, Mutseta MN, et al. Linkage to care after HIV self-testing in Zimbabwe: a cluster-randomized trial. 25th Conference on Retroviruses and Opportunistic Infections; 2018 Mar 4-7; Boston, USA.

20. Mutseta M. Impact of HIVST on uptake of HIV testing, Experiences from the STAR Project in Malawi, Zambia and Zimbabwe. 9th International AIDS Society Conference on HIV Pathogenesis and Treatment; 2017 Jul 23-26; Paris, France.

21. Mavedzenge S, Sibanda E, Dirawo J, Hatzold K, Mugurungi O, Cowan F. Feasibility of HIV self-test programming among female sex workers in Zimbabwe. 9th International AIDS Society Conference on HIV Science; 2017 Jul 23-26; Paris, France.

22. Johnson CC, Fonner V, Sands A, Ford N, Obermeyer CM, Tsui S, et al. To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status. Journal of the International Aids Society. 2017;20.

23. Moore A, Cassidi T, Steele SJ, Shroufi A, Ntuli N, Ndani L, et al. Self-testing: an effective means of increasing HIV-testing and status awareness. 9th International AIDS Society Conference on HIV Pathogenesis and Treatment (IAS 2017); 2017 Jul 23-26; Paris, France.

24. Cambiano V, Ford D, Mabugu T, Napierala Mavedzenge S, Miners A, Mugurungi O, et al. Assessment of the potential impact and cost-effectiveness of self-testing for HIV in low-income countries. J Infect Dis. 2015;212(4):570-7.

25. Working Group on Modelling of Antiretroviral Therapy Monitoring Strategies in Sub-Saharan A. Sustainable HIV treatment in Africa through viral-load-informed differentiated care. Nature. 2015;528(7580):S68-76.

26. Mangenah C, Mwenge L, Sande L, Ahmed N, d’Elbée M, Chiwawa P, et al. Economic cost analysis of community-based distribution of HIV self-test kits in Malawi, Zambia and Zimbabwe. Journal of the International Aids Society. accepted.

27. Phillips A, Cambiano V, Bansi‐Matharu L, Nakagawa F, Wilson D, Jani I, et al. Cost‐of‐testing‐per‐new‐HIV‐diagnosis as a metric for monitoring cost‐effectiveness of testing programmes in low income settings in Southern Africa: health economic modelling analysis. 22nd International AIDS Conference; 2018 Jul 23-27; Amsterdam, The Netherlands.

28. Phillips AN, Cambiano V, Nakagawa F, Revill P, Jordan MR, Hallett TB, et al. Cost-effectiveness of public-health policy options in the presence of pretreatment NNRTI drug resistance in sub-Saharan Africa: a modelling study. Lancet HIV. 2018;5(3):e146-e54.

29. Central Intelligence Agency. The World Factobok - Zimbabwe 2018 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/zi.html>.

30. Central Intelligence Agency. The World Factobok - Malawi 2018 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/mi.html>.

31. Central Intelligence Agency. The World Factobok - Zambia 2018 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/za.html>.

32. UNAIDS. Evidence for HIV decline in Zimbabwe : a comprehensive review of the epidemiological data.; 2005.

33. Vandepitte J, Lyerla R, Dallabetta G, Crabbe F, Alary M, Buve A. Estimates of the number of female sex workers in different regions of the world. Sex Transm Infect. 2006;82 Suppl 3:iii18-25.

34. Wilkinson T, Sculpher MJ, Claxton K, Revill P, Briggs A, Cairns JA, et al. The International Decision Support Initiative Reference Case for Economic Evaluation: An aid to thought. Value in Health. 2016;19(8):7.

35. Salomon JA, Vos T, Hogan DR, Gagnon M, Naghavi M, Mokdad A, et al. Common values in assessing health outcomes from disease and injury: disability weights measurement study for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2129-43.

36. Unitaid, Organization WH. Market and technology landscape: HIV rapid diagnostic tests for self-testing. 4th Edition. Geneva: Unitaid; 2018.

37. Mwenge L, Sande L, Mangenah C, Ahmed N, Kanema S, d’Elbée M, et al. Costs of facility-based HIV testing in Zambia, Malawi and Zimbabwe. PLoS ONE 2017;10(12):e0185740.

38. Clinton Health Access Initiative. ARV Market report; The state of the antiretroviral drug market in low- and middle-income countries, 2016-2021. 2017.

39. Tagar E, Sundaram M, Condliffe K, Matatiyo B, Chimbwandira F, Chilima B, et al. Multi-country analysis of treatment costs for HIV/AIDS (MATCH): Facility-level ART unit cost analysis in Ethiopia, Malawi, Rwanda, South Africa and Zambia. Plos One. 2014;9(11).

40. Siapka M, Remme M, Obure CD, Maier CB, Dehne KL, Vassall A. Is there scope for cost savings and efficiency gains in HIV services? A systematic review of the evidence from low- and middle-income countries. B World Health Organ. 2014;92(7):499-511.

41. Woods E, Revill P, Sculpher M, Claxton K. Country-level cost-effectiveness thresholds: initial estimates and the need for further research. University of York; 2010. Contract No.: 109.

42. Claxton K, Walker S, Palmer S, Sculpher M. Appropriate Perspectives for Health Care Decisions. 2010(54).

43. Ochalek JM, Claxton KP, Revill P, Sculpher M, Rollinger A. Supporting the development of an essential health package: principles and initial assessment for Malaw. York, UK: University of York; 2016. Contract No.: 136.

44. Nsanzimana S, Remera E, Kanters S, Mulindabigwi A, Suthar AB, Uwizihiwe JP, et al. Household survey of HIV incidence in Rwanda: a national observational cohort study. Lancet HIV. 2017;4(10):e457-e64.

45. Anderson SJ, Cherutich P, Kilonzo N, Cremin I, Fecht D, Kimanga D, et al. Maximising the effect of combination HIV prevention through prioritisation of the people and places in greatest need: a modelling study. Lancet. 2014;384(9939):249-56.

46. McGillen JB, Anderson SJ, Dybul MR, Hallett TB. Optimum resource allocation to reduce HIV incidence across sub-Saharan Africa: a mathematical modelling study. Lancet HIV. 2016;3(9):e441-e8.

47. Thirumurthy H, Masters SH, Mavedzenge SN, Maman S, Omanga E, Agot K. Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. Lancet HIV. 2016;3(6):e266-74.

48. Masters SH, Agot K, Obonyo B, Napierala Mavedzenge S, Maman S, Thirumurthy H. Promoting partner testing and couples testing through secondary distribution of HIV self-tests: A randomized clinical trial. Plos Med. 2016;13(11):e1002166.

49. Johnson L. Optimal HIV testing strategies to increase HIV diagnosis in South Africa. 25th Conference on Retroviruses and Opportunistic Infections; 2018 Mar 4-7; Boston, USA.

50. Maheswaran H, Clarke A, MacPherson P, Kumwenda F, Lalloo DG, Corbett EL, et al. Cost-Effectiveness of Community-based Human Immunodeficiency Virus Self-Testing in Blantyre, Malawi. Clin Infect Dis. 2018;66(8):1211-21.

51. Central Intelligence Agency. The World Factobok - Lesotho 2018 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/lt.html>.

52. Ministry of Health, Community Development, Gender EaCMTM, Ministry of Health (MoH) [Zanzibar], National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), et al. Tanzania HIV/AIDS and Malaria Indicator Survey 2011-12. Dar es Salaam, Tanzania, and Rockville, Maryland, USA: TACAIDS, ZAC, NBS, OCGS and ICF International.; 2013.

53. Uganda Bureau of Statistics (UBOS), Inc. II. Uganda Demographic and Health Survey 2011. . Kampala, Uganda, and Rockville, Maryland, USA: UBOS and ICF International Inc. ; 2012.

54. Ministry of Health [Lesotho], International. I. Lesotho Demographic and Health Survey 2014. Maseru, Lesotho and Rockville, Maryland, USA: Ministry of Health [Lesotho] and ICF International. ; 2016.

55. Huerga HM. Mbongolwane and Eshowe HIV Impact in Population Survey 2014.

56. Sharma M, Ying R, Tarr G, Barnabas R. Systematic review and meta-analysis of community and facility-based HIV testing to address linkage to care gaps in sub-Saharan Africa. Nature. 2015;528(7580):S77-S85.

57. Government of Malawi, Health Mo. Integrated HIV Program Report - January-March 2016.

58. The Namibia Ministry of Health and Social Services (MoHSS), ICF International. The Namibia Demographic and Health Survey 2013. Windhoek, Namibia and Rockville, Maryland, USA: MoHSS and ICF International; 2014.

59. National Population Commission (NPC) [Nigeria], International I. Demographic and Health Survey 2013. Nigeria Abuja, Nigeria and Rockville, Maryland, USA: NPC and ICF International; 2014.

60. Maman D, Chilima B, Masiku C, Ayouba A, Masson S, Szumilin E, et al. Closer to 90-90-90. The cascade of care after 10 years of ART scale-up in rural Malawi: a population study. J Int AIDS Soc. 2016;19(1):20673.

61. Gaolathe T, Wirth KE, Holme MP, Makhema J, Moyo S, Chakalisa U, et al. Botswana's progress toward achieving the 2020 UNAIDS 90-90-90 antiretroviral therapy and virological suppression goals: a population-based survey. Lancet Hiv. 2016;3(5):E221-E30.

62. MacLeod WB, J; Crawford, K.; Carmona, S. Analysis of Big Data for better targeting of ART Adherence Strategies. Spatial clustering analysis of viral load suppression by South African province, district, sub-district and facility (April 2014–March 2015). 2015.

63. Brown LB, Havlir DV, Ayieko J, Mwangwa F, Owaraganise A, Kwarisiima D, et al. High levels of retention in care with streamlined care and universal test and treat in East Africa. Aids. 2016;30(18):2855-64.

64. Hatzold K, Mutseta M, Sibanda E, Gudukeya S, Tumushime M, Lopez C, et al. Closing the HIV testing gap: Facility-based integration of HIV self-testing, a way to improve testing coverage, yield and efficiency of client-initiated HIV testing services in Zimbabwe. 9th International AIDS Society Conference on HIV Pathogenesis and Treatment; 2017 Jul 23-26; Paris, France.

65. Chanda MM, Ortblad KF, Mwale M, Chongo S, Kanchele C, Kamungoma N, et al. HIV self-testing among female sex workers in Zambia: A cluster randomized controlled trial. Plos Med. 2017;14(11):e1002442.

66. Ortblad K, Kibuuka Musoke D, Ngabirano T, Nakitende A, Magoola J, Kayiira P, et al. Direct provision versus facility collection of HIV self-tests among female sex workers in Uganda: A cluster-randomized controlled health systems trial. Plos Med. 2017;14(11):e1002458.

67. Pant Pai N, Balram B, Shivkumar S, Martinez-Cajas JL, Claessens C, Lambert G, et al. Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis. Lancet Infect Dis. 2012;12(5):373-80.

68. World Health Organization. HIV assays: laboratory performance and other operational characteristics. Rapid Diagnostic tests (Combined detection of HIV-1/2 antibodies and discriminatory detection of HIV-1 and HIV-2 antibodies). Report 18. 2015.

69. Fonner VA, Denison J, Kennedy CE, O'Reilly K, Sweat M. Voluntary counseling and testing (VCT) for changing HIV-related risk behavior in developing countries. Cochrane Database Syst Rev. 2012;9:CD001224.

70. Kennedy CE, Fonner VA, Sweat MD, Okero FA, Baggaley R, O'Reilly KR. Provider-initiated HIV testing and counseling in low- and middle-income countries: a systematic review. AIDS Behav,. 2013;17(5):1571-90.

71. Cremin I, Nyamukapa C, Sherr L, Hallett TB, Chawira G, Cauchemez S, et al. Patterns of self-reported behaviour change associated with receiving voluntary counselling and testing in a longitudinal study from Manicaland, Zimbabwe. AIDS Behav,. 2010;14(3):708-15.

72. Oldenburg C, Chanda MM, Ortblad KF, Mwale M, Chongo S, Kamungoma N, et al. Effect of HIV self-testing on the number of sexual partners among female sex workers in Zambia: A randomized controlled trial. AIDS. 2018.