ANNEX 4. Report on the attitudes, values and preferences on HIV self-testing among key populations

Attitudes and acceptability on HIV Self-Testing among Key Population[1]

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4.1 Purpose and introduction

The focus of this review is to determine (1) the different values and preferences of HIV self-testing (HIVST) among key populations (KP), available in the literature and (2) the level of acceptability toward HIVST among KP.

HIVST is a potential strategy to overcome disparities in access to and uptake of HIV testing, particularly among KP. A literature review was conducted on the acceptability, values and preferences among KP. Data was analyzed by country income World Bank classification, type of specimen collection, level of support offered and other qualitative aspects. Most studies identified were from high-income countries and were among men who have sex with men (MSM), who found HIVST to be acceptable. In general, MSM were interested in HIVST because of its convenient and private nature. However they had concerns about the lack of counselling, possible user error and accuracy. Data on the values and preferences of other KP groups regarding HIVST is limited. This should be a research priority, as HIVST is likely to become more widely available, including in resource-limited settings.

Key populations (KP) are disproportionately affected by HIV; their pooled HIV prevalence is 10-50 times greater than in general populations (1-4). Every year there are over two million new HIV infections worldwide, and it is estimated that 40% of all new adult HIV infections are among KP (5, 6). Despite such high HIV burden and the increasing global coverage of HIV testing and treatment services, KP remain underserved (5).

HIVST refers to the process of self-collecting a specimen, self-performing a test and self-interpreting the result, in order to know his or her own HIV status. HIVST may stimulate demand for and increase uptake of HIV testing services (HTS) among KP, who may be more reluctant to or unable to seek existing services, reducing existing disparities in coverage and access to HIV testing. Understanding the values and preferences of HIVST will help to realize the potential impact of self-testing as part of the global HIV response

Values and preferences are defined as participants' views on HIVST, concerns they might have about HIVST, if they are willing to pay or buy a HIV self-test, a test kit either specifically packaged for HIVST or a rapid diagnostic test (RDT) distributed or used for HIVST; and other qualitative issues reported by participants.

Acceptability of HIV self-testing is the willingness to take a test in the future or as an increased frequency of testing with a HIV home-test.

So far there is only one rapid diagnostic test available as over-the-counter sell and specifically packaged for self-testing with the approval of the United States Food and Drug Administration. Despite HIVST policy development testing and availability is at varying stages across countries; reports suggest that HIV rapid diagnostic tests have been "informally" available for self-testing for some time, and their availability and use are increasing, especially among KP (7).

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4.2 Methods

Search strategy

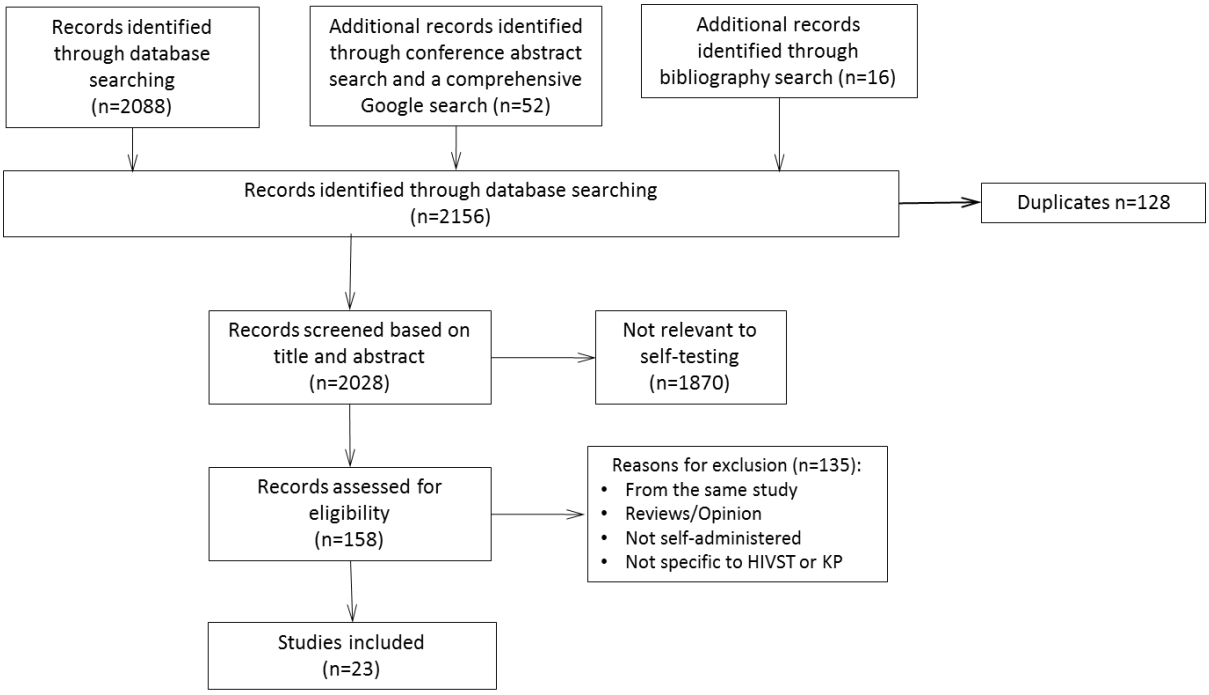
The primary method of study identification was electronic searches in 5 international databases from April to July 2014: PubMed, PopLine, Scopus, EMBASE and PsycINFO and five major HIV/AIDS conference databases (British HIV/AIDS Association, Conference on Retroviruses and Opportunistic Infections, European AIDS Society Conference, International AIDS Society and US National HIV Prevention Conference) for publications between January 1995 and July 2014. Gray literature (defined here as "reports that are produced by all levels of government, academics, business and industry in print and electronic formats but that are not controlled by commercial publishers") was identified through a comprehensive Google search. The electronic searches were supplemented with bibliographic back-referencing. Experts and authors of pertinent studies were contacted for any further references and clarifications (Figure 4.1A). The search was conducted according to the PRISMA checklist (see Appendix).

Our search terms included ((HIV OR HIV seropositivity OR HIV infections) AND ((self *test*) OR (home*test*) OR (rapid*test*))). The search was restricted to human subjects. No language or geographic limitations were placed on the search. Abstracts were included if full-texts were not available.

Selection criteria

Studies were only included if they used original data, included at least one of the five KP groups (defined as MSM, SW, transgender people, PWID and people in prison), used qualitative and/or quantitative methods that evaluated any aspect on HIVST values and preferences. All other articles were excluded. Studies examining home specimen collection kits were excluded, because participants did not interpret their test result (Fig.4.1A).

Fig.4.1A.Selection of studies.



Data collection and analysis

The data collection and analysis processes proceeded in several steps. First, two reviewers independently screened studies: Cheryl Johnson and Carmen Figueroa. One reviewer (CF) read study titles and abstracts meeting the inclusion

criteria, and the other (CJ) evaluated the screening criteria and approved selected studies. Disagreements between reviewers were resolved through discussion and consensus by CJ and CF. The quality of studies was assessed by CF, using appropriate checklists for included study designs.

Literature was summarized qualitatively according to study design and methodology, location, resource and population. Extracted data was coded by country income according to the World Bank[4], the educational level (college, high school, elementary or less), the type of specimen collection (oral fluid-based, blood-based, or not specified), KP group (MSM, SW, PWID, transgender people, or people in prison) and the type of support provided (supervised, unsupervised, or not specified). Reported acceptability was categorized as high (>=67%), moderate (66-34%) or low (<=33%).

Approaches to HIVST were defined in accordance to the 2014 WHO and UNAIDS technical update on HIV self-testing (8). Supervised approaches were defined as those which involved direct support from a health worker or a volunteer before or after individuals tested him or herself. Unsupervised approaches were defined as situations when HIVST offered without requiring direct support, but could include the provision of information about where or how to access support services. Studies with no information or comparing types of approaches or specimen collection were analyzed separately. The studies reviewed, included both those where participants were able to perform home tests, and those which did not include self-tests but explored survey participants' values and preferences.

We examined the process of linkage within HIVST for studies where HIVST was performed and where HIVST was not performed by participants answering a questionnaire about HIVST. We primarily analyzed linkage in any study reporting linkage from HIVST to further HIV testing, to receiving a HIV diagnosis in a facility, and/or to enrolment in HIV prevention, care or treatment services. As a secondary analysis we also examined studies which reported on participants' "intention to link" following a reactive HIV self-test result.

Quality Assessment

A quality critique of quantitative data from cross-sectional (Table S1-S2) and cohort studies (Table S3) was performed using the STROBE checklist (9). Reports were critiqued using the STROBE checklist as they were reporting outcomes of a cross-sectional study (10, 11). For a conference abstract reporting a randomized control trial (12)(Table S4) we used the CONSORT guidelines (13). Qualitative studies (11, 14-17), were evaluated with a guide for critically appraising qualitative research (18). Due to lack of standardized reporting of primary and secondary outcomes, and heterogeneity of data on values and preferences, a meta-analysis was not conducted.

4.3 Results

We identified 2,156 citations from databases, abstracts and bibliography searches, after removing duplicates and irrelevant articles. After an initial screening, we retrieved 158 citations, following which we removed 135 references that did not pertain to HIVST or KP, or were reviews using data from other studies. Ultimately, 23 studies met our inclusion criteria and were analyzed for this review: 16 (69.6%) were peer-reviewed articles (14-17, 19-30), five (21.7%) were abstracts (12, 31-34) and two (8.7%) were reports (10, 11). Figure 4.1A shows the process of selection. All studies reported on values and preferences on HIVST (Tables 4.2A-4.3A) and 14 studies reported also on acceptability (Figure 4.2A).

One study (4.3%) was performed in a low-income country (LIC) (11). Four studies (17.4%) were performed in middle-income countries (MIC) (17, 26, 30, 35) and 18 studies (78.3%) were performed in high-income countries (HIC) (10, 12, 14-16, 19-22, 25, 27-29, 31-34). Age was reported in 21 studies (91%), and ranged from 13 to 76 years (10-12, 14-16, 19-33). Education level was reported in 14 studies (61%) (11, 14-16, 19, 22-30). In 11 studies more than half of the total sample had at least a college education (14-16, 19, 22-26, 28, 30). All studies included MSM (100%) (10-12, 14-17, 19-34), three studies (13%) included female sex workers (FSW) (11, 17, 30), one study (4.3%) included PWID (29), one study

[4] Group WB. New Country Classifications. http://data.worldbank.org/news/new-country-classifications [updated 07/02/201322 December 2014].

(4.3%) included transgender women (32), and no studies included people in prison. Sample size varied from 27 to 5,908 participants. Thirteen studies used oral fluid-based HIV RDTs (11, 12, 14-17, 19-21, 27, 29, 30, 32), five used fingerstick/whole blood-based HIV RDTs (10, 22, 25, 28, 33), three used both types of HIV RDTs (24, 26, 34) and two did not provide information on the type of specimen collection used (23, 31). Nine studies used an unsupervised approach (10, 15, 16, 19, 21, 24, 28-30), seven used a supervised approach (12, 14, 17, 20, 25, 27, 33), six did not report this information (11, 23, 26, 31-33), and one compared both approaches (22). In 10 studies participants performed a HIVST RDT (n=10/23), (10, 12, 14, 15, 17, 22, 25, 27, 30, 33), of which six used a supervised approach (12, 14, 17, 25, 27, 33) and three used an unsupervised approach (10, 15, 30) and one used both (22). The remainder did not self-test for HIV but were surveyed about their values and preferences (n=13/23) (11, 16, 19-21, 23, 24, 26, 28, 29, 31-33). Nearly all studies (95.7%) were observational (14 cross-sectional, one qualitative, two cohort, five mixed method (cross-sectional and qualitative)) (10, 11, 14-17, 19-34) and one study (4.3%) was a randomized control trial (12) (Table 4.1A).

Table 4.1A: Characteristics of included studies.

No.	Author and year	Setting	Sample size	Type of approach	Type of test	Performed HIVST	Study design	Key populations (%)	Median or Mean Age (SD or IQR)	Summary score for quality critique[a]
1	Xun 2013 (30)	China	1137	Unsupervised	Oral fluid-based	Yes	Quantitative cross-sectional	MSM (32.6%) FSW (35.6%) VCT (31.8%)	MSM: 26 y (IQR 23-31) FSW: 25 y (IQR 23-28)	66% (21/32)
2	Carballo-Diéguez 2012 (15)	USA	57	Unsupervised	Oral fluid-based	Yes	Quantitative and qualitative cross-sectional	MSM (100%)	34.3 y (SD 11.9)	
3	MiraTess 2008 (10)	Netherlands, Germany, United Kingdom, Austria, Switzerland and Belgium	1122	Unsupervised	Blood-based	Yes	Quantitative survey	MSM (36%) Women and HTX men (64%)	n/a (IQR 13-76)	47% (15/32
4	Marley 2014 (17)	China	800	Supervised	Oral fluid-based	Yes	Quantitative and qualitative cross-sectional	MSM (46.3%) FSW (25%) VCT(28.6%)	n/a	66% (21/32)
5	Ng 2013 (27)	Singapore	994	Supervised	Oral fluid-based	Yes	Quantitative cross-sectional	MSM (16%) HTX men or women (84%)	32.4 y (IQR 27.1-40.5)	66% (21/32)
6	Katz 2012 (12)	USA	133	Supervised	Oral fluid-based	Yes	Randomized control trial	MSM (100%)	39 y (IQR 30-48)	59% (10/17)
7	Carballo-Diéguez 2012 (14)	USA	27	Supervised	Oral fluid-based	Yes	Quantitative and qualitative cross-sectional	MSM (100%)	34 y (SD 11.4)	
8	Mayer 2014 (33)	USA	161	Supervised	Blood-based	Yes	Quantitative cohort study	MSM (97.5%) TG (2.5%)	36.5 y (SD n/a)	36% (4/11)
9	De la Fuente 2012 (22)	Spain	519	Supervised and Unsupervised	Blood-based	Yes	Quantitative cross-sectional	MSM (36.7%)	n/a*	56% (18/32)
10	Lee 2007 (25)	Singapore	350	Supervised	Blood-based	Yes	Quantitative cross-sectional	MSM (10%) HTX men or women (90%)	33 y (IQR 27-41)	69% (22/32)
11	Han 2014 (24)	China	1342	Unsupervised	Oral fluid-based and blood-based	No	Quantitative survey	MSM (100%)	n/a*	66% (21/32)
12	Spielberg 2003 (29)	USA	460	Unsupervised	Oral fluid-based	No	Quantitative survey	MSM (33.9%) PWID (24.3%) HTX men or women and lesbians (41.8%)	n/a*	63% (20/32)
13	Bavinton 2013 (15)	Australia	2018	Unsupervised	Oral fluid-based	No		MSM (100%)	34.3 y (SD 11.5)	63% (20/32)
14	Gray 2013 (16)	Australia	233	Unsupervised	Oral fluid-based	No	Quantitative and qualitative cross-sectional	MSM (96.1%) HIV non-positive or not aware (3.9%)	38.6 y (SD n/a)	59% (19/32)
15	Skolnik 2001 (28)	USA	134	Unsupervised	Blood-based	No	Quantitative survey	MSM (45%) HTX men or women and Bisexual women or lesbians (55%)	n/a (IQR 18-59)	56% (18/32)
16	Chen 2010 (21)	Australia	172	Unsupervised	Oral fluid-based	No	Quantitative cross-sectional	MSM (100%)	32 y (IQR 15-71)	56% (18/32)
17	Ochako 2014 (11)	Kenya	982	n/a	Oral fluid-based	No	Quantitative and qualitative cross-sectional	MSM (10.2%) FSW (10.2%) GP (79.6%)	MSM: 24 y (IQR 18-49) FSW: 26 y (IQR 18-49) GP: 27 y (IQR 18-49)	72% (23/32)
18	Lippman 2014 (26)	Brazil	356	n/a	Oral fluid-based and blood-based	No	Quantitative survey	MSM (100%)	26 y (IQR 22-33)	63% (20/32)
19	Bilardi 2013 (20)	Australia	31	Supervised	Oral fluid-based	No	Qualitative description	MSM (100%)	n/a*	n/a
20	Chakravarty 2014 (32)	USA	310 couples	Supervised	Oral fluid-based	No	Quantitative cohort study	MSM (100%)	43.1 y (IQR n/a)	45% (5/11)
21	Wong 2014 (34)	Hong Kong SAR, China	1122	n/a	Oral fluid-based and blood-based	No	Quantitative cross-sectional	MSM (100%)	n/a	73% (8/11)
22	Greacen 2013 (23)	France	5908	n/a	n/a	No	Quantitative survey	MSM (100%)	35 y (IQR 27-43)	59% (19/32)
23	Bavinton 2014 (31)	Australia	567	n/a	n/a	No	Quantitative survey	MSM (87.1%) non-HIV-positive men (12.9%)	38.5 y (SD n/a)	54% (6/11)

a The summary score for quality critique represents the number of criteria reported over the total number of criteria.

* Age reported as a percentage

HIVST: HIV self-testing, n/a: not available, MSM: Men who have sex with men, HTX: Heterosexual, FSW: Female sex workers, TG: Transgender people, VCT: Voluntary Counselling Testing, GP: General population, IQR: Interquartile range, SD: Standard deviation,

4.3.1 Acceptability

Out of 14 studies, eight were consistent with a high acceptability, as defined above (11, 12, 15, 19, 22, 23, 26, 31), five studies with moderate (16, 17, 25, 30, 34) and one study with low acceptability (32). The acceptability rate ranged from 21% to 98%. All studies included MSM (11, 12, 15-17, 19, 21-23, 26, 30-32, 34) and three studies included FSW (11, 17, 30). Chakravarty et al reported the lowest acceptability, this study was in MSM couples in USA, surveyed about an oral fluid-based HIV RDT, and 21% of HIV negative men aware of the test were extremely likely to use the test (32).

Two studies reported acceptability by KP type (11, 30). In Kenya, participants where surveyed about an oral fluid-based HIV RDT, and FSW (98%) reported a higher acceptability than MSM (57%) (11). In China, acceptability was very similar between MSM (58.2%) and FSW (51.1%), in this study, participants were surveyed also about an oral fluid-based HIV RDT, but 6.9% had ever taken one before (30) (Figure 4.2A-4.3A).

In five studies (n=5/14) participants self-administered an HIV RDT, but did not necessarily interpreted their test results (Figure 4.3A) (12, 15, 17, 22, 30), remainder studies (n=9/14) participants were surveyed about HIVST (11, 16, 19, 21, 23, 26, 31, 32, 34). Overall, no large differences in acceptability were identified across type of approach, type of specimen collection, having performed an HIVST, country income, group of KP, or educational level of population.

Fig.4.2A.Studies evaluating HIV self-testing acceptability (n=14/23).

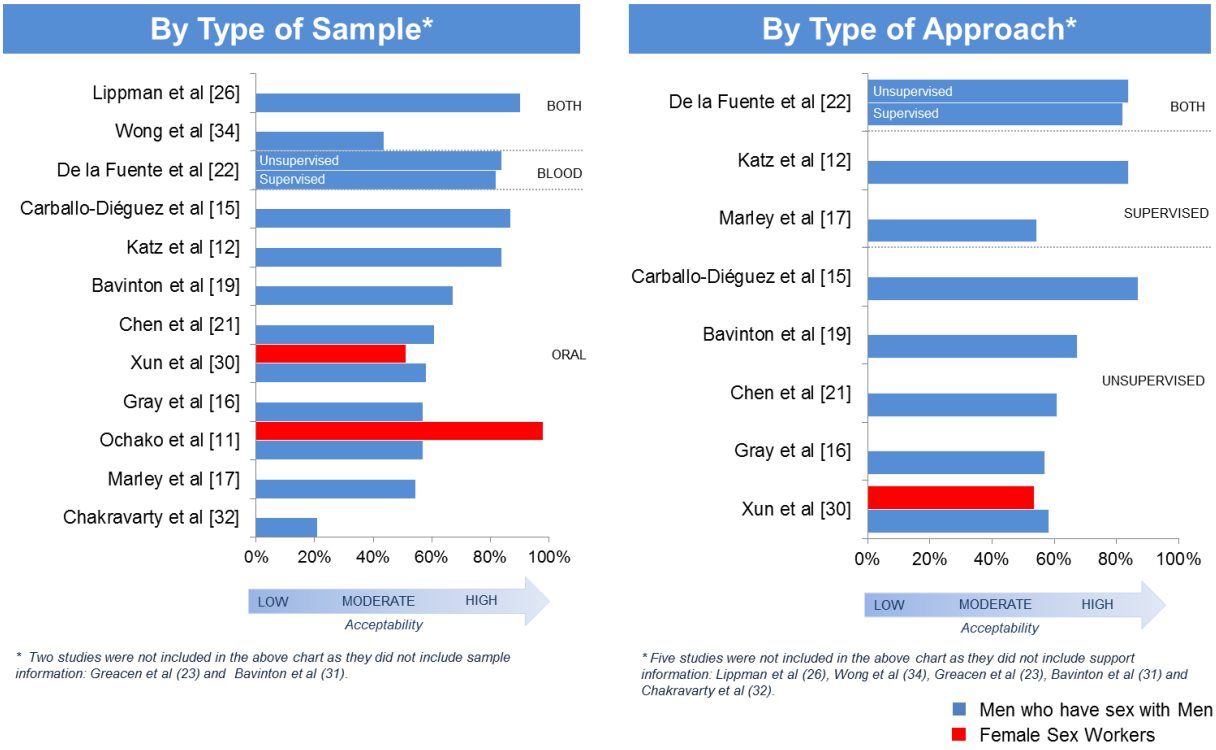
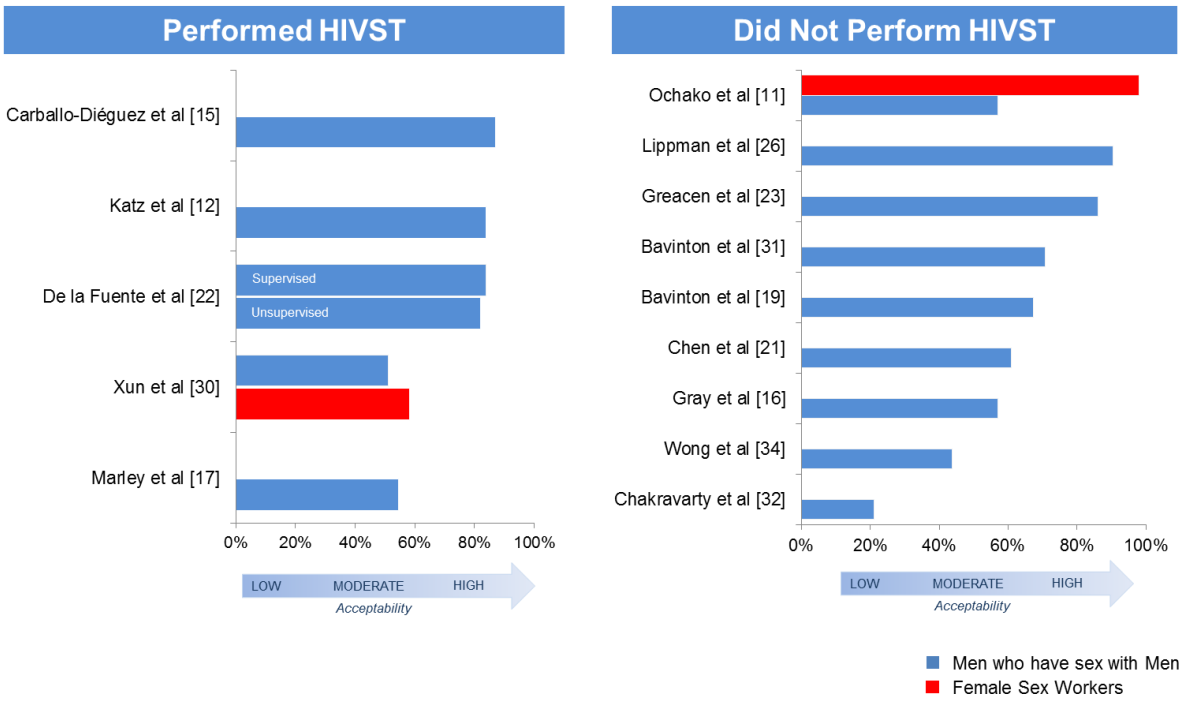


Fig.4.3A: HIV self-testing experience among studies (n=14/23) evaluating acceptability.



4.3.2 Values and Preferences for HIVST

Twenty-three studies assessed key population values and preferences on HIVST (Tables 4.2A-B-4.3A).

Benefits of HIVST

Findings about benefits were variously documented in 18 articles, including: (a) Convenience, (b) Privacy, (c) Painless, and (d) Easiness to Use.

Across reviewed studies convenience (n=13/18) (10, 11, 14, 17, 19-21, 23, 27-29, 32, 34) and privacy (n=12/18) (10, 11, 17, 19-21, 23, 26, 28, 29, 31, 34) were reported as benefits of HIVST most frequently, followed by easiness-to-use (n=8/18) (10-12, 17, 20, 21, 25, 33) and painlessness (n=4/18) (17, 20, 21, 30). Ochako et al reported that in Kenya HIVST is easy to use, even for people with low education (11).
Privacy was more frequently reported as a benefit of HIVST in studies using an unsupervised approach (n=5/6) (10, 19, 21, 28, 29) compared to those using a supervised approach (n=2/6) (17, 20). Although approach was not reported 71% of MSM in Brazil, reported that HIVST would offer more privacy than HIV testing facilities (26). In general, the benefits for HIVST described by participants across studies remain similar; even when analyzed by country income, type of KP, participant education level, type of specimen collection, having performed an HIVST and type of approach.

Preferences for HIVST attributes

Twelve articles provided information on KP preferences (Figure 4.4A) (11, 14-17, 20, 24-27, 33). Preferences for test type of sample collection (oral fluid-based or fingerstick/whole blood-based) (n=7/12), distribution (n=7/12), instructions (n=2/12), the availability to link to counseling (n=4/12), and how they would like to use the test (n=6/12) were reported. Preferences for HIVST attributes varied across country income setting, type of approach, having performed a self-test for HIV and type of specimen collection. However, in general, participants reported preferring HIVST with an oral fluid-based HIV RDT (n=4/12), to blood-based HIV RDT (n=3/12) (15-17, 26).

Table 4.2A. Values and Preferences of studies with supervised support

	Low Income Country	Middle Income Countries		High Income Countries				
Study	**Ochako et al (11)[1]**	**Lippman et al (26)[1]**	**Marley et al (33)**	**Bilardi et al (20)**	**Ng et al (27)**	**Katz et al (12)**	**Chakravarty et al (32)[1]**	**Carballo-Diéguez et al (14)**
Study aims	Identify willingness to use oral fluid-based RDTs for self-testing, and factors associated with the potential adoption and use of HIVST	Determine the acceptability of HIVST, compared to clinic-based HIV testing, and explore preferences for HIVST	Assess feasibility and acceptability of oral fluid-based RDT among MSM, FSW and VCT clients; assess the quality of HIVST with oral fluid-based RDTs compared to VCT and assess attitudes towards the HIVSTamong FSW	Explore the views of MSM on HIVST, including acceptability, potential use, benefits and limitations	Compare user acceptability and feasibility on HIVST using RDTs versus RDTs used at the POC by trained personnel, including user attitudes towards oral fluid-based RDTs used for HIVST	Described ease of use and acceptability of HIVST using oral fluid-based RDT among high risk MSM	Explore the attitudes on HIVST among MSM couples	Assessed whether at-risk HIV-uninfected MSM would use HIVST to screen potential sexual partners prior to intercourse
Participants pros'	MSM: 70% easy to use; 68% guarantees confidentiality and privacy; 28% required no visit to a health facility; 21% saves times; and 12% convenient.* FSW: 70% guarantees confidentiality and privacy; 52% easy to use; 32% convenient; and 23% required no visit to a health facility.*	68%(244/356) Privacy	FSW: 96.5%(193/200) convenient, 95.5%(191/200) painless, 13%(26/200) easy to use and 14%(28/200) privacy.	Convenience, privacy, painless, and easy to use*	95% Convenience*	63.2% Easy to use*	56% Convenience*	Convenience*
Concerns	MSM: 44% (n/a) were afraid of a positive result. FSW: 3% (3/100) were afraid of a positive result, 1% (1/100) afraid of misinterpreting the results, and 1% (1/100) believed health workers should perform the test.	30.6%(109/356) User error and 22%(79/356) lack of counseling	FSW: 55.5%(111/200) accuracy	Lack of counselling, accuracy*	n/a	n/a	Confidentiality and lack of time*	User error*
Preferences	MSM: 56% would procure and perform the test on their own; 49% preferred to obtain the test kits in either private chemists/pharmacies or 47% in government clinics.* FSW: 95% would procure and perform the test on their own; 75% preferred to obtain the kits from private chemists/pharmacies, 53% in government facilities and 13% in supermarkets/shops.*	47%(167/356) preferred HIVST over testing in clinics; 60%(213/356) would HIVST to make choices about unprotected sex with regular partners and 52%(184/356) with new partners	FSW: 42.8%(83/200) preferred saliva testing, while 57.2%(111/200) still preferred blood testing; 7.5%(5/200) wanted simplified procedure and 7%(14/200) wanted the test to be offered free	Available OTC and online, provide access to 24h counseling and with proper instructions.*	88.9% (884/994) available OTC, 88.6% (881/994) prefer to do it in private and 73.9% (735/994) felt that post-test counseling was necessary	n/a	n/a	Available as OTC*
Willingness to pay (US$)	Range in study $ 0.54-4.35 MSM: 57% would be willing to pay. Mean max price $ 3.35. FSW: 94% would be willing to pay. Mean max price $ 3.1	n/a	n/a	In average $ 9.2-18.5	28% (277/994) Would pay at least $ 15	46% Would pay ≤ $ 20 26% would pay ≥ $ 40	n/a	n/a
Serious adverse self testing events	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Linkage to care	MSM:50% would seek post-test counseling and confirmation of results.* FSW: 75% would go to a health facility/VCT for confirmation.*	n/a	n/a	n/a	n/a	2 HIV reactive tests: (1) search confirmatory testing and care immediately (2) search confirmatory testing and care after 2 months	n/a	n/a

1 Type of approach non available. 2 Both types of approach: supervised and unsupervised * Percentage or Raw number not available

n/a: not available, MSM: Men who have sex with men, FSW: Female sex workers, VCT: Voluntary Counselling Testing, RDT: Rapid diagnostic test, OTC: Over-the-counter, HIVST: HIV self-testing, POC: Point of care

Table 4.2B. Values and Preferences of studies with supervised support (cont.)

	High Income Countries					
Study	**Mayer et al (33)**	**De la Fuente et al (22)[2]**	**Lee et al (25)**	**Wong et al (34)[1]**	**Greacen et al (23)[1]**	**Bavinton et al (31)[1]**
Study Aims	Assessed the feasibility and acceptability of biweekly HIVST at home using whole blood-based/fingerstick RDT	Evaluate the feasibility of HIVST including obtaining the sample and interpreting results (not their own)	Compare user acceptability and feasibility of using RDTs for HIVST versus RDTs by trained providers at the POC	Describe the patterns of HIVST users among MSM	Estimate the proportion of MSM interested in authorized kits for HIVST, their reasons for being interested and their correlates	Explore the motivations of using and implications of using HIVST
Participants pros'	n/a	n/a	88%(300/350) Easy to use	50% Easy to use, 41.2% convenience, 25% privacy*	23% Convenience and 17% privacy*	47.6% Privacy*
Concerns	n/a	n/a	n/a	n/a	6% Accuracy, 6.1% lack of counselling and 3.6% of user error	n/a
Preferences	56.5% preferred HIV testing at home, and 23.6% preferred testing in a doctor's office. 90.0% would be comfortable testing partners at home*	n/a	88% (304/350) Thought the kit should be sold in public outlets. 89% (307/350) preferred to take the test in private; 87% (296/350) thought counselling is needed before testing	16.2% Didn't want counselling*	n/a	n/a
Willingness to pay (US$)	n/a	87.3% Were willing to pay $ 1.25-49 5.2% were reluctant to pay.*	Between $ 7 and $ 13*	n/a	n/a	n/a
Serious adverse self testing events	n/a	n/a	n/a	n/a	n/a	n/a
Linkage to care	Two participants became HIV infected for an annualized incidence of 3.86 (0.47-19.74). Both were linked to care.	n/a	n/a	81.6% believed that they would get timely treatment if infected with the virus*	n/a	n/a

1 Support non available. 2 Both types of support: supervised and unsupervised * Percentage or Raw number not available

HIVST: HIV self-testing, n/a: not available, RDT: Rapid diagnostic test, MSM: Men who have sex with men, VCT: Voluntary Counselling Testing, POC: Point of care

Table 4.3. Values and Preferences of studies with unsupervised support

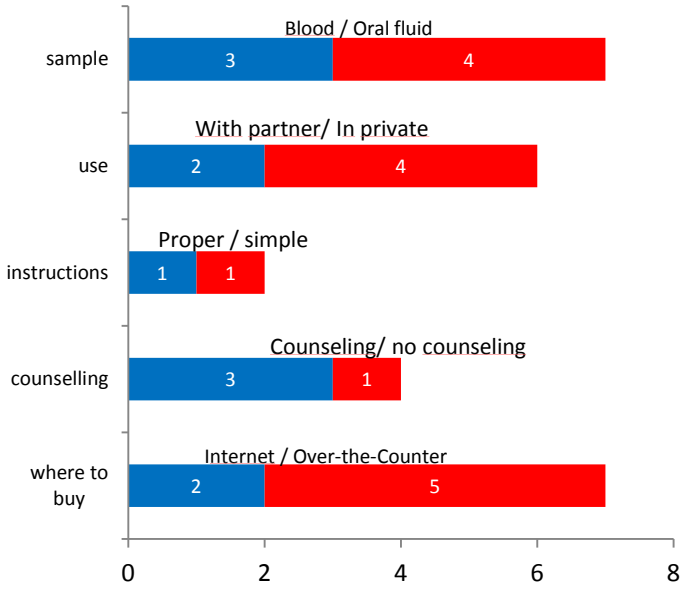
	Middle Income Countries		High Income Countries						
Study	**Xun et al (30)**	**Han et al (24)**	**Spielberg et al (29)**	**Bavinton et al (19)**	**Carballo-Diéguez et al(15)**	**Gray et al (16)**	**Skolnik et al (28)**	**Chen et al (21)**	**MiraTess 2008 (10)**
Study aims	Assess the willingness to accept the oral fluid HIV rapid testing and its associated factors among most-at-risk populations	Examines the frequency and the correlates of HIVST among MSM	Determine strategies to overcome barriers to HIV testing among persons at risk	Explore which gay men would increase their frequency of HIVST and examine reasons for not testing among men who have never been tested	Investigate if participants use the HIVST to test themselves/screen sexual partners prior to sexual intercourse and the strategies that they would use.	Determine the acceptability and epidemiological impact of increases in HIV testing	Examine preferences for specific types of HIV tests as well as for test attributes such as cost, counselling and privacy.	Examine the views of Australian MSM on the acceptability and potential uptake of rapid oral testing for HIV in clinic and home-based settings	Describe the people who prefer to test themselves, reason for testing and their experiences.
Participants pros'	MSM: 21% painless* FSW: 33% painless*	n/a	Privacy and convenience*	58.7%(1186/2018) convenience, 75.5%(1524/2018) immediate results and 42.3%(854/2018) privacy	n/a	n/a	24.6% Privacy and 30% convenience*	39% Convenience, privacy, painless and easy to use*	53% Privacy, 46% easy to use and 31% convenience*
Concerns	MSM: 49.1% accuracy and 7.5% not been free* FSW: 42.2% accuracy and 9.4% not been free*	n/a	31% Had concerns, mostly on accuracy, user error and lack of counseling*	n/a	User error and not being free*	n/a	n/a	54% Lack of counselling, accuracy and user error*	n/a
Preferences	n/a	34.7% Referred to obtain the test on the internet*	n/a	n/a	50 % use it with new partners and preferred oral fluid-based RDTs over fingerstick/whole blood-based RDTs for HIVST*	58.8% (137/233) preferred oral-based testing and 54.1% (126/233) finger-prick testing	n/a	n/a	n/a
Willingness to pay (US$)	Median price (IQR) MSM $6.5 (3.0-11.3) FSW $ 4.8 (1.6-8.1)	9.3% paid < $ 8 1.2% paid > $ 50	Median price (IQR) 30 US$*	n/a	n/a	n/a	24% would pay $ 50	n/a	n/a
Serious adverse self testing events	n/a	n/a	n/a	n/a	Intended to coerce someone to test for HHIV (1/57)		n/a	n/a	n/a
Linkage to care	n/a	n/a	n/a	n/a	If self-test result is reactive several participants will seek confirmatory testing followed by treatment*	n/a	n/a	n/a	If HIVST result is reactive 98% will link to care*

* Percentage or Raw number not available

n/a: not available, RDT: Rapid diagnostic test, MSM: Men who have sex with men, HTX: Heterosexual, FSW: Female sex workers, VCT: Voluntary Counseling and Testing, POC: Point of care, PWID: People who inject drugs, OTC: Over-the-counter

Five studies from Kenya, Singapore, USA and Australia reported MSM and FSW generally prefer HIVST to be available over-the-counter (11, 14, 20, 25, 27), three of which participants have performed an HIVST (14, 25, 27), and two studies from Australia and China, reported that MSM preferred HIVST to be available through the Internet, in neither of the two MSM participants have performed an HIVST (20, 24). MSM participants in Australia, desire HIVST to be available over-the-counter, but specifically with proper instructions for use on how to perform a HIV RDT and interpret the test result (20).
Three studies reported participants prefer having counseling available (20, 25, 27). However, one study in Hong Kong SAR China among MSM reported that 16.2% of participants prefer HIVST without counseling (34).

Fig.4.4A: HIV self-testing preferences (n=11/23).



Willingness to pay
Willingness to pay for a HIVST kit if sold was documented in 11 articles (11, 12, 17, 20, 22, 24, 25, 27-30). Willingness to pay varied across population, country income settings, type of specimen collection, and type of approach. In HIC settings, study participants were willing to pay between ≤ US$ 20 and ≥ US$ 50 (12, 20, 22, 25, 27-29). In MIC settings, participants were generally willing to pay between (US$ 1 to US$ 20) (24, 30). A study from China reported that MSM were willing to pay US$ 6.50 (US$ 3 - US$ 11), slightly more than FSW who were willing to pay US$ 5 (US$ 2 – US$ 8) (30). In LIC settings, participants were willing to pay between US$ 0.54-US$ 4.35 (11). According to this study in Kenya, MSM were willing to pay (US$ 3.35), slightly more than FSW who were willing to pay US$ 3.10 (11).
Participant willingness to pay in all supervised HIVST studies (n=4/11) ranged between (≥US$ 1 to ≤US$ 20) (12, 20, 25, 27). In 2/11 studies using an unsupervised approach participants' were willing to pay between (≥ US$ 20 to US$ 50) (28, 29). Reluctance to pay (range 5.2%-11%) was only reported in four studies where MSM and FSW participants have performed an HIVST, these studies examined both approaches and were in MIC and HIC settings (12, 17, 22, 30); all but one used oral fluid-based HIV RDT (12, 17, 30).

Reported concerns of HIVST
Concerns about HIVST were documented in 11 articles (11, 14, 15, 17, 20, 21, 23, 26, 29, 30, 32). The majority of the studies, in which concerns were reported, stated that participants had concerns about user error (n=7/11) (11, 14, 15, 21, 23, 26, 29); followed by low accuracy (n=6/11) (17, 20, 21, 23, 29, 30), lack of counseling (n=6/11) (11, 20, 21, 23, 26, 29) and HIVST not being free (n=2/11) (15, 30).

Concerns were more commonly reported in studies using oral fluid-based RDT (n=9/11) (11, 14, 15, 17, 20, 22, 29, 30, 32). Lack of counseling was not a concern in studies where MSM and FSW participants have performed an HIVST (15, 17, 20, 30). However, concerns for HIVST generally remain the same when analyzed by country income, KP group, participant education level, and type of approach.

Linkage to care

Six studies reported on some aspect of linkage to care from HIVST, of which the majority were in HIC settings (10-12, 15, 32, 33). Two studies, Katz et al (2012) and Mayer et al (2014) reported actual linkage and enrolment in care following HIVST (12, 33). Katz et al (2012) reported two participants with reactive self-test results who were diagnosed HIV positive: one participant searched immediately for additional HIV testing and care and the other waited two months before seeking further HIV testing and care (12).

The remainder of the studies reported on "intention to link" following HIVST. In studies from HIC settings, the majority of participants reported that if they received a reactive HIV self-test result they would seek for additional testing and if diagnosed HIV-positive, then treatment (range: 81.6%-100%) (10, 15, 34). A study in LIC setting reported that 50% of MSM would seek post-test counseling and confirmation of results and 75% of FSW stated that they would go to a health facility for confirmation, after self-testing for HIV (11). Overall, no differences were found when analyzed by test type of specimen collection, educational level, having performed an HIVST and type of approach.

Adverse events resulting from HIVST

There was little information on adverse events reported in reviewed studies. In this review, one study among MSM in the USA, who had performed an oral fluid-based HIV RDT, reported that complicated situations could lead to verbal confrontations or violence among participants who self-tested or proposed self-testing with a sex partner. Also they reported that special circumstances, such as infidelity, could lead to coercively test a partner, a potentially more adverse event (15). No other serious adverse events were identified.

4.3.3 Quality of studies

Quality of studies varied. In general, studies did not report sufficient information about qualitative methods and data collection tool, there was also a lack of compliance on how they assessed and measured the different values and preferences. Qualitative data were sparse and an incomplete reporting of data in abstracts and reports limited the evaluation of quality. This lack of clear evaluation of values and preferences limited our understanding of collected data.

4.4 Discussion

Twenty-three studies reporting acceptability and other values and preferences of KP regarding HIVST were identified. Values and preferences were largely consistent. This may be because many of the included studies had some similar study characteristics. For instance, the majority of included studies were from HIC settings (n=18/23), among participants with high educational level (n=11/23), using oral fluid-based RDT (n=13/23), using unsupervised approaches (n=9/23), and were almost exclusively among MSM (n=23/23). Very few studies in this review included FSW, PWID, transgender people (n=5/23).

Evidence for high acceptability was evident among MSM in HIC settings using oral specimen collection. This aligns with existing literature on HIVST, which suggest users (including the general population) may prefer oral fluid-based HIV RDT to fingerstick/whole blood-based HIV RDT because they are reportedly easier to perform and are perceived to be less painful (36, 37). Out of all studies reviewed, Chakravarty et al reported the lowest acceptability of HIVST. However this study only reported acceptability among HIV-negative MSM who were aware of HIVST and reported that they were "extremely likely" to self-test for HIV. Since the study did not report on other levels of acceptability, such as "somewhat likely", "likely" or "very likely", we could not infer whether this is reflective of actual acceptability of HIVST among MSM (32).

Research is still ongoing and there are emerging reports from KwaZuluNatal, South Africa which suggest that fingerstick/whole blood-based HIV RDT can also be easy to perform and accurate, when accompanied with clear

instructions, packaging and appropriate test system design (38). In April 2015, two fingerstick/whole blood-based RDTs recently satisfied the legislative requirements in the European Econonomic Area: the BioSure HIV Self-Test (BioSure Ltd , UK), sold online at £29.95 (39) and the autotestVIH (Aaz Labs, France) will be sold in pharmacies around 23-28 euros (40); as an additional option for people to now their HIV serostatus. Various other products are under development and could be adapted for HIV self-testing, including painless or integrated lancets, simplified sampling systems, integrated buffer delivery systems and shorter minimum and maximum reading time (7).

Some studies report that participants desire access to counseling (20, 25, 27), while a study in Hong Kong SAR China with MSM, reported that 16% preferred HIVST because of the "lack of counseling" (34). Ways to provide information about or how to link to counseling services, as part of HIVST, should therefore be considered including: face-to-face through community health workers, internet-based, SMS or mobile phones, or computer-based programs.
Studies with unsupervised or an unknown approach to HIVST frequently reported concerns on user error and poor accuracy. These concerns could potentially be overcome by providing links to support and counseling services and clear instructions for use. There might be a small controversy with the benefit of privacy and the concern of an increased user error, depending on the approach, in our findings MSM were not strongly positioned that HIVST has to be performed strictly by a professional (20, 25, 27, 34). In particular, KP may need more information on how user error can be reduced, accuracy rates and the need for confirmation; especially if HIVST is unsupervised.
Willingness to pay was difficult to compare across all studies, as there were different price points and some used overlapping intervals. Overall willingness to pay was higher in HIC settings (12, 20, 22, 25, 27-29) compared to MIC settings (24, 26, 30) or LIC settings (11), and lower in supervised HIVST (12, 20, 25, 27) than for unsupervised HIVST (24, 30). This may be because supervised HIVST is viewed as similar to current HIV testing services, which are often free of charge. KP may also be willing to pay more for unsupervised HIVST because it offers greater privacy; which was a key benefit and value of HIVST, reported by KP.

All studies in the USA (reporting willingness to pay between US$ 1 to ≥US$ 50) were conducted using oral fluid-based HIV RDT (12, 28, 29), and prior to the US Food and Drug Administration approval of the OraQuick® In-Home HIV Test (41). Currently, this product retails direct to consumers for US$ 40 (42). The studies reviewed suggest that reluctance to pay was only reported in studies were participants have performed an HIVST, also concerns about the cost of HIVST, were both in MIC and HIC settings. Thus, for HIVST to have higher uptake, it will likely need to be subsidized or free of charge to clients. So far a lowest price has been negotiated, for research purposes the professional use version of this test is available in Kenya for approximately US$ 11 (43) and in Malawi for US$ 3 (44).

Evidence on linkage to care and treatment among KP is limited and requires further research. Two studies among MSM in the USA reported actual linkage to HIV testing and diagnosis and enrollment in HIV care and treatment (12, 33). Three studies reported that more than 80% of participants with a potential or an actual HIV positive test result would seek confirmatory HIV testing and care (10, 12, 34). Proactive approaches to support the unique needs of KP may be considered and adapted, for example a study in Malawi among general population offering home (ART) assessment found a three-fold increase in linkage to ART, compared to facility-based HIV testing (44). It is essential that users with a reactive HIV self-test result first link to further testing and receive an HIV diagnosis; and that users also link to HIV prevention, care and treatment services, as appropriate to their HIV status, in a timely manner. Special attention should be paid to additional risks for KP, including young and adolescent KP. In highly criminalized settings KP may be more vulnerable to delay or not to seek HIV services. Without such support for safe linkage to HIV services, HIVST may be of limited benefit to KP in such settings.
We found no clear evidence to support adverse events as a result of HIVST, such as adverse emotional reactions to positive tests, inter-partner violence, coerced/forced testing, psycho-social or mental health issues, and suicide or self-harm. This is in line with a recent literature review which states that very few studies report harm across various self-tests, including HIV; however it does note that monitoring and reporting systems for harmful outcomes are rare (45).

4.5 Strengths and Limitations

We used a comprehensive and systematic literature search and systematic process for identifying relevant publications. In addition to this, we examined and coded the different values and preferences for HIVST among KP, which can provide evidence to weigh the potential benefits and risks of HIVST.

The majority of studies that met inclusion criteria were among MSM and in HIC settings. Only two studies provided data on user preferences among MSM and FSW (11, 17). Our search was for KP, however due to the nature of self-testing, people in prison or closed settings, would not be eligible for HIVST. Almost all studies were observational and used a cross-sectional research design. Only one study in this review was a randomized control trial. We cannot therefore rule out selection bias, including sample representativeness and non-response rate.

The inclusion criteria for this review were overly inclusive to capture all or any values and preferences on HIVST among KP. Therefore, study designs, characteristics and sample sizes were heterogeneous, and results may not be generalizable.

Most studies had incomplete reporting of data items and low compliance with the STROBE reporting checklist.

4.6 Recommendations and Conclusions

Our review showed that MSM in HIC settings find oral fluid-based HIVST to be highly acceptable, using a supervised or an unsupervised approach. However, concerns about counselling, user error and poor accuracy still remain. Data on social harm and adverse events resulting from HIVST was not reported. We recommend the implementation of a rigorous monitoring and reporting system to better understand user concerns, risk of adverse event and potential social harm. A surveillance system will allow programme managers and policy-makers to consider the potential risks and benefits of introducing HIVST among KP.

Information on HIVST values and preferences among KP, other than MSM, and in low- or middle-income settings is limited, in our findings convenience and private nature of HIVST is advantageous to MSM, and may be advantageous for other KP, including SW, PWID and transgender people in HIC, MIC or LIC settings. We recommend researchers, policy-makers and programme managers should consider developing studies or strategies using HIVST as an additional approach to reverse inequities in access to HIV testing for KP and to better understand the potential impact of self-testing as part of the global HIV response.

References

1. Baral S, Beyrer C, Muessig K, Poteat T, Wirtz AL, Decker MR, et al. Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. The Lancet infectious diseases. 2012;12(7):538-49.
2. Baral S, Todd CS, Aumakhan B, Lloyd J, Delegchoimbol A, Sabin K. HIV among female sex workers in the Central Asian Republics, Afghanistan, and Mongolia: Contexts and convergence with drug use. Drug and alcohol dependence. 2013;132, Supplement 1(0):S13-S6.
3. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. The Lancet infectious diseases. 2013;13(3):214-22.
4. United Nations Office on Drugs and Crime, Canadian HIV/AIDS Legal Network. Accessibility of HIV Prevention, Treatment and Care Services for People who Use Drugs and Incarcerated People in Azerbaijan, Kazakhstan Tajikistan, Turkmenistan and Uzbekistan: Legislative and Policy Analysis and Recommendations for Reform. Ashgabat: UNODC Regional Office for Central Asia. https://www.unodc.org/documents/centralasia//Accessibility_of_HIV_prevention_treatment_and_care_eng.pdf, 2010 [26 June, 2014].
5. Joint United Nations Programme on HIV/AIDS. The Gap Report. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2014/UNAIDS_Gap_report_en.pdf 2014 [14 August, 2014].
6. World Health Organization. The global health sector strategy on HIV/AIDS 2011-2015: an interim review of progress. http://apps.who.int/iris/bitstream/10665/112790/1/9789241507295_eng.pdf 2014 [26 July 2014].
7. World Health Organization. March 2014 supplement to the consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, recommendations for a public health approach. www.who.int/iris/bitstream/10665/104264/1/9789241506830_eng.pdf 2014 [30 July 2014].
8. World Health Organization, Joint United Nations Programme on HIV/AIDS. A short technical update on self‑testing for HIV. http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2014/JC2603_self-testing_en.pdf 2014 [20 July 2014].
9. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies. PLoS medicine. 2007;4(10):e296.
10. MiraTes-Europe-BV. HIV home testing, the key to reaching high risk groups. http://www.aidsactioneurope.org/clearinghouse/search/hiv-home-testing. : 2008.
11. Ochako R, Vu L, Peterson K. Insights Into Potential Users and Messaging for HIV Oral Self-Test Kits in Kenya, 3ie Grantee Final Report. http://www.3ieimpact.org/media/filer_public/2014/07/21/insights_into_potential_users-final.pdf Washington, DC, International Initiative for Impact Evaluation (3ie). 2014.
12. Katz D, Golden M, Hughes J, Farquhar C, Steckler J. Acceptability and Ease of Use of Home-self-testing for HIV among MSM. Conference on Retroviruses and Opportunistic Infections (CROI 2012) March 5-8, 2012; Seattle, Washingnton.
13. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. PLoS medicine. 2008;5(1):e20.
14. Carballo-Diéguez A, Frasca T, Balan I, Ibitoye M, Dolezal C. Use of a Rapid HIV Home Test Prevents HIV Exposure in a High Risk Sample of Men Who Have Sex With Men. AIDS and behavior. 2012;16(7):1753-60.

15. Carballo-Diéguez A, Frasca T, Dolezal C, Balan I. Will gay and bisexually active men at high risk of infection use over-the-counter rapid HIV tests to screen sexual partners? Journal of Sex Research. 2012;49(4):379-87.
16. Gray RT, Prestage GP, Down I, Ghaus MH, Hoare A, Bradley J, et al. Increased HIV Testing Will Modestly Reduce HIV Incidence among Gay Men in NSW and Would Be Acceptable if HIV Testing Becomes Convenient. PloS one. 2013;8(2):e55449.
17. Marley G, Kang D, Wilson E, Huang T, Qian Y, Li X, et al. Introducing rapid oral-fluid HIV testing among high risk populations in Shandong, China: feasibility and challenges. BMC public health. 2014;14
18. Attree P, Milton B. Critically appraising qualitative research for systematic reviews: defusing the methodological cluster bombs. Evidence & Policy: A Journal of Research, Debate and Practice. 2006;2(1):109-26.
19. Bavinton BR, Brown G, Hurley M, Bradley J, Keen P, Conway DP, et al. Which gay men would increase their frequency of HIV testing with home self-testing? AIDS and behavior. 2013;17(6):2084-92. Epub 2013/03/26.
20. Bilardi JE, Walker S, Read T, Prestage G, Chen MY, Guy R, et al. Gay and bisexual men's views on rapid self-testing for HIV. AIDS and behavior. 2013;17(6):2093-9. Epub 2013/01/09.
21. Chen MY, Bilardi Je Fau - Lee D, Lee D Fau - Cummings R, Cummings R Fau - Bush M, Bush M Fau - Fairley CK, Fairley CK. Australian men who have sex with men prefer rapid oral HIV testing over conventional blood testing for HIV. Int, J Std Aids. 2010;21(6):428-30.
22. de la Fuente L, Rosales-Statkus ME, Hoyos J, Pulido J, Santos S, Bravo MJ, et al. Are participants in a street-based HIV testing program able to perform their own rapid test and interpret the results? PloS one. 2012;7(10):e46555. Epub 2012/10/12.
23. Greacen T, Friboulet D, Blachier A, Fugon L, Hefez S, Lorente N, et al. Internet-using men who have sex with men would be interested in accessing authorised HIV self-tests available for purchase online. AIDS care. 2013;25(1):49-54.
24. Han L, Bien CH, Wei C, Muessig KE, Yang M, Liu F, et al. HIV Self-Testing Among Online MSM in China: Implications for Expanding HIV Testing Among Key Populations. J Acquir Immune Defic Synd. 2014;67(2):216-21.
25. Lee VJ, Tan SC, Earnest A, Seong PS, Tan HH, Leo YS. User acceptability and feasibility of self-testing with HIV rapid tests. J Acquir Immune Defic Synd. 2007 Aug 1;45(4):449-53.
26. Lippman SA, Périssé ARS, Veloso VG, Sullivan PS, Buchbinder S, Sineath RC, et al. Acceptability of self-conducted home-based HIV testing among men who have sex with men in Brazil: data from an on-line survey. Cadernos de Saúde Pública. 2014;30:724-34.
27. Ng OT, Chow AL, Lee VJ, Chen MIC, Win MK, Tan HH, et al. Accuracy and User-Acceptability of HIV Self-Testing Using an Oral Fluid-Based HIV Rapid Test. PloS one. 2012;7(9).
28. Skolnik HS, Phillips KA, Binson D, Dilley JW. Deciding where and how to be tested for HIV: What matters most? Journal of Acquired Immune Deficiency Syndromes. 2001;27(3):292-300.
29. Spielberg F, Branson BM, Goldbaum GM, Lockhart D, Kurth A, Celum CL, et al. Overcoming barriers to HIV testing: preferences for new strategies among clients of a needle exchange, a sexually transmitted disease clinic, and sex venues for men who have sex with men. Journal of acquired immune deficiency syndromes (1999). 2003;32(3):318-27. Epub 2003/03/11.
30. Xun H, Kang D, Huang T, Qian Y, Li X, Wilson EC, et al. Factors associated with willingness to accept oral fluid HIV rapid testing among most-at-risk populations in China. PloS one. 2013;8(11).
31. Bavinton B, Grulich A, Keen P, Zablotska I, Murphy D, Brown G, et al. Motivations for and implications of using home HIV tests among Australian gay men. AIDS 2014 - XX International AIDS Conference; July 2014; Melbourne, Australia.

32. Chakravarty D, Darbes L, Neilands T, Beougher S, Finlayson S, Hoff C. Attitudes about rapid, over-the-counter HIV home-testing kits among couples comprised of men who have sex with men. AIDS 2014 - XX International AIDS Conference; July 2014; Melbourne, Australia.
33. Mayer K, Tomassilli J, Gelman M, Altfeld M, Allen T. HIV self-testing among men who have sex with men (MSM): acceptability of biweekly finger pricks to perform the alere determineTM HIV-1/2 Ag/Ab assay. AIDS 2014 - XX International AIDS Conference; July 2014; Melbourne, Australia.
34. Wong HTH, Lee SS. Patterns of in-home self-testing for HIV among an internet sample of men who have sex with men (MSM) in an Asian population. AIDS 2014 - XX International AIDS Conference July 2014; Melbourne, Australia.
35. Han X, Xu J, Chu Z, Dai D, Lu C, Wang X, et al. Screening acute hiv infections among chinese men who have sex with men from voluntary counseling & testing centers. PloS one. 2011;6(12).
36. Gaydos CA, Hsieh YH, Harvey L, Burah A, Won H, Jett-Goheen M, et al. Will patients "opt in" to perform their own rapid HIV test in the emergency department? Ann Emerg Med. 2011;58(1 Suppl 1):S74-8. Epub 2011/06/28.
37. Peck R, Lim J, van Rooyen H, Mukoma W, Chepuka L, Bansil P, et al. What Should the Ideal HIV Self-Test Look Like? A Usability Study of Test Prototypes in Unsupervised HIV Self-Testing in Kenya, Malawi, and South Africa. AIDS and behavior. 2014;18(4):422-32.
38. Dong K, Regina R, Hlongwane S, Ghebremichael M, Wilson D, Dong K. Can laypersons in high-prevalence South Africa perform an HIV self-test accurately? AIDS 2014 - XX International AIDS Conference July 2014; Melbourne, Australia.
39. Ltd BU. http://hivselftest.co.uk/ [31 May 2015].
40. AAZ-LMB. http://www.seronet.info/article/autotests-vih-la-dgs-sexplique-71823 [31 May 2015].
41. Food and Drug Administration. OraQuick® In-Home HIV Test Summary of Safety and Effectiveness. www.fda.gov/downloads/.../UCM312534.pdf 2012 [26 June, 2014].
42. OraSureTechnologies. OraQuick. https://shop.oraquick.com/ [9 August 2014].
43. Curran K, Johnson C, Ngure K, Mugo N, Baeten J, Heffron R, et al. The potential role of HIV self-testing within pre-exposure prophylaxis implementation. AIDS 2014 - XX International AIDS Conference July 2014; Melbourne, Australia.
44. MacPherson P, Lalloo DG, Webb EL, et al. Effect of optional home initiation of hiv care following hiv self-testing on antiretroviral therapy initiation among adults in malawi: A randomized clinical trial. JAMA : the journal of the American Medical Association. 2014;312(4):372-9.
45. Brown A, Djimeu E, Cameron D. A Review of the Evidence of Harm from Self-Tests. AIDS and behavior. 2014;18(4):445-9.

4.7 Appendix

Table S1: STROBE reporting criteria for cross-sectional studies (full-text)

	STROBE Recommendation (For cross-sectional studies – full-text)	De La Fuente 2012 [22]	Carballo-Dieguez 2012[14]	Gray 2013 [16]	Lee 2007 [25]	Ng 2012 [27]	Skolnik 2001 [28]	Xun 2013 [30]	Lippman 2014 [26]	Marley 2014 [17]	Spielberg 2003 [29]	Carballo-Dieguez 2012 [15]	Greacen 2013 [23]	MiraTes 2007 [10]	Chen 2010 [21]	Ochako 2014 [11]	Han 2014 [24]	Bavinton 2013 [19]
1.	Indicate the study's design with a commonly used term in the title or the abstract	NR	R	R	R	R	NR	R	R	R	R	NR	R	NR	R	R	R	R
2.	Provide in the abstract an informative and balanced summary of what was done and what was found	R	R	R	R	R	R	R	R	R	R	R	R	NR	R	R	R	R
3.	Explain the scientific background and rationale for the investigation being reported	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
4.	State specific objectives, including any pre-specified hypotheses	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
5.	Present key elements of study design early in the paper	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
6.	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	R	R	R	R	R	R	R	R	R	R	NR	R	R	R	R	R	NR
7.	Give the eligibility criteria, and the sources and methods of selection of participants	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R

8.	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
9.	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
10.	Describe any efforts to address potential sources of bias	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR
11.	Explain how the study size was arrived at	NR	NR	NR	NR	NR	R	R	R	R	R	R	R	NR	R	R	R	R
12.	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	R	R	NR	R	R	NR	R	NR	NR	R	NR	NR	NR	NR	R	NR	R
13.	Describe all statistical methods, including those used to control for confounding	NR	R	R	R	R	NR	R	R	R	R	NR	R	NR	R	R	R	R
14.	Describe any methods used to examine subgroups and interactions	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R
15.	Explain how missing data were addressed	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
16.	If applicable, describe analytical methods taking account of sampling strategy	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
17.	Describe any sensitivity analyses	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR

18.	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	NR	R	NR	R	R	R	R	R	R	R	R	R	R	R	R	R	NR
19.	Give reasons for non-participation at each stage	NR	R	NR	R	NR	NR	R	R	R	NR	R	R	NR	R	R	R	R
20.	Consider use of a flow diagram	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
21.	Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders	R	R	R	R	R	R	R	R	NR	R	R	R	R	R	R	R	R
22.	Indicate number of participants with missing data for each variable of interest	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR
23.	Report numbers of outcome events or summary measures	R	NR	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
24.	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	R	NR	NR	R	R	R	NR	NR	NR	NR	NR	R	NR	NR	NR	R	NR
25.	Report category boundaries when continuous variables were categorized	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	R	NR	R	R	NR
26.	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

27.	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NR	NR	R	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR
28.	Summarize key results with reference to study objectives	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
29.	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	R	R	R	R	R	R	R	R	R	R	R	R	NR	R	R	R	R
30.	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	R	R	R	R	R	R	R	R	R	R	R	NR	R	R	R	R	R
31.	Discuss the generalizability (external validity) of the study results	NR	R	R	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	R
32.	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	R	R	R	R	R	R	R	R	R	R	R	R	R	NR	R	R	R

R-reported, NR not reported.

Table S2: STROBE reporting criteria for cross-sectional studies (conference abstracts)

STROBE Recommendations (For conference abstracts)	Bavinton 2014 [31]	Wong 2014 [34]
1. Indicate the study's design with a commonly used term in the title	NR	NR
2. Contact details for the corresponding author	R	R
3. Description of the study design	R	R
4. Specific objectives or hypothesis	R	R
5. Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes	R	R
6. Give the eligibility criteria, and the major sources and methods of selection of participants	NR	R
7. Clearly define primary outcome for this report.	R	R
8. Describe statistical methods, including those used to control for confounding	NR	NR
9. Report Number of participants at the beginning and end of the study	NR	R
10. Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals	NR	NR
11. General interpretation of study results	R	R

R-reported, NR not reported.

Table S3: STROBE reporting criteria for cohort studies (conference abstracts)

STROBE Recommendations (For conference abstracts)	Chakravarty 2014 [32]	Mayer 2014 [33]
1. Indicate the study's design with a commonly used term in the title	NR	NR
2. Contact details for the corresponding author	NR	R
3. Description of the study design	R	NR
4. Specific objectives or hypothesis	R	NR
5. Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes	R	NR
6. Give the eligibility criteria, and the major sources and methods of selection of participants	NR	NR
7. Clearly define primary outcome for this report.	R	R
8. Describe statistical methods, including those used to control for confounding	NR	NR
9. Report Number of participants at the beginning and end of the study	NR	R
10. Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals	NR	NR
11. General interpretation of study results	R	R

R-reported, NR not reported.

Table S4: CONSORT reporting criteria for RCT (conference abstract)

	CONSORT Recommendations (For conference abstracts)	**Katz 2012 [12]**
1.	Identification of the study as randomized in the title	NR
2.	Contact details for the corresponding author	R
3.	Description of the trial design (e.g. parallel, cluster, non-inferiority)	R
4.	Eligibility criteria for participants and the settings where the data were collected	R
5.	Interventions intended for each group	R
6.	Specific objective or hypothesis	R
7.	Clearly defined primary outcome for this report	R
8.	How participants were allocated to interventions	NR
9.	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	R
10.	Number of participants randomized to each group	NR
11.	Trial status	NR
12.	Number of participants analysed in each group	NR
13.	For the primary outcome, a result for each group and the estimated effect size and its precision	R
14.	Important adverse events or side effects	R
15.	General interpretation of the results	R
16.	Registration number and name of trial register	NR
17.	Source of funding	NR

R-reported, NR not reported.

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4-5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5-6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	N/A
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5-6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5-6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6-7
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8-9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-17

Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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